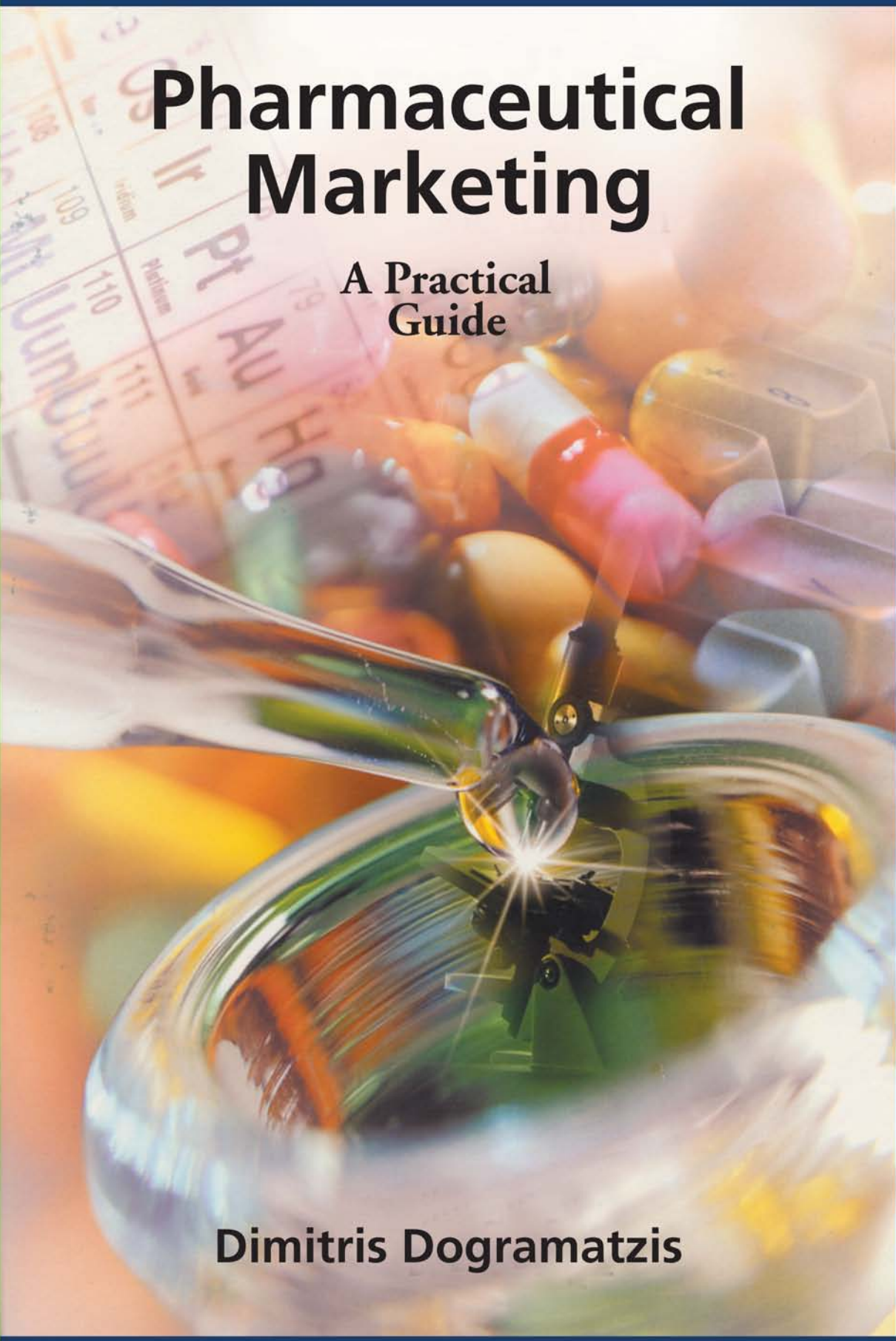
Pharmaceutical Marketing

A Practical Guide



Dimitris Dogramatzis

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Contents

To my newborn son, Vasilis

Preface

This book is a manual devoted to the analysis and discussion of all aspects of pharmaceutical marketing. The discipline itself is a dynamic field, practiced by all pharmaceutical companies and their collaborating partners—one of the largest industrial sectors in the world. Despite the size of the pharmaceutical/healthcare industry, its vitality and growth, and the significant human resources contributing to its success, there is still a large gap between the marketing books, lecture hours, and knowledge devoted to the marketing of consumer goods and those focused on the marketing of pharmaceutical products. This gap spans the globe.

In the past, there have been isolated but enlightened attempts to categorize, analyze, and study this interesting discipline. Building on this platform, this book aims to shed light on all aspects of pharmaceutical marketing, based on the day-to-day operating needs and the skills and tools necessary to fulfill them. The information in this book is based on the author's twenty-year history in the pharmaceutical industry, including undergraduate, graduate, and postgraduate educational backgrounds in pharmacy and pharmacology, as well as professional positions in pharmaceutical sales, medical marketing, product management, disease management, and general management with major multinational companies. Furthermore, this book incorporates the results of a global industry analysis, as well as a list of related journals and books, training materials, industry reports, and consultancy reports. Above all, it includes information about the undisputed information medium of our time: the World Wide Web.

The information gathered from these materials has been painstakingly transformed into practical advice that focuses on all aspects of pharmaceutical marketing and solves most of the day-to-day pharmaceutical marketing dilemmas. It uses industry's current marketing tools to offer insight into actual problem-solving situations, rather than theoretical ones.

The book is aimed at pharmaceutical industry employees involved in management, product marketing, medical marketing, disease management, sales, distribution, pricing, and regulatory affairs. Furthermore, it serves as a valuable educational tool for all industry stakeholders, namely, government regulators, trade association officials, pharmaceutical wholesalers, management consulting firms, marketing research professionals, over-the-counter (OTC) drug marketers, public relation agencies, advertising agencies, sales training professionals, business and marketing editors, disease managers, and managed care executives. Last but not least, undergraduate and graduate students in management, marketing, and pharmaceutical and healthcare marketing may gain valuable insight into this dynamic industry and become better prepared for entering this challenging and rewarding field. In fact, this book has been designed using standalone educational/informational modules that may be used as course materials by interested educators and their audiences. Finally, this practical guide is a document that may have limitations in areas of expertise practiced by colleagues over years and decades. It cannot possibly remain up-to-date in such a constantly changing business environment around the globe. The author appreciates any suggestions the readers may have and remains committed to updating its contents when the need arises. His long-term vision is to improve the pharmaceutical marketing profession via new educational programs and study materials that closely match the progress frequently seen in other marketing specializations or industry sectors.

ORGANIZATION

This book is organized in six parts, containing twenty-two chapters, as well as a reference section and two appendices.

Part 1, *The Pharmaceutical Market* consists of three individual chapters, focusing on the operational environment of today's pharmaceutical marketing, including healthcare systems and regulation, the pharmaceutical industry sector, and major industry stakeholders, as well as the elements of pharmaceutical marketing.

Chapter 1, *The Healthcare Environment* addresses the dynamic nature of healthcare systems around the world, their components, and the relationships among the components. It also discusses major differences between healthcare systems in other countries and the healthcare reform phenomenon that is currently engulfing the globe. Furthermore, it provides an overview of the worldwide need for healthcare regulation, and presents the major processes regulated internationally. It also focuses on two of the most important regulatory submissions, namely, the Investigational New Drug (IND) and the New Drug Application (NDA) processes and their requirements.

Chapter 2, *The Pharmaceutical Industry Environment* looks at a major industrial sector in search of higher productivity and long-term viability under constantly evolving regulatory and competitive environments. The chapter provides an overview of the pharmaceutical industry, its associated industries, and common organizational structures, while presenting a variety of industry statistics and insights on competitive

forces. It explains the nature and importance of the multiple stakeholders associated with the industry, who are categorized in five main groups—prescribers, influencers, regulators, financers, and consumers. Furthermore, the interrelationships and potential conflicts between the different stakeholders are presented and analyzed.

Chapter 3, *The Pharmaceutical Marketing Environment* discusses how products satisfy customer needs and wants and the importance of customer satisfaction. In addition, it addresses the role of marketing in society, and analyzes the marketing management function in today's business world. It also deals with the four Ps of marketing, namely, product, price, place, and promotion, and their role in the marketing management process and environment. Chapter 3 further confronts the ethical dilemmas often faced by pharmaceutical marketers around the world, and discusses the pharmaceutical product marketing mix, as well as the marketing environment. In addition, it focuses on two major professional avenues available to industry marketers, namely, product management and medical marketing.

Part 2, *Marketing Strategy* is the core section of this pharmaceutical marketing guide. It consists of eight chapters, which discuss strategy components ranging from the need for a global strategy cascade, the elements of marketing research, market segmentation, and the importance of competitor and situational analyses, to the concepts of positioning, targeting, profiling, product life cycle, new product development, and portfolio management methods. Furthermore, it discusses common competitive strategies, as well as the intensifying competition between ethical and generic drug manufacturers.

Chapter 4, *What Is Marketing Strategy?* introduces the reader to the definition of marketing strategy and its cascade from the corporate vision to local marketing tactics. The process of strategic planning and the relationship between strategy and tactics are also presented.

Chapter 5, *Marketing Research* gives an overview of the increasing information needs of today's marketers and the components of marketing information systems. It provides an analytic list of pharmaceutical marketing research subjects often investigated by internal marketing research departments or outside specialized agencies. It also describes the process and methodology of marketing research, explaining in detail the qualitative and quantitative research methods, as well as the primary and secondary sources of information available to pharmaceutical marketers.

Chapter 6, *Market Segmentation* gives the definition of a market and explains the need for distinct market segment identification and detailed analysis. Several segment strategies are discussed.

Chapter 7, *Situational Analysis* provides a model for self-analysis of a firm's resources and competencies. It also shows the way these relate to the resources and competencies of the competitors or the prevailing environmental conditions. It discusses various analytic tools, their essential steps, and sources of information. It concludes by describing a method for deriving the key success factors needed for any specific operational environment. This chapter introduces the importance of competitor analysis, the essential steps required, and the process of competitor strategic groupings and their benchmarking. A variety of information sources and information-sharing systems are presented and discussed.

Chapter 8, *Positioning, Targeting, Profiling* builds on the concept of market segmentation, leading into the process of product positioning, targeting, and profiling in order to gain and sustain the essential competitive advantage.

Chapter 9, *New Product Development* begins with the definition of a new pharmaceutical product, and proceeds with the detailed analysis of the new product development process, modern pharmaceutical R&D strategies, and benchmarking. This chapter also discusses the importance of the time-to-market parameter, and how to successfully prepare the market for the introduction of a new product.

Chapter 10, *Product Life Cycle and Portfolio Management* shows the fascinating life cycle of a pharmaceutical product, starting from the conception, patent protection, and development phases, through the introduction, growth, and maturity phases, and ending with the inevitable decline phase or the eventual withdrawal. Product adoption and diffusion models are presented, together with potential strategies for modifying existing products. This chapter also deals with what a balanced portfolio means to a pharmaceutical company, and discusses ways and means for successful portfolio assessment and management, presenting a variety of portfolio models.

Chapter 11, *Competitive Strategies* deals with the ever-increasing rivalry among ethical manufacturers, and details the most commonly used competitive moves. These are classified according to the method used, the competitor's industry position, or the industry life cycle stage. In addition, it discusses the most important competition arena facing the pharmaceutical industry—that between ethical and generic manufacturers. The reasons behind therapeutic substitution are presented, as well as the main drivers behind the rise of generics across international healthcare markets. Furthermore, the main competitive strategies of the two "gladiators" are presented.

Part 3, *Distribution Strategy* gives an overview of pharmaceutical distribution and presents modern distribution strategies implemented by industry members.

Chapter 12, *Overview of Pharmaceutical Distribution* addresses the three main distribution channels, namely, the ethical, OTC, and Web distribution alternatives, and their main characteristics and functions.

Chapter 13, *Distribution Strategy* focuses on the structure and extent of the various distribution channels, the methods of selecting able distributors, and the need for superior customer services nationally and internationally. Supply chain management principles are discussed in brief, since this is a whole new field that cannot be sufficiently presented within the confines of a practical pharmaceutical marketing guide. Finally, the reverse distribution of expired quantities and certain ethical considerations of pharmaceutical distribution are discussed.

Part 4, *Pricing Strategy* contains chapters on pricing concepts and strategy. Chapter 14, Pricing Strategy discusses the elements of price and why a product may have a wide range of prices in a single market. The influence of government price control is analyzed, as well as the important element of reimbursements and the rising need for detailed pharmacoeconomic studies in several markets.

Chapter 15, *Pricing Strategy* proceeds into the critical price-quality strategy consideration industry managers are faced with, and extensively presents the price influencing factors. The price elasticity concept is discussed, as well as pricing tactics for both new products and established ones. The impact of price discounting is also presented.

Part 5, *Communication Strategy* consists of five chapters covering all aspects of an integrated communications strategy, ranging from the personal selling task and advertising, to public relations, sales promotion, and the role of the internet in pharmaceutical promotion.

Chapter 16, *Integrated Communications* describes the process of communication and how the prescribing decision can be influenced by a company's integrated com-

munications plan. Furthermore, the elements of a communications strategy are discussed, and promotional planning is reviewed in detail.

Chapter 17, *Personal Selling* focuses on the distinct characteristics of personal selling and its main tasks and activities. Various selling styles implemented by industry sales representatives, which lead the way into the analysis of the structured sales interview concept are presented. Sales force management is also discussed in depth, as well as the increasingly important key account management principle, and the sensitive marketing and sales departments' interaction.

Chapter 18, *Advertising* deals with the idiosyncrasies of pharmaceutical advertising, and the tight regulatory constraints that pharmaceutical marketers often have to work with. Various advertising channels and activities are compared, and advertising planning and development methods are presented. Furthermore, the way the product life cycle affects advertising planning is presented.

Chapter 19, *Public Relations (PR) and Sales Promotion* deals with the important public relations concept and common PR initiatives pharmaceutical marketers are involved with. Crisis management is addressed, and considerable attention is given to the concept of sales promotion and to the available ways and means of measuring the effectiveness of PR programs.

Chapter 20, *The Internet* focuses on the exploding opportunities this medium offers present-day marketers, while noting the significant ethical and legal aspects still waiting to be fully resolved around the world. Methods of developing Web sites, and measuring their effectiveness on pharmaceutical promotions are presented. The chapter also stresses the importance of incorporating the internet into the overall marketing strategy of a pharmaceutical firm.

Part 6, *Forecasting, Planning, and Evaluating* consists of two chapters dealing with sales forecasting, the marketing planning process, and methods used in the evaluation of marketing performance.

Chapter 21, *Forecasting and Planning* discusses the importance of proper forecasting on diverse organizational functions and analyzes the different forecasting process stages. Various forecasting methods are presented, as well as the concept of creating different forecasting scenarios in relation to forecast evaluation methods used. Furthermore, it deals with the omnipresent marketing plan, and takes the reader gradually through all its essential parts, starting from the introductory executive summary all the way to the required appendices. A variety of planning tools and models are presented and discussed.

Chapter 22, *Evaluating Marketing Performance* is fully devoted to the process known as the marketing audit. Attention is given to common analysis tools, such as market share, sales, cost, profit, contribution, variance, customer satisfaction, performance, and return-on-investment analyses, as well as the insights they provide into the whole marketing planning process.

This book also contains two appendices, namely, Appendix A, Glossary, and Appendix B, Core Concepts on the Web, as well as a reference section.

SPECIAL FEATURES

Each chapter begins with an industry fact, reproduced with the kind permission of well-known industry associations (e.g., the Pharmaceutical Research and

Manufacturers of America [PhRMA], the Association of the British Pharmaceutical Industry [ABPI], the Pharmaceutical Manufacturers Association of Canada [PMAC], or the American Pharmaceutical Association [APhA]). The contents of each chapter include introductory material, the main body of text, and a large number of related industry statistics and models (figures and tables). In addition, a comprehensive list of references and related Web sites is included.

Dimitris Dogramatzis, PhD
August 2001

The Author

Having received a Bachelor's diploma in Pharmacy from the University of Patras, Greece, Dr. Dimitris Dogramatzis spent the next seven years in Texas studying and working for the University of Texas System. During this time, he completed his PhD in Pharmacology and Toxicology at the University of Texas Medical Branch at Galveston. Later he went on to complete two successive postdoctoral trainings at the University of Texas Medical Branch at Galveston and the M.D. Anderson Cancer Center at Houston, Texas.

After military service as an Army Pharmacist with the Greek Army Medical Corps, he joined the pharmaceutical industry in 1991. His successful industry career includes field sales, medical marketing, product management, disease management, country and regional management positions with Hoffmann-La Roche, Lundbeck, and Serono. In 1998, he founded the new Greek subsidiary of the Serono International Group, Serono Hellas, and has been its Managing Director. In late 2000, he was appointed Serono's Regional Vice President for Northern Europe. He is responsible for the UK, Ireland, the Netherlands, Sweden, Denmark, Norway, Finland, and Iceland markets.

He has written extensively in English and Greek for basic research and business publications. His academic publications include congress abstracts, full papers, and

review articles, while his business publications include several interviews, full articles, two book chapters, and a book.

Dr. Dogramatzis is a member of the American Association for Cancer Research, the M.D. Anderson Associates, the Greek Pharmacist's Association, the Greek Pharmaceutical Marketing Association, and the Greek Association of Chief Executive Officers. He is also a member of the American Marketing Association and UK's Institute of Directors.

Part 1

The Pharmaceutical Market

1. The Healthcare Environment
2. The Pharmaceutical Industry Environment
3. The Pharmaceutical Marketing Environment

1

The Healthcare Environment

> Medicines are cost effective and frequently reduce the need for costly hospital care. An average prescription costs around £9.40, while a week in hospital costs about £1,100.
>
> The Association of the British Pharmaceutical Industry (ABPI), 1998

Asking readers worldwide to recollect whether they have been exposed to some marketing activities in the recent past is easy. Barring the remote chance that they have recently been rescued from a deserted island in the middle of the Pacific Ocean, they all have been witnesses to the far-reaching activities and implications of marketing. For example, we all have been exposed to fast-action television commercials, or huge road billboards, or glossy magazine advertisements, or Sunday newspaper inserts. This high level of exposure to marketing activities has created some positive, neutral, and even negative feelings. However, despite our varying spectrum of feelings, we all are loyal customers of our morning milk, athletic shoes, or laundry detergent brands.

This book is one more marketing book among the thousands of other titles you can order through your local, or for that matter, virtual, bookstore. What is different about this book is that it focuses on the marketing of pharmaceutical products as an inseparable part of their commercialization and eventual use in the treatment of disease. In doing so, this book covers the basic concepts of marketing and the marketing mix, presents the healthcare and pharmaceutical industry environments, and also takes the

reader on a detailed journey through the marketing analysis, planning, implementing, and evaluating activities followed by pharmaceutical marketers around the world.

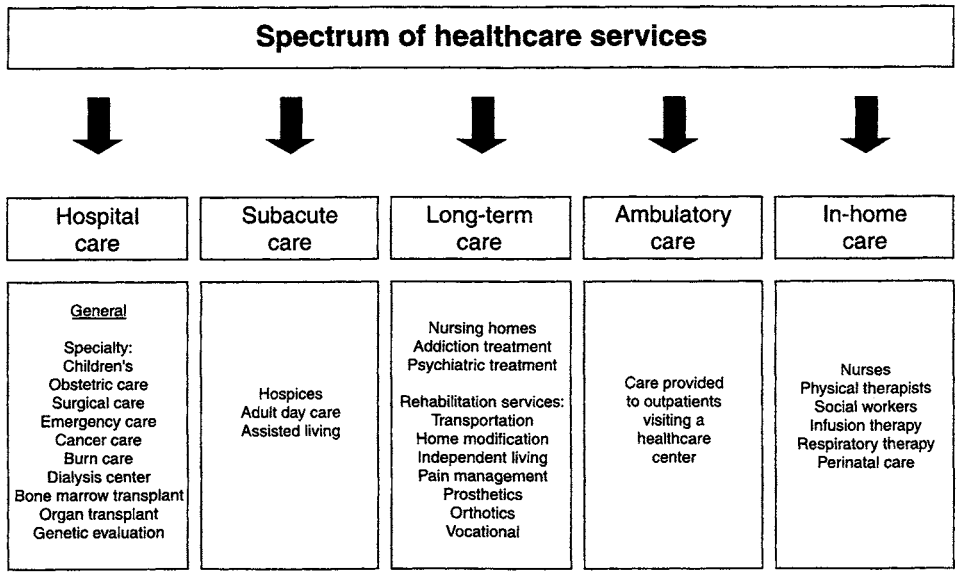
HEALTH CARE

The operational stage of the pharmaceutical industry is the healthcare environment. Before we proceed in discussing the multiple facets of this dynamic setting, let us first define some basic terms. *Health* is a complete state of physical, mental, and social well being (WHO–World Health Organization). *Illness* is a person's own perception of how he or she feels, and *disease* is a judgment of one's state of health by a medical professional. *Health care* is any helpful activity intended to maintain or improve health. The provision of health care to persons in need is done through a variety of products (pharmaceuticals, diagnostics, laboratory devices, surgical instruments, medical disposables, and so on) and services, which are commonly classified as preventive, acute, chronic, restorative, and palliative. The settings of healthcare provision can also be diverse (see Figure 1.1), and are categorized in five large segments, namely hospitals, subacute, long-term, or ambulatory care facilities, as well as patient homes.

OVERVIEW OF A HEALTHCARE SYSTEM

The network of healthcare facilities, products and services, professionals, patients, and other related groups of individuals is collectively called a healthcare system. A healthcare system is designed to provide everyone with *easy* access to *high quality* health care at *affordable* cost. Nevertheless, most experts would agree that this statement is closer to

Figure 1.1. Spectrum of healthcare services



an ideal situation than to the reality of the healthcare marketplace around the world. The reason for this discrepancy is the extreme difficulty in achieving equilibrium between the three main components of accessibility, high quality, and affordability, despite the numerous political initiatives and different healthcare system structures tried to date. Indeed, a healthcare system is in constant flux due to social change, different priorities, new technology, and disease trends. This is the dynamic environment within which pharmaceutical marketers operate, and this chapter discusses some of its attributes that are important to the pharmaceutical industry today.

System Components

Table 1.1 gives an overview of the groups of individuals interrelated within a healthcare system framework.

Primary providers are those facilities and individuals directly involved in treating people in need, that is, hospitals, other healthcare facilities, and physicians. Naturally, the recipients of their services are not only patients, but also "healthy patients," such as people receiving immunizations, regular check-ups, women in delivery, and so on. *Secondary providers* are organizations or individuals providing resources needed for integrated health care. For example, reimbursement funds provide treatment funds coming from the state's financial chest, insurance companies cover expenses via proactive patient contributions, and employers contribute resources for keeping their labor forces healthy, while pharmaceutical and medical device companies manufacture critically essential healthcare products. Other healthcare system players include the various *planning and regulatory bodies* that are trusted to provide the necessary long-term resource planning or the overseeing and controlling of healthcare facilities, professionals, products, and services used in the process. The *healthcare professionals* deeply involved in the provision of health care are nurses, pharmacists, psychologists, or social workers, who contribute to the function of primary providers. *Patients,* or consumers in general, are those at the receiving end of the healthcare continuum, and, together

Table 1.1: Overview of a Healthcare System

Primary Providers (providing health services)	**Secondary Providers (providing resources)**	**Planning/Regulatory Bodies**	**Healthcare Professionals**
Hospitals	Reimbursement funds	Government authorities	Nurses
HMOs	Insurance companies	Political parties	Pharmacists
Clinics	Employers		Psychologists
Nursing homes	Pharmaceutical companies		Social service workers
Physicians	Medical device companies		

Patients (consumers)	**Provider Associations**	**Professional Associations**	**Media and Public**
Patients	Hospitals	Physicians	Media
Patient groups	Reimbursement funds	Wholesalers	Public
Patient families	Employers	Pharmaceutical scientists	
	Insurance		
	Pharmaceuticals		
	Medical devices		

with their families or patient groups, form one of the building blocks of a healthcare setting. Furthermore, the *media*, and the *public* in general, have a powerful influence on the level of service or the resources allocated to health care, and should be given the proper attention by government regulators or pharmaceutical marketers alike.

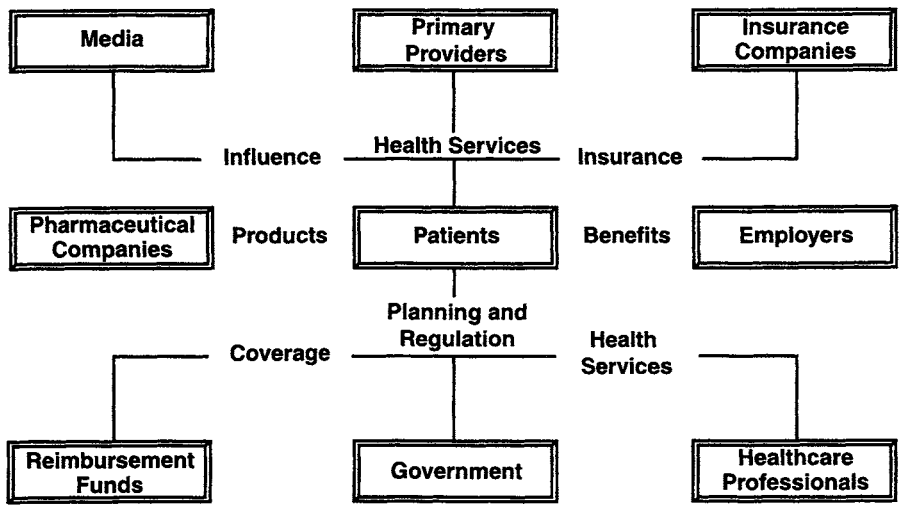
In order for any healthcare system to work effectively and efficiently, abundant resources must be made available to the processes involved, including the (a) financial, (b) human, (c) infra-structural, and (d) technological processes. The total amount of resources allocated, the contribution of total resources across these categories, the timing of allocation, and the long-term planning of this process are often hotly contested issues within several national healthcare systems, proving the enormous challenges of balancing the triad of essential components mentioned at the beginning of this chapter.

Intercomponent Relationships

The various components of a healthcare system are deeply interrelated within the system network. Thus, a variety of exchanges and relationships exist among the components, some of which are illustrated in Figure 1.2. For instance, primary providers and other healthcare professionals provide healthcare services to patients; insurance agencies provide insurance; reimbursement funds provide reimbursement; employers contribute benefits; pharmaceutical companies create essential medicines; the government is responsible for planning and controlling the system; and the media play a significant influencing role.

A closer look at the model in Figure 1.2, however, reveals that all these components not only provide unidirectional services to the patient component, but also closely interact amongst themselves in a variety of ways. These include not only collaboration and synergy, but also competition, conflict, and collision. For instance, government

Figure 1.2. Healthcare intercomponent relationships



and private healthcare facilities are in competition for the same customers; healthcare professionals protect their turf from the sole responsibility of physicians; employers are often forced to ration their benefits to their working force; and the media are more often than not confronting the government or employer healthcare initiatives. As far as the pharmaceutical industry is concerned, it has long been recognized that every single component of a healthcare system is directly or indirectly related to the performance of the industry; thus all these components have a "stake" in the industry or are "stakeholders" of it (see Chapter 2).

HEALTHCARE REFORM

One of the most controversial issues in health care is the direction state governments should take in order to optimize the three guiding principles of an ideal system, namely, accessibility, high quality, and affordability. This debate has been going on for at least the second half of the Twentieth Century, during which numerous attempts have been made to this end. The phenomenon of a constantly changing healthcare system is especially evident in the United States, where the wide-ranging changes during the last decades have been called *healthcare reform.* Table 1.2 categorizes the various approaches used to date. The result of this reform has been the ascendance of *managed care,* a process still in transition in the United States. It is also gradually being imported into the northern European countries. Managed care is an attempt to control the access, delivery, and financing of health care. An overview of the managed care setting is given in Table 1.3.

The healthcare environment before and after the implementation of managed care can be described as follows.

Before managed care

- employer and patient copay for health insurance coverage;
- patient ails and visits a physician;
- physician provides service and charges a fee (fee-for-service model); and
- patient brings bill to insurance agency for reimbursement.

After managed care

- employer and patient copay for health insurance coverage;
- Health Maintenance Organizations (HMOs) comprise hospitals and staff/independent physicians;
- HMOs sign contracts with employers, specifying a preset level of service coverage mandating the cascade capping of employer costs, hospital charges, physician charges, and HMO profits;
- patient ails and contacts the HMO;
- HMO refers patient to collaborating physician/hospital; and
- standardized fees are precovered by the HMO–employer contract.

An alternative Managed Care Organization (MCO) is the Preferred Provider Organization (PPO), which is an intermediary contractor between employers and hospital and physician groups. The latter can be *preferred* (those offering incentives to employers and therefore recommended by them) or just *participating* providers.

Table 1.2: Healthcare Reform in the United States

	1960s	1970s	1980s	1990s
Stage	Prepaid Group Practice (PPGP)	HMO	Managed Care Plans (MCP)	Market-Oriented Managed Care (MOMC)
Emphasis	Community health	Cost containment	Education, compliance, and accountability	Cost containment
Problem	No integration No accountability Wasting of resources	Rising healthcare costs Government imposes in-patient treatment cost ceilings Hospitals competing for patients	Employers still faced with rising costs	Growth of managed care Heavy competition
Solution	Start looking at the healthcare continuum	Health Maintenance Organization Act (1973) Create hospital/physician networks (horizontal integration)	Create managed care organizations	Create closed system of health care (vertical integration)
Patient Copayment	Very low	Lower cost alternative	Prepaid level of service (capitation)	Prepaid level of service (capitation)
Coordination	None	Loose	Strong	Managed competition

The main purpose of managed care has been the creation of (a) patient focus, (b) informed and compliant patients, and (c) cost-minded, accountable, compliant, informed, and participative healthcare professionals. These points also outline the underlying healthcare system conditions that precipitated the introduction of managed care, namely, the dependence of advanced healthcare systems on patient focus, as well as information, compliance, and accountability of every stakeholder involved. Such feats could be facilitated by the following activities: increasing patient satisfaction; enhancing the quality of service through education, prevention, and compliance with commonly agreed standards; reducing malpractice; expanding the patient base

Table 1.3: Overview of a Managed Care System

		Health Plan		Payer
Hospital	→ Bill	Indemnity, HMO, PPO Self-funded	→ Health care	Employer, Government, Patients
Physicians	← Utilization Management	Indemnity, HMO, PPO Self-funded	← Premium	Employer, Government, Patients

through more effective service; increasing the flow of information among all stakeholders; and lowering healthcare overhead costs.

HEALTHCARE REGULATION

Pharmaceutical products have numerous similarities to fast-moving consumer goods (FMCG) and other types of products, and so the core marketing principles apply equally to these disciplines. In analyzing the pharmaceutical marketing environment (see Chapters 4 through 11), however, an industry marketer will immediately recognize significant idiosyncrasies that set this industrial sector apart. One of these idiosyncrasies is the volatile healthcare environment already discussed, while another is the intense regulatory environment that surrounds health care in almost all countries of the world. The driving force behind this regulatory framework, the very essence of health care, is the delivery of services to patients in need. It often is associated with the preservation and nurturing of human life itself, a fact that, on the one hand, places a much-needed regulatory net around health care, and, on the other, restricts the activities of all persons involved. The following sections focus on healthcare regulation and discuss the different processes under regulation, with an emphasis on the regulatory approval of new pharmaceutical products to the marketplace.

Regulation Is Important

A drug may be broadly defined as "any chemical agent that can alter processes of living." More specifically, a clinician is interested in substances having a pharmacologic effect in humans, with tolerable adverse events. Inherent in this definition are several aspects of pharmaceutical marketing that are discussed in detail throughout this book. More specifically, a drug can affect human's health, with processes and effects that can only be properly characterized by the expertise of a specialist. These effects may not even be imminently evident, but may require years to manifest. It is evident, however, that the promise of improving one's health may render the potential drug susceptible to false claims by an ill-intended or careless manufacturer. Additionally, state governments spending significant funds for providing free medical and pharmaceutical care, or prescribers wishing to use a new drug, and patients asking for the best possible treatment, must be able to distinguish efficacious, tolerable, and cost-effective medications from those that clearly would not add anything to modern therapeutics. Some infamous healthcare tragedies of the past are listed in Table 1.4.

For the reasons mentioned, health care is, and must continue to be, regulated in a scientifically based and objective manner that is equally fair to all interested parties in all areas of the world. As Figure 1.3 shows, modern-day pharmaceutical marketers find

Table 1.4: Infamous Healthcare Tragedies

Chronology	Product	Problem
1957–1961	Thalidomide	Birth defects
1970s	Dalkon shield (IUD)	Injuries
1978–1986	Bjork-Shiley heart valve	Valve failures and deaths
1985–1987	Therac-25 linear accelerator	Overexposure and deaths
1990s	French blood contamination	Contamination of blood products with AIDS virus

Figure 1.3. Pharmaceutical marketers in the center of a strict regulatory environment

themselves operating within a framework of regulatory agencies and regulations that either have been put in place by national and international bodies or have been self-imposed by the pharmaceutical industry. The latter has led to the arbitrary distinction between pharmaceutical manufacturers: There are those who not only abide by external regulatory directives but also follow internal, self-imposed regulations, and are thus called "ethical manufacturers," and there are those who are often not involved in original research, producing products that have lost patent protection and aggressively marketing them on the basis of price, mostly in the nonprescription or "over-the-counter" (OTC) realm. Both sides have their own raison d'être, and are compared in Chapter 11.

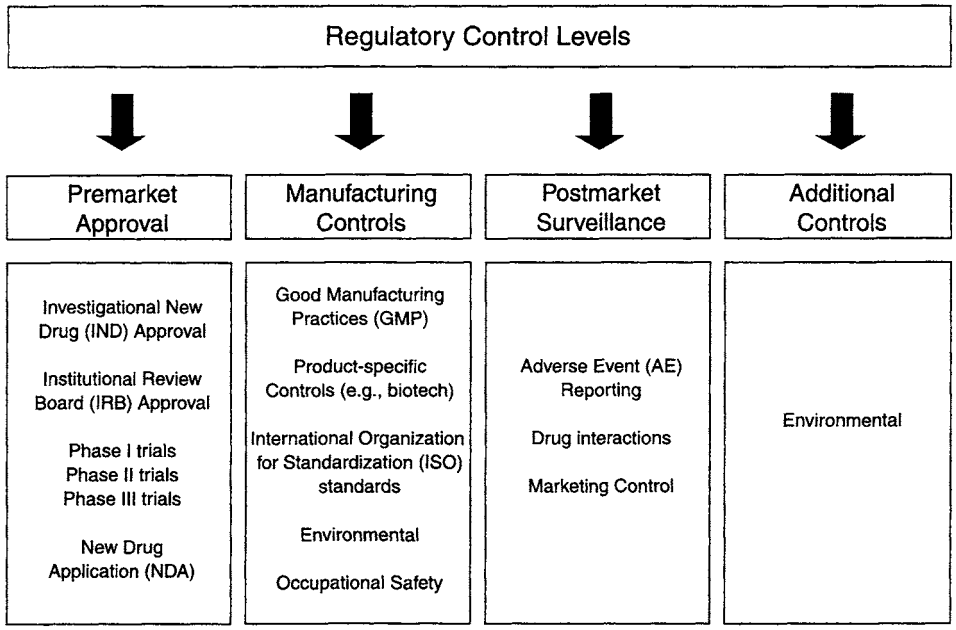
Healthcare Processes Under Regulation

The international healthcare regulation network covers all aspects of healthcare delivery, including facilities, professionals, medical devices, and pharmaceutical products. A closer look at the healthcare processes under regulation reveals that they can be classified as supply- or demand-side processes. For example, national and international bodies may focus on patent protection, registration, pricing, and manufacturing of new products (supply-side) or may impose restrictions to their trade across national borders, marketing, and prescribing (demand-side). This chapter focuses more on those regulatory restrictions imposed on pharmaceutical products, a summary of which is shown in Figure 1.4.

MAJOR INTERNATIONAL REGULATORY BODIES

The global pharmaceutical industry is strongly influenced by the presence of three major international regulatory bodies, namely, the **U.S. Food and Drug Administration** (FDA), the **European Agency for the Evaluation of Medicinal Products** (EMEA), and the **Japanese Ministry of Health and Welfare** or Kosheisho. The three agencies regulate almost every facet of pharmaceuticals in

Figure 1.4. Regulatory control levels



their respective regions and each has been one of the most important industry-influencing factors within those regions. Indeed, their influence on their respective industries is so pervasive that they have helped form three respective industry groupings, the American, European, and Japanese groups of companies (for more information on industry's strategic groupings, see Chapter 7). The major historical milestones and respective drug-approval regulatory requirements of the three agencies are as follows.

The U.S. Food and Drug Administration

Historical milestones

1862 Bureau of Chemistry (within the Department of Agriculture) set up by President Lincoln.
1902 Biologics Act.
1906 Federal Food and Drug Act.
1938 Food, Drug, and Cosmetics Act required new drugs to be safe before marketing.
1962 Kefauver-Harris Amendments required U.S. drug manufacturers to show their products' effectiveness and safety before marketing.
1976 Medical Device Amendments.
1997 Modernization Act.

The FDA is responsible for the regulation of pharmaceutical products, medical devices and disposables, as well as cosmetics and food. Its regulatory organization is

represented in Figure 1.5, characterized by the presence of the Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs, and other central administrative or local departments.

The FDA's responsibilities related to pharmaceutical regulation are divided into five major units, namely, applications, standards, pharmacovigilance, compliance, and supporting departments (see Figure 1.6).

For the purposes of this book we will focus on new drug approval procedures, especially those applying to experimental new drugs (IND) and drugs seeking marketing licensing approval (NDA). The abbreviated new drug approval procedure (ANDA) applies to generic pharmaceuticals, a subject that is presented in Chapter 11.

Investigational New Drug (IND) application

Clinical trial sponsors submit an IND application to the FDA prior to clinical trial testing of new drugs or new formulations of already approved drugs. The application is a legal record with the FDA indicating that the sponsor is conducting a clinical trial of the product. The FDA has thirty days to respond to the application, and, if positive, the trial may then start. It is the responsibility of the trial sponsor to ensure that the investigator complies with the protocol submitted with the IND application. The contents of the application are (1) sponsor and trial monitor names; (2) commitment for not starting the trial before the application is approved; (3) commitment that the institutional review board (IRB) and the sponsor will comply with all relevant FDA guidelines; (4) investigational plan; (5) investigator's brochure; (6) trial protocol; (7) chemical, manufacturing, and quality assurance data; (8) pharmacological and toxicological data; and (9) marketing experience data. INDs can be distinguished in three major types, as described in Table 1.5.

Figure 1.5. Pharmaceutical regulation organization of the FDA

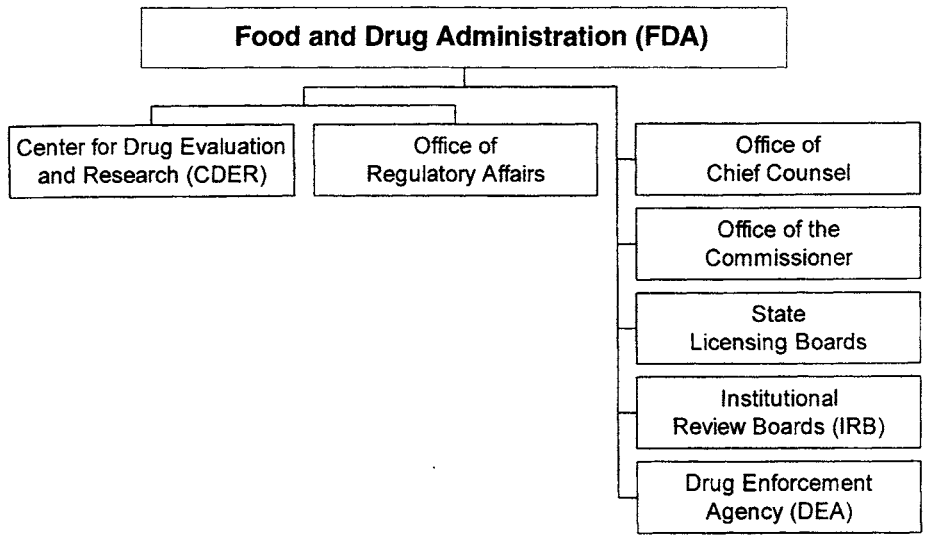
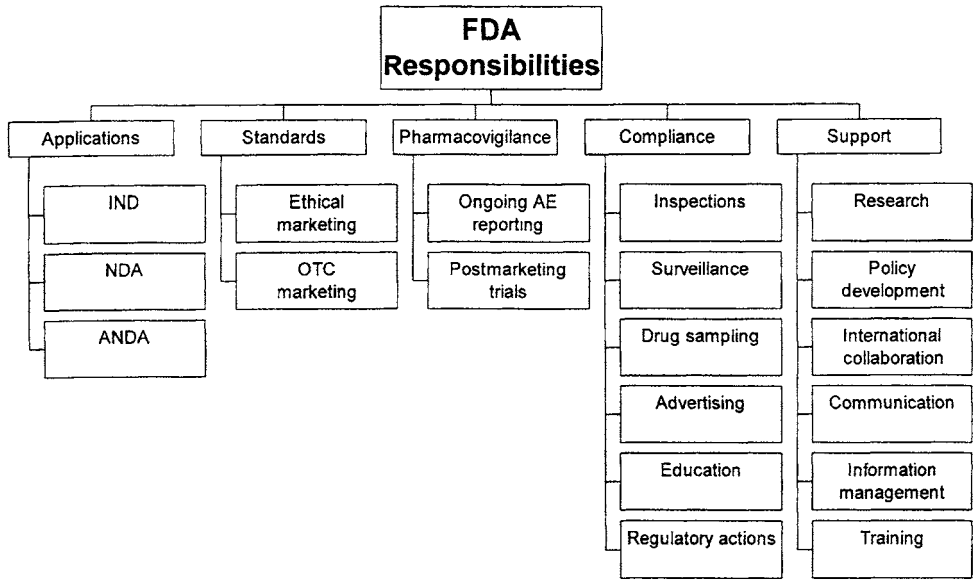


Figure 1.6. FDA responsibilities



Clinical trials

Having obtained an IND, pharmaceutical drugs may enter their clinical trial testing period. Clinical trial standards have evolved as a response to the Nuremberg Trials' revelations concerning Nazi experiments on human subjects without their knowledge or consent. Today, the conduct of trials is regulated by a variety of international legislation, including the following:

- Nuremberg Code (1946)
- Guidelines for the Ethical Conduct of Biomedical Research (1949)
- World Medical Association, Declaration of Helsinki (1964; updated 1989)
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Report, 1979)
- U.S. Food and Drug Administration (FDA), Code of Federal Regulations
- International Conference on Harmonization (ICH), Good Clinical Practice Guidelines

Table 1.5: Three Major Types of INDs

Treatment	A drug intended for serious/life-threatening disease, with no satisfactory alternatives. The drug must already be in controlled clinical trials. The sponsor must be actively pursuing an FDA approval.
Compassionate (Named patient)	Submitted by a single investigator, for a single (named) patient. Required for importing a small quantity of a drug registered for this indication into another country.
Emergency	Used in life-threatening diseases, with no existing alternatives (e.g., AIDS). FDA authorizes the drug shipment before the IND submission.

New Drug Application (NDA) approval

Following the completion of all required clinical trial stages (see Chapter 9), pharmaceutical manufacturers apply to the FDA for a marketing authorization license, using the NDA procedure. Applications may eventually lead to an agency decision letter, announcing its (a) approval, (b) request for additional studies, or (c) termination.

European Agency for the Evaluation of Medicinal Products

The European Union's equivalent to the U.S. Food and Drug Administration is the European Agency for the Evaluation of Medicinal Products (EMEA).

Historical milestones

1952	Belgium, Federal Republic of Germany, Italy, France, Netherlands, and Luxemburg set up the European Coal and Steel Committee (ECSC).
1958	The European Economic Community (EEC) is formed (Rome Treaty).
1965	First EEC Directive on medicinal drug regulation.
1975	Analytical, pharmacotoxicological, and clinical standards and protocols for the testing of medicinal products are created. The Committee for Proprietary Medicinal Products (CPMP) is established.
1987	The procedure for placing high technology medicinal products, especially biotechnological, on the market is created.
1993	The European Agency for the Evaluation of Medicinal Products (EMEA) is formed and based in London. The centralized approval procedure is introduced.
2000	Regulation 2000 describing new regulatory framework is currently under discussion.

The European medicines regulatory framework follows a hierarchical structure (see Figure 1.7), comprising both centrally located regulatory officials and nationally positioned officials.

The European Union uses three different NDA processes, which are illustrated in Figure 1.8. Furthermore, other national regulatory authorities, including some central European countries and Switzerland, are increasingly using the decentralized procedure (or mutual recognition). The centralized and decentralized approval procedures are presented in Tables 1.6 and 1.7.

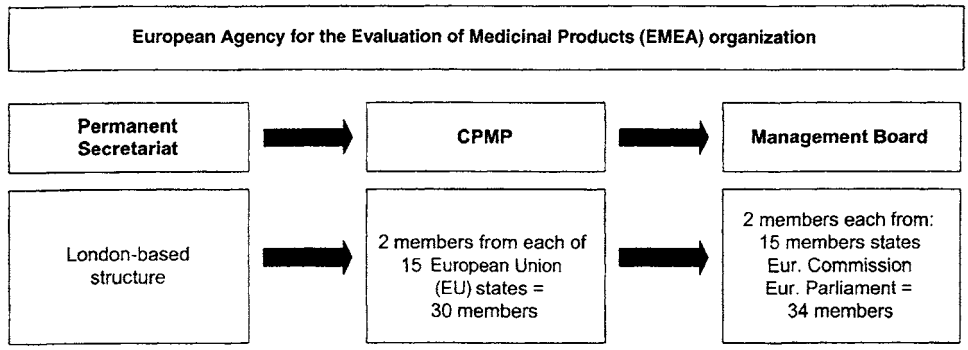
The centralized approval procedure described in Table 1.6 applies to all biotechnology products as well as to a special list of other products, gives a ten-year marketing exclusivity within all Member States, requires a single Pan-European trademark, and does not give a choice of Rapporteur.

In contrast to the centralized procedure, the mutual recognition procedure (see Table 1.7) can use different trademarks and gives a choice of a Reference Member State; however, this procedure requires the extra step of obtaining national licenses.

Japan Ministry of Health and Welfare (Kosheisho)

The drug regulatory agency of Japan is in the Ministry of Health and Welfare.

Figure 1.7. The European Agency for the Evaluation of Medicinal Products (EMEA) organization



Historical milestones

1946 The Kosheisho was formed following World War II. Responsible for all aspects of pharmaceutical regulation, it requires all new drug regulatory submissions to contain data on a population of Japanese patients.

1967 Development of "Basic policies for approval to manufacture drugs."

IND procedure

A clinical trial application is submitted to the Inspection and Guidance Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare (MHW). Trials on native Japanese patients were previously required for approval.

Figure 1.8. The European NDA approval processes

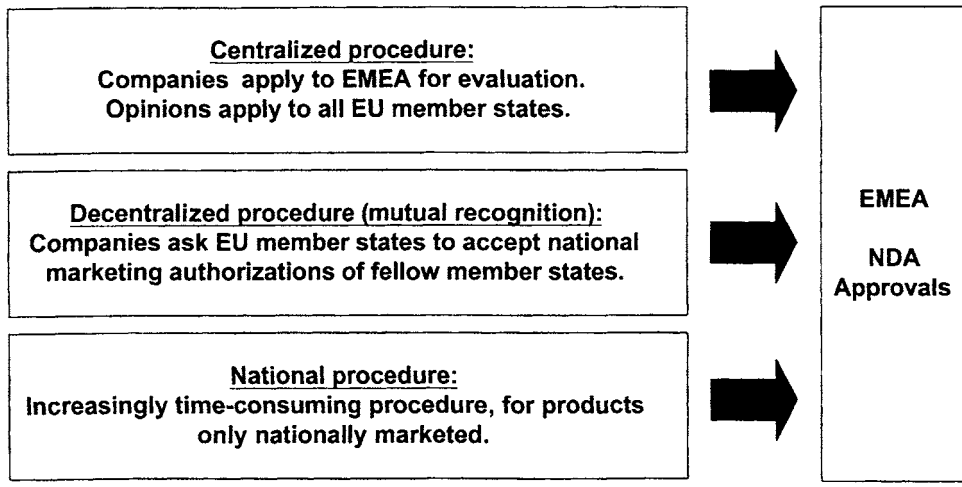


Table 1.6: EMEA's Centralized Approval Procedure

Timing	Presubmission Phase Procedure
4 months before submission	Applicant informs EMEA of intention to submit application (possible date), proposal for Rapporteur, draft Summary of Product Characteristics (SPC), location(s) of manufacture of finished product and active material, type of application trade name, and so on. EMEA appoints a Technology Project Manager.
3 months before submission	Committee for Proprietary Medicinal Products (CPMP) confirms that product qualifies for an evaluation under the centralized procedure and appoints Rapporteur and Co-Rapporteur.
Application submission to EMEA	1 full copy of the dossier, 1 extra copy of Part 1, SPC, Patient Information Leaflet (PIL), labeling in all official languages and fees.
Within 10 working days of submission	Validation by EMEA, and Rapporteur and Co-Rapporteur receive dossier copies.

Timing	Evaluation Phase Procedure
Day 1	Establishment of timetable, identification of sensitive issues, verification of quality of translations (SPC, PIL, Labeling), and inspections, where appropriate.
Day 60	Plenary session of CPMP, where Rapporteur and Co-Rapporteur convey first impression on data and the desirability to convene ad hoc expert groups.
Day 90	Rapporteur and Co-Rapporteur circulate preliminary Assessment Report(s) to CPMP members requesting possible comments.
Day 120	Plenary session of CPMP or Committee for Veterinary Medicine (CVMP) leading to possible positive opinion, or identification of serious objections leading to a negative opinion, or preparation of consolidated list of questions that would suspend the clock in consultation with the company.
Clock stop	
Day 150	Rapporteur and Co-Rapporteur send draft Assessment Report (AR) to CPMP members.
Day 180	Plenary session of CPMP: possibility of oral explanations (the clock may be stopped if company agrees to provide additional data).
Day 210	CPMP: Adoption of opinion to be transmitted within 30 days to Commission, Member States, and Applicant. Decision-making phase, or appeal by company within 15 days of receipt of the opinion.

NDA procedure

Following regulatory dossier submission to local prefectural authorities, the Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, and MHW issue two types of product licenses: (1) **shonin**—product approval for efficacy and safety and (2) **kyoka**—license to handle the shonin-approved product based on personnel and facilities qualification.

Table 1.7: EMEA's Mutual Recognition Procedure

National Phase	
Timing	**Procedure**
Up to 210 days	Application is submitted to first Member State. Assessment report summary of product characteristics. First authorization given.
Up to 90 days	Request by first Member State to update assessment report.

Mutual Recognition Phase	
Timing	**Procedure**
Up to 90 days	Application and updated assessment report sent to other Member States for mutual recognition. Application dossier and summary of product characteristics are certified to be identical. Other Member States recognize licensing decision.
Up to 30 days	Opinion, assessment report, and summary of product characteristics are submitted to the European Commission. Draft Commission decision.
Up to 28 days	Member States submit technical questions. New CPMP decision. Council majority decision. Final national decision.

NEED FOR HARMONIZATION

The independent historical development of the three major international regulatory agencies has led to a fragmented global pharmaceutical market. Obviously, this diversity of regulatory procedures presents major problems to the agencies themselves (recognition issues, competition, consumer pressures to harmonize), the industry (repetitive procedure, time delay, resource wasting), and the consumer (seeking alternative sources of newly approved innovative products). These problems have led the three regulatory bodies involved to

Table 1.8: International Conference on Harmonization (ICH) Topics

Abbreviation	Topic	Subtopics	
Q	Quality	Q1	Stability testing
		Q3	Impurity testing
S	Safety	S1	Carcinogenicity testing
		S2	Genotoxicity testing
E	Efficacy	E2	Clinical safety data management
		E4	Dose response studies
		E6	Good clinical practices
M	Multidisciplinary	M1	Medical terminology
		M2	Electronic standards for transmission of regulatory information
		M3	Timing of preclinical studies in relation to clinical trials
		M4	Common technical document

(ICH, 1990. Reprinted with permission from the International Conference on Harmonization.)

start discussing ways of standardizing their procedures, and eventually harmonizing their regulatory requirements under the coordinating efforts of the International Federation of Pharmaceutical Manufacturers Association-endorsed (IFPMA) International Conference on Harmonization (ICH).

Historical milestones

1980s	The European Union moves toward a common pharmaceutical environment. WHO Conference of Drug Regulatory Authorities (Paris) sets the groundwork for a common approach between U.S., European, and Japanese authorities. The IFPMA is asked to create a joint regulatory-industry initiative on international harmonization, leading to the creation of the ICH in a European Federation of Pharmaceutical Industries' Associations-sponsored (EFPIA) meeting in Brussels.
1990	Terms of Reference and Topics of Interest are defined during ICH steering committee meeting in Tokyo.
1992	ICH process is set during steering committee meeting in Washington.

The ICH focus topics are shown in Table 1.8.

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2

The Pharmaceutical Industry Environment

> In Canada, the research-based industry has invested more than 3.2 billion Canadian dollars in research and development since 1988. In 1995 alone, the industry invested 624 million Canadian dollars—an increase of 276 percent since 1987.
>
> Pharmaceutical Manufacturers Association of Canada (PMAC) 1998

The pharmaceutical industry is involved in discovering new or improved therapies that treat unmet medical and consumer needs. This industry is among the largest and most dynamic industrial sectors, accounting for approximately 300 billion U.S. dollars in yearly revenues. This chapter focuses on the examination of the main characteristics, influencing factors, and future trends affecting the industry.

PHARMACEUTICAL INDUSTRY OVERVIEW

The number of global competitors in the industry is approximately two hundred multinational companies, with most of their headquarters based in the United States, Germany, Switzerland, United Kingdom, France, or Japan. The industry has enjoyed an annual growth of more than 10 percent in the 1990s, while several expert reports estimate the average profit margin of the top ten players at around 30 percent.

Within the industry, two major groups can be identified. Typical *pharmaceutical multinational* giants trace their roots to the beginning of the Twentieth Century, gradually growing past their national borders and establishing subsidiaries around the globe (some with more than one hundred). They are responsible for introducing several innovative pharmaceutical products (new chemical entities or NCEs) to the world market, some of them becoming "blockbusters," that is, achieving more than 500 million U.S. dollars or, for others, one billion U.S. dollars in yearly global sales. These global integrated organizations belong to the elite of all business corporations, and some employ more than 100,000 employees worldwide (see Table 2.1).

On the other end of the industry spectrum, the group of *biotechnology companies* has risen to fame only during the last two decades, focusing on harnessing the recombinant DNA techniques and developing biotech drugs for treating serious diseases. These companies have based their ascendance on their human and technological resources, and some have surpassed the U.S. billion-dollar size without ever promoting or selling their products! Instead, they have allied with the typical pharmaceutical behemoths, which pay them large royalties for marketing their biotech products around the world. Furthermore, there is yet another group of biotech companies conducting original research for the last ten years, but not yet achieving profitability because they have not had any major research and development (R&D) breakthroughs and have depended on venture capital investments throughout their young life.

Table 2.1: Top 25 Pharmaceutical Companies Worldwide in 1998

Rank	Company	Pharmaceutical Prescription Sales (U.S. million dollars)	Percent Change vs. 1997
1.	Merck & Co	15,297	+ 12
2.	Aventis	13,650	NC
3.	Glaxo Wellcome	13,252	0
4.	AstraZeneca	12,754	NC
5.	Pfizer	11,788	+ 28
6.	Bristol-Myers Squibb	11,300	+ 15
7.	Novartis	10,001	+ 3
8.	Lilly	8,622	+ 17
9.	Johnson & Johnson	8,562	+ 11
10.	Roche	8,131	+ 24
11.	American Home Products	8,103	+ 2
12.	SmithKline Beecham	7,714	+ 5
13.	Abbott	7,123	+ 3
14.	Schering-Plough	6,695	+ 17
15.	Warner-Lambert	5,604	+ 55
16.	Sanofi-Synthelabo	4,830	NC
17.	Bayer	4,823	+ 1
18.	Pharmacia & Upjohn	4,756	+ 9
19.	Searle	2,894	+ 18
20.	Schering AG	2,655	+ 6
21.	BASF	2,563	+ 10
22.	Amgen	2,514	+ 13
23.	Novo Nordisk	2,016	+ 8
24.	Merck KgaA	1,668	- 2
25.	Akzo Nobel	1,447	+ 13

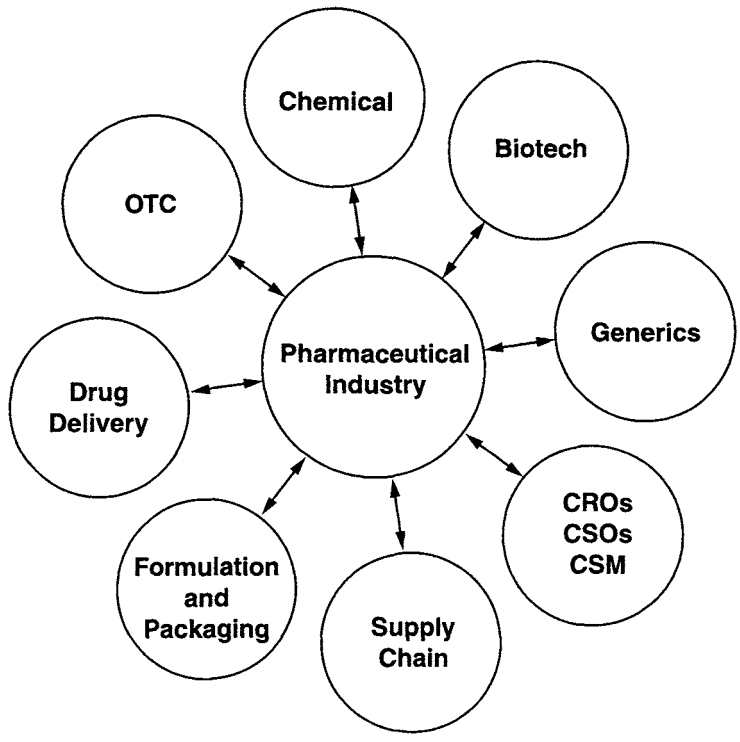
Indeed, there are very few "fully integrated" biotechnology companies that develop and market their products worldwide, thus bridging the gap between the giant pharmaceutical and minute biotechnology company extremes.

The concentration of global players within the industry has caused an intensely competitive market environment in most geographical or therapeutic market segments. Under these circumstances, some competitors continue to be successful across different therapeutic directions and are fortunate to have productive R&D departments that allow them to maintain a broadly focused market strategy. However, most multinational players have decided to focus their resources on specific areas of expertise, where their long-lasting history of innovation and commercial success allows them to be relatively protected from the competition of the giants. Such players are called "niche" players, which is a term borrowed from the biology microenvironment.

ASSOCIATED INDUSTRIES

There are a host of associated industries closely involved with the pharmaceutical industry (see Figure 2.1). The chemical industry is the main supplier of raw materials to the pharmaceutical industry, while the biotech industry has established strong contractual and mutually benefiting agreements. Generics and OTC manufacturers are often serious rivals of pharmaceutical manufacturers. Their characteristics are discussed in Chapter 11.

Figure 2.1. Industries associated with the pharmaceutical industry



Supply chain intermediaries cover the vast distribution needs of the pharmaceutical industry, and they are presented in Chapter 12. Drug delivery specialists help pharmaceutical industry's R&D departments achieve challenging routes of administration for their products. Formulation and packaging companies provide integration services to the industry. Finally, a series of subcontractors has seen their operations explode because the industry is frantically consolidating, downsizing, or outsourcing its noncritical or nonexpertise activities. Thus, contract research organizations (CROs) are overtaking important clinical trial activities, clinical site management (CSM) companies are overseeing the expeditious and efficient conduct of patient or investigator inclusion tasks, and contract sales organizations (CSOs) are lending their trained field sales forces to pharmaceutical companies with growing sales needs.

ENVIRONMENTAL FORCES

The pharmaceutical industry is in the midst of sweeping environmental changes imposed by the managed care reform and global government cost-containment initiatives, as well as a series of customer and industry dynamics. The industry's major growth driver has dramatically changed over the past two decades, going through an innovation phase (early 1980s), a price increase phase (late 1980s), a cost reduction and consolidation phase (early 1990s), and a recent resurgence of innovation (late 1990s). Some of the recent trends with the highest impact on the industry were the globalization and consolidation drives. The sweeping advances made possible through recent technological advances have startled even the toughest critic.

The increased industry rivalry within the traditionally largest markets (U.S., Europe, and Japan), as well as the severe competitive pressures coming from the generics manufacturers and the growth in suppliers' power, has forced the multinational pharmaceutical players to pursue an intensive globalization campaign, seeking to enter and conquer previously underdeveloped markets. This expansion has mainly capitalized on emerging market opportunities in Eastern European countries, the former Soviet Union, China, and Latin America. Despite its merits, however, globalization remains a challenging and potentially risky business tactic. Several experts have suggested the following requirements for an effective globalization: (a) local expertise, (b) sales capabilities, (c) customer service network, and (d) supply base.

A consolidation wave has also recently swept through the industry, exhibiting repeated industry mergers and acquisitions of previously fierce competitors. The scope of such consolidating activities includes economies of scale, critical mass, financial position, filling of technical gaps, sharing distribution networks, and therapeutic area synergy.

Some major industry mergers and acquisitions in the 1990s

American Home Products/Cyanamid
BASF/Boots
Cardinal Health/Bergen Brunswig
Ciba/Sandoz
Glaxo/Wellcome
Hoechst/Marion Merell Dow
Hoechst/Rhône Poulenc Rorer
Nycomed/Amersham

Pharmacia/Upjohn
Rhône Poulenc/Fisons
Rhône-Poulenc/Rorer
Roche/Boehringer Mannheim
Roche/Syntex
Veba/Degussa

Table 2.2 sheds some light on some of the most promising recent technology advances according to experts' predictions and expectations. The main advancement fields are biotechnology, other enabling technologies, disease diagnosis, product development, product delivery, and healthcare informatics.

Future Trends

The next few years will continue to be challenging and demanding for the world's pharmaceutical industry. To prepare for the changes ahead, pharmaceutical marketers should proactively record and evaluate the possibility and impact of emerging trends so that proper measures and changes in corporate strategies can take place as early as necessary. Table 2.3 summarizes some of the industry's emerging trends, including external influences and customer and industry dynamics. Chapter 7 focuses on ways of analyzing the environmental situation and assessing the potential impact of the prevailing trends.

MAJOR STAKEHOLDERS

A pharmaceutical company's *stakeholder* is any person or group of persons with which the company has, or wants to develop, a relationship. These parties have an interest, or "stake," in the company's success. The thorough knowledge of their characteristics and needs is a must for all industry marketers, and careful attention should always be given to their analysis, crafting a relationship strategy, and evaluating their responses.

Stakeholders to the pharmaceutical industry belong to its internal and external environment. Thus, its internal stakeholders include every single company employee, either working relatively independently or as seen through the eye of a business unit, action committee, task force, functional team, or union. Obviously, the employee's education and training, as well as his or her motivation and sharing of the company's vision, are issues to be meticulously cared for by the organization's human resources department. Although employees' contributions have an enormous effect on the company's success, only a small portion of this book (Part 5, Communications' Strategy) is dedicated to their needs and wants. Including more information about internal stakeholders would be beyond the boundaries of this book. Instead, emphasis will be given to the external customers of the pharmaceutical organization who belong to a diverse mixture of interest groups. Kotler and Clarke (1987) categorize these external stakeholders into three main groups (see Figure 2.2). *Inputting stakeholders* include suppliers, regulators, and politicians, because they all play a significant influencing role in the company's success. *Mediators* include prescribers, university professors, and other healthcare professionals who stand between the company and its final customers, the patients. *Consumers*

Table 2.2: Technology Advances Affecting the Pharmaceutical Industry

Sector	Example	Description
Biotechnology	Gene therapy	The harnessing of recombinant DNA technology in identifying faulty genes and repairing them by administering a "fixed" copy
	Recombinant proteins	Using recombinant DNA techniques to make unlimited quantities of proteins lacking in a patient (e.g., insulin, growth hormone)
	Recombinant antibodies	"Custom-designing" recombinant antibodies that can search and destroy dangerous antigens (e.g., cancer cells, viruses)
Enabling technologies	Proteomics	The systematic characterization of protein profiles expressed in a given tissue, cell, or biological system (healthy or diseased)
	Rational drug design	Using computer-aided molecular modeling to design new entities that will bind a known receptor ligand like a "lock and a key"
	Combinatorial chemistry	Using automated sequencers to synthesize thousands of new molecular combinations and then screening them in test systems
	Small molecule chemistry	Using available technologies to synthesize small molecular entities, as opposed to large protein sequences
Disease diagnosis technologies	Genomics	Characterization and sequencing of the genome, and analysis of the relationship between gene activity and cell function
	Functional genomics	Systematic analysis of gene activity in healthy and diseased tissues
	Pharmacogenomics	The study of how a patient's response to a drug is affected by his/her genes; predicting a drug's good or bad responders
Product technologies	Natural candidates	Focusing on promising drugs that have been isolated from natural sources and improving their characteristics
Drug delivery technologies	Carrier molecules	Laboratory coupling of active substance with a "carrying" attachment that can guide it in the body to the problem site
	Space manufacturing	Avoiding the confines of earth's gravity by achieving new physical forms in space laboratories (crystalls, liposomes, emulsions)
	Oral peptide delivery	Solving the problem of painful injections by creating peptides protected from the degradating enzymes of the enteric route
	Oral vaccines	Protecting the body from infections by administering a vaccine resistant to enzyme degradation
Healthcare informatics	Outcomes measurement	Collecting large amounts of patients' clinical outcome data and then making rational, outcome-based clinical decisions
	Knowledge sharing	Using information-management systems to collect, store, retrieve, and disseminate knowledge to all interested parties
	Bioinformatics	New science combining biology and computers enabling the Human Genome Project (HGP) and other biological data to be used in drug discovery and clinical development
	Virtual trials	Testing new molecules' pharmacokinetic and pharmacodynamic effects on computer models, without ever injecting a human

Table 2.3: Pharmaceutical Industry's Environmental Changes in the Third Millenium

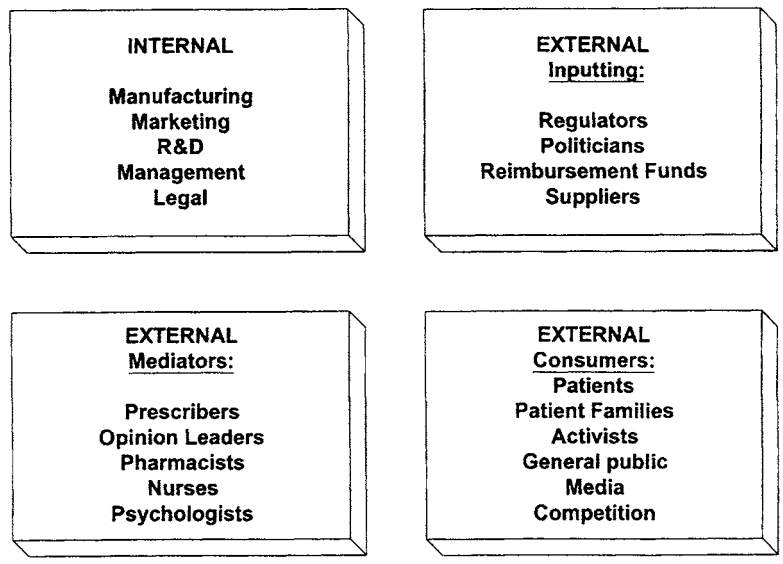
External Influences	Customer Dynamics	Industry Dynamics
Demographic shift	Increased sophistication	Technology advances
Epidemiological changes	Increased copayment	Economic pressure
Changing geopolitics	More health conscious	Shortage of innovation
Emerging ethical issues	Consumerism	Diversification
Healthcare system changes	Social changes	Increased rivalry
Regulatory changes	Patient advocacy movement	Generic competition
State cost-containment	Negative perception of industry	Virtualization
		Consolidation
		Globalization
		Integration
		Pharmaeconomics
		Patent expiration
		Direct-to-consumer marketing

include not only patients and their families or advocacy groups, but the media, general public, and the competitors, too.

A detailed mapping of the major external industry stakeholders and their needs and relevant issues is presented in Table 2.4.

A commonly used analytic tool for identifying and characterizing stakeholder groups is the analysis grid shown in Figure 2.3. Groups are individually identified and characterized according to their type (influencing, supporting, conflicting, and so on), role, importance to the pharmaceutical industry, prevailing trends, and anticipated future importance.

Figure 2.2. Different stakeholders within the pharmaceutical market environment

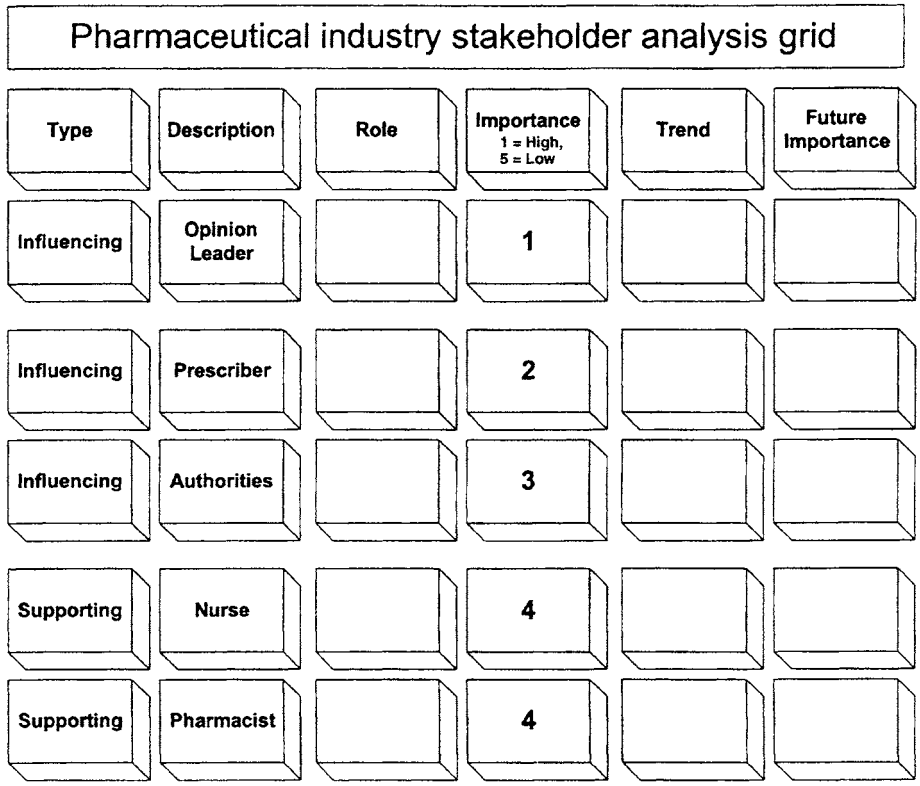


(Adapted from P. Kotler and R. N. Clark, 1987)

Table 2.4: Pharmaceutical Environment's Major Stakeholder Characteristics

			Who Are They?		
Patients	**Prescribers**	**Hospitals**	**Influencers**	**Financers**	**Regulators**
Patient Patient advocates Patient families	Physicians Nonspecialists/Specialists	Hospitals (State, Private, Military) Clinics HMOs Ambulatory care Nursing homes	Opinion Leaders (OLs) Pharmacists Wholesalers Nurses Social workers Consultants Suppliers	Reimbursement funds Insurance companies Employers MCOs	Ministry of Health Registration Authority Pricing Authority Patent Office Drug Organization Ethics Committees Formulary Committees
			Needs		
Best possible health care Lowest cost Information Choice Privacy Humane treatment Efficacy Safety	Pursue medical rationale Efficacy Safety Tolerability Quality of life Credibility Practice expansion Information	Increase clientele Increase market share Contain costs	OLs need professional recognition and advancement Healthcare professionals need access to choice Pharmacists need information and protection of profit margin	Protect patient benefit Contain costs	Preserve public health Provide coverage Ensure efficacy and safety Ensure fair pricing
			Issues		
Prescription vs. OTC choice Compliance	Up-to-date information	Discounts Long payment terms			

Figure 2.3. Pharmaceutical industry stakeholder analysis grid

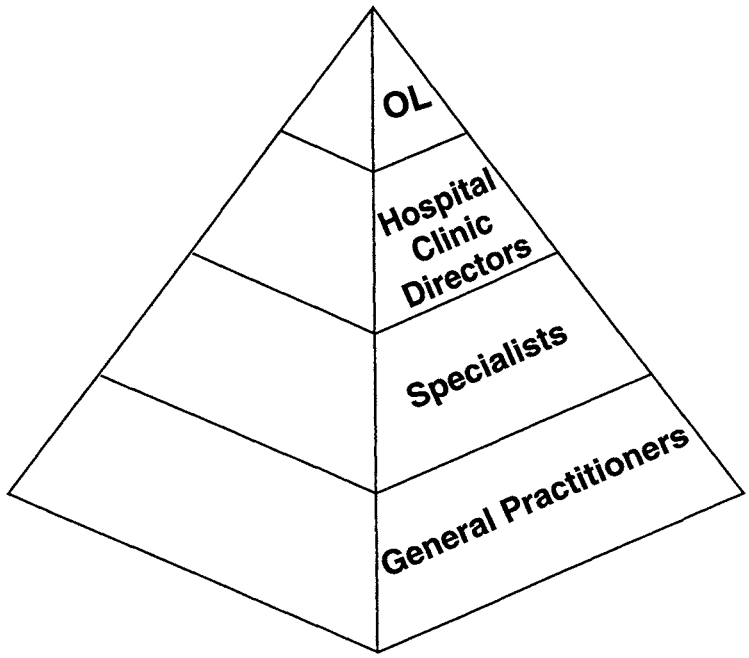


Prescribers

The primary providers of health care to the patients are actually the direct customers of pharmaceutical marketing. They pursue medical knowledge, maintain their patient base (if in private practice), and also follow some degree of cost-to-benefits logic (if working under a managed care environment). Pharmaceutical companies promoting different therapeutic categories come in contact with various physician categories and specializations. One of their important categorization criterion is professional rank or title—starting with the entry-level medical resident (or specializing physicians in some markets), and progressing to the academic ranks of fellow or lecturer, assistant professor, associate professor, and full professor. Should the physician be working for a state healthcare system, he or she climbs through the medical service ranks of consultant, registrar, senior registrar, and clinic director. Furthermore, medical specialties affect their work settings, the types of patients they come in contact with, and the medicinal therapeutic classes they utilize in their practice.

The professional ranking of physicians creates a hierarchical tree, which is observed and respected in all markets. Thus, younger and more junior physicians look up to their more experienced and senior colleagues for advice and guidance creating what has often been called a "pyramid of influence," as seen in Figure 2.4.

Figure 2.4. The pyramid of influence



The top of the pyramid is occupied by the commonly called opinion leaders (OLs), who are usually full university professors or leaders of medical associations. They have gained the respect of their peers after long years of pioneering the use of new methods and medications and successful practice.

Next on the pyramid are the hospital clinic directors or department heads, who lead a team of various-ranking institutional physicians, and may or may not be involved in the teams' promotions. The people in this category sometimes have the right to determine first treatment choice within the department, while in other settings the choice is completely up to the treating physician in the unit.

Medical specialists form the next hierarchical level, becoming experts in their field following long years of focused training and practice.

Finally, there is a large body of general practitioners (GPs), alternatively called pathologists or family physicians in some countries, who do not have a medical specialty training and work in medical settings where they come in contact with a large number of diverse medical cases. They usually refer the difficult cases to specialists.

The pyramid of influence describes the ongoing flow of knowledge and influence from the Opinion Leaders all the way to the GPs, and should be utilized in the same way by pharmaceutical marketers introducing a new medicine to the market. In other words, gaining the early approval of top ranking OLs can later be used in a cascade of influence or knowledge sharing to present the merits of the new medicine throughout the pyramid. Opinion Leaders are usually introduced to new drugs through the clinical trial process, and this introduction is one of the major responsibilities of medical marketing managers.

The medical prescribing decision is a process that has attracted the attention of marketers, psychologists, and others. Obviously, the identification of distinct decision-making steps and the influencing factors involved might yield important information for the successful marketing of prescription pharmaceuticals to physicians. The prescribing decision-making process involves a primary decision of selecting the therapeutic class most appropriate to every case, as well as a secondary decision of selecting a brand among those offered within the therapeutic class. The steps involved in both processes are (a) problem recognition; (b) an information search on available treatment options and medicinal choices; (c) an evaluation of existing therapeutic alternatives; (d) the actual prescribing decision; and (e) a postprescribing evaluation of the benefits received from the treatment selected (see also Chapter 16).

Influencers

This large and diverse group of stakeholders comprises Opinion Leaders (who may or may not be active prescribers themselves), pharmacists, other healthcare professionals (nurses, psychologists, social workers, rehabilitation workers, and so on), supply chain intermediaries (distributors, wholesalers, suppliers), hospital administrators, external consultants, medical sales representatives, and others. Although their characteristics and needs are diverse, they can all influence the prescribing decision, and thus are important industry stakeholders. These stakeholders need to be carefully identified and must have their needs fulfilled in order to facilitate the commercial success of pharmaceutical products.

Opinion Leaders

As previously mentioned, **Opinion Leaders** may not be active prescribers, holding, instead, academic, administrative, or even political positions that keep them away from everyday medical practice. Nevertheless, being at the top of the pyramid of influence, they need to be approached early by pharmaceutical marketers and given access to a new product's clinical trial profile so that they may become educators or conference speakers of the product's merits from the beginning. Their invitation to premarketing brainstorming sessions and activities or inclusion into advisory boards or task forces are critical later during the product's launch phase. The OLs' motives include professional visibility and recognition, the right to educate or influence others, the possibility of influencing policy making, and the opportunity to contribute to clinical practice guideline creation or new product development. Marketers should bear in mind that a subtle, respectful, and nonbiased approach is needed, instead of a "hyperactive," force-feeding, or hard-selling one.

Pharmacists

Pharmacists are becoming increasingly important in the managed care trend sweeping across the United States and northern Europe. In view of the cost-containment principle of these environments and the accountability of prescribers and pharmacists, increasingly more substitution rights are given to the pharmacists. Thus, a pharmacist, or Pharmacy Benefits Manager (PBM), relies on the recommendations of institutional or national formularies when selecting a less expensive therapeutic equivalent of the one prescribed, often a generic. Manufacturers, then, are obliged to present detailed, pharmacoeconomic data to the pharmacists in support of their claims, or are forced to

significantly lower their prices in order to avoid formulary exclusion. The outcome of these substitution practices is further presented in Chapter 11.

In addition, **hospital or retail pharmacists** have other distinct needs and wants that should be considered. For example, large packaging may quickly take up valuable shelf space and light- or temperature-sensitive formulations may require expensive climate-controlled facilities. Also, patient information material, in-store displays, and large manufacturer advertising campaigns that will lead customers into their pharmacies are some of the needs of this stakeholder category.

Healthcare professionals

Healthcare professionals are another valuable link in the healthcare delivery chain. Their efforts support those of the primary providers and are responsible for significant contributions into patient treatment. Actually, chronic patients may see their nurse or physical therapist more often than their treating physician and nurses and physical therapists are the ones that explain adverse drug events and the importance of compliance to patients. In some cases, busy physicians only select a therapeutic class, while their long-time nurse chooses the product brand to be given to an inpatient. Pharmaceutical marketers need to evaluate the contribution of healthcare professionals on a per hospital basis, and proceed into educating and informing these stakeholders about certain disease or product characteristics.

Hospital administrators and medical sales representatives

Hospital administrators are the behind-the-scenes financial managers who often mandate hospital drug budgets and, depending on their influence, may be treated as influencers or actual customers (described later in this chapter). Finally, medical sales representatives are among the most undervalued influencers; and their tasks and activities are discussed in Chapter 17.

Regulators

As seen in the previous chapter, the pharmaceutical industry is one of the most government-regulated industrial sectors (others include food, air travel, and so on). There are multiple regulatory controls and levels, starting with the institutional, to the local, national, international, or even global level. Furthermore, regulation is not only restrictive and inhibiting, but can be promoting or even rewarding. The major aspects of government influence on the pharmaceutical industry are summarized in Table 2.5.

Most experts would agree that the main industry issues facing government regulation are collaboration, compliance, harmonization, negotiation, and lobbying. The latter is a critical activity that global players need to conduct with commitment and determination across legislative or national borders. Furthermore, it has been often proven that direct confrontation with national authorities has not led the industry to any significant gains, but instead has caused added resistance and animosity.

Financers

This category includes those stakeholders who provide resources to a healthcare system, such as state reimbursement funds, insurance agencies, and employers. Their

Table 2.5: Aspects of Government Influence on the Pharmaceutical Industry

Funding	Regulating	Promoting	Rewarding
R&D grants	Patent protection	Influence on other governments	Innovation awards
Social security	Registration	Local industry incentives	Export awards
Facility creation	Reimbursement	Substitution legislation	Quality awards
	Pricing	Disease diagnosis campaigns	Orphan drug exclusivity
		Manufacturing	
		Marketing	
		Prescribing decision	
		Trade barriers	

motives are open accessibility for all citizens and employees to health care, fairness, transparency, accountability, and cost containment. Once again, the managed care reform has shifted the traditional "fee-for-service" relationships to a relationship where financers directly negotiate with MCPs on service level and costs. In turn, MCPs strongly negotiate with providers as they do with pharmaceutical manufacturers on treatment costs and cost-to-benefit ratios. This chain of events has increased the player awareness of pricing strategies and pharmacoeconomics, and forced pharmaceutical manufacturers to become more efficient and pharmacoeconomics-minded. The influence of these trends is further discussed in Chapters 14 and 15.

Consumers

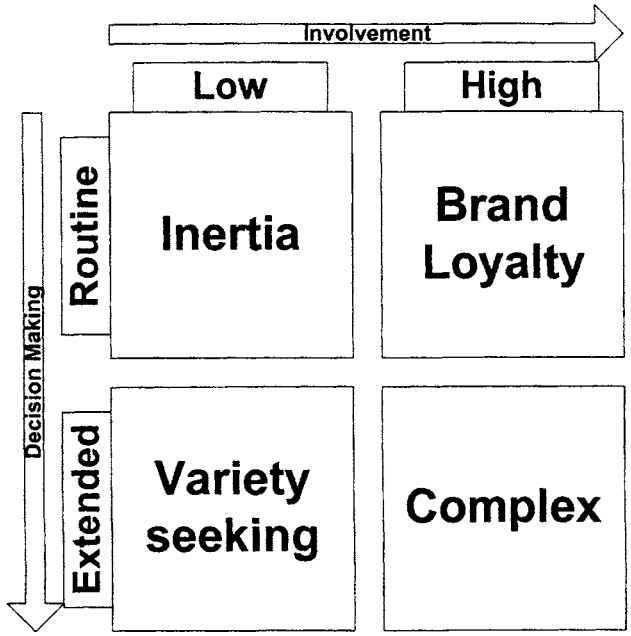
Although prescribers are the industry's direct customers, the final consumers of pharmaceutical products are individual (patients) and organizational buyers. We will study these two categories and attempt to identify their needs and motives when purchasing pharmaceuticals.

Patients

A large amount of literature has been devoted to the study of patient needs, wants, and rights. Within the context of this book, the focus is on the patients' needs as well as the important concept of compliance. These are directly related to industry's marketing strategies. Figure 2.5 shows the processes involved in consumer decision making and involvement in the purchase of pharmaceuticals. When decision making is routine and involvement is low, a consumer is driven by inertia when selecting a pharmaceutical that is available without a prescription (OTC), as in the case of a topical antihistaminic medication. If, however, the consumer's involvement is high then he or she is driven by brand loyalty, as in the case of chronic treatments for asthma or ulcer. The effects of product branding then become crucial, and they are discussed in Chapter 8. Conversely, if consumer decision making is extended but involvement is low, a consumer may seek multiple medical consultations and a variety of pharmaceutical interventions. Finally, if both decision making and consumer involvement are high, as in the case of a severe and chronic disease, then the consumer is faced with a complex situation that will require repeated medical visits and diagnostic tests and a complicated pharmacological treatment scheme, as well as additional lifestyle changes (altered diet, physical exercise, and so on).

One of the most important healthcare issues, which has direct implications on the pharmaceutical industry, is the issue of patient noncompliance. Some impressive patient

Figure 2.5. Consumer decision making and involvement in the purchase of pharmaceutical care



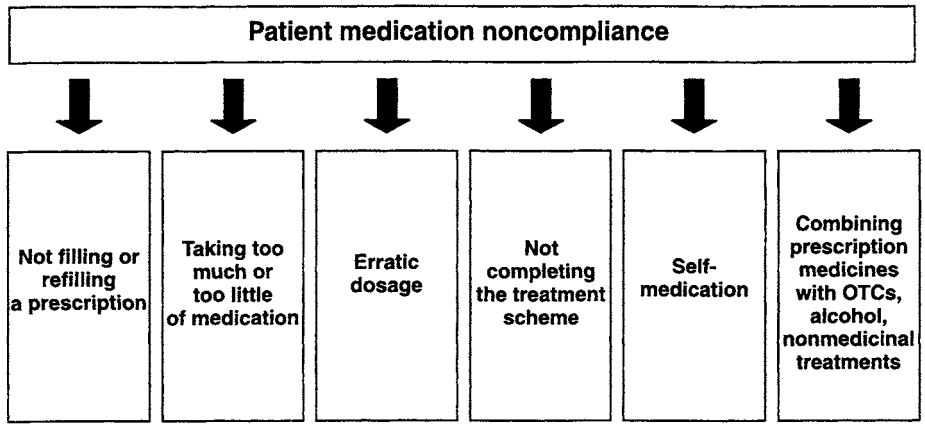
(Adapted from H. Assael, 1987)

compliance statistics are: 20 percent of prescriptions are never filled; more than 50 percent of patients make significant mistakes in following the prescribed dosage scheme; more than 50 percent of patients attempting a lifestyle change never complete it; and almost 90 percent of patients attempting radical diets fail to lose weight. What is patient noncompliance then? There are actually several different types including (a) adherence to prescribed medications, (b) undergoing required laboratory tests, (c) attendance of follow-up schedule, and (d) making lifestyle changes.

Figure 2.6 summarizes the basic types of patient medication noncompliance. This phenomenon is a frequent origin of suboptimal treatment outcomes and doubts coming from prescribers, patients, and their families on the merits of pharmaceutical care, as well as a waste of health system resources. There are multiple factors contributing to this type of patient noncompliance such as treatment scheme complexity, perception of the disease, family input, elderly patients, patient information quality (Summary of Product Characteristics [SmPC], patient literature, and so on), and poor communication with healthcare professionals (physicians, nurses, pharmacists, and so on).

These obstacles to good compliance have been recently confronted by both healthcare providers and the pharmaceutical industry, leading to more "holistic" or comprehensive healthcare delivery methods, covering wellness, prevention, treatment guidelines, compliance-improving tools, education, information, products, and services. These methods belong to the commonly called **disease management** initiatives.

Figure 2.6. Patient medication noncompliance



Organizational buyers

Organizational buyers of pharmaceutical products share certain similarities with individual consumers, but are also characterized by large differences that require special industry approaches. This customer grouping is composed of physicians and nurses, hospital pharmacy directors, formulary specialists, pharmacy benefit managers, financial administrators, and others who usually work in teams assigned to compare, evaluate, and purchase large pharmaceutical orders from manufacturers. Team members hold the role of users, influencers, buyers, deciders, and gatekeepers, while their groups have been collectively called "buying centers" or "purchasing teams." Table 2.6 summarizes the main differences of organizational buyers from retail (independent) pharmacists, their buying structure, and the steps involved in their purchasing decision, as well types of purchases and prevailing trends.

Table 2.6: Characteristics of Hospital Buying

Versus Retail	Buying Structure	Buying Phase	Buying Type	Trends
Fewer	User: Physician, Nurse	Problem recognition	First purchase	Supplier quality assurance
Larger	Influencer: Clinic Director	Need recognition	Repurchase	Value-added engineering
Closer relationships	Buyer: Purchasing Department	Product specifications	Modified repurchase	Just-in-time delivery
Derived demand	Decider: Board of Directors	Supplier identification		Tender business
Inelastic demand	Gatekeepers: Accountants	Proposal gathering		Long payment terms
Professional purchasing		Ordering		Hospital formularies
Systems buying		Performance evaluation		Strategic alliances

(*Scrip*, 2426/27, April 7/9, 1999. Reproduced with permission from PJB Publications Ltd.)

The organizational buying decision is more complex than the individual customer's decision making, and involves the following steps (Robinson et al. 1967):

1. identification of need
2. determination of product characteristics and quantity needed
3. definition of exact product specifications and critical needs
4. identification and evaluation of potential suppliers
5. collection and analysis of proposals
6. evaluation of proposals and selection of suppliers
7. selection of order frequency
8. performance feedback and evaluation

Pharmaceutical marketers must pay significant attention to assigning steps to and analyzing the organizational buyer decision-making process on a per hospital basis. It is also important to be aware of which specific processes and tools have been in place at that institution so that an optimal approach is designed and implemented. Some of the most common methods used by managed care pharmacy directors to create a prescription benefit are the following:

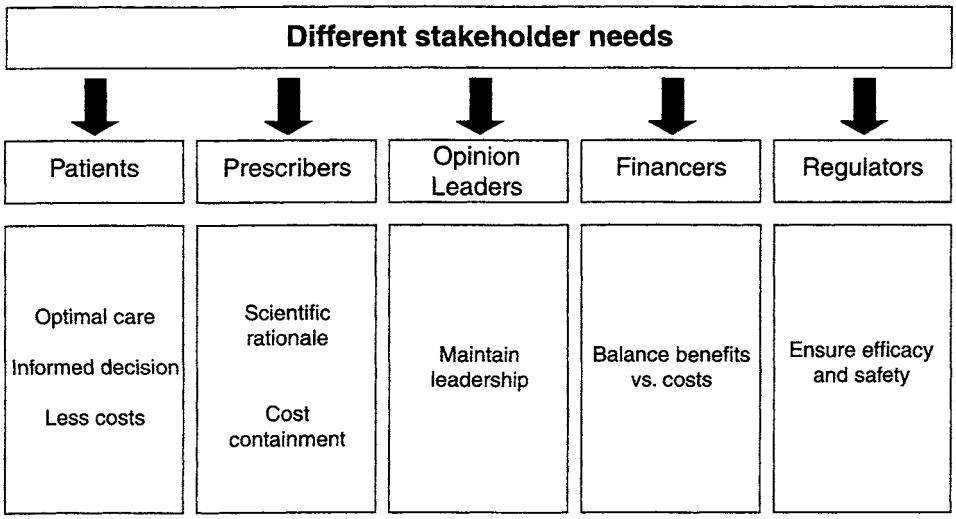
1. pharmacy and therapeutics committee
2. therapeutic equivalency programs
3. generic equivalency programs
4. tenders
5. academic detailing
6. coinsurance
7. dispensing limitations
8. drug utilization review (DUR)
9. drug utilization evaluation (DUE)
10. outcomes management

A practical approach of industry marketers toward today's managed care buying teams involves identifying the players involved and their decision-making steps. This is the first critical step in crafting an institution-specific strategy. Furthermore, formulary management within the institution needs to be addressed and hospital-required disease management programs and activities must be "packaged" with the pharmaceutical products under discussion. Ambulatory patients need to be the focus of such an effort, because in-hospital stay represents only a small fraction of the overall treatment schemes needed for chronic and severe diseases. Additionally, there is an increasing trend for a just-in-time (JIT) delivery schedule, which needs to be discussed and arranged with the company's supply chain colleagues. Overall, addressing the needs of the organizational buyer is a multidisciplinary and arduous process that needs to be adapted to different institutions and modified if competitive or other environmental forces necessitate it.

Different Stakeholder Needs

In conclusion, the industry's stakeholders represent a diverse and large group of individuals and organizations with their own specific needs and desires. Figure 2.7 summarizes the main stakeholder groups and their respective needs. The needs of different

Figure 2.7. Different stakeholder needs



stakeholders are often in conflict. For example, fully insured patients demand the best possible care irrespective of costs, while their insurers try to contain costs and protect their profitability. Also, opinion leaders may be promoting the use of newer, more efficacious and expensive pharmaceutical products, while an active prescriber with an elderly clientele is more concerned with the drugs' interactions profile or their costs. Finally, patient advocate groups often confront the regulators, demanding faster access to innovative and promising medications.

Once again, a strategic, multidisciplinary approach by the pharmaceutical industry is needed, and addressing every single stakeholder's needs in a nonbiased and balanced way is a prerequisite for success in today's marketplace.

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3

The Pharmaceutical Marketing Environment

> The value of UK pharmaceutical exports in 1997 was £5.5 billion—equivalent to more than £90,000 per employee.
>
> ABPI, 1998

The preceding chapters focused on the operational environment (the "battlefield") of pharmaceutical industry, presenting the characteristics of the healthcare environment, healthcare regulation, and the pharmaceutical industry and its stakeholders. This chapter discusses the recurring ethical considerations of pharmaceutical marketing and analyzes the product mix and marketing environment of this industry. The reader also will be invited to study the elements of product management and medical marketing and to identify the similarities and idiosyncrasies of the marketing of pharmaceutical products versus other market sectors.

THE CONCEPT OF MARKETING: PRODUCTS SATISFY NEEDS

It is difficult to avoid marketing activity in the electronic age we all live in. In other words, marketing is all around us. It reaches us in our home, through television, radio, newspapers, magazines, or even by word-of-mouth from someone who has been satisfied by the merits of a recently purchased product. We are also exposed to marketing's

activities while driving (via radio or road signs) or while shopping or working or jogging at the park. One would suggest that marketing is visible everywhere.

Can marketing also be "invisible" to the naked eye? The answer is yes, through myriad ways. Can the visiting prime minister of a developing country be "marketing" his country to the leaders of a transnational group of countries, or even the board of directors of the World Bank? Can a singer be "marketing" her albums when she sings the national anthem at a sporting event? Can arms' dealers be "marketing" their products when they comment on their capabilities on an evening TV news show? Or, can the makers of a fountain pen be "marketing" their product when it is "casually" zoomed in on during a blockbuster movie? Most of us would agree that these are all different forms of marketing and they can all be practiced and improved upon by studying the science of marketing.

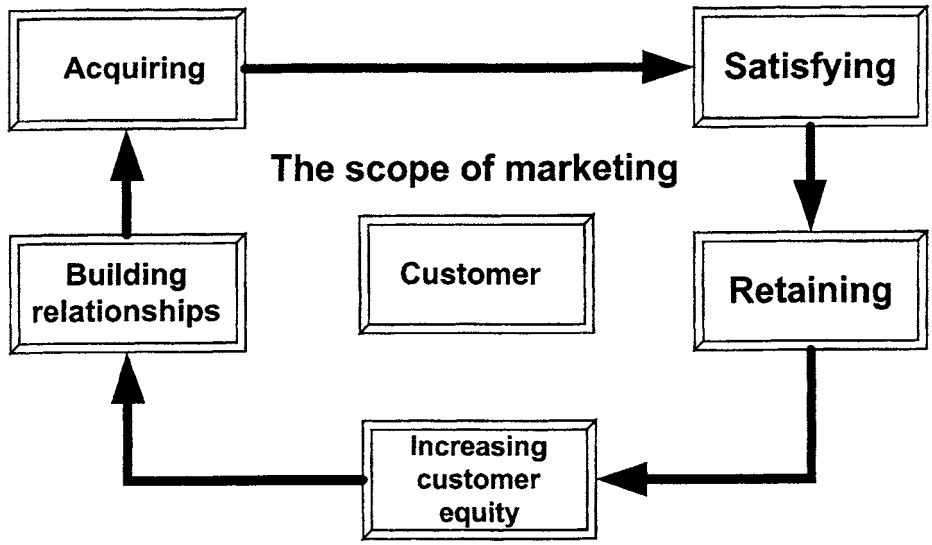
Looking back at the previous examples, one might think that marketing is strictly for-profit. Why else might a person or an organization invest in a marketing activity if not for profit? The answer this time is that marketing is not only for-profit. There are several examples of people or organizations involved in not-for-profit marketing. For example, the armed forces are actively seeking some brave new recruits. Physicians are sending reminder cards to their patients to remind them of a checkup. Religious organizations are involved in marketing in order to strengthen their parish and increase the level of donations. Finally, environmental, human rights, and patient organizations are investing millions of dollars for marketing their agendas and improving their effectiveness. Obviously, the organizations mentioned are depending on the results of their campaigns to ensure their long-term survival.

Based on this information, how can we define marketing? Here are some definitions of marketing from famous organizations or marketing thinkers. Marketing is the process of planning and executing the conception, pricing, promotion, and distribution of ideas, goods, and services to create exchanges that satisfy individual and organizational goals (American Marketing Association, 1985); marketing is the management process responsible for anticipating and satisfying customer requirements profitably (The Chartered Institute of Marketing, in Jenner, 2000); marketing is a social and managerial process by which individuals and groups obtain what they need and want through creating, offering, and exchanging products of value with others (Kotler and Clarke, 1987); and marketing is the entirety of the business from the perspective of the customer (Drucker, 1993). Looking through these definitions one concept stands out—*satisfying customer needs*. Most experts would agree that marketing is all about identifying customer needs and wants, and building products that will satisfy them. More precisely, marketing's scope is satisfying customer needs, thus retaining them, which leads to building long-term relationships and ultimately acquiring more customers (see Figure 3.1).

The satisfaction of customer needs, wants, or demands is one of the core concepts of marketing. As the other chapters of this book show, the role of marketing within today's organizations, from the conception of a new product idea to the product's decline and potential market withdrawal, is of paramount importance for satisfying those customer needs. The pioneering work of Maslow has categorized these customer needs, from the absolutely essential physiological needs, to the need for safety, to social and love needs, to the self-esteem and self-actualization needs (see Figure 3.2).

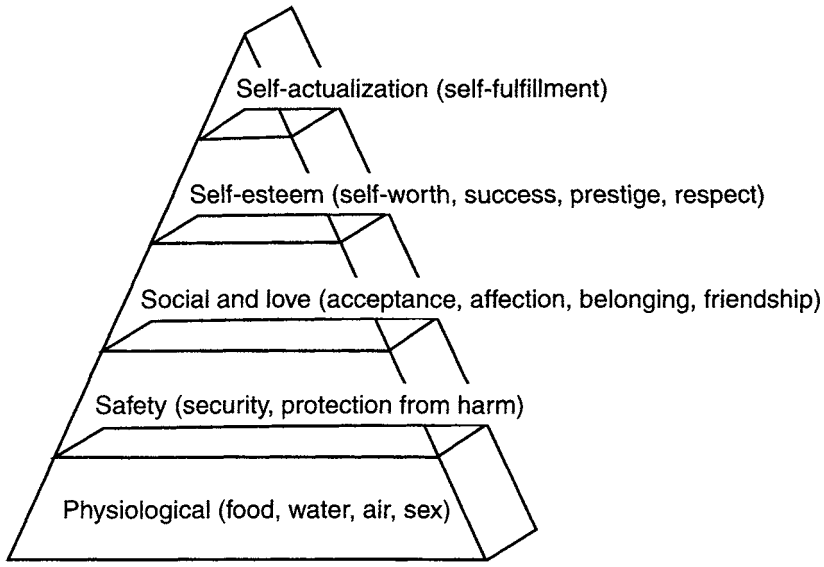
The needs' hierarchical pyramid model has been used extensively by marketers in assessing, categorizing, and targeting their product offerings toward the satisfaction of

Figure 3.1. The scope of marketing



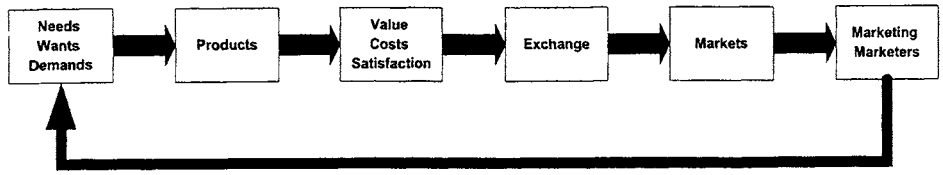
these needs. Products exist today that satisfy almost all of these human needs to a varying degree of customer satisfaction. However, one of the axioms of today's marketing is that not all of these needs have been satisfied by marketable products, or that the customer may not be aware of some of these needs, which are voids that marketing attempts to fill. Another way of looking at the needs-to-marketing relationship is the schematic presented in Figure 3.3. Thus, customer needs, wants, and demands necessitate the design and commercialization of new products, which in turn represent an

Figure 3.2. Maslow's Hierarchy of Needs



(Maslow, 1954)

Figure 3.3. Core concepts of marketing



internal customer value, a cost, and a level of satisfaction. This leads to a monetary exchange, which is the prerequisite for the formation of a market and the application of marketing.

MARKETING MANAGEMENT

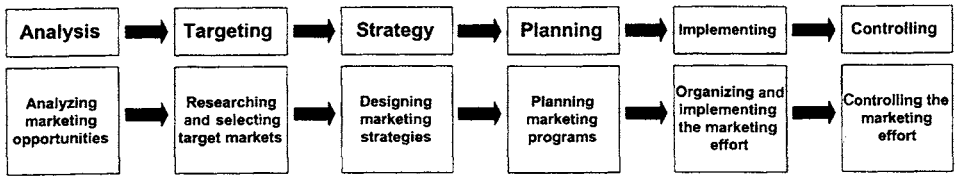
Having discussed the concept of marketing, we can now discuss the art of blending all the required marketing activities into a coherent, strategic framework. *Marketing management* is the analysis, planning, implementation, and control of programs designed to bring about desired exchanges with target markets for the purpose of achieving organizational objectives (Kotler, 1980). As Figure 3.4 shows, the marketing management process has six distinct components. These include

1. analysis of the environment, competition, and the organization, which leads to the identification of marketing opportunities;
2. study of the market and identification of distinct market segments;
3. marketing strategies specifically designed for the chosen market segments;
4. detailed planning of marketing programs and activities created to achieve the previously set strategic objectives;
5. organization and implementation of a network of marketing activities; and
6. evaluation and control of all marketing activities.

These marketing processes and activities are planned, executed, and evaluated by a variety of marketing managers, who hold different titles and stand at different hierarchical levels within the organization.

Is marketing management, then, a creative activity or a science? It is probably a blend of both. As a science, marketers can study today's marketing intricacies and techniques in an academic environment. As a creative activity, some marketers without an academic marketing background can succeed with charisma and enthusiasm. Whatever the contribution of each pathway, a sound academic base can only enhance and bring such charisma to the surface.

Figure 3.4. The marketing management process



PHARMACEUTICAL VS. CONSUMER MARKETS

Suppose you were a successful consumer goods marketer that, after a proven track record, was hired by a pharmaceutical multinational to market its new line of antibiotic products. With the didactic content of your MBA studies fresh in your mind and the successes of your marketing career fresh in your heart, you would go about creating new product development plans, advertising campaigns, and unique selling points. Clearly, however, after talking to prescribers, regulators, and your own medical sales representatives, you would discover that pharmaceutical markets bear distinct differences from your prior battlefields.

Peculiarly enough, the patient consuming your product is neither the decision maker, nor the buyer. Additionally, ethical, regulatory, and liability considerations would be much higher in the case of antibiotics than electric home appliances. And finally, brand loyalty and price sensitivity would be less of a problem than the fierce competition seen in the computer or travel industries. An overview of the main differences between consumer and pharmaceutical markets is presented in Table 3.1.

What, then, are some of the particular aspects of pharmaceutical marketing? They are: (a) more stringent regulation of the industry as opposed to consumer markets—a level of regulation matched by very few other sectors (for example, airline travel); (b) the necessity for huge R&D investments, often surpassing 20 percent of annual revenues; (c) the sensitive issue of patient rights; and (d) a variety of other ethical issues, such as animal welfare and environmental protection.

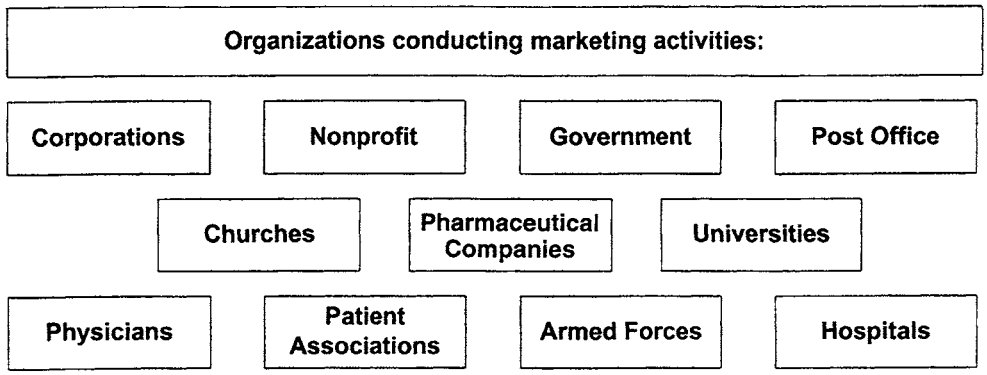
ETHICAL CONSIDERATIONS OF PHARMACEUTICAL MARKETING

As previously noted, pharmaceutical and consumer markets, with their many similarities, also have significant differences that set them apart. Related to the idiosyncrasies of the pharmaceutical market is the fact that the marketing of pharmaceutical products, although revered and admired in other sectors, is all too often the recipient of strong criticism from consumers and authorities alike. In fact, the marketing of pharmaceutical products is often thought of as wasteful, intrusive, and manipulative, as well a cause for lower healthcare quality, social inequality, and unnecessary demand. And indeed, in the lay person's eyes, a medication is only a social good, which should be either completely reimbursed by the state or sold at cost by the manufacturer for the good of humankind.

Table 3.1: Comparison of Pharmaceutical to Consumer Markets

	Pharmaceutical	Consumer
The consumer is the decision maker	Not true	True
The consumer pays directly for the product	Not true	True
Product brand loyalty	Higher	Lower
Importance of ethics	Higher	Lower
Degree of government regulation	Higher	Lower
Liability considerations	Higher	Lower
R&D complexity	Higher	Lower
R&D on humans necessary	Yes	No
R&D costs	Higher	Lower
Price sensitivity	Lower	Higher

Figure 3.5. Organizations conducting marketing activities



In other words, why should pharmaceutical manufacturers use extravagant advertising, which drives their prices up or creates social inequalities among different social classes?

Several authors have already addressed these ethical issues, and the debate is frequently rekindled. The following list summarizes why some of these criticisms are faulty, using the framework first proposed by Kotler and Clarke (1987) on healthcare marketing in general.

Criticism	Why false
Wasteful	The pharmaceutical industry is a for-profit sector, like so many others (automobiles, energy, and food). Industry players allocate a small portion of their revenues to marketing activities in defense of industry or generics competitors (see Figure 3.5). A scenario of completely abolishing marketing expenses by shifting them into new R&D is a utopia because R&D, or any other department, cannot work in a vacuum.
Intrusive	Healthcare professionals often describe horror stories of hard-selling industry representatives. While this phenomenon may hold true for a small percentage of sales professionals or their employers, it is by no means representative of the vast majority of innovative manufacturers who maintain high-quality, ethical standards of conduct, abide by national and international guidelines, and have gained the respect and partnership status from healthcare professionals around the world.
Manipulative	Industry critics often attack all industry-sponsored medical activities, including congresses, continuing medical education, and research. Nevertheless, the conduct of these activities is supervised and controlled by relevant institutional, government, or trade bodies, and the synergy resulting from such interaction is recognized by many as a force of innovation and advancement.
Lowers healthcare quality	The promotion of pharmaceutical products cannot influence the healthcare professionals' and patients' mindset if the promoted products lack necessary merits or do not satisfy unmet therapeutic needs. To the contrary, the successful commercialization and promotion of innovative medicines is the sole fuel used by

large R&D departments constantly looking for new therapeutic solutions.

Creates social inequality

The promotion of innovative and often high-priced pharmaceutical products is not the origin of social inequality per se. Industry professionals are not designing new product offerings with certain social classes in mind. Instead, they are offering new innovations to humankind's therapeutic medicine chest. However, government or private organization insurance and reimbursement policies may be deemed unequal, and it is up to the citizens or employees to correct these injustices within the available democratic procedures.

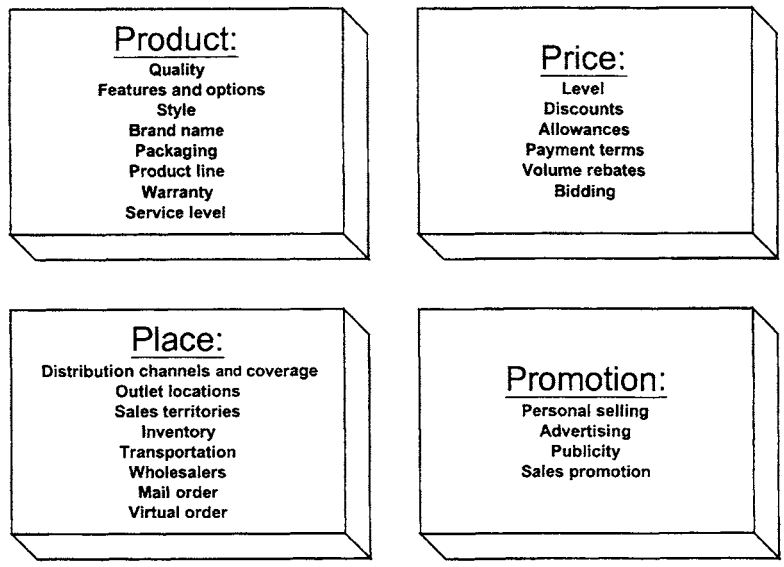
Creates unnecessary demand

The promotion of pharmaceutical products to prescribers or direct-to-consumers (DTC) is not the cause of overprescribing or overconsuming pharmaceutical medications. These phenomena are related to a variety of demographic and social factors, which can be influenced positively through education and information for prescribers and patients on the merits of optimal treatment guidelines, compliance, and mutual dialogue. These are issues that have been addressed by the disease management movement.

THE MARKETING MIX

The result of marketing activities is a mix of product characteristics and benefits, commonly called the *marketing mix*, a term first introduced by Borden in 1964. The basic elements of the marketing mix are the product, price, place, and promotion (collectively coined the four Ps of marketing). Figure 3.6 shows some of the main elements constituting each of the four Ps, which are discussed in detail (see also Table 3.5).

Figure 3.6. Marketing's 4 Ps



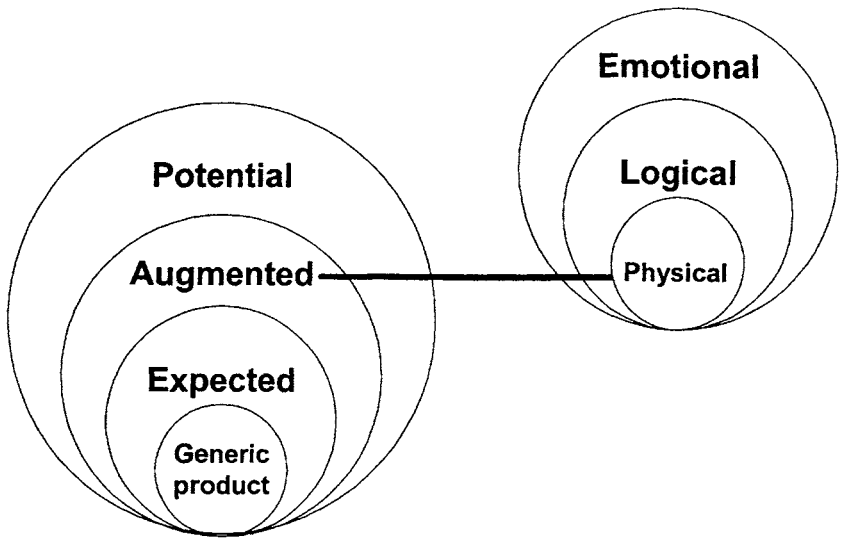
Product

The foremost element of the marketing mix is the product. This term encompasses the combined offerings of the seller to the customer, and may have a tangible or intangible nature. For example, a product can be a physical good (leather bag, computer, or pencil), a service (haircut, shoe polish, or train ticket), or even an idea (environmental protection, political amnesty, or patient advocacy). A variety of definitions have been given to describe the product, including the following two: (1) "Anything that can be offered to a market for attention, acquisition, use, or consumption that might satisfy a want or need" (Kotler, 1991); and (2) a good, service, or idea consisting of a collection of tangible and intangible attributes that satisfies consumers and is received in exchange for money or some other unit of value (Zikmund and D'Amico, 1996).

One of the elements of the product concept is the existence of multiple product features that, even in the case of goods, can be tangible or intangible and physical or emotional. Figure 3.7 presents the concept of core and augmented product features. For discussion purposes let us use the example of an automobile for looking at the various product features associated with it.

Generic product features is a term describing the inherent product features, which, in the car's case, are its engine, seats, windows, body, and so on. This term should not be confused with the "generic pharmaceutical" term, which is explained later. *Expected* features are those existing in the mind of the customer, which are not necessarily present in all makes and models, such as fast acceleration or high maximum speed. *Augmented* product features is an extremely critical term, used to describe all other features, services, and benefits the car manufacturer bestows on its model in order to make it more appealing to the customer. For example, a spare tire is an augmented feature, as is financing provided by the dealer, or free engine service, or free roadside assistance for a period of time. These augmented features play a significant role in the commercial success of the car model; thus car marketers go to great lengths in offering the most appealing features to their clientele.

Figure 3.7. Core versus augmented product features



They can even be categorized as physical (car alarm or gold plated key ring), logical (roadside assistance), and emotional (a convertible's image as a status symbol).

Products similar in nature and aimed at the same customer segment are often grouped by organizations in product lines or sets of products with similar features and marketing needs. A company's *product portfolio* is characterized by product line width and depth, as shown in the example of a pharmaceutical portfolio in Figure 3.8. Thus, a product line width is the number of different product lines within the organization, while a product line depth is the number of individual products within the same product line.

A *pharmaceutical product*, or drug, is broadly defined as any chemical agent that affects the processes of living. Related terms include *pharmacology*, the science focusing on the history, source, physical and chemical properties, compounding, biochemical and physiological effects, mechanisms of action, absorption, distribution, biotransformation and excretion, and therapeutic and other uses of drugs; *pharmacokinetics*, the pharmacologic area dealing with the absorption, distribution, biotransformation, and excretion of drugs; and *pharmacodynamics*, the area dealing with the study of the biochemical and physiological effects of drugs and their mechanisms of action (Goodman Gilman, 1990). Figure 3.9 shows a pharmaceutical product's essential fingerprint signatures. These include the product's nomenclature, its mandatory accompanying documentation, and its labeling.

Recent decades have seen a dramatic transformation of the characteristics and values of any pharmaceutical product. These shifts have come about from environmental changes such as the empowerment of patients, government measures around the globe to reduce healthcare costs, changing prescriber needs, or even the increased globalization and communication between healthcare stakeholders around the world. A decade ago, a concerned patient needed only a blood cholesterol-reducing pill. Today, the concerted environmental forces surrounding the pharmaceutical industry are demanding a more efficacious, safe, and easy to use medication, accompanied by disease treatment

Figure 3.8. Product line width and depth

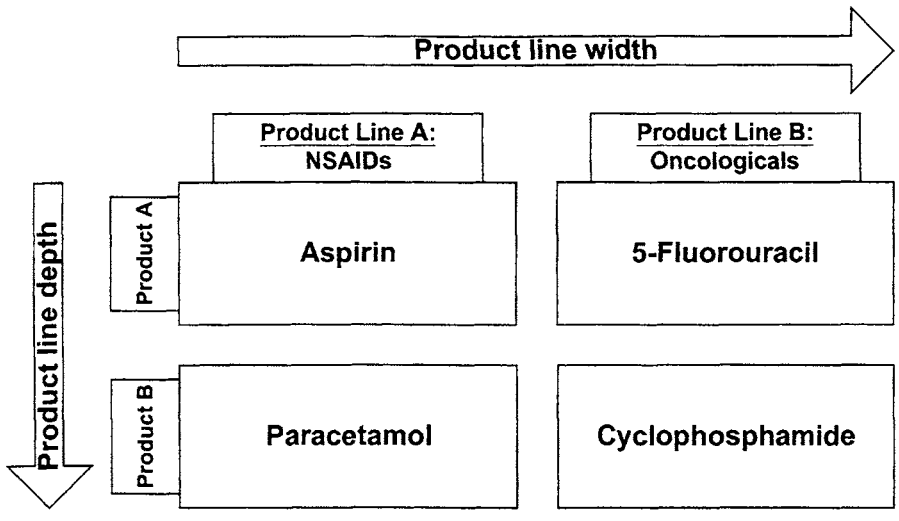
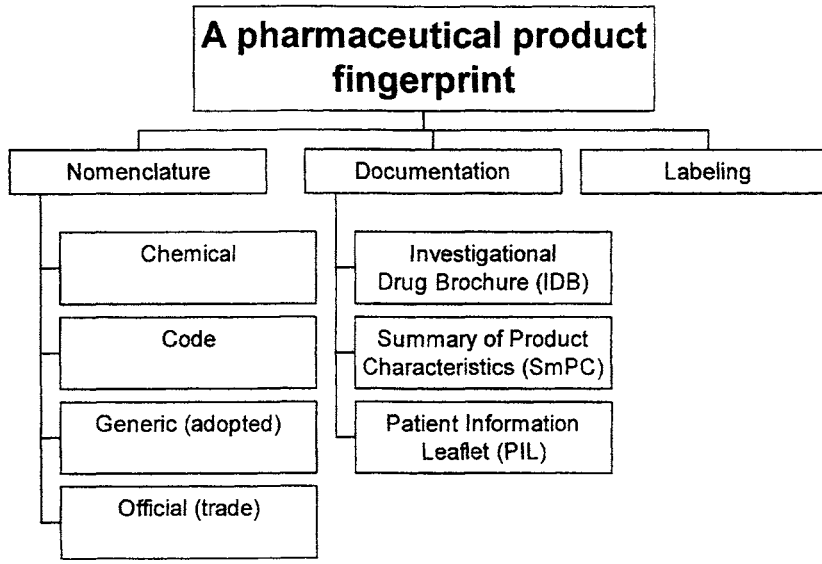


Figure 3.9. A pharmaceutical product fingerprint



guidelines, offered by a company that cares about the patient's quality of life as well as the environment, at an affordable price in all parts of the world (Table 3.2).

Due to the changing nature of pharmaceutical products, each product aimed at successfully competing in its therapeutic category has to carry a set of product and economic components that are well defined and superior to the offerings of competitors. Together, these components make up only a part of the perceived product value in the eyes of stakeholders. Product components can be distinguished in core values (efficacy, safety, and ease of use) and augmented values (see Table 3.3).

But why do physicians prescribe a particular pharmaceutical over a competitive product? And, why do patients seem to develop a brand loyalty to one of the many products taken by them during their life? It is important to realize that, as in the case of a consumer buying a "hole" instead of a "drill," a patient buys a product benefit instead of a product characteristic. Indeed, patients of all ages buy a decrease in body temperature or relief from the itching caused by a topical burn. A concerned mother

Table 3.2: The Evolving Nature of a Pharmaceutical Product

View	Description	Customer Benefit
Old	Blood cholesterol-reducing pill	Cholesterol lowering
Modern	Revolutionary, efficacious, and safe active substance plus	Efficacy and safety
	Patient-friendly administration device plus	Painless use
	Disease management services plus	Treatment guidelines
	Innovative disease prevention ideas plus	Prevention
	Patient well-being-minded employees plus	Caring
	Patient-, environment-, and cost-minded organization plus	Affordability, Ecology
	Product availability for all mankind (not market-restricted)	Universal access

Table 3.3: Characteristics of Pharmaceutical Products

Product Components		Economic Components	
Core values	**Augmented values**	**Price-related**	**Nonprice-related**
Efficacy	Ease of use	Actual price	Distribution channels
Safety	Temperature stability	Competitive pricing	Channel intensity
Tolerability	Shelf life	Price-value relationship	Channel length
Speed of action	Patient education	Discounts	Channel integration
Quality	Physician information	Return-on-investment	Promotional level
Cost	Patient association support		Promotional channels
	Mail delivery		Advertising intensity
	Company Web site		Personal selling effort
	Branding		

buys decreased swelling in her child's allergic skin. Table 3.4 provides examples of various patient benefits offered by modern pharmaceuticals.

Place

The second element of the marketing mix is place—are the customers exposed to the company's product offerings in the right place, at the right time, and in the right condition? The term "place," therefore, refers to physical distribution, channel management, and customer service. The process of physical distribution involves activities such as transportation, warehousing, materials handling, packaging, and so on, and is extensively discussed in Chapters 12 and 13.

A *channel of distribution* is a group of individuals, processes, and systems that have been set in place to facilitate the transfer of a product from the manufacturer to the hands of the final consumer in an efficient and effective manner. In essence, the involved individuals are distribution intermediaries, and include distributors, wholesalers, agents, brokers, shippers, freight-forwarders, retailers, and others. A typical ethical pharmaceutical distribution system is shown in Figure 3.10.

Figure 3.10. Ethical pharmaceutical distribution channels

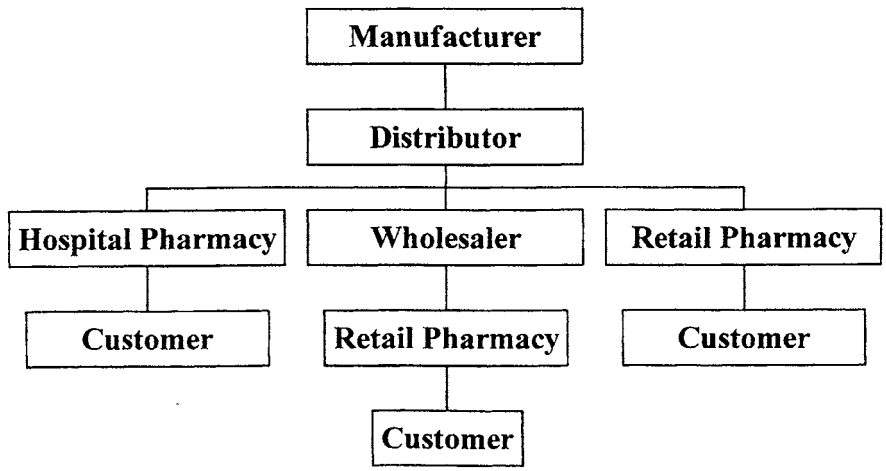


Table 3.4: Are Patients Shopping for a "Drill" or a "Hole"?

Product Characteristic	Patient Benefit
Efficacy	No fever . . . independence
Safety	No complications . . . risk-free mindset
Tolerability	No injection site redness . . . Same appearance
Dosage	Once weekly . . . Freedom to travel
Route of administration	Oral syrup . . . Mixing with morning milk
Formulation	Pre-filled syringe . . . Hassle-free therapy
Information	Informed choice

Price

The third element of the marketing mix—price—refers to pricing objectives and strategies, price adjustments, and payment terms. This is an often-misunderstood term because it represents different things to different people. In general terms, price is the value attributed to a product or service. What is important in every exchange of a product or service for a price is the price fairness, or price-benefit relationship. For example, a high profit-earning price for the seller may be an unfairly high price for the buyer. Alternatively, a budget price sought by the buyer may not be the optimal income-making price for the seller. Therefore, it becomes essential for each seller to thoroughly evaluate the customers' price perceptions and expectations, and charge his or her product offerings accordingly. In the eyes of the buyer, a product's price perception is a mix of its quality, functionality, competitors' product prices, and personal benefits expected from its purchase. On the seller's side, price is revenue- and profit-making; thus the profitability, financial stability, and long-term survival of the organization may depend on setting a proper price.

The elements of price, price-influencing factors, and concepts of price sensitivity and elasticity, as well as different pricing strategies as pertaining to the sale of pharmaceutical products are thoroughly discussed in Chapters 14 and 15.

Promotion

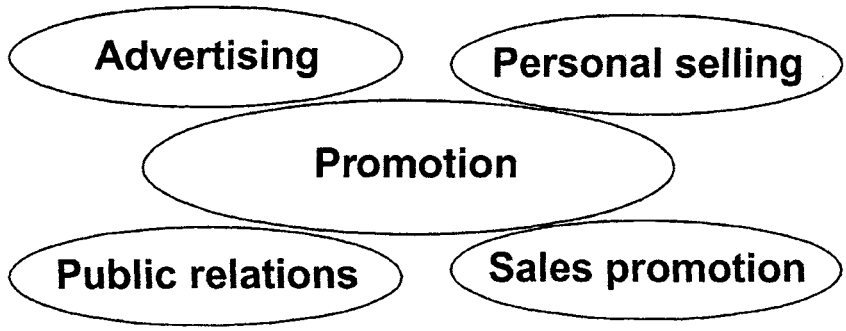
Once marketers have created a product that is appealing to customers, identified a fair price, and made it physically available to the final consumers, they must then present their products by marketing them to consumers. This important task is achieved through promotion, which includes advertising, public relations, sales promotion, and personal selling. These elements are shown in Figure 3.11.

The four elements of promotion comprise what is called the *promotional mix,* which companies create in various ingenious ways to communicate their product or company advantages to their publics. These elements are represented in Table 3.5 and further discussed in Chapters 16 through 20.

PHARMACEUTICAL MARKETING ENVIRONMENT

Let us now look more closely at the pharmaceutical marketing environment and try to identify the various internal and external factors that have an influence on pharma-

Figure 3.11. The elements of promotion



ceutical products' success in the marketplace. Table 3.6 lists the main environmental factors contributing to the industry's environment. A marketer would identify internal industry factors intrinsic to the pharmaceutical company as the mission, resources, and culture. Other factors include those who have a close relationship to its operations or can be affected by its strategy and tactics, such as distributors, prescribers, and financers. On the other end of the spectrum, external factors include political, economic, social, technological, or natural factors, whose influences are more indirect but often very important for the success of the company's efforts.

The analysis of environmental factors affecting the industry is critical to the design of successful marketing strategies, and is described by the terms *situational* and *competitor analysis*, which are presented in subsequent chapters. Furthermore, suppliers' power and other competitive forces surrounding the industry are discussed in Chapters 12 and 13.

PRODUCT MANAGEMENT

A company's marketing department structure is illustrated in Figure 3.12. Central to this organizational structure is the existence of distinct strategic business units (SBUs), usually focused on separate therapeutic areas, and directed by Business Unit Managers (BUMs). Each BUM leads a structure of marketing and sales professionals to collectively work for the achievement of the business unit goals. The core professionals working for a given business unit are product managers, medical affairs managers, and sales managers.

Pharmaceutical product managers, or brand managers, are the core marketing strategists of the company. They are supposed to be true "product champions," that is, the professionals deeply involved and knowledgeable in all aspects of product development, premarketing, marketing, and life-cycle management. The merits of this critical position have been studied by many marketing experts who have expressed both advantages and potential disadvantages for such a job title (see Figure 3.13). Nevertheless, it remains at the core of pharmaceutical marketing departments worldwide and is responsible for most pharmaceutical product aspects consumers are aware of.

Figure 3.12. A company's marketing department organization

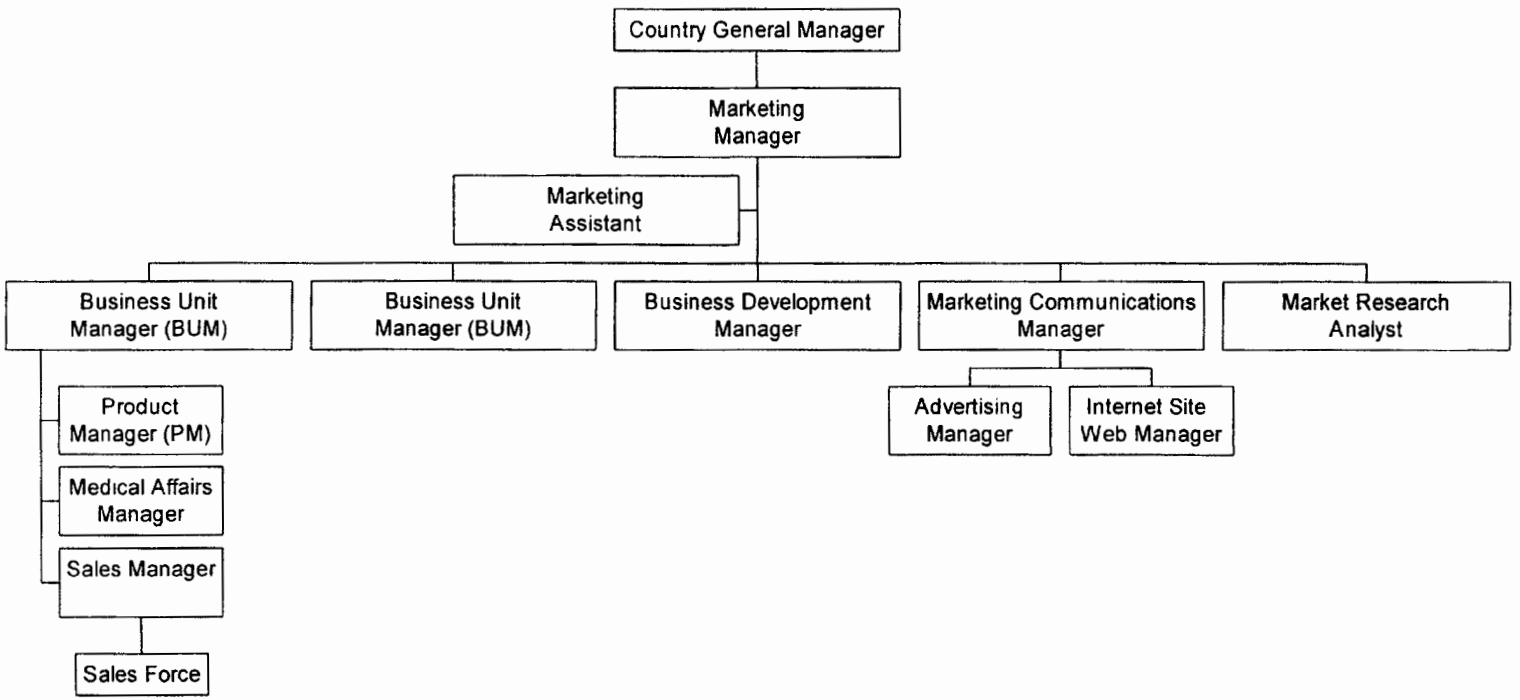


Table 3.5: Marketing Mix Variables for Pharmaceutical Products

4 Ps	Component	Description
Product		
	Benefits	Better quality of life, reduced disease symptoms, reduced hospitalizations, independence, ability to work and enjoy family life
	Attributes	Formulation characteristics and ease of use, taste (if oral), local discomfort (if injectable), needleless injector device, child-safe bottle cap
	Quality	Efficacy, safety, tolerability, active substance, inactive ingredients, packaging, administration device, precipitation of solution
	Safety	Safety, tolerability, drug interactions, contraindications, special warnings, overdosage, existence of antidote, safety index, long-term effects
	Warranties	Active substance quantity, expiration date, no solution precipitation, no binding with container glass or IV tubing, return policy, credit
Price		
	Pricing objectives	Meet competition, build image, satisfy intermediaries, increase sales volume, sensitize customer, maximize income, abide by regulation
	Customer demand	Customer perceptions, adoption rate, primary and secondary demand, elasticity of demand, cost structure, life-cycle stage, market potential
	Competitor pricing	Price levels and cost structure, pricing objectives and policies, discounts, tender pricing, price leadership, price war, entry barriers
	Discounts	Cash or volume discount, free delivery, promotional allowance, price hold, extended credit, lower interest, sale or return policy, package deals
Place		
	Channel objectives	Delivery speed, frequency and consistency, inventory availability, condition of delivered goods, invoicing accuracy, customer service
	Channel structure	Integration, number of intermediaries, distributors, wholesalers, retail independents, retail chains, brokers, agents, shippers, Web dispensing
	Trade barriers	Import quotas and licensing, standards requirements, domestic subsidies, customs, taxation, profit repatriation, parallel imports, embargoes
	Physical distribution	Water, railroad, motor, air, shippers, freight forwarders, intermodal carriers, brokers, agents, time, costs, reliability, bill of lading, tracking
Promotion		
	Promotion objectives	Inform, persuade, remind, prescribing decision, push and pull, target audience, product characteristics
	Advertising	Regulation, direct and indirect channels, objectives, budgeting, message decision, media and agency selection, production, evaluation
	Personal selling	Prospecting, uncovering customer needs, product detailing, key accounts, information, demonstration, negotiation, maintaining relationships
	Public relations	Press relations, events, exhibitions, speeches, philanthropy, written and audiovisual PR material, internal PR, agency selection, planning
	Sales promotion	Premium incentive, point-of-purchase display, coupon, specialty printing, promotion fulfillment, telepromotions, refunds, rebates, sweepstakes

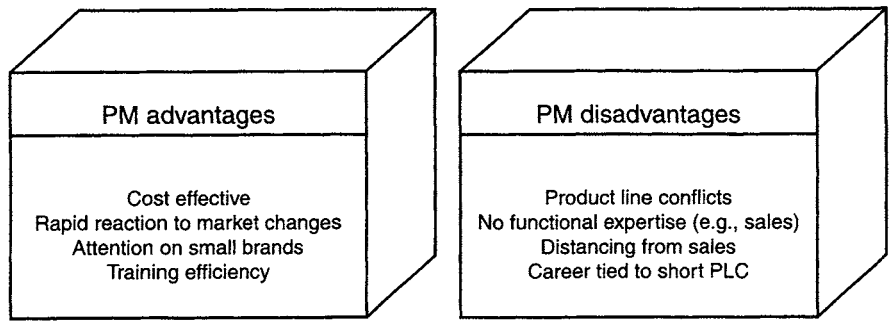
Table 3.6. Overview of the Pharmaceutical Marketing Environment

Internal			
Influencing Factors	**Players**		
	Suppliers	**Intermediaries**	**Customers**
Financial resources	Raw material producers	Distributors	Physician s
Mission	R&D material producers	Advertisers	Nurses
Structure	Equipment manufacturers	PR firms	Patients
Technology		Financial services	Hospitals
Culture			Wholesalers
R&D			Pharmacists
Quality/Leadership/Creativity			General public

External Factors				
Political	**Economic**	**Social**	**Technological**	**Natural**
Legislation	Inflation rate	*Demographic:*	New products	Shortages
Government agencies	Interest rate	Age structure	New markets	Renewable
Lobbyists	Credit availability	Family	Increased efficiency	Energy costs
Governments are:	Disposable income	Race	Robotics	Pollution
Regulator	Propensity to save	Geography	Biotechnology	Emissions
Purchaser	Reimbursement	Ethnic	Genomics	Packaging
Supplier	HMOs	Religion	Internet	Government intervention
Competitor		Education		
		Occupation		
		Culture:		
		Basic values		
		Perceptions		
		Preferences		
		Behaviors		

The key responsibilities of a pharmaceuticals product manager include the following: managing, improving or modifying existing products; providing information/reports for management; strategy development/marketing planning; new product development; pricing policy; monitoring product performance/satisfaction; monitoring sales/profit performance; forecasting/liaison with production; setting up/supervising trials and testing; advertising, PR, and promotions; opinion leader relationships; and office/field sales training and support.

Figure 3.13. Product management structure advantages and disadvantages



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Part 2

Marketing Strategy

4

What Is Marketing Strategy?

> Pharmaceutical companies put one dollar out of every five dollars of revenue back into research and development—a higher percentage than virtually any other U.S. industry.
>
> Pharmaceutcial Research and Manufacturers of America (PhRMA), 1998

The previous chapter described marketing management as the analysis, planning, implementation, and control of programs designed to bring about desired exchanges with target markets for the purpose of achieving organizational objectives. One of the core elements of this process is planning, that is, setting the course toward a desired destination. The planning process has also been called "crafting a strategy," in reference to the war strategies crafted by skillful, decisive generals. In the business world, *strategy* is a statement describing the general course the company will follow to achieve its objectives. It helps companies focus on a "strategic competitive advantage," avoiding wasted efforts and resources seeking customers whose needs can be better satisfied by a competitor. A strategy is needed for these two reasons: (1) to proactively design the course of action; and (2) to align and coordinate every member of the organization.

Who sets the strategy in the organization? Is it a top-down approach, where top company executives design the company strategy and communicate it directly to the front sales people? Or can it be a bottom-up approach, where skilled sales and marketing managers

respond to the customers by designing the company strategy for everyone else to follow? The answer is that corporate strategy follows a thoroughly planned cascade, as seen in Figure 4.1, starting with the definition of the company's vision by the top management.

The first step in this procedure is setting the corporate *vision*, namely, the desired state of the organization in the future. Next, comes setting the *mission*, that is, creating a set of directions to achieve the vision. The mission is a reflection of internal capabilities. It emphatically describes the reason for the company's existence. Some of the essential contents of a company's mission statement are its core products, target customers, company values, and geographical and technological areas that define its existence. A detailed presentation of the contents of a mission statement is presented in Table 4.1.

Following setting the company's mission, corporate objectives are defined; for example, the required standards of company performance within a given therapeutic category worldwide. The corporate objectives are then translated into SBU objectives, as in Chapter 3. You may remember that an SBU is a functional team usually focused on marketing a single therapeutic area. Some of the basic SBU characteristcs are that it is separately planned, has respective competitors, and possesses a responsible and accountable management team.

An SBU objective could be the capture of a 50 percent unit market share, or a 20 percent value sales growth in the next year. These objectives are then broken down into individual product objectives, such as 20 percent market share of product A and 7 percent market share of product B. The individual product objectives are transformed into marketing objectives, for example, the prescriber awareness level of the given products is to be over the 80 percent mark by the end of next year. The marketing objectives give rise to sales objective, that is, to achieve a certain amount of unit/value sales for product A. Finally, total company sales of product A are broken down into district sales and then into personal sales representative objectives, which in turn help define company's objectives from individual prescribers or hospitals. A detailed example of the strategic cascade is presented in Table 4.2.

During the process of crafting a corporate strategy cascade, pharmaceutical marketers should remember the following important points. The vision must be communicated throughout the organization; a clear strategic direction must be formulated; the strategy must be linked to the planning and budgeting process; and the strategy must be effectively implemented, evaluated, and periodically revised.

Figure 4.1. Corporate strategy levels

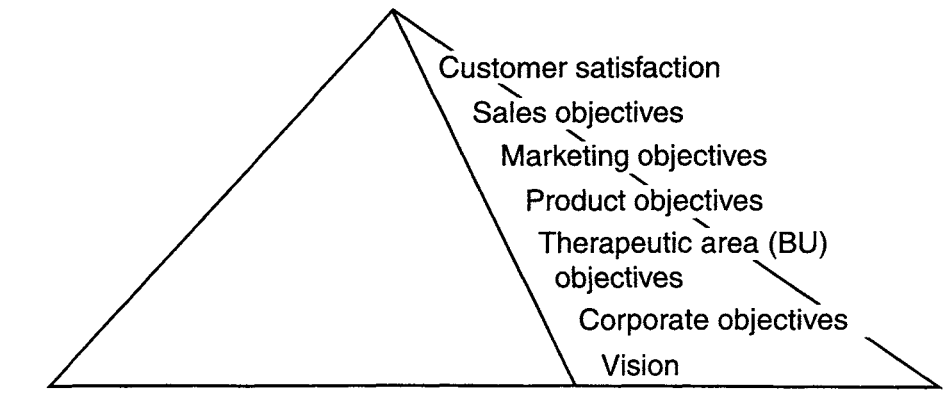

Table 4.1: What's in a Mission Statement?

Alternative Names	Role	Contents	Example
Mission	Set the starting points	Core products	To become market leader in . . .
Corporate objectives	Give directions	Target customers	By yearly growing by . . .
Reason for existence	Unite the people	Geographic areas	. . . by the year . . .
Credo	Define product mix	Core technologies	Harnessing biotechnology . . .
Creed	Define markets	Company values	. . . to provide our partners with . . .
Corporate belief	Describe organizations	Survival, profit, and growth goals	And becoming the preferred partner . . .
Corporate goals and values	Set geographical areas		
Corporate philosophy	Define market ranking		
Management statement	Identify core technologies		
Raison d'être	Define desired growth		
Guiding principles	Identify the self-concept		
Foundations	Set desired public image		
Value statement			
Business purpose			

CASE STUDIES

Let us now study the mission and value statements of two of the world's foremost pharmaceutical multinationals, namely, Merck & Co., Inc. and Schering-Plough Corporation.

Merck & Co., Inc.

Merck & Co., Inc. is a leading research-driven pharmaceutical products and services company. Merck discovers, develops, manufactures, and markets a broad range of innovative products to improve human and animal health. The Merck-Medco Managed Care Division manages pharmacy benefits for more than forty million Americans, encouraging the appropriate use of medicines and providing disease management programs.

Table 4.2: The Corporate Strategy Cascade

Level	Example of Goal
Vision statement	Become the preferred partner to our stakeholders.
Mission statement	Capitalize on our biotech expertise within categories X and Y.
Corporate objective	Achieve market leadership in the therapeutic category.
Business unit objective	Show a 15% market growth in the category.
Product/market objective	Increase product A's market share by 7%.
Marketing objective	Communicate product A's unique selling points to specialists.
Sales objective	Reach value sales of 65 million Euros with product A.
Sales district objective	Achieve sales of 11 million Euros for the South district.
Sales person objective	Have sales of 1.5 million Euros coming from John Smith's territory.
Key account objective	Achieve sales of 260,000 Euros from Professor Z.
Customer satisfaction	Get a 90% Quality of Life rating from Professor Z's patients.

Our Mission

The mission of **Merck** is to provide society with superior products and services—innovations and solutions that improve the quality of life and satisfy customer needs—to provide *employees* with meaningful work and advancement opportunities and investors with a superior rate of return.

(Merck & Co., Inc., 1999. Reprinted with permission of Merck & Co., Inc.)

Our Values

Our business is preserving and improving human life. All of our actions must be measured by our success in achieving this goal. We value above all our ability to serve everyone who can benefit from the appropriate use of our products and services, thereby providing lasting consumer satisfaction.

We are committed to the highest standards of ethics and integrity. We are responsible to our customers, to Merck employees and their families, to the environments we inhabit, and to the societies we serve worldwide. In discharging our responsibilities, we do not take professional or ethical shortcuts. Our interactions with all segments of society must reflect the high standards we profess.

We are dedicated to the highest level of *scientific excellence* and commit our *research* to improving *human* and animal health and the quality of life. We strive to identify the most critical needs of consumers and customers, we devote our resources to meeting those needs.

We expect *profits*, but only from work that satisfies customer needs and *benefits humanity*. Our ability to meet our responsibilities depends on maintaining a financial position that invites investment in leading-edge research and that makes possible effective delivery of research results.

We recognize that the ability to excel—to most competitively meet society's and customers' needs—depends on the integrity, knowledge, imagination, skill, diversity and teamwork of employees, and we value these qualities most highly. To this end, we strive to create an environment of mutual respect, encouragement and teamwork—a working environment that rewards commitment and performance and is responsive to the needs of employees and their families.

(Merck & Co., Inc., 1999. Reprinted with permission from Merck & Co., Inc.)

Schering-Plough Corporation

Schering-Plough is a worldwide pharmaceutical company committed to discovering, developing and marketing new therapies and treatment programs that can improve people's health and save lives.

The Company is also a recognized leader in biotechnology, genomics and gene therapy.

Core product groups are allergy/respiratory, anti-infective/anticancer, dermatologicals and cardiovasculars.

Pharmaceutical product lines are complemented by health management programs, a growing worldwide animal health business as well as leading consumer brands of sun care, foot care and over-the-counter products.

Innovative research, effective marketing and solid financial management have enabled the Company to achieve significant sales growth, deliver superior financial results and reward shareholders.

FROM WORLDWIDE VISION TO LOCAL TACTICS

How do pharmaceutical company managers move from a theoretical and futuristic vision statement to actual strategy and tactics pertaining to every level of the organization, down to the level of a single medical sales representative? In broad terms, there are three main considerations in crafting a corporate strategy.

- Where are we now?
- Where do we want to go?
- How do we get there?

The distinct steps involved in the pharmaceutical strategy framework, as well as each step's content, time frame, and objectives are summarized in Table 4.3.

DEFINITION OF MARKETING STRATEGY

Having defined its core portfolio strategies for the organization for the next several years, a company then creates individual department strategies covering every organizational aspect and contributing to the overall strategic plan. Thus, as Figure 4.2 shows, strategies are created for manufacturing, finance, R&D, distribution, human resources, and marketing functions.

Marketing strategy is a plan identifying what basic goals and objectives will be pursued and how they will be achieved within the specified time. The strategy development framework is shown in Figure 4.3.

See Table 4.4 for marketing strategy components. The detailed analysis and discussion of these elements is presented in the following chapters.

Marketing strategies may refer to therapeutic areas (e.g., infectious diseases), product lines (e.g., third generation cephalosporins), or individual products (e.g., cephalosporin A). The latter is a *product strategy*, that can apply either to a global or a national scale.

Table 4.3: Pharmaceutical Strategy Framework

Strategy Level	Content	Area	Responsibility	Time frame	Objectives	Example
Vision	Desired future company state	Company in the future	Board of Directors	Long term	Long-term profitability and survival	Top five global companies
Strategic Plan	Which therapeutic areas, which regional markets	Company therapeutic/ regional priorities	Executive Committee	5 years	Focus on core competencies and core national markets	Central Nervous System (CNS) and cardiovascular leader in U.S., Europe, Asia
Business Plan	Portfolio selection, resource allocation	Allocation of resources across company departments	Executive Committee	3 years	Balanced portfolio selection and strategy-driven resource allocation	Sales and R&D investments equally in three therapeutic areas
Therapeutic Area Strategy Plan	Which products, which customers, which claims	Therapeutic area worldwide	Headquarters therapeutic area team	3 years	Building a sustainable ompetitive advantage for every product	Product X the leading anti-asthma choice by respiratory doctors
Global Marketing Plan	Product, distribution, pricing, and promotional strategies	Therapeutic area marketing mix	Headquarters therapeutic area marketing team	Next year	Designing the elements of each product's marketing mixon a global scale	Intensive distribution, premium pricing, heavy advertising
Local Marketing Plan	Implementation of marketing mix in national market	SBU within a national market	National SBU marketing team	Next year	Adjusting the global marketing mix strategy to individual national markets	Detailed marketing mix a ctivity plan for product X in market

Figure 4.2. Corporate strategy components

STRATEGIC PLANNING

Strategic planning is the process of envisioning a desired future state, defining goals and objectives, and designing marketing and other organizational strategies and tactics to be implemented in the future. Planning is not only analysis and evaluation of the status quo, but also consideration of possible future scenarios, and design of alternative company strategies in anticipation of changing trends. Planning takes place at all company levels within the strategic cascade framework described at the beginning of this chapter. Thus, it can be in the form of executive committee planning sessions at a remote resort, planning the company's future in the next twenty-five years, or it can be the individual brainstorming of sales force representatives for next week's call plan. Furthemore, strategic planning is an essential tool for either headquarter or subsidiary organizations, each looking at marketing strategy from their respective operational environment's perspectives. This fact does not, by any means, imply that subsidiary entities may have opposing or conflicting strategies with those set by headquarters. Instead, they should both be focused on the same objectives and goals and define their activities within their respective geographical boundaries.

Figure 4.3. Strategy development framework

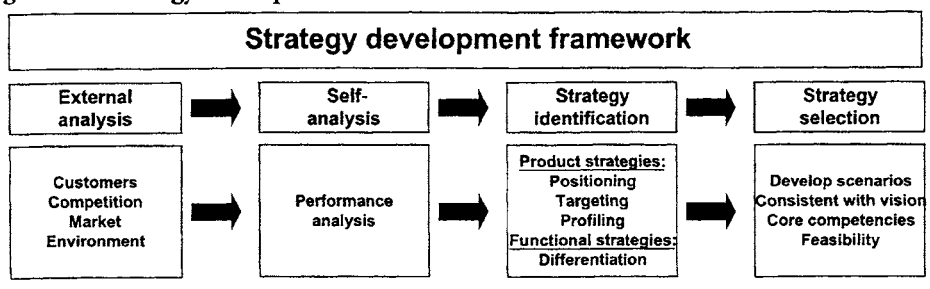

Table 4.4: Marketing Strategy Components

	Corporate Strategy	
1.	Strategic objective	Expand market share, increase profitability.
2.	Strategic focus	Expand market, penetrate market, increase productivity.
3.	Customer targets	Target segments, position the product.
4.	Competitor targets	Define competitive positioning and competitive strategy.
5.	Differential advantage	Create a segmentation and positioning plan.
6.	Marketing mix	Products, prices, promotions, distribution.
7.	Organization and implementation	Structure and systems, professionalism, commitment.

(Doyle, 1994.)

The planning process can be divided into distinct planning stages, as described in Table 4.5. Each of these planning stages are presented in later chapters, under the scope of a practical pharmaceutical marketing guide.

STRATEGY VS. TACTICS

Let us now focus on some relevant terms associated with strategic planning. A *strategy* is a statement describing the course toward objectives. *Objectives* are the desired destination points of the strategic journey. A pharmaceutical marketing objective is a pharmaceutical product's goal within a defined market and time; for example, to achieve sales of 1 million U.S. dollars in the oral contraceptives market in 2001. *Tactics* are the specific activities designed to implement the crafted strategy; for example, the implementation of a TV advertising campaign during the next few months. Furthemore,

Table 4.5: Pharmaceutical Planning Stages

Identify and evaluate opportunities	Analyze market segments and select target markets	Plan a market position and develop a marketing mix strategy	Prepare and execute a marketing plan	Control efforts and evaluate the results
Identify unmet therapeutic needs	Situation analysis	Position product offering	Describe situation	Evaluate sales and shares
Assess total market size	Environmental scanning	Profile product offering	Present therapeutic areas	Evaluate positioning
Construct patient journeys	Environmental monitoring	Develop product strategy	Describe positioning	Evaluate pricing
Identify target physicians	SWOT analysis	Develop distribution strategy	Define sales objectives	Evaluate distribution
Evaluate physicians' needs	Competitor analysis	Develop pricing strategy	Describe marketing tactics	Evaluate promotion
Identify pipeline candidate	Identify key success factor	Develop promotional mix	Allocate resources	Make adjustments
Assess candidate's profile	Identify leadership niche	Set marketing goals	Perform profit and loss	Measure changes

Table 4.6: Examples of Pharmaceutical Marketing Strategy and Tactics

Strategy	Tactics
Become market share leader.	Hire and train 15 new sales representatives.
Grow sales by 20% every year.	Visit key accounts once weekly.
Penetrate 10% of market in launch year.	Prepare 3 new detail aids per year.
Achieve 75% product awareness level.	Organize launch symposium on Malta.
Have sales force ranked among top 5.	Conduct 4 prescriber focus groups.
Capture 40% unit market share next year.	Conduct DTC campaign during hay fever season.
Gain product reimbursement fast.	Distribute 1,000 new product gimmick.s

assumptions are "calculated guesses" of the future on which important strategic implications are based; for example, it is assumed that the newly launched product will gain reimbursement status in its third year of sales. Table 4.6 lists some examples of pharmaceutical product strategies and tactics.

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5

Marketing Research

> In 1997, of a worldwide total of 52.2 million deaths, 17.3 million were due to infectious/parasitic diseases, 15.3 million due to circulatory diseases, 6.2 million due to cancer, 2.9 million due to respiratory diseases, and 3.6 million due to perinatal conditions.
>
> WHO, 1998

In the constantly changing pharmaceutical market environments characterized by vast R&D costs, heightened competition, increased regulation, and ever more demanding consumers, pharmaceutical marketers are called upon daily to make critical judgments and decisions. They evaluate a market's potential, the possible influence of new government regulatory restrictions, the effect of past price lowering by competitors, or the extent to which a new product satisfies the needs of prescribers and patients.

In addition to their prior education and professional experience, they rely on accurate, timely, and detailed information describing the factors that have, are, or will be affecting their business-operating environment in the future. This same information allows them to identify potential problems and opportunities, compare their therapeutic offerings with the competition, and test new ideas against customers needs, wants, and attitudes. Some experts even claim that, in the Twenty-first Century, the pharmaceutical industry will be relying equally on internal competencies, financial resources,

and information. Based on this, the logic that underlies the concept of marketing research may now be better understood. Some definitions of marketing research are:

> the systematic and objective process of obtaining information needed for taking marketing decisions (Zikmund and D'Amico, 1996)

and

> the function that links the consumer, customer, and public to the marketer through information—information used to identify and define marketing opportunities and problems; generate, refine, and evaluate marketing actions; monitor marketing performance; and improve understanding of marketing as a process. Marketing research specifies the information required to address these issues, designs the method for collecting information, manages and implements the data collection process, analyzes the results, and communicates the findings and their implications goals (American Marketing Association, 1987)

This chapter describes what marketing research is, the process of designing and conducting research, and analyzing the data collected. It also presents some of the most common information needs of pharmaceutical marketing professionals. Let us look more closely at why market research is done in the first place: to identify unmet therapeutic needs; to predict customers' demand for a new medication; to identify why the competition is successful; to find out the market size and growth; to know all category product sales and market shares; to assess proper pricing; to identify demand seasonalities or trends; to prevent crises and failures; to identify key targets; to evaluate the company's public image; to measure prior successful new product launches; and to suggest potentially successful advertising and promotion programs.

RISKS OF RESEARCH

Marketing research involves several risks, and this is especially evident in the sensitive field of pharmaceuticals intended for human use. For instance, poorly designed marketing research may contain investigator's bias or lead to erroneous interpretations that may lead the company into an expensive and fruitless R&D plan or to implement a bad marketing strategy. Such potential research risks include the following: bias (sampling/nonsampling); confusing, subjective managerial beliefs with statistical significance; confusing relationship with causality; expense; lack of confidentiality; over-relying on quantitative data; poor design; time delay; wrong assumptions; wrong data; wrong interpretation; and wrong type of research.

The following terms describe marketing research excellence. *Research reliability* refers to whether the marketing research yields the same results in repetitive measurements. *Research validity* refers to whether the marketing research yields the result it is supposed to give.

INFORMATION NEEDS

The pharmaceutical industry's information needs are diverse and constantly expanding. These needs can be categorized in large groupings, which include all aspects of the mar-

ket environment, competition, and stakeholders. In general, pharmaceutical marketers need information about prescribers, patients, retail pharmacies, hospital pharmacies, wholesalers, academics, competition, and the market. A detailed listing of frequently conducted marketing research tests by the industry is presented later in this chapter.

MARKETING INFORMATION SYSTEM

Following the definition of a marketing information need, the design of a thorough marketing research plan, and the collection of relevant data, the pharmaceutical marketer is often faced with the problem of vast amounts of data that need to be properly stored, retrieved, analyzed, and distributed to all pertinent personnel within the organization. Therefore, it becomes critical to the whole process of marketing research to design and implement a marketing information system (MIS) that conducts all these tasks with accuracy, timeliness, and confidentiality.

Marketing information systems systems are usually based on computer hardware and software systems, and are set up as illustrated in Figure 5.1. Let us look more closely at this schematic. Internal and external information sources are combined to create an internal marketing information database. A marketing decision maker (e.g., a marketing manager, a product manager, or a marketing research specialist) is then required to extract meaningful conclusions from the collected data that adds competitive advantage to the whole organization. In their evaluations, these professionals often rely on an associated system called a *decision support system,* that is, a computer-based application that offers the opportunity to incorporate market histories, product life cycles, and future forecasts in a comprehensive *marketing scenario playing.*

The process in which a pharmaceutical marketer seeks answers to her or his marketing questions starts with strategic research and then moves to concept, or performance, research (as shown in Figure 5.2).

Figure 5.1. A marketing information system

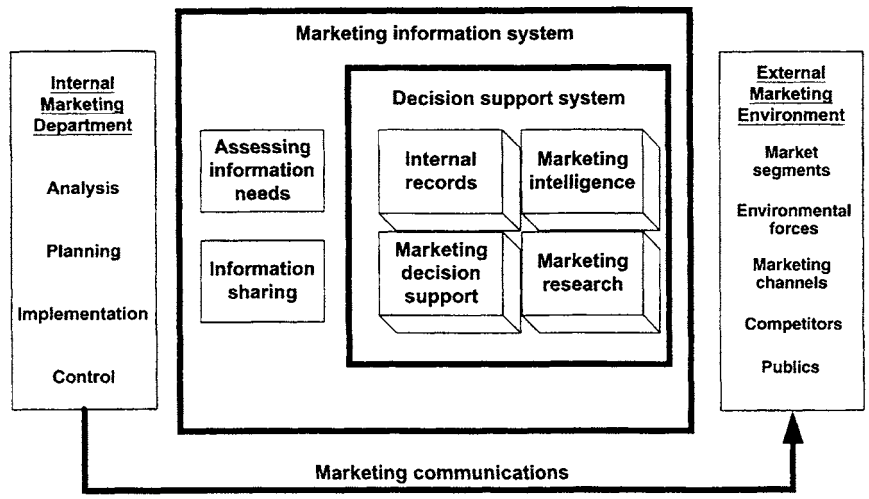
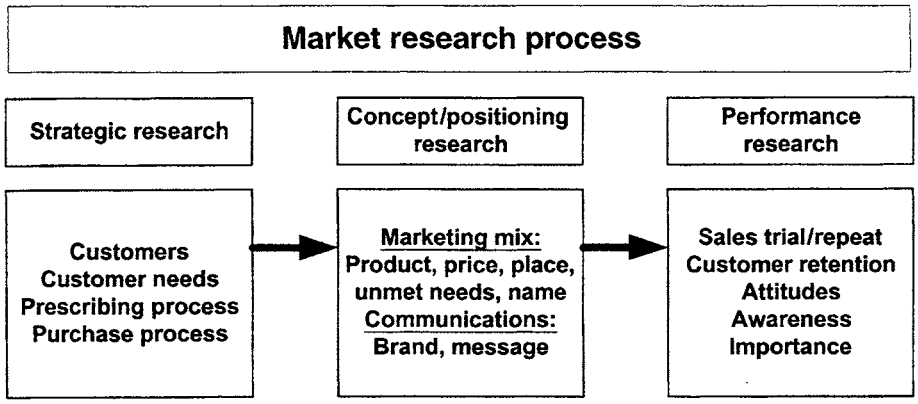


Figure 5.2. The marketing research process



PHARMACEUTICAL MARKETING RESEARCH SUBJECTS

Industry marketers have conducted marketing research on a wide variety of subjects. They are presented below, along with their functions in the pharmaceutical industry as determined by market researchers.

Prescriber

A prescriber's function includes: brand awarenes; brand mapping; brand name testing; campaign concept; company image; compliance testing; conjoint analysis; convention research; creative input; customer attitudes; drug benefits rating; lead user analysis; message recall (promotion audit); needs analysis; new product assessment; new product forecasting; new product pricing; OL consensus; opportunity to prescribe; perceptual mapping; prescribing habits (date, specialty, monthly prescriptions, brand name, therapeutic usage, new or continuing patients, authorized refills, size, value, strength, dosage); price elasticity; product design and packaging; product positioning; product profiling and segmentation; receiving promotional materials; readership; sales aid quality; sales force quality; segmentation study; and situation analysis.

Patient

A patient's function includes: alternative therapy awareness (brand, generic, OTC, nonpharmacological); brand awareness; brand name testing; campaign concept; company image; compliance survey; conjoint analysis; creative input; customer attitudes; drug benefits rating; medication history; message recall; needs analysis; new product assessment; new product forecasting; new product pricing; patient journey; perceptual mapping; prescription by demography; prescription history (length before switching, compliance, payment method, physician specialty); price elasticity; product design and packaging; product image (value, adverse events, satisfaction, quality of life); product positioning; product profiling and segmentation; product switching (brand to brand/generic); quality of life; segmentation study; situation analysis; and taste testing.

Pharmacy Wholesaler

A pharmacy wholesaler's function includes: attitude surveys (on return policy, terms and conditions, competitive products); manufacturer-sponsored deals, and sales to retail outlets.

Retail Pharmacy

A retail pharmacy's function includes: attitude surveys (on return policy, terms and conditions, competitive products); inventory and stocking; manufacturer-sponsored deals; market forecasting; brand and generic manufacturers carried; price lists; and retail sales.

Hospital Pharmacy

A hospital pharmacy's function includes: attitude surveys (on return policy, terms and conditions, competitive products); brand and generic manufacturers carried; competitor distribution; incidence of infection, manufacturer-sponsored deals; market forecasting; patient stay duration; pharmacy inventory, usage, and stocking; price lists; price elasticity; product dosage scheme prescribed; product efficacy by pathogen; product formulary status; therapeutic class new member net price paid; product prescribed; product route of administration preferred; product usage by diagnosis; product usage by medical specialty; prophylactic/postoperative use; therapy prescribed on discharge; and treatment outcome.

Competitor

A competitor's function includes: core competencies; corporate strategy and goals; distribution strategy; financial analysis (assets, stock performance, brokerage house reports); licensing strategy; management (key personnel, quality); organization (size, structure, climate); patent portfolio; pricing strategy; R&D portfolio; sales performance; sales organization; and strengths, weaknesses, opportunities, and threats (SWOT) analysis.

Industry/Market

The industry/market's functions include: business strategy; disease management; disposal of noncore interests studies; due diligence studies; emerging technologies; future trends; generic penetration; industry news; investment research; key success factors; legal/regulatory environment; licensing opportunities; life cycle stage; market characteristics; market potential, market segmentation; market share analysis; merger/acquisition candidates; new product launches; patents survey (new, expiring); pricing environment; R&D survey (chemical class, trial phase, mechanism of action, company, market); prescription-to-OTC switches; and therapeutic area analysis.

Public

The public's function includes: attitudes; child-proof medication packaging; demographic changes; disease awareness; disease epidemiology; expectations from the government;

healthcare priorities; healthcare services satisfaction; information distribution; lifestyle needs and wants; patient family member needs; and unmet therapeutic needs.

PROCESS AND METHODOLOGY

The marketing research process can be divided into distinct steps, namely, (1) defining the problem; (2) setting the research objectives; (3) designing the research plan; (4) selecting the optimal sample and its size; (5) collecting the data; (6) analyzing the data collected; (7) creating a model based on the data; and, finally, (8) evaluating this model and deciding on the optimal marketing strategy. A closer look at each of these important steps follows.

Defining the Problem

This step is critical to the whole research process because the wrong definition of a problem may lead pharmaceutical marketers to misleading and dangerous conclusions. To illustrate the value of this step, think of a company that has just launched an innovative, efficacious, and safe new asthma medication with disappointing first-quarter sales. The marketing team is urgently assembled to discuss the reason for sluggish sales, focusing on a single prescriber complaint of a high price burden for her patients. A marketing research agency is called in and asked to investigate the price differential among all therapeutic category competitors. Much later, this leads to the conclusion that the high price of the innovative new product may, indeed, be blamed for the disappointing sales, and a brave price cut is suggested. Simultaneously, however, thousands of prescribing and purchasing interactions in the market may be revealing other important factors, which have not reached the company. Can it be that the product formulation is not patient-friendly? Or is it the prescribers who have never been properly detailed on the revolutionary and safe mechanism-of-action of the new product? Or, irrelevant to the product characteristics itself, is it the low company image?

A commonly employed method used in marketing research problem definition is *exploratory research*. This process uses a small number of interviewees and explores their beliefs, attitudes, or actual experiences regarding a particular product to uncover the often concealed reasons for their presribing or purchasing behavior. A more thorough and expansive marketing research is then designed based on these findings. The purposes of exploratory research are: (a) to develop hypotheses; (b) to better define the problem; (c) to establish research priorities; (d) to collect information on research methodologies; and (e) to test various alternatives.

Setting the Research Objectives

In setting the research objectives, the marketer must strive to be open-minded enough to allow for investigation of far-fetched hypotheses, yet try to stay focused on the problems and issues that are influencing the market conditions or the product's acceptance. Often, research objectives are distinguished as primary and secondary objectives, with emphasis and thoroughness placed on primary objectives, and less time and effort alotted to secondary objectives. Consider the following example.

A migraine medication is to be introduced to the Italian market. The company marketers are busy creating their product's targeting and positioning. They have conducted their exploratory research, which led them to the definition of the following research objectives: (1) *Primary*: which medical specialty primarily consults migraine sufferers, what is their practice and prescription volume, what are their unmet needs, and what are their current prescribing habits? (2) *Secondary*: how do they react versus the product's campaign alternatives, their brand awareness, and competitor company image? The process of choosing marketing research objectives is described in Table 5.1.

Designing the Research Plan

Research planning involves the following three main steps.

Selecting a marketing research agency

This is a very sensitive process because, when identifying an able, external partner, it must possess essential characteristics. They are (1) recognition among pharmaceutical marketing peers, (2) prior therapeutic category expertise, (3) available human resources, (4) practical location, and (5) reasonable prices. Following the evaluation of several candidates, a decision is made, task forces are assigned at both the pharmaceutical company and the agency, and the pharmaceutical team thoroughly informs their marketing research partner of the nature of the problem.

Preparing the research brief for the agency

This document has to be thoroughly researched and prepared so that it clearly describes the problem and presents all knowledge about the problem with the external partner.

Table 5.1: Choosing a Marketing Research Objective

Type	Exploratory Research	Descriptive Research	Causal Research
The problem	Unsure of problem	Aware of problem	Problem clearly defined
Example of problem	Why are sales declining?	Which physicians are prescribing the product?	Will patients purchase more in a new formulation?
	Would prescribers be interested in a combination drug?	Who prescribes our competitors' drugs?	Which ad campaign is optimal?
	Would patients be interested in an oral formulation?	What features do patients prefer?	Will prescribers appreciate a DTC campaign?
Typical Design	**Qualitative**	**Survey**	**Experimentation**
Research method	Focus groups, in-depth interviews, secondary data analysis, case studies, observations, projective techniques (word association, sentence completion)	Personal/phone interviews, mail surveys, tracking studies (retail or hospital), test markets	Experiments Quasi-experiments Test markets

Mutual trust and confidentiality are prerequisites for a successful interaction of this kind. The main parts of such a research brief are the following: (1) problem history and definition, (2) product characteristics, (3) therapeutic category details, (4) regional market characteristics, (5) research objectives, (6) potential research subjects required (e.g., OLs), (7) time requirements, (8) budget allocation, and (9) reporting needs.

Agreeing on the research plan with the agency

In order to avoid possible misunderstandings, conflicts, and delays, the final research plan is mutually agreed upon and respectively signed. The research plan usually focuses on the following details: (1) research background, (2) objectives, (3) methods, (4) analysis method, (5) data ownership and confidentiality, (6) pharmaceutical company responsibilities, (7) reporting frequency and format, (8) timetable, (9) research costs and incidentals, (10) any subcontractors involved, (11) task forces, and (12) breach of agreement arrangements.

PRIMARY AND SECONDARY DATA SOURCES

Pharmaceutical marketing research relies on two broad data sources. *Secondary data* describe all information already available through a variety of sources to the marketing team. In contrast, *primary data* are any pieces of information systematically collected for the purpose of the ongoing marketing research project. These two types of research data require different collection methods, as shown in Table 5.2.

Some of the secondary research methods are desk research, do-it-yourself, syndicated, omnibus, and ad-hoc.

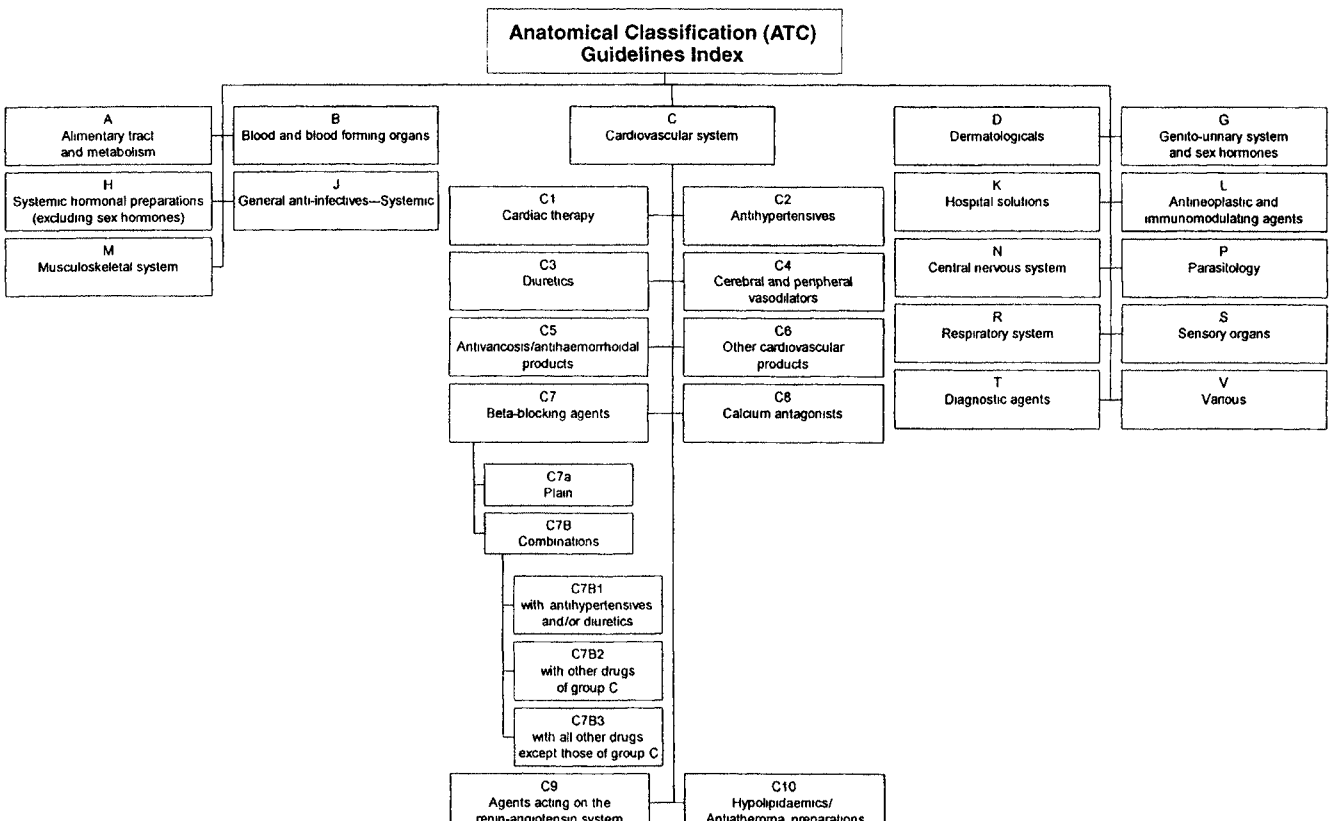
Drug classification according to the underlying disease state is a very significant tool in researching and quantifying pharmaceutical product sales. The Anatomical Classification (ATC) guidelines have been developed by the European Pharmaceutical Marketing Research Association (EPhMRA) and an example of this system is provided in Figure 5.3.

Table 5.2: Primary and Secondary Research Data Collection Methods

Secondary	
Internal	**External**
Sales force	Books
Marketing	Journals
R&D	Government
Legal	Consultants
Manufacturing	Media
Trade	Motion detector

Primary			
Observation	**Survey**	**Simulation**	**Experiment**
TV monitoring	Personal interview	Health foods outlet	Taste test
Scanner-based	Phone interview		Control method
Eye-tracking	Mail survey		Standard test
Pupilometer	Internet survey		
Psychogalvanometer	Mall intercept		
	Home interview		
	Questionnaire		

Figure 5.3. Anatomical classification system



Marketing research also can be categorized according to the methodology used, that is, qualitative and quantitative, or according to the purpose of the research, that is, into exploratory, descriptive, and causal (see Figure 5.4).

QUALITATIVE AND QUANTITATIVE METHODS OF RESEARCH

Qualitative data refer to people's opinions, beliefs, attitudes, motivations, and dispositions. Such data cannot be accurately quantified and measured, and tend to be subjective and tentative. However, the data are invaluable for the study of consumer behavior and play a significant role in pharmaceutical marketing research. Examples of such data include patient needs analysis, or prescriber brand name testing, campaign concept testing, and perceptions of company image.

Quantitative data, on the other hand, can be precisely identified, and usually refer to market conditions and actual usage rates rather than attitudes and beliefs. Classic examples of pharmaceutical market quantitative data are sales volume (units and values), market growth, market shares, new product launches, pricing environment, target physician number, or formulation penetration rates. A multivariate comparison of quantitative versus qualitative research methodologies is presented in Table 5.3. What the table shows is that both types of research methodology yield useful marketing data, and have an indispensable place in the armamentarium of a pharmaceutical marketer faced with critical marketing situations. Some of the most commonly used pharmaceutical marketing research data sources are described in Table 5.4.

Selecting the Optimal Sample and Its Size

There are instances when a marketing organization requires the feedback of a very large group of individuals as a measure of future success in their field. A survey of the whole group is called a *census*—such as the general population census of various national statistical agencies around the world. Examples of such groups of individuals include all full university professors of cardiology in Italy, all members of a national growth hormone diagnosis committee in Greece, or all managed care pharmacy directors in a particular American state. In the vast majority of pharmaceutical marketing research projects, however, there are not enough financial and human resources to survey the whole study population, that is, prescribers, patients, and so on. So a *small,*

Figure 5.4. Marketing research categories

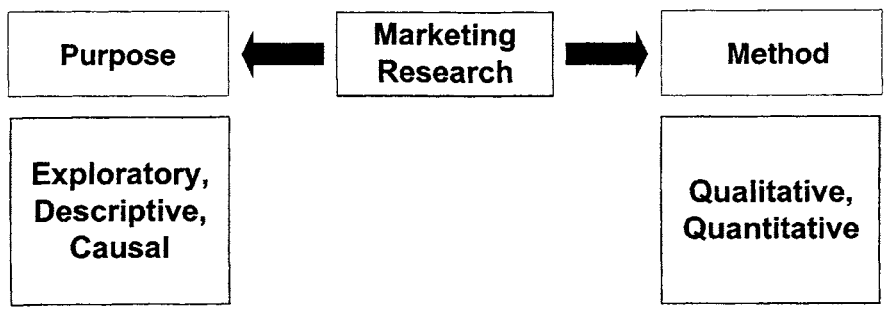


Table 5.3: Quantitative vs. Qualitative Research

Characteristic	Quantitative	Qualitative
Question nature	"How many"	"Why" the customer behavior, what if
Research nature	Quantity-defining	Exploratory
Focus	Historic	Future
Findings' nature	Objective, measurable	In-depth, subjective, hard to measure
Findings	Numbers	Opinions, beliefs, attitudes, motivations, and dispositions
Sample size	Large	Small

representative sample of this population must be carefully selected to avoid some of the perils of marketing research (previously mentioned in this chapter). The process of sample selection is called sampling, and requires the following questions to be addressed.

What is the target population?

If exploratory research findings reveal that laxatives are mainly prescribed by gerontologists (or elderly-treating specialists), then an investigation into this small group is launched. If, however, laxatives are prescribed by family physicians, then a representative sample of this larger physician population must be selected. Finally, if generic OTCs are dominating the market, then supermarket pharmacists or the patients themselves should be asked about their attitudes and purchasing behavior.

How big should the sample be?

The sample should be big enough to show statistical significance about the product differences that the study is trying to quantify, and small enough to be contained within the competing business unit budgets of the same pharmaceutical organization.

How is the sample to be selected?

Attention is needed in the actual sample selection because it may negatively influence the outcome of the research. Marketing research specialists have employed probability sampling techniques (e.g., the random, computer-generated selection of citizens across the country to be asked about their knoweldge of hormone replacement therapy benefits), and nonprobability techniques (e.g., the chain pharmacy intercepts of mild acne sufferers who are looking for an OTC therapy in Chicago, Houston, and Los Angeles) (see Table 5.5).

Collecting the Data

The collection of primary data is done using one of the following research methodologies: (a) survey, (b) observation, or (c) experimentation. Let us look more closely into these methodologies.

Survey

A survey is a systematic research effort collecting information from a sample of individuals, using a questionnaire. Pharmaceutical market surveys can be descriptive (demographic, psychographic), attitudinal, or focusing on prescribing or purchasing behavior (past, future). An *attitude* is defined as an acquired, long-term disposition to

Table 5.4: Pharmaceutical Market Data Sources

Primary: information derived from research specifically designed to answer a particular set of questions		
Observation	Company audits	
	Hospital audits	
	Retail audits	Intercontinental Medical Statistics (IMS)
	Trade shows	Medical society congresses
	Want ads	
	Reverse engineering	
	Hiring key employees	
	Plant tours	
Experimentation	Market testing	
Questioning	Mail survey	Physicians or patients
	Telephone survey	Physicians or patients
	Personal interview	Sales force, Suppliers, Physicians, Pharmacists, Employees, Consultants
	Focus group	Physicians, Nurses, Pharmacists, Patients, Patient families
Secondary: information already collected by someone else for another reason		
Internal	R&D	Scientific publications
	Marketing	Marketing plans
	Sales	Sales force reports
	Other	Patent databases, Job applicants
External	Trade press	*Pharmaceutical Executive, Applied Clinical Trials, Pharma. Business, SCRIP*
	Medical press	Medical research journals, News journals
	Lay press	Newspaper articles, Newspaper publishers, TV and radio stations, Business publications (*Forbes, The Wall Street Journal, Business Week, Fortune, Financial Times, The Economist*), Clipping services
	Books	Science, Technology, Marketing, Management, Biographies
	Databases	Moody's, Dun & Bradstreet, Financial Times
	Government	Health department, Patent office, Census department, Pricing, Reimbursement, Formulary committees
	Trade Associations	Prescribers, Manufacturers, Wholesalers, Pharmacists, Nurses
	Universities	Medical department organizing a satellite symposium backed by the competitor, or a business department holding a case study library
	Chamber of Commerce	
	Investment bankers	Bank reports
	Libraries	
	Internet	Medicine- and pharmacy-related sites, patient sites
	Consultants	Industry reports, reviews, white papers, articles and case studies.
	Customers	Direct information from various customers (see Trade)
	Competitor's	Annual reports, Stock Exchange reports (10Ks), Shareholder meetings, Investor's information, Web site, Press kits, Press releases, Promotional material, Advertising, Employee newsletters

Table 5.5: Marketing Research Sampling Methods

Probability	Nonprobability
Simple random	Convenience
Stratified random	Judgment
Cluster	Quota

consistently respond in a given manner to various aspects of the world. Some of the best known attitude measurement methods are **paired set comparison** (product A versus product B, product B versus product C, product A versus product C), **perceptual mapping** (product placement on quality versus price axes), **constant sum** (usually 100 points, divided between various options), **continuous rating** (worst/below average/average/good/very good/best), **Likert scaling** (responses to "strongly agree/stronly disagree" questions), **semantic differential** (5- or 7-point scale with opposite pairs of descriptive words), and **projective techniques** (word association, picture interpretation, completion test, third person, or role playing).

The most commonly used survey research methods are: (a) personal interview, including in-home (door-to-door), in-medical-practice (hospital, clinic, long-term care facility, private office), in shopping center (mall intercept), in pharmacy (purchase intercept technique [PIT]), self-administered, or omnibus; (b) telephone survey (operator- or computer-assisted); (c) mail survey; (d) fax survey; (e) e-mail survey; (f) internet survey; and (g) focus group, including physical gathering, telephone conference, video conference, or Web conference. Various questionnaire designs include open-ended, fixed alternative, and mutually exclusive.

Observation

Observation is the systematic recording of customer behavior, events, or objects. Some of the observation research subjects are (a) physical actions, (b) verbal/expressive behavior, (c) temporal patterns, and (d) spatial relations. The methodologies employed are broadcasting cameras, web-casting cameras, mechanical counters, infrared motion detectors, and human observers. A more elaborate observation method is using trained marketing research professionals (mystery shoppers) who approach research subjects and gather valuable information on their behavior and patterns by pretending to be naïve customers.

Consider the following example. A French OTC antihistaminic medication manufacturer has just implemented a massive pharmacist educational campaign expecting to influence their medication recommendations or specialist referrals to patients. Mystery shoppers are then used to randomly approach pharmacists across France and monitor their antihistamine recommendations to patients.

Observations can be conducted in (a) standard test markets (for example, metropolitan area retail pharmacies), (b) control (or laboratory) settings (for example, a conference room where ten invited prescribers are asked about their brand name preferences), or (c) in simulated test markets (for example, a shopping mall store temporarily converted into a nutritional supplements/healthy living store with the purpose of studying the interested buyers' behavior in detail).

Experimentation (test marketing)

Experimentation is often used by pharmaceutical marketers to test specific product characteristics or marketing campaign items in an effort to fine-tune their R&D or promotional activities in advance of the actual product launch. Common examples of such tests are prescribers' brand name or campaign testing, price elasticity, and patients' tastes and packaging testing.

Analyzing the Data Collected

Once the data collection phase has been completed, the data are entered into a suitable electronic database. Erroneous data are cleaned (e.g., a questionnaire's entry of a subject's age as 156 corrected to 56 [editing]), certain variables are coded for easy statistical comparisons, (e.g., 1 = strong preference, 2 = moderate, and so on), and, finally, various statistical tests are utilized for their analysis.

Creating a situational model based on the data

The systematic collection and analysis of marketing research data eventually leads to the creation of a detailed situational model describing customers' attitudes and behaviors. Such research-backed, overall-picture models are extremely valuable tools for marketing decision making. Classic pharmaceutical industry examples of such models include the prescribing-decision process maps, patient purchasing decision trees that show information and disease treatment model trees that show information from patient symptomatology to diagnosis to treatment, as well as long-term follow up.

Evaluating the model and deciding on the optimal marketing strategy

The final step in the marketing research process is the evaluation of the situational model by an interdisciplinary team of company experts, ranging from R&D to upper management, marketing, sales, manufacturing, advertising, and others working in functional teams toward the improvement of the product's competitive advantage.

A potential risk among giant pharmaceutical industry players is the lack of knowledge-sharing among these cross-functional teams, with the resulting break in communication and vast amounts of useful marketing research information remaining underutilized for large periods of time. Therefore, it is of paramount importance that each organization constantly work on improving the collection, archiving, and dissemination of marketing information so that all levels are fed with valuable information and made capable of contributing to the overall, long-term capability and viability of the company.

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6

Market Segmentation

> Pharmaceutical company research spending has nearly doubled every five years since 1970.
>
> PhRMA, 1998

Inexplicably, customers do not always recognize a company's vast product superiority. Thus, they do not all respond in the same way to the company's marketing activities. Indeed, their responses depend upon their personal characteristics, their psychological attitudes and beliefs, as well as on several environmental factors. It seems logical, then, to study in detail all these different factors and to attempt to categorize the customers in several distinct groups that can be predictably targeted by a company's marketing activities. Furthermore, if such distinct groups can be characterized in great detail, then it may be appropriate to perform different marketing activities and allocate various amounts of resources to each segment. This is the essence of customer segmentation, and it applies to pharmaceutical marketing as well.

MARKET DEFINITION

In defining a market, we can think of all potential customers sharing a particular need or want. Thus, in the consumer goods world, we can think of sports car markets, home appliance markets, or cola drinking markets. Pharmaceutical marketers may define

their markets using various criteria. Figure 6.1 provides examples of such criteria. A potential nonsteroidal anti-inflammatory agent (NSAID) market can be defined by buyer (adult, children, elderly, women only), by product (aspirin, Tylenol®, ibuprofen), by formulation (pill, tablet, syrup, injectable), or by patient diagnosis (flu, other infections, premenstrual syndrome, other medication's adverse event). Figure 6.2 shows a pharmaceutical market segment by diagnosis.

Regardless of the overall market definition, pharmaceutical markets follow consumer goods markets in being nonhomogeneous. For example, in defining a car market for an automobile brand, we can identify yuppies with a need for a status symbol, workers in need of a utility truck, parents in need of a polymorphic car, or young university thrill-seekers looking for a sports convertible sedan. Likewise, even though millions of prescribing physicians or patients around the world rely on a specific pharmaceutical product, their needs or wants may be distinctly different. Prescribers of a certain medication have different needs and, therefore, are driven by different buying criteria. An academic professor of rheumatology may be looking for a breakthrough NCE, allowing him or her to gain fast, personal, clinical experience and then transfer it to less senior colleagues or medical residents. A private clinic physician may be operating in a managed care setting, driven by medical outcomes and economic restraints that force her or him to prescribe branded generics. A private practitioner in a rural community may be looking for a balance between efficacious, safe, and economic alternatives. Finally, an aspiring medical resident may be relying on her or his newly acquired medical knowledge, thus driving his or her decisions toward the therapeutic class' "reference drugs," that is, those that have been in use for several years and have become so popular that all newer medications are compared to them.

On the other hand, patients have the power to influence their physician in prescribing a medication for which they have heard positive comments, or even select an OTC alternative. An elderly person on a pension may be looking for an efficacious, but mainly safe medication that will not interact with other comedications or disease

Figure 6.1. Pharmaceutical market definition methods

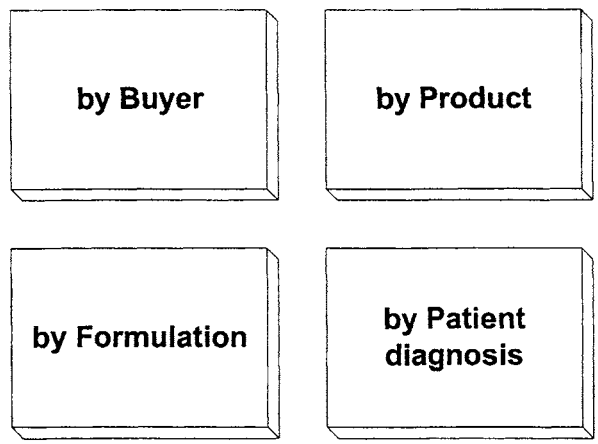
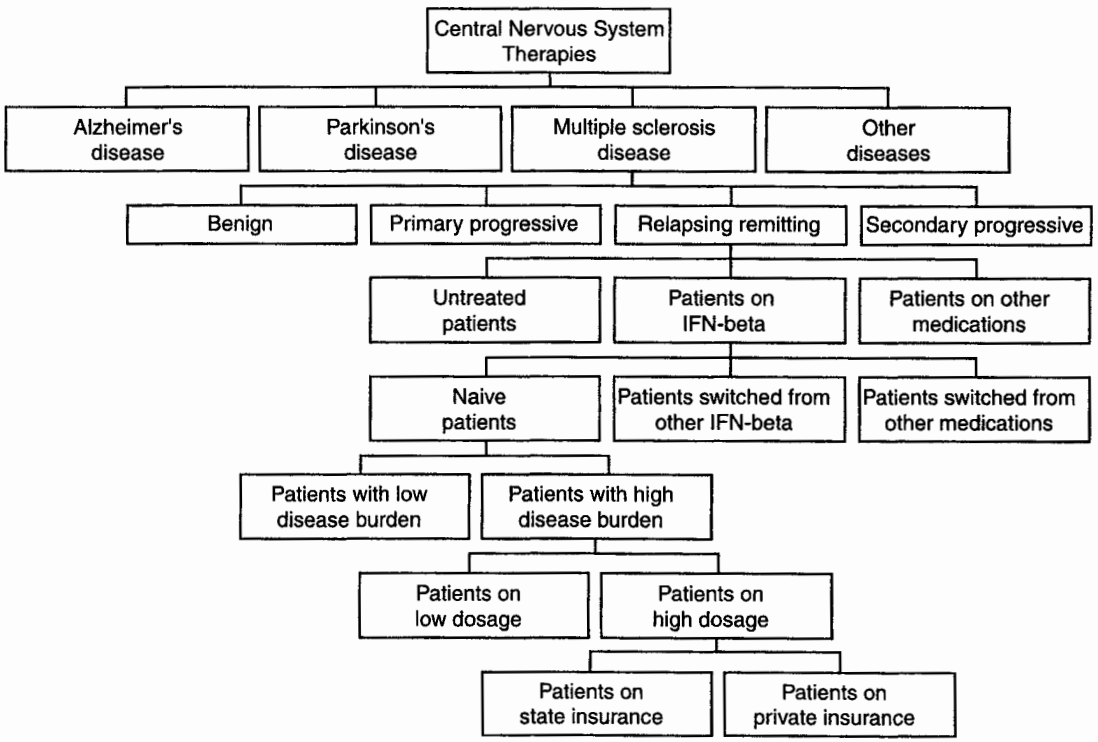


Figure 6.2. A pharmaceutical market segment example



states at a cheap price. A working professional may need an efficacious product that will not cause drowsiness or other severe adverse events. A young mother may ask her daughter's pediatrician to give her a prescription for a cough syrup advertised on national TV. Finally, oncology or AIDS patients may be open to experimental and powerful medications that may extend their hopes for survival.

Based on these observations, market research data, sales force suggestions, and countless other information sources, pharmaceutical marketers are trying to identify markets and submarkets for their products, allowing them to optimally target their campaigns and resources toward these different groups of customers. Each distinct group of customers constitutes a market segment, and the process of identifying each segment and its characteristics is called market segmentation.

THE CONCEPT OF MARKET SEGMENTATION

Because a single product is not likely to appeal to all customers, an effort is made to identify *groups of customers* that find different product variations to be attractive. *Segmentation* is the process of analyzing and breaking down the whole market into specific submarkets, each with their own characteristics and needs. *Micromarketing* is the process of creating and offering customized products combined with customized communications to each submarket's customers.

As mentioned earlier, there are several reasons for seeking an effective market segmentation. First, the pharmaceutical markets (prescribers, patients, and other stakeholders) are not homogeneous in their needs and wants. Second, pharmaceutical companies working in the global environment are unable to target mass, undifferentiated markets in many countries. In addition, it is impossible to gain competitive advantage without effective market segmentation strategies—in any therapeutic category or geographical market of the world. Some of the important benefits of pharmaceutical market segmentation are: (1) designing optimal product/market matches; (2) proper promotion strategies; (3) effective advertising media allocation; and (4) identifying the most appropriate distribution channels, and exploiting neglected segments.

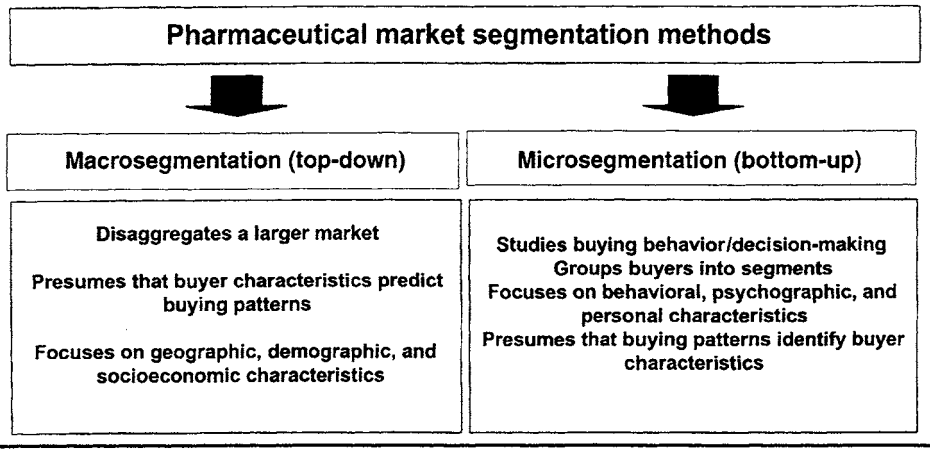
SEGMENTATION METHODS

There are two different, equally effective market segmentation methods, as shown in Figure 6.3. The *top-down approach* presumes that buyer characteristics predict buying patterns, while the *bottom-up approach* assumes the opposite (i.e., that the buying patterns can indeed identify buyer characteristics).

To illustrate the essence of the top-down approach, let us think of the United States market as an OTC antacid. Based on epidemiological data, the respective ailment will be most prevalent among young professionals in high-stress jobs, often found in large metropolitan centers. Based on this observation, an OTC marketer would apply geographic, demographic, or socioeconomic data (freely available from state statistical offices or private research firms) when trying to define respective patient segments—potentially responding favorably toward a local lay-press campaign promoting the antacid.

On the opposite side, let us imagine the European market for a new, highly priced prescription hormone replacement therapy (HRT). A pharmaceutical conglomerate

Figure 6.3. Pharmaceutical market segmentation methods



seeking to implement country-specific, physician-detailing campaigns will start by studying gynecologist's prescription habits and their decision-making processes regarding HRT. Are these physicians believers in the necessity for life-long, expensive HRT treatments for their patients? Are the physicians aware of the problems postmenopausal women experience? And, are physicians influenced by women's requests for some replacement therapy, or do they try to avert them from a long-term, yet unproven treatment? Information on their attitudes and trends may allow the grouping of prescribers into distinct segments (e.g., academic physicians recommending HRT based on their up-to-date medical knowledge, and private rural practitioners who are more skeptical and in need of more education on HRT). Following this segmentation, two or more physician-detailing campaigns are test-marketed and then implemented across Europe. The campaigns are focused on the scientific expertise of opinion-leading academicians and the susceptibility of private OB/GYN specialists to magazine advertisements or local-town presentations by visiting university professors.

Segmentation Criteria

The segmentation criteria used by the pharmaceutical industry are similar to those frequently used by other industries (Table 6.1). Different criteria may apply to the multiple stakeholders of the pharmaceutical industry, as described in Chapter 5. For instance, demographic, socioeconomic, or consumption pattern criteria may be especially suitable toward patient segments, while psychographic and behavioral criteria may be equally important in segmenting prescriber groups. Furthermore, selected criteria may be applicable to other health personnel, government employees involved in pharmaceutical purchasing, the media, or the general public.

Successful Segmentation Criteria

In identifying and selecting target pharmaceutical market segments, marketers are often faced with the following dilemma: How deep into the segmentation scale do we

Table 6.1: Segmentation Criteria Used by the Pharmaceutical Industry

#	Criteria	Examples
1.	Demographic	Age, race, gender, migration, urbanization, income, family composition, education
2.	Socioeconomic	Political system, Gross National Product (GNP), Gross Domestic Product (GDP), business cycle (prosperity, recession, depression, recovery), competition
3.	Geographic	Continent, climate region, geopolitical group of countries, country
4.	Psychographic	Attitudes, interests, opinions
5.	Behavioral	Lifestyle, social class and subcultures, purchasing structure, buying situation
6.	Consumption patterns	Usage rate, loyalty
7.	Consumer predispositions	Purchase predisposition, purchase influence

go? Or, how small of a segment can we successfully identify? As a rule, pharmaceutical marketers should only focus their marketing efforts and resources on market segments with the following characteristics:

Differentiable (i.e., private gynecologists who work in metropolitan areas and see women suffering from premenstrual syndrome (PMS), and are in need of a strong NSAID analgesic, or the patient segment suffering from this problem)

Measurable (i.e., hospital oncologists who treat inpatients, and the treatments used are monitored by an independent marketing research agency [e.g., IMS])

Accessible (i.e., remote provincial town physicians may not be reachable by medical sales forces; also, a remote country market may not be accessible by an efficient distribution channel)

Substantial (i.e., infectious disease patients in a large underdeveloped country are a prime market segment for a generic antiviral agent; on the other hand, a rare genetic disease may not be a prime candidate for extensive R&D or post-launch marketing investments)

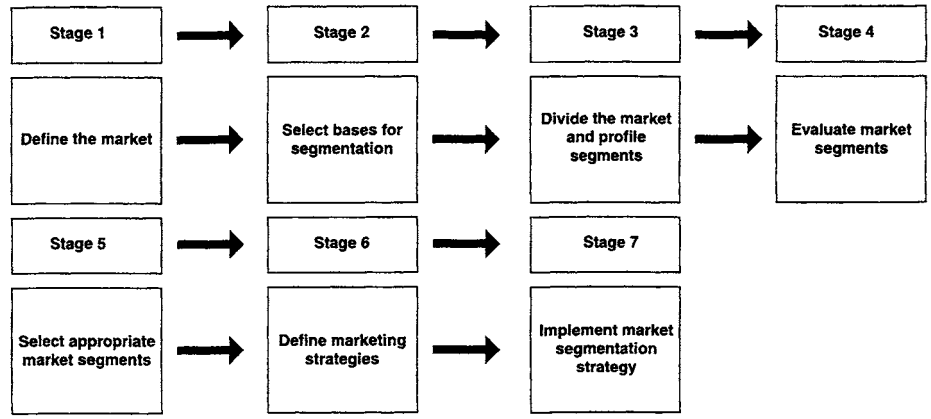
Actionable (i.e., the market segment chosen will be responsive to a marketing action because it has the authority [for prescribers] or purchasing power [hospital administrators or hospital outpatients] to select the pharmaceutical product in promotion)

Defendable (i.e., a segment relatively protected from existing competitors or potential new entrants; for example, if the segment is characterized by only mature, identical products currently involved in a price war, it may not be a sound strategy to enter and defend this undifferentiated, and extremely price-sensitive market)

Segmentation Steps

Market segmentation involves several distinct steps, as shown in Figure 6.4. The market is first defined by using the criteria mentioned earlier. The proper selection of segmentation criteria then leads to the identification of distinct market segments with

Figure 6.4. The market segmentation steps



homogeneous profiles. Those individual segments are then analyzed in detail, leading to the identification of the optimally suited segments to the product characteristics and unique advantages. Marketers will then construct marketing strategies toward these segments, and define the tactics and resources that will be used in achieving a competitive advantage within the selected segments.

Market segment patterns

The implementation of precise segmentation strategies and the use of proper segmentation criteria for each customer mix eventually lead to the definition of distinct market segments, which helps design and implement segmental marketing strategies. Looking at the resulting segments, a marketer should be able to decide whether a single marketing strategy is applicable, whether the respective segment needs further evaluation, or whether it is not a good candidate for the product in review. Consider the following examples. A relatively small, national market for a central nervous system (CNS) product is characterized by the presence of one hundred psychiatrists, all of who have graduated from the only academic department situated at the capital's university; it is a *homogeneous market* of future prescribing psychiatrists. Rarely, however, is a marketer faced with such an optimal case. More frequent is the identification of distinct, *clustered market segments* requiring their own marketing approaches and tactics, such as in the case of academic centers of excellence, private clinic physicians, or private practitioners. Finally, a generic antipyretic medication may strain a company's resources when selecting a target segment among thousands of prescribers belonging to various specialties in a *diffuse market environment.*

Segment Analysis (Profiling)

Following the identification of individual market segments, pharmaceutical companies often employ complex segment analyses before deciding to enter and compete in each of these segments. For instance, the launch of an NCE or an existing product's line extension (new formulation, new strength) is often preceded by a segment analysis period. Some of the most frequently used analytical tools follow.

Customer behavior analysis

The customer behavior of either prescribers (prescribing behavior) or patients (purchasing behavior) was described in detail in Chapter 2. Two behavioral analysis approaches are shown in Figures 6.6 and 6.7. Furthermore, a customer behavioral analysis is a part of the segment analysis shown in Table 6.2.

Perception mapping

Perception mapping investigates the attitudes and perceptions of prescribers, pharmacists, nurses, patients, and others in relation to selected product attributes (efficacy, safety, tolerability, onset of action, ease of use, taste, price, and so on), and plots the comparison of multiple products in relation to two of these attributes on a two-dimensional scale, as shown in Figure 6.8. The product comparison allows the definition of the optimal two-attribute quadrant, which becomes the focus of every future R&D or marketing effort (e.g., by improving the taste, lowering the price, and so on). Perception mapping helps to (a) understand the market structure (see Figure 6.5), (b) determine product/company perceptions, (c) identify underserved market segments, and (d) test perceptions in relation to new products.

Attribute analysis

Attribute analysis allows the investigation of the relative competitive advantage of each of the product's attributes in relation to its competitors' (see Table 6.3). Additionally, the rating of these attributes according to their value for the customer allows the exact product "positioning" in the area where it presents the highest competitive advantage. The process of product positioning is discussed in Chapter 8.

Figure 6.5. Characteristics of pharmaceutical market segments

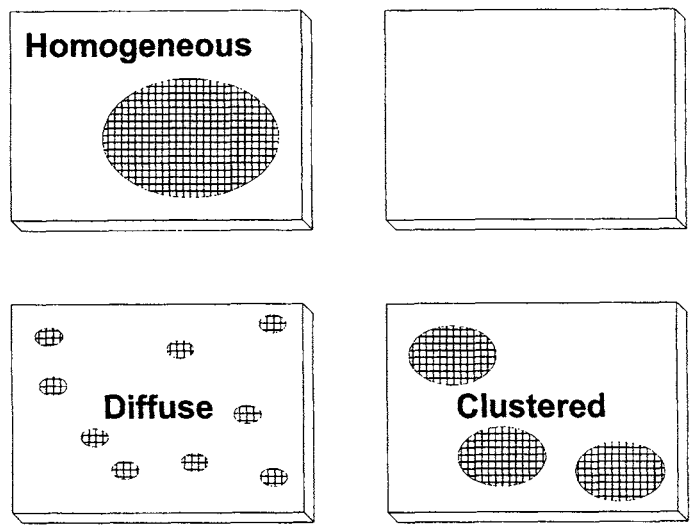
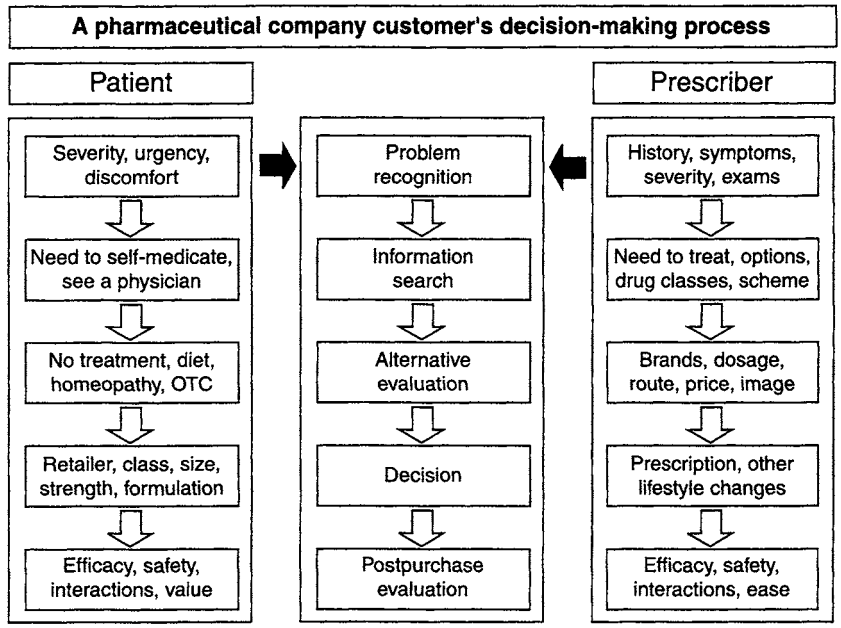


Figure 6.6. A pharmaceutical company customer's decision-making process



Economic attractiveness

This criterion is especially critical in the initial R&D phases of selecting from among alternative lead compounds belonging to several therapeutic categories. Thus, multiple data sources are used in defining the respective therapeutic category size. Some of the most frequently used variables for economic attractiveness are: (a) disease incidence and

Figure 6.7. Customer behavior analysis

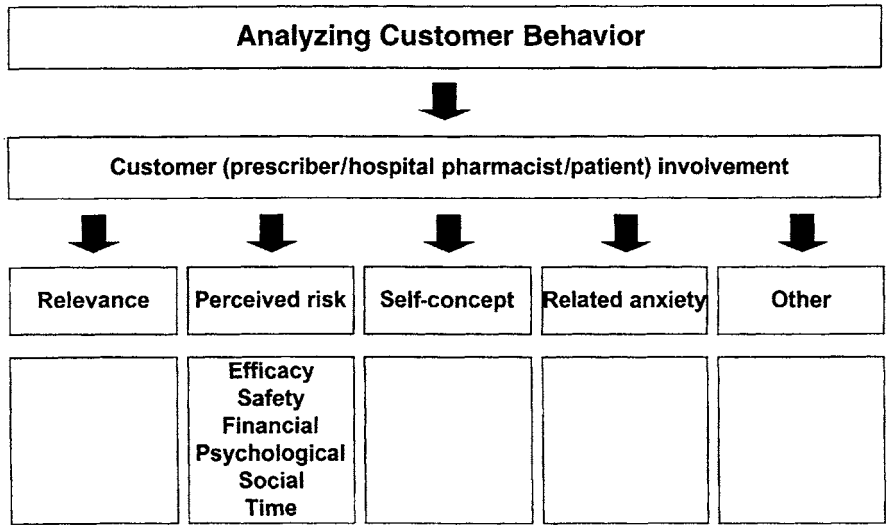


Table 6.2: Pharmaceutical Segment Analysis

Market Potential	Therapeutic Area A	Therapeutic Area B	Therapeutic Area C
Potential market size			
Available market size			
Served market size			
Average prescription value			
Value market potential			
Volume market potential			

Opportunity	Therapeutic Area A	Therapeutic Area B	Therapeutic Area C
Market growth			
Number of competitors			
Patient satisfaction			
Price sensitivity			
Promotional responsiveness			
Level of habit			
Customer number			
Market complexity			

prevalence rates; (b) seasonality prevalence fluctuations; (c) percentage and actual number of treated patients; (d) market size in values, units, and annual growth; (e) reimbursement situation; (f) pricing environment; and (g)number of physicians.

Competitive activity

Competitive activity within the segment is another significant indicator for evaluating the market attractiveness. The number of competitors present and their respective market shares are of primary importance. Additionally, their overall performance, other

Figure 6.8. Perception mapping

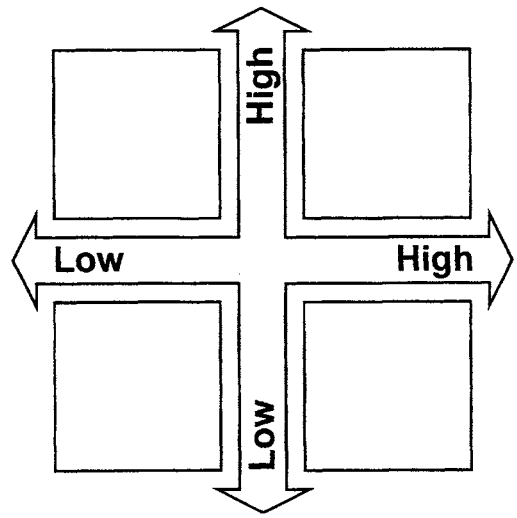


Table 6.3: A Pharmaceutical Product Attribute Analysis

Product	Your Prescribers		Competitor A		Competitor B		Competitor C	
Attribute	**Importance**	**Score**	**Importance**	**Score**	**Importance**	**Score**	**Importance**	**Score**
Efficacy								
Safety								
Tolerability								
Adverse Events								
Onset								
Other								

	Your Patients		Competitor A		Competitor B		Competitor C	
	Importance	**Score**	**Importance**	**Score**	**Importance**	**Score**	**Importance**	**Score**
Efficacy								
Safety								
Tolerability								
Adverse Events								
Onset								
Other								

recent product priority conflicts they may be facing, and their marketing strategies and investments, as well as the success of recent product launches are significant indicators.

Product differential advantage

As seen in the introductory chapters of this book, creating and sustaining a competitive advantage is the epitome of every successful marketing strategy across all industrial sectors, including the pharmaceutical industry. Therefore, when evaluating whether to enter a distinct market segment, it is important to compare the product's differential advantage to the claims of all other competitive products far in advance of market entry. If the results of such analysis indicate a competitive advantage for the product, then the decision to enter the segment is strongly supported. Very often, pharmaceutical companies realize that they can no longer defend their competitive advantage within a specific segment worldwide, and eventually decide to diversify this unit, concentrating on fewer, more promising markets.

These market segment attractiveness criteria may be then consolidated and weighted amongst each other, thus giving an overall market segment attractiveness ranking, and offering marketers a very valuable tool in selecting optimally from among various segments and creating market strategies for each (see Table 6.4).

Different Segment Strategies

Following the identification of unique market segments, and the analysis of their economic attractiveness, competitive intensity, and differential product advantages of each, corporate marketing departments must decide on the segment strategies suitable for each of their products. The final selection may depend on several factors, the most important of which are the following: *market characteristics* (size, growth, competition, physician number, consumer attitudes); *regulatory environment* (reimbursement, pricing, cost-containment); *product characteristics* (differential advantage, life cycle stage,

Table 6.4: Identifying Pharmaceutical Market Segment Attractiveness

Criteria	Weight 1 = High, 5 = Low	Segment A GP	Segment B OB/GYN	Segment C Pediatric	Segment D Oncology
Disease incidence					
Disease prevalence					
Local patient population					
Patients treated					
Patients treated with product category					
Unit market size					
Annual market growth					
Reimbursement for indication					
Physician number					
Competition					
Differential advantage					
Attractiveness Score					

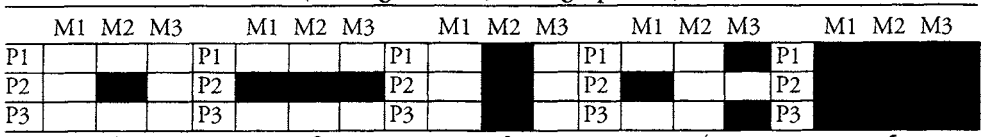
branding, pricing policy); and *company characteristics* (corporate strategy, portfolio priorities, therapeutic category expertise, resources). Segment strategies are broadly divided into four categories, namely mass, differentiated, niche, or custom, in increasing degree of segment differentiation.

Undifferentiated (Mass Marketing)

An undifferentiated segment strategy implies that the product is to be marketed widely to the masses, employing a homogeneous marketing approach across all prescribing physicians, dispensing pharmacists, or consuming patients. Obviously, the product characteristics support such a strategy by offering relief from a widely spread ailment (e.g., fever) often seen by all medical specialties, and acting through a safe and efficacious mechanism across all patient segments (see Table 6.5). This strategy requires marketing tactics that will appeal to all prescribers and patients alike, and offers the advantages of a universally homogeneous campaign. On the other hand, vast amounts of marketing resources need to be budgeted toward multiple medical specialties and millions of patients around the world. Furthermore, it is difficult to create a unique

Table 6.5: Market Segment Strategies

(M : single market, P : single product)



1	2	3	4	5
Single-segment Concentrated Target marketing	Single-product Multiple market Differentiated	Single-market Product variety Differentiated	Selective market Differentiated	Full coverage Undifferentiated Mass marketing

(Adapted from Abell, 1980)

competitive advantage when trying to appeal to a vast consumer base, and this increases the threat of competition. When trying to protect themselves from competition, pharmaceutical conglomerates often rely on intensive branding campaigns, making their offerings stand out from the crowd. The significance and tactics of branding are discussed in a later chapter.

Differentiated (Multiple-Market or Product-Variety Marketing)

Differentiated segment strategies call for the creation, implementation, and evaluation of multiple marketing campaigns aimed at different market segments (see Table 6.5). To illustrate the value of a differentiated strategy, envision a CNS-oriented pharmaceutical company with a wide antidepressant portfolio. The company has identified the unique market segments of the adult depressed population and the elderly population, as well as the sufferers from obsessive-compulsive disorder (OCD), who may be helped by antidepressant therapy. When selecting its marketing strategies, the company may offer a different antidepressant for each of these segments (selective market strategy); or may offer all products—at different prices or dosages—to a single segment (single-market, product-variety); or may even offer one product—at different dosages—for all segments (single-product, multiple-market).

Before such decisions can be made, however, the company has to consider the following: Can our product serve the needs of multiple segments? Can we successfully invest in and defend several segments simultaneously? And, do we have the resources required? A differentiated segment strategy offers a better chance of satisfying different customer needs, but may require increased marketing investments compared to the undifferentiated strategy.

Single Segment/Niche (Concentrated or Target Marketing)

Focusing on a single segment (niche market) by building a prohibitive competitive advantage within that segment and defending against any potential entrant is a common strategy among many small or medium-sized pharmaceutical companies that do not have the resources to compete on more, larger market segments. For instance, a company may try to become a world's specialist in Parkinson's disease, avoiding to compete in other CNS therapeutic areas, and diversifying previously existing business units in oncology or rheumatology.

Such a strategy offers unique advantages, such as focusing all resources in one therapeutic area, building a formidable portfolio, constructing barriers to entry of new competitors, and implementing a sharply focused marketing campaign. A niche strategy, however, does not come without disadvantages. Strictly confined R&D programs have inherent risks of producing promising lead compounds, which fail to progress into marketable products, and thus delay new product introductions for a long time. In addition, the niche market conditions may abruptly change, by either revolutionary new chemical entities launched by a giant new entrant or by a change in the regulatory environment leading to reduced prices or reimbursement coverage. These may sharply decrease the company's profitability. Furthermore, a niche market offers finite growth opportunities and limits the company's long-term financial stability and survival.

Custom (Single Customer Marketing)

The dilemma of how small a segment to focus on has also confronted other industry sectors, leading in some cases into the strategy called *mass customization*—meaning microtargeting down to the level of each individual consumer, such as in the case of custom-made blue jeans to fit the individual buyer. One of the available techniques in targeting individual customers is *database marketing*, which allows the collection and management of large amounts of customer information. Furthermore, the new phenomenon of *Web marketing*, is depending heavily on this approach, and is discussed in Chapter 20.

7

Situational Analysis

> As the human genome is mapped, the number of potential new targets for pharmaceutical intervention will increase as much as twentyfold—increasing the hope for effective new treatments.
>
> PhRMA, 1998

When discussing strategy, the first question a marketing strategist has to address is "where are we now?" This is done by looking thoroughly at the internal and external situations, so that a realistic assessment of the company's current situation is reached. The process of studying the internal and external environments is called *situational analysis*. As Table 7.1 shows, a variety of informational sources are used as input to the situational analysis process. Several analytic techniques, such as perceptual mapping and comparative scaling, are then used to arrive at the desired outputs in the form of key success factors (KSFs), strategy, and tactics.

TYPES OF SITUATIONAL ANALYSIS

Figure 7.1 shows a detailed listing of the different analysis types used by a marketing strategist. External analysis covers the different existing environmental forces (macroenvironment), the therapeutic area market segments, customers, and competitors (microenvironment), as well as the prevailing macro- and microenvironmental

Table 7.1: Situational Analysis Inputs and Outputs

Input	Situational Analysis	Output
Product information	Perceptual mapping	KSFs
Company information	Comparative scaling	Strategy
Market information	Performance analysis	Tactics
Competitor information	SWOT	
Environmental information		

trends, and the industry's KSFs. The elements of the macroenvironment were covered in Chapter 2, the segment analysis components (markets and customers) were covered in Chapter 6, the competitor and KSF analysis are discussed later in this chapter, while the trends forecasting are presented in Chapter 21. This chapter focuses on the elements of internal analysis, as well as competitor analysis. Before discussing these components, some of the commonly used situational analysis techniques are shown.

SITUATIONAL ANALYSIS TECHNIQUES

Two of the most commonly used techniques for assessing customer attitudes toward the organization's product offerings are the perception mapping and comparative product scaling techniques. Figure 6.8 (page 98) depicts a two-dimensional perception map used to evaluate customer attitudes and perceptions on competitive products. The two axes used may refer to a variety of product core and augmented variables, such as perceived efficacy, safety, tolerability, ease of use, price, accompanying information, speed of action, taste, and so on. When competitor products are mapped this way, marketers can identify unmet customer needs, for example, identifying an area void of products with both high efficacy and good price, which can then be communicated to their R&D departments for future development.

Comparative product scaling is another technique that can plot customer perceptions of multiple products on a variety of measures, as seen in Figure 7.2. This visual technique can also show significant gaps in a company's product performance compared to those of the competitors, and, ultimately, can lead to the development of a new and improved therapeutic solution.

Finally, situational analysis techniques can focus independently on the external and internal environment, or combine a mixture of both. SWOT analysis is a primary example of an analytic tool employing data from both environments. Another such tool is the situational grid, which compares a company's position (strong [S], moderate [M], weak [W]) to the industry attractiveness within the given market segment (see Table 7.2).

RESOURCE ANALYSIS

A company's resources may be *assets* (tangible and intangible) or *internal capabilities*. Tangible resources include land, research and manufacturing facilities, office space, and financial assets. These items can be measured precisely by using long-existing accounting methods. Intangible assets are harder to evaluate; therefore, proper quantitative measures must be thought out carefully. Examples of essential intangible components that are difficult to analyze include the number and economic value of patents

Figure 7.1. Types of situational analysis

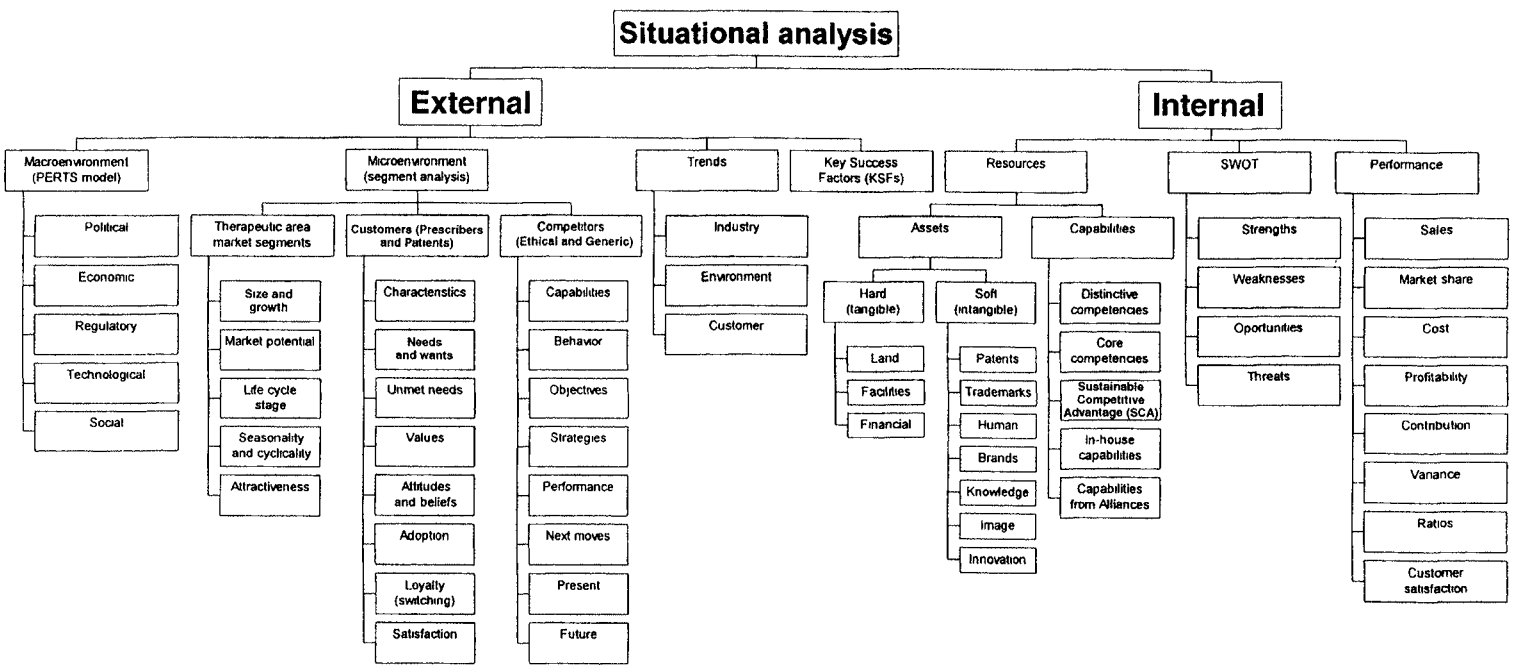
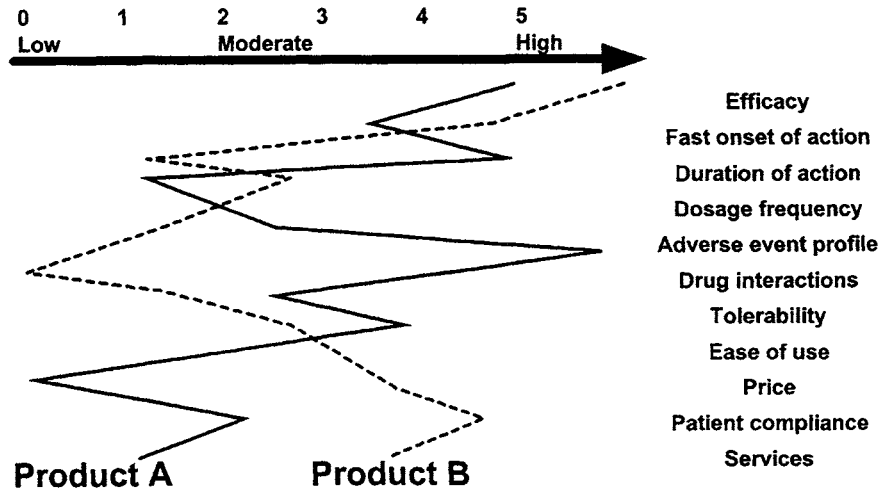


Table 7.2: Situational Analysis Grid

Factor	Market Attractiveness	S	M	W	Company Position	S	M	W
Market								
Extent								
Growth								
Customers								
Potential								
Product								
Product Life Cycle (PLC) stage								
Complexity								
Added value								
Patents								
Differentiation								
Competition								
Concentration								
Capacity								
Vertical integration								
Price sensitivity								
Profitability								
Profit								
Cost structure								
Gross margin								
Personnel								
Structure								
Working condition								
Quality								
Other Factors								
Team spirit								
Government support								

Figure 7.2. Comparative product scaling



and trademarks, human capital, brand equity, and the level of organizational knowledge, as well as the company's image and innovation. Nevertheless, as common business knowledge proclaims, "What is hard to measure is hard to manage," so various ways of analyzing and evaluating intangible assets have been created. Other experts have even suggested the use of enterprise-wide "scorecards," namely, the creation of a corporate grading scale, allowing frequent comparison of actual performance to the required standards. For an excellent effort in describing such a scorecard, see *The Balanced Scorecard*, by Kaplan and Norton (1996). Table 7.3 identifies some quantitative parameters that are used for analyzing intangible assets in the pharmaceutical industry.

SWOT ANALYSIS

SWOT stands for the strengths of, weaknesses of, opportunities for, and threats to an organization. Strengths and weaknesses are internal, while opportunities and threats are external. Figure 7.3 shows the four elements of SWOT analysis.

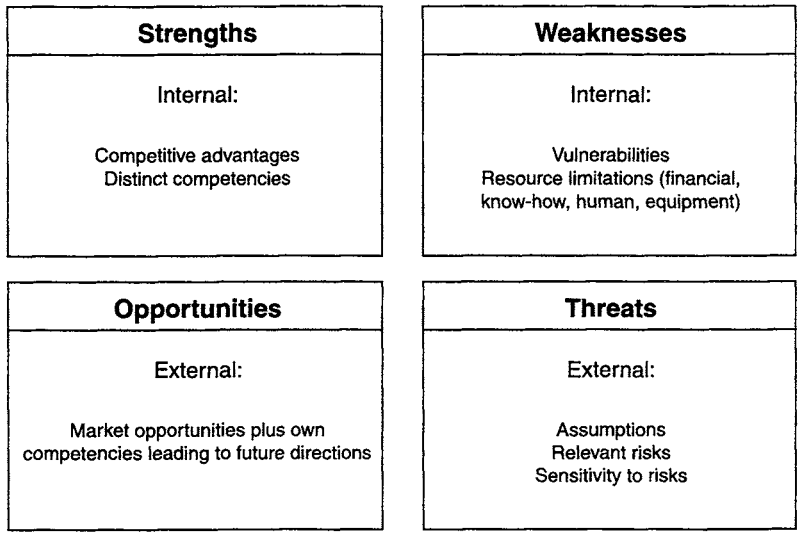
As previously mentioned, SWOT analysis uses both internal and external analysis tools. In product SWOT analysis, a given product is compared to its direct competitors within the given market segment. In company SWOT analysis, the whole organization is compared to its organizational competitors. Both are useful tools, and are widely used by pharmaceutical marketers designing a company's strategy.

As Figure 7.4 shows, a set of seven essential steps are needed to conduct a focused SWOT analysis. First, the relevant market segments are identified (product strength or

Table 7.3: Intangible Asset Measures in the Pharmaceutical Industry

Human Capital	Brand Equity	Knowledge	Image	Innovation
Employee articles	Awareness	Intranet infrastructure	Perception maps	Patents submitted
Employee books	Acceptability	Information Technology (IT) investment	Stock price	Patents awarded
Employee speeches	Loyalty	In-house databases	Press quotes	Patent royalties
Employee courses	Preference	Library holdings	Industry ranking	Products in pipeline
No. of MDs/PhDs	Price premium	Inquiries answered	Customer loyalty	INDs submitted
Trade association seats	Unit volume	Knowledge professionals	Job applications	NDAs submitted
Employee awards			Employee satisfaction	NDAs awarded
				Product launches
				New product sales
				R&D investment
				Clinical trials running
				NCEs introduced
				Innovation awards
				Enabling technologies

Figure 7.3. SWOT analysis



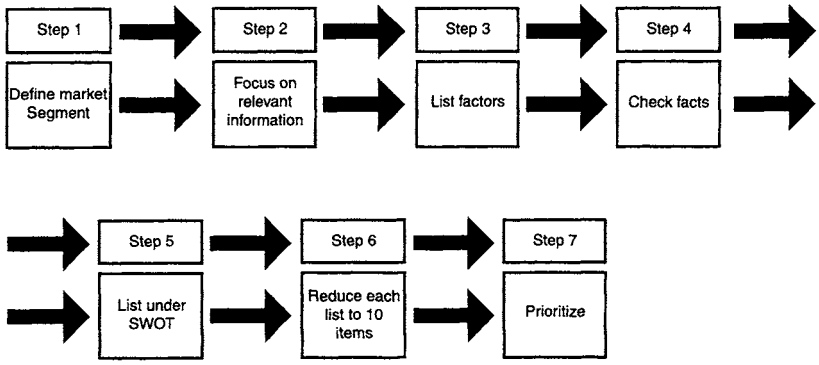
formulation versus similar competitor offerings, or full product line versus competing product lines, or even the whole company versus its industry competitors). Second, extensive relevant information is collected and filtered so that only data applicable to the SWOT analysis become the focus. Third, a number of important factors are listed and then placed under the four quadrants of the SWOT analysis grid. Attention needs to be given to clearly distinguish strengths (internal) from opportunities (external), or strengths from potential weaknesses (e.g., a wide product line is a strength; that it requires extensive resources and may dilute a company's product priorities is a weakness). Next, each of the four identified lists is reduced to a maximum of ten important issues, because the essence of a SWOT analysis is the identification of KSFs and action points. Additionally, a long list may defeat the purpose of the analysis. Finally, the chosen items are prioritized. At this point they are ready to be converted into strategy and tactics by the marketing strategists. Table 7.4 shows a SWOT analysis grid that can be used for several market segments.

Table 7.4: SWOT Analysis Grid

		Segment A		Segment B		Segment C	
Strengths and Weaknesses (SW)	**Weight**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**
Total	100						

		Segment A		Segment B		Segment C	
Opportunities and Threats (OT)	**Weight**	**Rating**	**Score**	**Rating**	**Score**	**Rating**	**Score**
Total	100						

Figure 7.4. SWOT analysis steps



What are some of the specific SWOT analysis parameters most commonly used by pharmaceutical marketing specialists? Table 7.5 provides an exhaustive list of strengths, weaknesses, opportunities, and threats applicable to the pharmaceutical industry.

PERFORMANCE ANALYSIS

A company's performance analysis may focus on several of the organization's functions and processes. While some of these functions are listed in Figure 7.5, they are presented in depth in Chapter 22.

DERIVING THE KEY SUCCESS FACTORS

Following the completion of the internal situation analysis, including SWOT analysis, an organization is in a better position to evaluate which elements are required for future market success and how the company can fulfill each of the prerequisites. These critical elements are called the key success factors (KSFs), some of which can be found in Table 7.6.

COMPETITOR ANALYSIS

Barring the slim chances of working for a government monopoly or for a company performing so well that it has completely forced all its competitors out of the market, the vast majority of marketing professionals working in free enterprise economies operate in increasingly complex and competitive environments. Under these circumstances,

Figure 7.5. Internal performance analysis tools

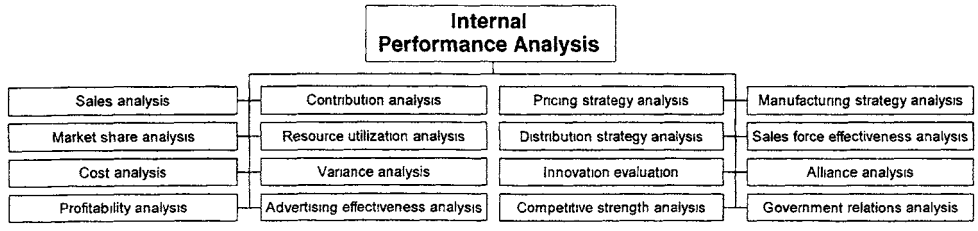


Table 7.5: Common Examples of Pharmaceutical SWOT Factors

S (internal)	W (internal)	O (external)	T (external)
Efficacy	Weak R&D portfolio	Unmet therapeutic need	Industry rivalry
Safety	Lack of financial resources	Market size	Competitive mergers
Tolerability	Lack of human resources	Market growth	Competitive technological breakthroughs
No interactions	Old manufacturing technology	Low market fragmentation	Eroding market share
Long half-time	Lack of technology know-how	High pricing environment	Regulatory delays
Innovative class	Lack of disease expertise	Pricing received	Late market entry
Crosses bodily barriers	Complex dosage scheme	Reimbursement received	New product launches
Patient-friendly dosage	Limited clinical data	Positive clinical results	Entry of generics
Patient-friendly formulation	Low acceptance of new drug	Positive publicity	Patent expiration
Mixing during administration	Low prescriber awareness	Disease treatment guidelines	Increased regulation
Fast onset of action	Multiple product priorities	Chronic treatment possibilities	Price reductions
No impurities	Limited premarketing effort	Changing world climate	Price wars
Best clinical trial program		Changing epidemiology	Negative publicity
Room temperature storage		Changing politics	Low physician compliance
Large prescriber experience		Sales seasonality	Low patient compliance
Large patient experience		Population aging	Aggressive competitive campaign
Good patient compliance		Higher disease awareness	Competitive clinical trial program
Cost-effective		Patient education	Loss of tender business
High gross margin		Patient advocacy groups	Government bias to competitor
Long patent protection		Societal attitude changes vs. disease	
Therapeutic category leadership		Discovery of new diagnostic	
Large therapeutic category portfolio		Globalization	
Superior segment knowledge		Reduction of trade barriers	
Specialized sales force		Comarketing	
Good company image		Tender business	
Good contact with prescribers		Many new products vs. old one	
Contact with authorities		Competitor withdrawals	
Global reach		Research/Quality award	
Disease management program		Governmental anti-generic barriers	
Pharmacoeconomic expertise			

Important: Always choose the ten most important factors to list. A larger SWOT list defeats its purpose.

Table 7.6: Key Success Factors (KSFs)

KSF	Description	Impact	Action Required
Product A in new segment	Introduce A to GPs	High	Segment data, focus group, teasing campaign.
Product B launch	Launch B in Egyptian market	Low	OLs, symposium, campaign.
Product C formulations	Nasal formulation is needed	High	Collect testimonials, contact R&D.
Product D diversification	D is entering decline	Moderate	Identify partner, negotiate, diversify.
Promotional campaign	Repositioning campaign needed	Moderate	Choose agency, brief, plan, test, create.
Clinical trials	OL experience	High	Include local center, get approval.
Marketing information	Competitor has surprised us	High	Collect competitive data, set up system.
Sales force	Sales call frequency is low	High	Recruit, train, motivate, and align representatives.

current and potential competitors, as well as supply chain players who accumulate bargaining power, exert a continuous, competitive pressure on the organization, which threatens its market share and even its very existence. The exact nature of these competitive forces surrounding an organization is further discussed in Chapter 11.

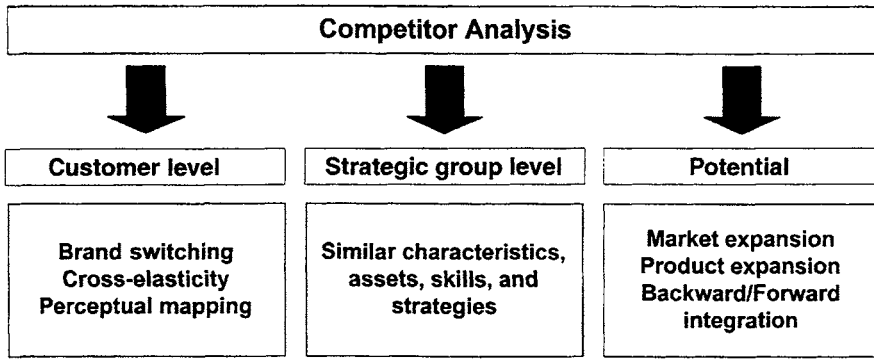
Operating under these conditions, today's marketers are forced to continuously monitor the competition, study its strengths and weaknesses, understand its driving motives, and attempt to identify its future moves. The process of studying and evaluating competitors' capabilities and motivations is collectively called *competitor analysis*, and it plays a very critical part in influencing the design of the organization's strategy. Figure 7.6 shows the three levels of competitor analysis, namely, the customer level, the strategic group level, and the potential level.

To summarize, performing competitor analysis is important because it: (1) determines a competitor's corporate strategy; (2) defines corporate R&D activity; (3) monitors competitor's product introductions; (4) analyzes the market for a product introduction; (5) provides financial information about a corporation; (6) profiles competitor's key executives; and (7) determines industry's KSFs.

Essential Steps of Analysis

Let us now focus on the steps of analysis involved in studying the competition. Figure 7.7 shows that competitor analysis is conducted in six consequent steps. The first step is identifying all current and potential competitors. Potential competitors are organizations that have not yet entered the marketplace but their continuous expansion or diversification may lead them into our competitive arena. The second step is a behavioral analysis of the identified competitors; that is, identifying how these players behave in

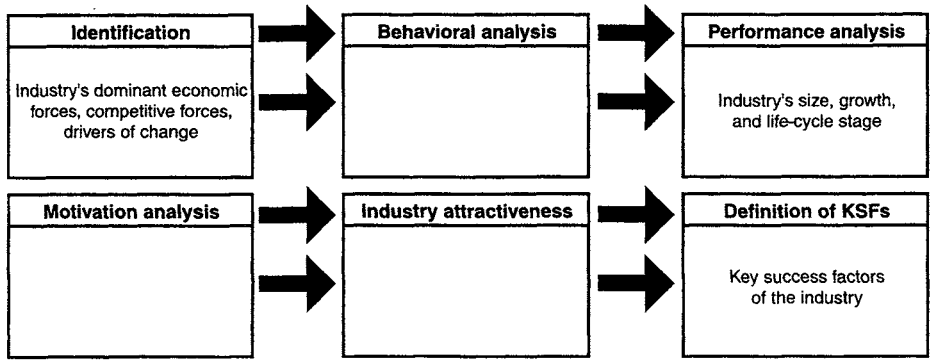
Figure 7.6. Competitor analysis levels



the marketplace, how they launch their products, how they respond to our moves, what response they have toward new government regulations, and so on. The third step is the detailed study of the competitors' performances over a prolonged historic period, which includes looking at their annual unit and value sales, their growth and market shares, their new product introductions, their pricing and promotional strategies, and so on.

The data gathered until this point are used to understand the competitors' motivation; that is, what drives their strategic intent, what are their long-term objectives and goals, or what kind of vision do they hold for their organizations. Then, based on this information, an industry attractiveness analysis is performed. This allows our company to evaluate the future potential of this market segment and to determine whether our organization can sustain its competitive advantage given the existing competitive environment. Eventually, the major characteristics of our operating market segment, its influencing factors, and, especially, the key factors required for long-term success within this sector become apparent. Therefore, the industry's KSFs are mapped and then incorporated into the organization's own strategy for long-term viability and growth.

Figure 7.7. Essential steps in competitor analysis



Competitor Identification

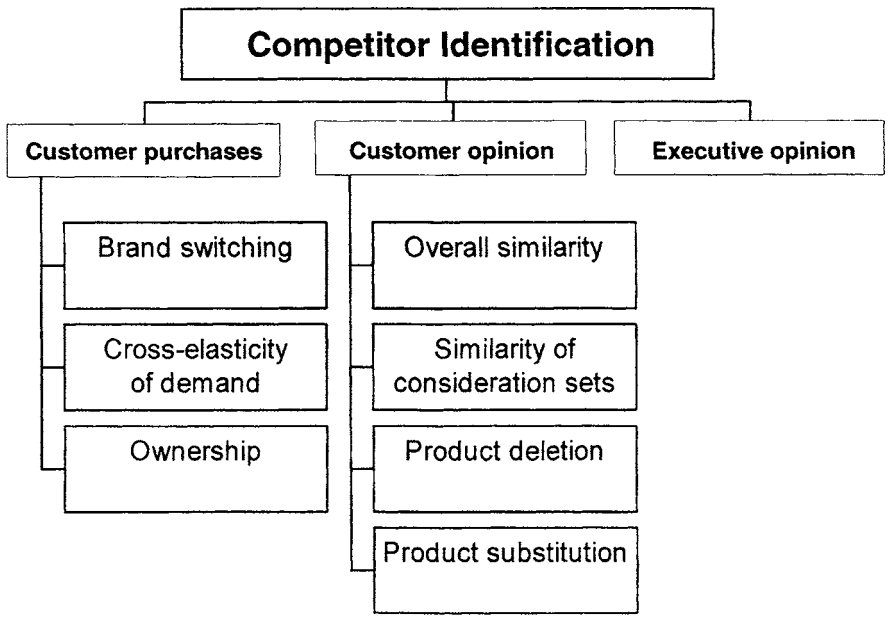
The identification of competitors includes current and potential market players. Pharmaceutical marketers looking for their competitors should be broad-minded in their searches. Obvious sources of information would, of course, be their customers (prescribers and patients), their sales and marketing colleagues (who can discuss which of their current needs are satisfied by another player), or a new competitor who has just visited their medical practice to announce an impending new product launch. Nevertheless, pharmaceutical products belonging to a certain therapeutic class may face present and future competition from products belonging to another therapeutic class, or even from nonmedicinal remedy manufacturers who have convinced a portion of disease sufferers on their product's merits. Thus, the identification and listing of all potential alternatives may provide a marketer with good leads when trying to identify his or her competitors. Examples of different therapeutic interventions are listed in Chapter 11.

In addition to identifying therapeutic alternatives as a source of competitors, a marketer can use customer purchases or customer and executive opinions as well (see Figure 7.8).

Competitor Strategic Grouping

After identifying a variety of industry competitors, a marketer evaluates these players in-depth, individually, as mentioned earlier. This analysis will often reveal great similarities among certain competitors, allowing the clustering of these players in a "*strategic group*," that is, grouping competitors who share similar resources, capabilities, and strategies, and exhibit similar market behaviors and performances. Within every industry, there are usually sectors than can be regarded as distinct groups. Companies within a strategic group

Figure 7.8. Competitor identification methods



have similar strategies and positions. Furthermore, mobility barriers inhibit a firm's movement from one strategic group to another. Examples of mobility barriers include large capital investments made at an early industry stage or the progressive specialization of human resources or manufacturing. Table 7.7 shows some of the factors that may influence the creation of a distinct strategic group within the pharmaceutical industry.

Figure 7.9 shows an example of a strategic group map, which is a tool often used in competitor identification. This two-dimensional map illustrates clusters of competitors in two distinct areas with similar characteristics.

Members of the same strategic group often behave in a concerted and predictable way to environmental changes because of their similar characteristics, motivations, and strategies. Segment analysis of strategic groups helps identify these reactions by focusing on the following parameters: (a) relative size, (b) growth rate, (c) internal rivalry, (d) KSFs, and (e) future strategic moves.

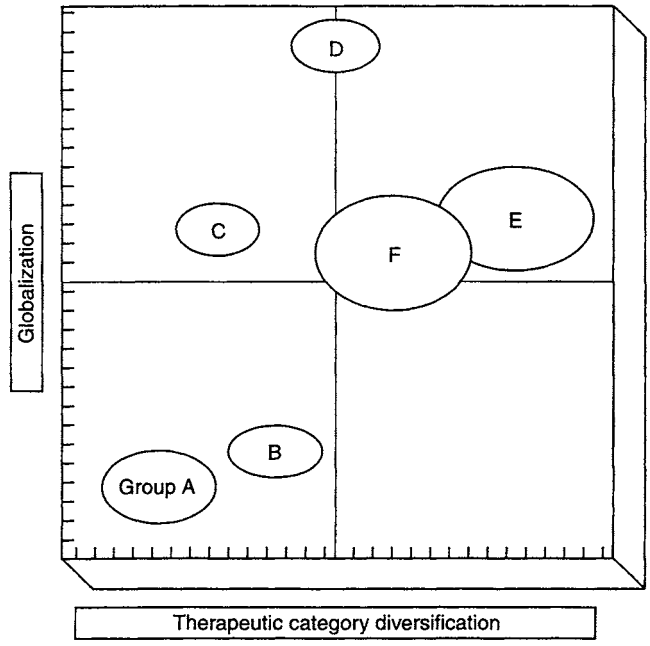
Competitor Behavioral Analysis

Behavioral analysis of competitors uses historically related data regarding their distinct behaviors and reactions in the marketplace. Some items to look for when studying a competitor's behavioral pattern include product launch pattern, moves to integrate backward and forward, responses to our moves, responses to a changing healthcare setting, responses to government changing regulations, pricing strategy changes, discounts and offers, tender bidding practices, restructuring, reorganization, sales force details during new product

Table 7.7: Factors Defining Pharmaceutical Industry's Strategic Groups

#	Factor	Parameters
1.	Therapeutic category specialization	Biotech vs. nonbiotech, category size and maturity, company leadership
2.	Innovation	Patents, NCEs submitted/approved, new product revenue, technologies
3.	Globalization	Foreign markets, subsidiaries vs. agents, local leadership
4.	Integration	R&D to market, outsourcing, backward (raw materials), forward (distribution)
5.	Branding	Number, customer recognition, competitive position, promotion
6.	Push & Pull	Prescribers only vs. DTC, promotion
7.	Channels	Multiple- vs. single-channel, full- vs. short-line, contract types, mail, Web
8.	Product quality	Batch recalls, customer complaints, customer service, company image
9.	Value-added	Dosage strength and formulation, packaging, usage instructions
10.	Costing	Integrated vs. outsourced, productivity, cost vs. quality-minded
11.	Services offered	Information, education, services, community relations, patient assistance
12.	Pricing	High vs. low, penetration vs. skimming, relationship to value, image
13.	Relationship with parent company	Subsidiary, joint venture, representative, agent, exclusive vs. nonexclusive

Figure 7.9. Strategic grouping by therapeutic category: diversification and globalization



launches, product life cycle management, legal actions against competitive threats, moves into the generics field, globalization initiatives, and public relations in times of crises.

Competitor Performance Analysis

Performance analysis follows the competitor's behavioral analysis. This is another critical step because it provides essential insights into the relationship between a competitor's behaviors and strategies and their results. This indicates necessary adjustments to our own strategies, too. A performance analysis can utilize long-term historical data about the competitor—usually the last five years in most industry analyses. Table 7.8 shows a competition analysis grid focusing on various performance indicators. Performance measurements can be expressed in absolute terms, such as annual unit sales volumes or rankings, using customer-based evaluations of arbitrary scales or weighted rankings, the last rankings weighted versus their impact on industry's performance, or utilizing visual mappings of performance measurements on two-dimensional (see Figure 7.10) or multidimensional maps.

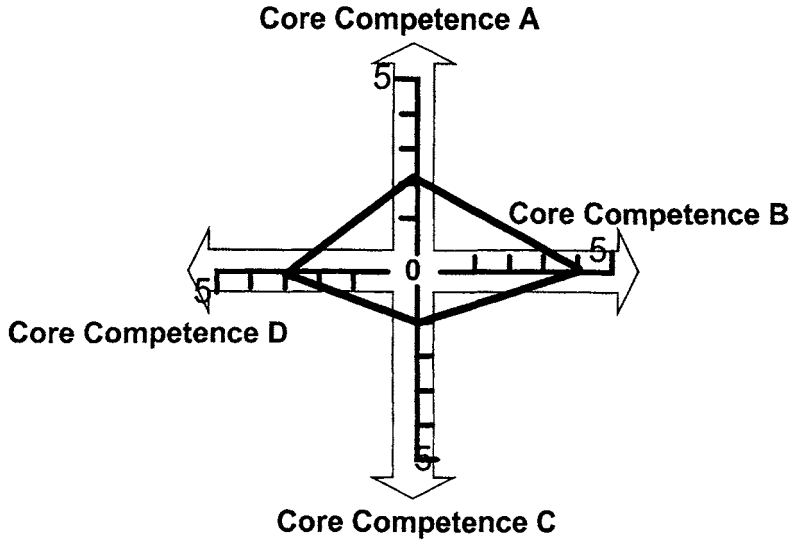
Competitive Benchmarking

The process of benchmarking uses industry-related standards of performance, or "*benchmarks,*" for measuring a company's performance level against that of other competitors, preferably that industry's leaders. The collection of extensive competitor information makes competitor benchmarking possible because it collects extensive information about competitors, allows constant monitoring of business performance,

Table 7.8: Competition Analysis Grid

Brand Name	Competitor	Sales Volume	Growth	Market Share	Profitability	Quality	Service	Customer Satisfaction	Image	Product Innovation	Service Innovation
1.											
2.											
3.											
4.											
5.											
6.	Our Firm										

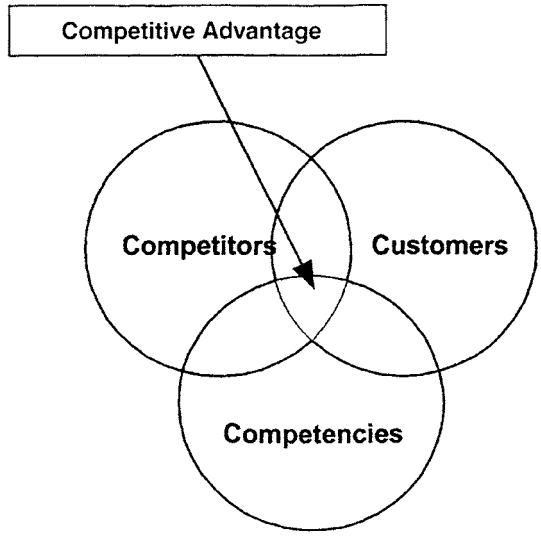
Figure 7.10. Multi-factorial competitor analysis grid



evaluates our own company compared to the top performing competitors, focuses on KSFs, and ranks competitors in relation to the KSFs.

Strategic benchmarking focuses on three elements (shown in Figure 7.11). Customers, competitors, and the industry's required competencies are thoroughly studied. The resulting standards of performance are put through rigorous tests of expert opinions, consultant inputs, and in-house specialist evaluations. The outcome is a list of commonly accepted benchmarks that can be used for comparing the company's

Figure 7.11. Competitive advantage focus



performance with its direct competitors or the industry's leaders. Furthermore, benchmarks are constantly reevaluated and adjusted as new technologies or new industry entrants continually raise the standards of excellence.

Competitor Motivation Analysis

The purpose of this part of competitor analysis is to unravel the competitors' inner motivations, objectives, goals, and intents. By looking at these parameters, a marketer can gain insights into where the industry is moving and what the prevailing marketing environment conditions will be in the future, and then adjust the company's direction as needed. Motivation analysis requires input from industry specialists—internal or external—that study the long histories of competitor behaviors and performances in search of what drove these parameters in the past. Based on this knowledge, the long-term objectives of the competitors can be ascertained, making the company's own competitive defense strategy more focused and efficacious. Table 7.9 shows a competition analysis grid that focuses on a competitor's intents and goals within different geographical boundaries.

INDUSTRY ATTRACTIVENESS ANALYSIS

Armed with the knowledge of competitor behavior, performance, and motivation, pharmaceutical marketers evaluate the industry attractiveness within the given market segment. The results of this analysis serve as useful indicators of the need for further exploiting this segment or looking within other portfolio sections for larger and more sustained opportunities. An industry attractiveness analysis is also a tool of portfolio analysis, a concept discussed in Chapter 10.

DEFINITION OF INDUSTRY'S KSFs

The results of competitor analysis help define those elements necessary for success within the given industry segment. These elements may be tangible or intangible, human or material. Whatever their nature, they are critical to the industry's success

Table 7.9: Competitor Analysis by Regional and Functional Area

Competitor:

Analyst: **Date:**

Sources of information:

Region	Strategic Intent	Competitive Position	Market Share Objective	Competitive Intensity	Competitive Strategy	KSFs	Next Moves
Local							
Regional							
National							
Economic Groups							
Geographical Groups							
Global							

within the segment, and are called *key success factors* or *KSFs*. Obviously, the ability to surpass competitors in KSFs leads to competitive advantage. KSFs commonly identified within the pharmaceutical industry include product innovation, marketing expertise, therapeutic area knowledge, sales force effectiveness, first-to-market products, enabling technologies, globalization, focus on core competencies, financial resources, product reimbursement, hospital formulary product inclusion, and information technology expertise. Table 7.10 shows a competitor analysis model applicable to the pharmaceutical industry.

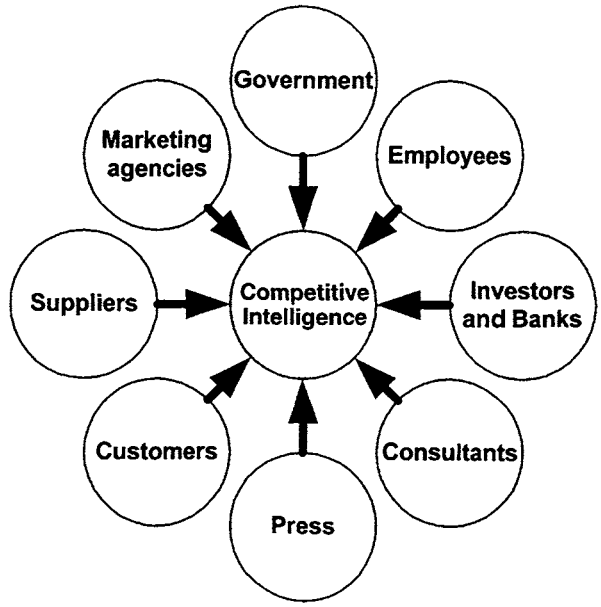
COMPETITIVE INTELLIGENCE

Competitive intelligence is related to, but not synonymous with, competitor information. Competitive intelligence is analyzed information on the competitors. It includes extensive collection, archiving and storage, and evaluation of relevant information by experts. This leads to the creation of valuable intelligence that can profoundly influence business decisions. The term "intelligence" has acquired a negative connotation, due to its extensive use in the military or spying sector and subsequent popularization by the movie industry. However, the collection and analysis of competitor information also has been one of the cornerstones of business success across every industrial sector. Therefore, the skilled practice of collecting and analyzing competitor information in all business ventures, including the pharmaceutical markets, is necessary. Sources of competitive intelligence are illustrated in Figure 7.12. Contrary to public belief, such intelligence is not all legally protected and hidden away from competitors' eyes. Instead, as Figure 7.13 shows, most of it is easily accessible and should be the focus of well organized and equipped corporate competitive intelligence-gathering departments.

Table 7.10: A Pharmaceutical Competitor Analysis Example

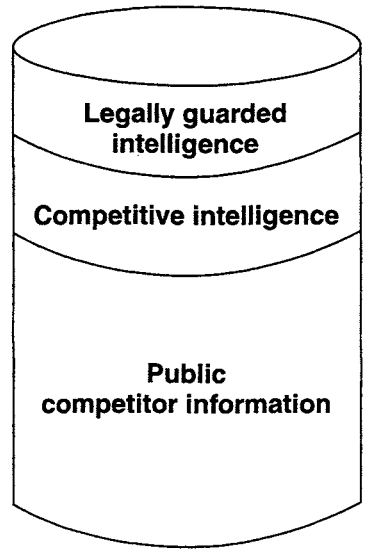
Date:				
Analyst:				
Grading:		**1 = Lowest, 5 = Average, 10 = Highest**		
Aspect:	**Parameters**	**Product A**	**Product B**	**Product C**
Customer need	Efficacy	5	7	9
	Safety	8	8	7
	Price	6	8	10
Industry competition	Sales volume	5	5	8
	Sales revenue	8	8	9
	Profit	9	6	8
	Market share	6	6	8
Product line competition	Strategy	7	7	5
	Differentiation	8	5	9
	Customer image	7	7	8
	Product Price	8	8	7
	Promotion strategy	8	6	7
	Distribution strategy	6	7	5
Organizational competition	Marketing structure	7	8	6
	Marketing strengths	8	8	9
	Sales force structure	8	7	7
	Sales force strengths	6	8	8

Figure 7.12. Competitive intelligence sources



Most experts would agree that competitive intelligence could come from far and diverse sources. These sources are not always in printed form, but may be in the public domain such as word-of-mouth information (not rumors), television news, Web sites, and so on. The gathering of such information requires specialized professional teams, comprising of competitive intelligence experts, analysts, librarians, and project leaders. These professionals should possess a number of key abilities, such as creativity,

Figure 7.13. Types of competitor information



experience, persistence, good listening and communication skills, and strategic ability, as well as good ethics.

Table 7.11 lists some competitive intelligence sources. In addition, the following list summarizes some well-known, commercially available pharmaceutical market intelligence databases.

Market Intelligence

BCC Market Research
Business & Industry
Datamonitor
EPSICOM Pharmaceutical & Medical Companies
FIND/SVP Market Research Reports
Freedonia Market Research
Frost & Sullivan Market Intelligence
Industry Express
PROMT
Trade & Industry Database
IMSWorld Drug Market-Countries
IMSWorld Pharmaceutical Company Profiles
IMSWorld Product Launches

Table 7.11: Competitive Intelligence Sources

Employees/ Investors	Promotional Activities	Customers	Trade	Public Domain	Government
Business articles	Advertising	Healthcare professionals	Banks	Antitrust litigation	Diagnosis expert committees
Books	Annual reports	Pharmacists	Commercial databases	Articles	Ethical committees
Calls for grants	Corporate material	Prescribers	Consultants	Backward engineering	Financial disclosures
Congress presentations	Manuals	Purchasing agents	Financial analysts	Books	Formulary committees
Courses taught	Promotional material		Licenses	Case studies	Government contract administration
Employee meetings	Publicity		Marketing agencies	Courses	Health department
Employee unions	Quarterly reports		Newswires	Directories	Insurance agencies
Executive interviews	Recruitment ads		Stock/bond issues	Environmental groups	Pricing authorities
Job candidates	Technical papers		Subcontractors	Grant proposals	Registration authorities
Medical literature			Suppliers	Internet	Reimbursement funds
Personnel changes			Trade association	Lawsuits	State committees
R&D scientists			Trade press	Local newspapers	
Sales force				Patents/ literature	
Shareholder meetings				Press	
Speeches				Security and Exchange Reports	
				Seminars	
				Who's Who directories	

Intellectual Property
Current Drugs Fast-Alert
IMSWorld Patents International

Regulatory
Diogenes FDA Regulatory Updates
FDC Reports
Federal Register
NDA Pipeline: New Drugs

Industry News
ADIS InPharma
ADIS PharmacoEconomics & Outcomes
Business Dateline
Drug News & Perspectives
Health News Daily
PharmaBiomed Business Journals
Marketletter Database
Pharmaceutical and Healthcare Industry News Index
Pharmaceutical News Index
Pharma Marketing Service

Research and Development
ADIS LMS Drug Alerts
R&D Insight
BIOSIS Previews
CA SEARCH: Chemical Abstracts
Derwent Drug File
Drug Registry File
Drug Data Report
Drugs of the Future
EMBASE
EMBASE Alerts
IMSWorld R&D Focus
International Pharmaceutical Abstracts
MEDLINE
Pharmaprojects

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8

Positioning, Targeting, Profiling

> In 1998, U.S. pharmaceutical companies were expected to spend more than $21 billion to discover and develop new medicines.
>
> PhRMA, 1998

In Chapter 6, we focused on market segmentation, namely, the identification of distinct market segments with similar characteristics and needs that can be selectively and separately targeted by pharmaceutical marketing campaigns. The purpose of identifying these segments and selecting some of them to target is twofold. First, any pharmaceutical company, however global and successful, cannot effectively target all identifiable market segments across all therapeutic areas and national markets because such a mass marketing approach would require massive resources not available anywhere within the industry. Second, in a utopian situation where such resources were available, it would be a huge waste of financial and human assets to pursue segments with low profitability. Instead, the focus should be on those segments of company expertise that would give it a sustainable competitive advantage and, therefore, a sales revenue and market share growth.

This chapter, then, focuses on the ways and means of selecting optimal targets and implementing a product strategy geared to produce a sustainable competitive advantage.

THE ESSENCE OF PHARMACEUTICAL PRODUCT STRATEGY

The process of selecting optimal market segments and finding the ideal way to "package" product benefits toward this segment is central to any pharmaceutical product strategy in any market. Thus, the strategic step of market segmentation is followed by three successive other steps, namely, targeting, positioning, and profiling. *Targeting* is defined as choosing the specific individuals to win over. *Positioning* is choosing the therapeutic segments in which to compete with a specific product. *Profiling* is choosing the promotional statements to compete for the target audience in the segments we have chosen. In other words, targeting refers to target customers, positioning refers to patients, indications, or situations, and profiling refers to promotional messages. Most marketing scholars agree that targeting, positioning, and profiling do not have priority over the other steps. However, the segmentation, targeting, and positioning (STP) model (see Figure 8.1) is a useful marketing mnemonic. It is the approach used in this book

TARGETING

Targeting is the process of selecting specific market segments on which to concentrate the marketing effort. This follows studying their needs and tailoring the product toward them. It is about establishing priorities among the different market segments. How then can an industry marketer decide on the optimal target selection? Four aspects present in every market segment need to be analyzed: the market, the customer, the competition, and the company itself (see Figure 8.2). In other words, does the company want to pursue this segment (the company's mission)? Does the company have the resources and capabilities to create a sustainable competitive advantage within this segment (the elements of internal analysis: resources, SWOT, and performance)? What about the segment itself (segment analysis)? Is it large and growing, with significant potential and in an early life cycle stage? Is it attractive? Who are the customers anyway (customer behavior analysis)? What are their characteristics needs, wants, attitudes, and beliefs? What do they think about our company? What about the segment competitors, existing and future (competitor analysis)? What are their capabilities, behaviors, performances, and motivations? How do we compare?

Following the analysis of these four critical aspects, a segment attractiveness study is performed. Different market segments are compared to each other, as shown in Figure 8.3. Targeting should then focus on segments of high importance and high chances of company success.

Figure 8.1. The STP model

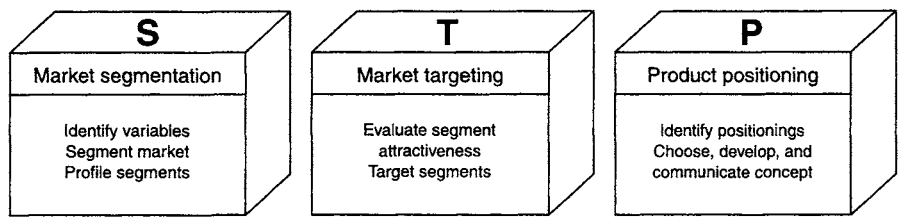
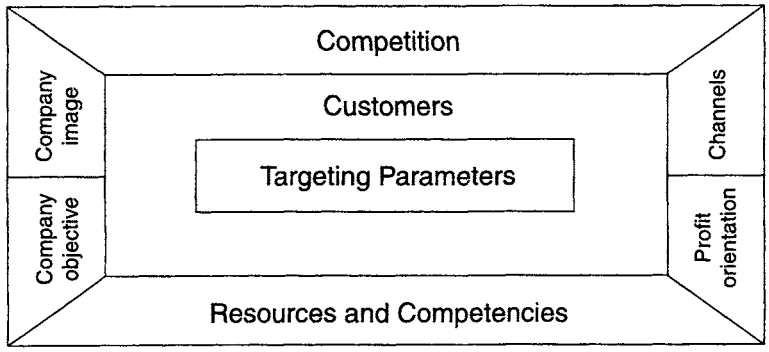


Figure 8.2. Targeting parameters



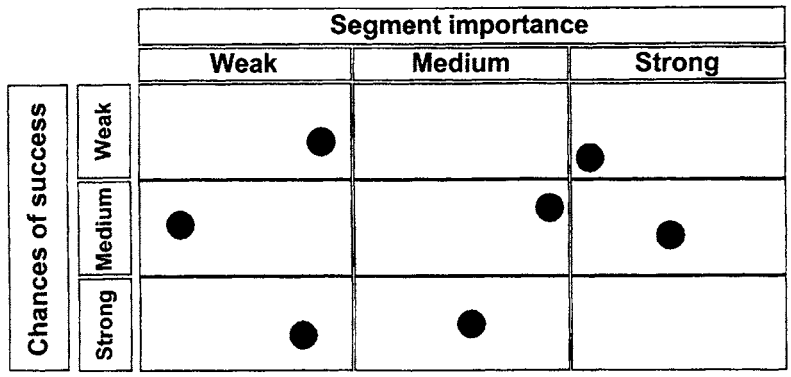
The analyzed segments may be ranked according to superiority, equivalence, or inferiority—referring to a company's standing against the competition. Obviously, attention should only be focused on the first two. Segments of inferiority should be avoided because they do not present the required conditions for a sustainable competitive advantage.

POSITIONING

When introducing a new pharmaceutical product to the world, marketers have to present the product to customers across the whole healthcare spectrum, in market segments where they believe this product holds the highest competitive advantage or is able to best satisfy customer needs. It is necessary to evaluate both their product characteristics and the competitor's, as well as select the product attributes (positioning) that matter to the customers.

Some definitions of positioning are: the act of designing the company's offer so that it occupies a distinct and valued place in the target customer's mind (Kotler, 1980); the process of adjusting and presenting a product in a way so that it is the most attractive

Figure 8.3. Segment importance and chances of success portfolio model



option for the customer; making a product stand out from competition in the mind of the consumer; the sum of mental connections between the consumer and the (a) attributes and features, (b) feelings and emotions, (c) price and value, (d) problems products can solve, (e) use or application, and (f) competition promised with the offering.

Product positioning is obviously based on the inherent, core product attributes, as well the augmented attributes that the company has decided to package with the product. Furthermore, product positioning is influenced by the official approval of the relevant local regulatory authorities. In most cases, however, the approved product indication allows use of the product by various medical specialties or by patients suffering from a variety of similar pathological states.

Before we describe the process of defining a new product positioning, let us first examine the critical importance of this decision. A company with a fresh EMEA marketing authorization of a new antihistamine preparation is considering its European Union launch plan, including candidate launch countries, formulations to be introduced, and medical specialties to be targeted, as well as their respective promotional budgets. In walking around this marketing maze, the European headquarters team is focusing on the following questions:

- Which pathological states is this product licensed to treat, and what is their market size?
- Which medical specialty is involved in treating these states, and with what percentage?
- How many physicians are in each of these medical specialties?
- Does the company have the know-how in the respective therapeutic categories (prescribers, patients, competitors, markets)?
- Does the company have a wider product portfolio to offer these specialties?
- What are the unique product advantages for each disease?
- What products are the competition offering in these therapeutic categories?
- In which disease state will our product will have the highest competitive advantage?
- What amount of resources will be required in order to pursue this market segment?

Following the in-depth evaluation of all of these questions, the company's marketers find out that their product will best be suited in the treatment of common allergies, which are more prevalent in certain countries than others. In these high-priority national markets, the primary medical specialists are GPs, and not the respiratory specialists. Physician numbers are gathered by contacting national medical associations, while an estimation of the required sales force sizes is also made. Later, a marketing research agency is contracted to approach selected target physicians and opinion leaders to ask them for their own, as well as their patients', needs. The product characteristics are then matched to these customer needs, and three out of the nine potential product's unique selling points are chosen as the most relevant. A comparison to the competitive products reveals that the product will indeed be able to keep its competitive advantage. A final decision is made to promote the new antihistamine among the selected medical specialty in some national markets with few of the available formulations, and at a competitive price range. In conclusion, the product is *positioned* in the selected market segments that offer the highest sales potential and opportunities to keep its competitive advantage. Product positioning, then, is defining promotional

avenues and budgets, which eventually result in the new product commanding a 30 percent market share in its first year.

What a good product positioning tries to achieve is twofold (see Figure 8.4). On the one hand, it mixes and matches the core and augmented product features to find the ideal combination that both satisfies the customer needs and is difficult for the competition to imitate. This leads to the creation of a unique selling proposition. On the other hand, this combination of product features must fit seamlessly with the company's overall strategy, that is, the company must have the knowledge, product portfolio, and resources guaranteeing success in this segment. Table 8.1 shows some typical examples of pharmaceutical positioning statements.

In order to define the exact positioning of a pharmaceutical product, a series of actions have to be implemented by a pharmaceutical marketer (see Table 8.2). The process starts with identifying all potential competitive products and comparing their features to the expressed needs of prescribers and patients. The process ends with determining the position where, due to product features, it would have the highest competitive advantage (see Figure 8.5).

The final outcome of the positioning finding process can be widely varied and sometimes distanced from the positionings chosen by fellow colleagues for the same product, in another regional or therapeutic area. This is due to the dynamic differences among different geographic pharmaceutical markets, educational differences between physicians working in these locations, diverse regulatory environments across national borders, or differences in patients' and families' perceptions toward a disease or its treatment. For instance, psychosis may be a societal taboo in some countries, as Alzheimer's disease may be in others. Such taboos may inhibit sufferers from visiting a specialized psychiatrist or neurologist, and suggest that a marketer may have to position them for both specialists and GPs alike, with completely different messages or approaches.

The following list shows a wide variety of potential pharmaceutical positioning approaches that can be used across therapeutic categories or national markets.

Antidote	Because there is a specific antidote available in case of overdose.
Application	Because our product is the only one indicated for this symptom.
Attribute	Because our product has the fastest onset of action.
Benefit	Because it is the most efficacious medication for the disease.
Company ethics	Because we focus on improving the quality of life of our patients.
Competition	Because we are the uncontested market share leaders.

Figure 8.4. The two goals of product positioning

Table 8.1: Pharmaceutical Positioning Statements

Market Segment	Brand	Frame of Reference	Differentiation	Competitive Edge
Of all analgesics,	Product X	is the only long-lasting product	that offers fast relief and tolerability	due to its targeted effect on brain ABC receptors.
In hormone replacement,	Product Z	is the standard of a new era	because it covers all your body's needs	by acting on central and peripheral E2 receptors.
In Parkinson's treatment	Product W	is the best choice	because it offers long relief with no side-effects	due to its innovative drug combination.
Among selective-serotonin reuptake inhibitors (SSRIs)	Product Y	is the most tolerable	because it offers superior efficacy and no side-effects	due to its selective 5-HT receptor actions.

Competitor (generic positioning)	Because it is just like another product you respect.
Compliance	Because the treatment allows the highest possible patient compliance.
Dependence	Because our product causes the least possible dependence.
Disease management (DM)	Because we are the only ones involved in DM treatment guidelines for the disease.

Figure 8.5. The two-dimensional product positioning map

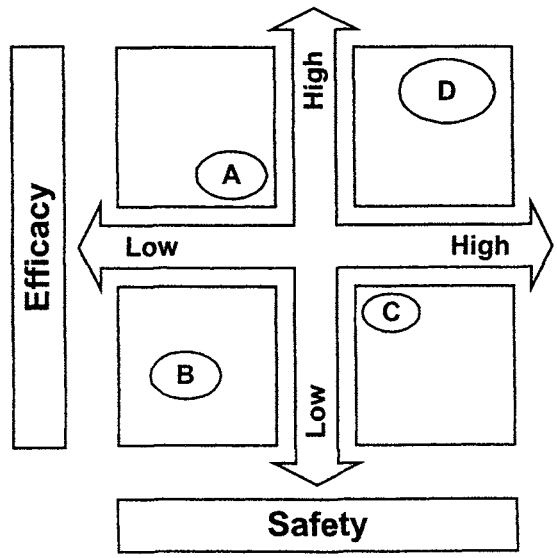


Table 8.2: Determining the Proper Positioning

1.	Identify competitive products	Product category and brand
2.	Identify determinant attributes	Features, Benefits, Applications, Surrogates, Salient
3.	Measure existing perceptions	Unaided recall, aided recall, spontaneity of brand recall, mental associations (brand and product class, brand and specific attributes)
4.	Analyze relative position of alternatives	Identify prescription, nonprescription, and nonpharmacological alternatives; use product-positioning maps; look for gaps
5.	Determine preferred set of attributes	Rank all attributes according to their customer preference; survey prescribers, patients, families, nurses, pharmacists, administrators
6.	Define positioning	Competitive strengths of different brands and intensity of rivalry
7.	Devise repositioning	Purchase intent share, growth of segments, evolution of ideal points, competitor positioning intensity and strategy, change in brand positions, emerging attributes, new brands, new segments

Dosage	Because our product is formulated for a wide dosage range.
Endorsement	Because clinicians or medical societies endorse it.
Experience	Because of our long company history.
Expiry	Because our lyophilized product can last up to three years.
Formulation	Because our product comes in a patient-friendly, easy to use formulation.
Indication	Because our's is the only product approved in this indication.
Innovation	Because we are introducing an NCE every three years.
Interactions	Because we have shown the lowest drug interaction rate in the therapeutic class.
Manufacturer	Because of who makes it.
No match	Because the product is the best; it has no equal.
Pharmacodynamics	Because the product has shown the best pharmacodynamics profile.
Pharmacokinetics	Because the product offers the optimal pharmacokinetics.
Price	Because our product is the most competitively priced.
Product class	Because our new generation product sets a new standard of treatment.
Quality	Because our device is the best in the world.

Rank	Because it is the best-selling product.
Reimbursement	Because our product is the only reimbursed therapeutic option.
Safety	Because this therapy offers unsurpassed safety.
Service	Because we offer the best educational service to physicians.
Specialization	Because we are the only exclusive therapeutic category specialists.
Storage	Because our product does not require refrigeration (stored at room temperature).
Target	Because the product was created especially for patients like you.
Technology	Because of how the product was made (biotech, genomics, and so on).
Tolerability	Because our's is the best tolerated treatment.
User	Because we only specialize in your specialty area.
Value	Because we offer the best value for your hospital costs.
Variety	Because we offer the widest variety of dosage strengths and formulations.

Occasionally the chosen positioning approach is suboptimal and the resulting product sales are disappointing. A closer look reveals that one of the following positioning errors has occurred: (a) positioning in a crowded segment, (b) positioning on an unimportant attribute, or (c) inflexible positioning. In this case, a careful repositioning is necessary. By going back to the positioning steps mentioned earlier, selecting a new approach, and reevaluating it under the constantly changing marketplace conditions, a company may avoid expensive and potentially irreversible positioning errors. *Strategic leverage* is defined as a company's ability to change its

Figure 8.6. Brand components and informational content

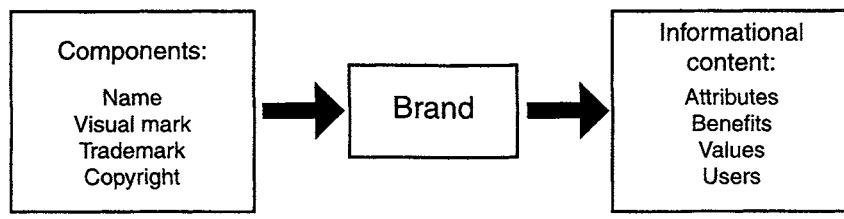
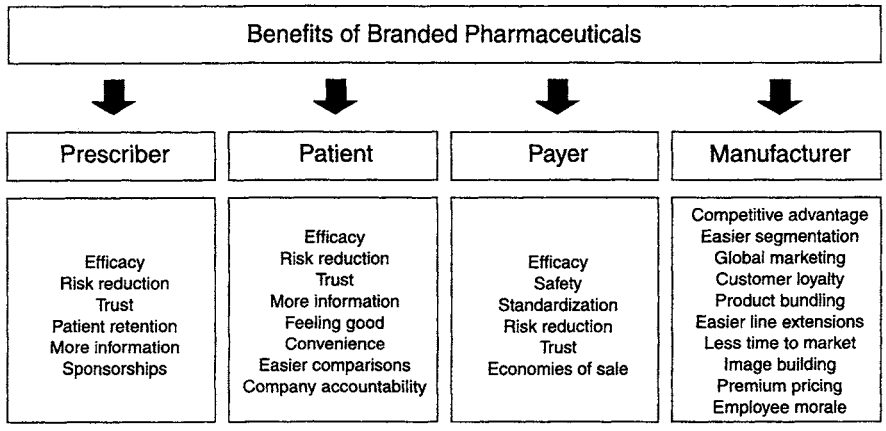


Figure 8.7. Benefits of branded pharmaceuticals



competitive positions multiplied by the resultant returns (revenues, market share, and so on).

The analysis of all competitive product attributes and the perceptions in the minds of prescribers, pharmacists, or patients may yield the conclusion that the market segment under review is a highly competitive one. In this case, establishing and defending our own product's competitive advantage would be extremely difficult. In addition, the market may be characterized by mostly mature products, all of which hold a relatively small market share (fragmented market). This situation, which has frequently confronted pharmaceutical marketers, has led to the creation of branding strategies, most often seen in consumer markets, in an effort to add a unique product personality, boost its competitive advantage, and prolong its life cycle.

BRANDING

A *brand* is defined as any name, term, sign, symbol, or design, or a combination, intended to identify goods or services of one seller and to differentiate them from those of the competition (Kotler, 1980). As Figure 8.6 shows, a brand is characterized by a unique name, visual mark, trademark, and copyright that are combined to confer a distinguished appearance and personality to a product. Furthermore, through a consistent, painstaking, and expensive branding effort, the brand is made to "contain" a distinct informational

Figure 8.8. Alternative manufacturer branding policies

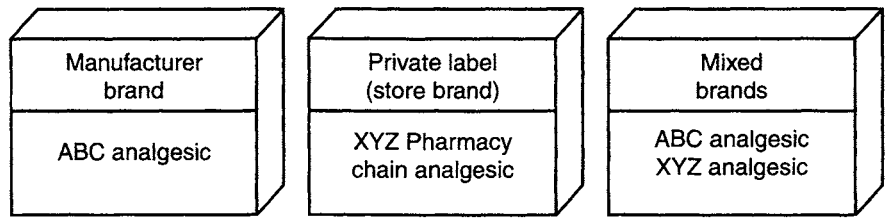


Table 8.3: Attributes of Branding

Goals	Advantages	Disadvantages
Association	Leveraging (extendable to new products)	Appeals to existing users
A signal of quality	Stickiness (makes comprehension easier)	Cannibalization among brands
A basis for differentiation	Facilitates trade support	Meaningless if too broad
A frame for customer experience		May not be relevant to changing needs

content that clearly identifies the product attributes, benefits, values, and users. For instance, a specific whiskey brand may constantly remind its customers of the spirit's unique taste, its ability to reduce stress and provide an easygoing party atmosphere, its exquisite "luxury" image, and young, healthy men and women enjoying life to the fullest. The competitive strength of a brand is measured by its *brand equity*, a term that refers to awareness, acceptability, loyalty, preference, price premium, and unit volume.

Most experts would agree that branding is key to the consumer goods' positioning. But is it equally applicable to pharmaceutical products? And can it really provide added value to the consumer? The answer to these questions can be found in Figure 8.7. A pharmaceutical branding policy can have direct benefits to the prescriber, patient, payer, and manufacturer of the product. It should be pursued after carefully weighing the advantages and disadvantages if market characteristics and manufacturer's resources allow.

Table 8.3 lists some important branding goals, advantages, and disadvantages. They should be evaluated on a per product basis, and careful decisions need to be made because branding strategies are both expensive and difficult to reverse.

Cannibalization refers to sales loss of an existing product resulting from the introduction of a new item in a product line or brand family. Furthermore, Figures 8.8 and 8.9 show the alternative manufacturer branding policies (manufacturer's own, private label, or mixed), and the alternative family branding policies (individual or blanket family), respectively.

PROFILING

Profiling is the selection of positive promotional statements (features and benefits), as well as negative statements (adverse events, overdosage, contraindications, and drug

Figure 8.9. Alternative family branding policies

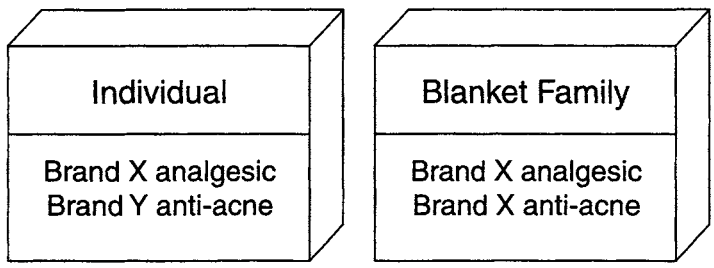


Table 8.4: The Pharmaceutical Positioning, Targeting, and Profiling Statements

Parameter	Targeting	Positioning	Profiling
Efficacy	Oncology specialists	First choice therapy for metastatic breast cancer	Most efficacious in prolonging survival
Safety	Gerontologists	For elderly insomnia sufferers	Safest choice for patients under multiple prescriptions
Tolerability	Pediatricians	Children under injectable antibiotic treatment	No irritation and pain for your young patients
Formulation	Gastroenterologists	Antipyretic for patients with stomach side effects	Problem-free fever reduction
Onset of action	Anesthesiologists	For sleep induction, in anesthetic drug cocktails	Highest versatility in all your operating room procedures
Price	General pathologists	Basic nutritional content, for ambulatory patients only	A nutritional supplement for all your hospital outpatients

interactions) that are used in support of the chosen targeting and positioning strategies. The process of profiling starts with studying the extensive product information available through its R&D phases. The results of the studies are gradually evaluated to determine the chosen market segments and the required product positioning. Only the required product attributes and benefits are presented to the consumer. A word of caution: profiling is not overboosting a product's attributes or lying. To the contrary, it is the selection of the regulatory approved product characteristics that will be *preferentially and repeatedly* communicated to the consumers (prescribers and patients). Examples of pharmaceutical targeting, positioning, and profiling statements are provided in Table 8.4.

FURTHER READING

Court, D. C., M. G. Leiter, and M. A. Loch. 1999. Brand leverage. *The McKinsey Quarterly* 2: 100–110.

9

New Product Development

> According to statistics, in 1995, the Canadian pharmaceutical industry had a return on capital of 13.6 percent—placing it tenth, far behind such industries as construction, wood products, and transportation equipment.
>
> Pharmaceutical Manufacturers Association of Canada (PMAC), 1998

The continuous innovation of new products has been, is, and will continue to be the cornerstone of pharmaceutical industry's success and long-term viability. Indeed, despite the recent industry moves toward cost-containment, globalization, integration, or merging, original product innovation continues to be the main element of the industry's profitability. Various experts have expressed the opinion that a new pharmaceutical product helps to add shareholder value; boost the workforce morale; capitalize on distribution strengths; contribute to regional competitiveness and prosperity, defend market share; expand and create new markets; exploit technology in new ways; increase sales and profits of the existing product portfolio; increase the company's integration; maintain an innovator's image; maintain and increase sales and profits; gain a competitive advantage for the company; open customer's doors; renew investor's interest; renew the company's vitality; replace other mature, less efficacious or safe products; take the company into new therapeutic fields; and use excess capacity.

This chapter is devoted to the detailed analysis of the new drug development process, the different drug discovery methods, and the role of innovation, as well as existing R&D strategies and R&D benchmarking.

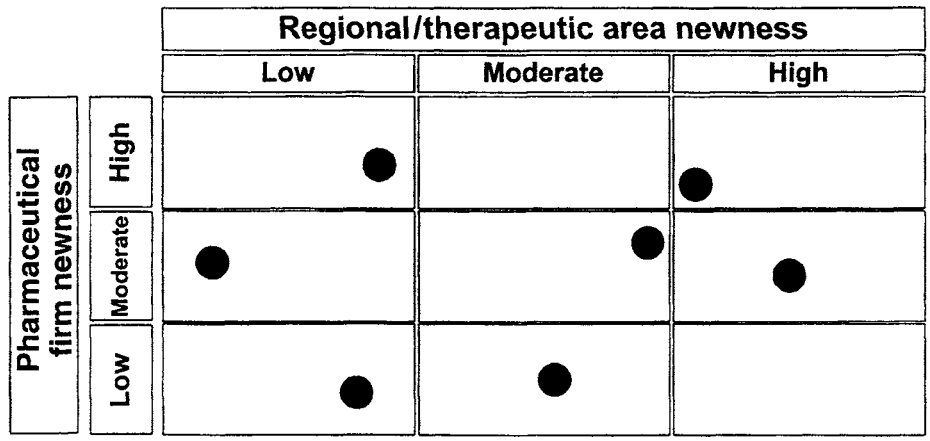
WHAT IS A NEW PRODUCT?

Before studying the core drug development processes, this chapter compares the proposed classification schemes for either consumer or pharmaceutical products. New consumer products have been classified as follows: new to the world (introduction of the VCR, fax machine, or DVD devices), new to the country, new to the firm, new category entry (sliced bread), product line addition (new ice cream flavor), product improvement (lighter and faster), cost reduction, or repositioning. They can also be classified as core/base (dishwasher, chocolate), breakthrough (fax machine), and platform (computer chips). Other marketing scholars have categorized new products according to the degree of innovation. Thus, the innovation scale ranges from the breakthrough products (or new to the world), to the pioneering (thinner, most portable computer ever made), to the adaptive (a two-in-one hair shampoo combination), and finally to the imitative (or, as commonly called in the industry, another "me-too" product). A product's newness for its company or launch market can be plotted in a two-dimensional model, as shown in Figure 9.1. The pharmaceutical industry's Holy Grail is always a new to the company/new to the market segment molecular (or chemical) entity, abbreviated as NME or NCE, and often used as the most prominent indicator of a company's drive for innovation.

FDA New Pharmaceutical Product Classification

Now look at industry-specific new pharmaceutical product classification, namely, the FDA rating and classification system for new drugs. FDA classifies investigational new drug applications (INDs) and new drug applications (NDAs) and assigns review priority on the basis of the drug's chemical type and potential benefit:

Figure 9.1. Firm versus market product newness



Chemical type

A new molecular entity or NME is an active ingredient that has never been marketed in this country. **A new derivative** is a chemical derived from an active ingredient already marketed (a "parent" drug). **A new formulation** is a new dosage form or new formulation of an active ingredient already on the market. **A new combination** is a drug that contains two or more compounds, the combination of which has not been marketed together in a product. **An already marketed drug product, but a new manufacturer** is a product that duplicates another firm's already marketed drug product with the same active ingredient, formulation, or combination. **An already marketed drug product, but a new use** is a new use for a drug product already marketed by a different firm.

Treatment potential

Priority review drug (P) is a drug that appears to have therapeutic qualities that surpass available therapy, and **Standard review drug (S)** is a drug that appears to have therapeutic qualities similar to those of an already marketed drug. Other designations that may apply simultaneously include: **SE1,** a new indication, or significant modification of existing indication, including removal of a major use limitation, such as second line status; **SE2,** a new dosage regimen, including an increase or decrease in daily dosage or a change in frequency of administration; **SE3,** a new route of administration; **SE4,** a comparative efficacy claim naming another drug, including a comparative pharmacokinetic claim; **SE5,** a change in regulatory approval application sections other than the Indications and Usage section that would significantly alter the patient population to be treated, such as addition of pediatric use and/or dosing information or geriatric use and/or dosing information; **SE6,** an Rx-to-OTC switch; **AIDS drug,** a drug indicated for treating AIDS or other HIV-related disease; **Subpart E drug (E),** a drug developed or evaluated under special procedures for drugs to treat life-threatening or severely debilitating illnesses (the name refers to Title 21 of the Code of Federal Regulations, Part 312, Subpart E, which governs this classification); and **Designated orphan drug (V),** a drug for which the sponsor received orphan designation under the Orphan Drug Act (such a sponsor is eligible for tax credits and exclusive marketing rights for the drug).

Type classification

A is an important therapeutic gain. **B** is a modest therapeutic gain. **C** is little or no therapeutic gain. **M** is a drug already marketed in a foreign country. **R** is a drug that is subject to specific, unique conditions of approval. **T** is an important problem in toxicity. **U** is a drug likely to be used in children. **D** is a special situation. **P** indicates that a very important feature of application is the packaging. **S** indicates that application is sensitive due to wide-publicity, congressional interest, unusual request from firm, and so on.

PHARMACEUTICAL R&D STATISTICS

R&D investment levels by the global pharmaceutical industry indicate the importance of new product innovation. According to a global survey conducted by the UK-based

Committee on Medicines Research (CMR) of pharmaceutical industry associations from thirteen countries, pharmaceutical R&D expenditure (excluding capital) was estimated to have reached 32.5 billion U.S. dollars in 1995. In comparison, the total amount of pharmaceutical sales in the respective markets during 1995 was estimated at 174.4 billion U.S. dollars, making R&D account for 18.6 percent of that year's total sales revenues.

The pharmaceutical R&D data presented in Table 9.1 and Figure 9.2 have been provided by PhRMA and EFPIA.

DRUG DISCOVERY METHODS

The main new drug development strategies are shown in Figure 9.3. These include the following.

Lead discovery and optimization: Naturally extracted or chemically synthesized substances are tested in experimental models (in vitro, ex-in vivo, and in vivo).

Structure modification of existing drugs: Chemical analogues of existing drugs are synthesized in the laboratory and tested for absorption, elimination, efficacy, safety, and interactions.

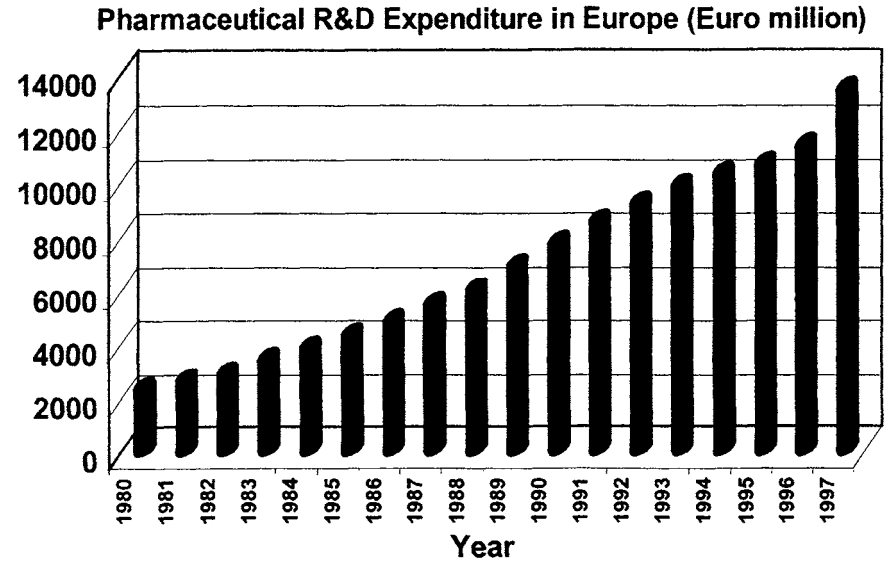
Table 9.1: U.S. Research-Based Ethical Pharmaceutical Companies Sales, Exports, and R&D, 1980–1999

Year	Company-financed Domestic U.S. R&D (U.S. Millions)	Domestic U.S. Sales (U.S. Millions)	U.S. Exports (U.S. Millions)	R&D as a Percent of Sales and Exports
1999	$20,111.8	$91,823.3	$4,880.2	20.8%
1998	17,222.5	81,289.2	4,462.0	20.1%
1997	15,422.0	71,761.9	4,025.9	20.3%
1996	13,576.4	64,741.4	3,794.4	19.8%
1995	11,833.9	57,145.5	3,993.3	19.4%
1994	11,100.8	50,740.4	3,606.1	20.4%
1993	10,473.0	48,590.9	3,982.7	19.9%
1992	9,309.1	48,095.5	4,042.7	17.9%
1991	7,923.6	44,304.5	3,523.5	16.6%
1990	6,800.1	38,486.7	3,420.6	16.2%
1989	6,019.3	32,706.6	3,145.8	16.8%
1988	5,228.7	28,582.6	2,696.2	16.7%
1987	4,503.2	25,879.1	2,013.3	16.1%
1986	3,870.9	23,658.8	2,044.2	15.1%
1985	3,307.7	20,742.5	1,556.9	15.1%
1984	2,976.4	19,026.1	1,340.8	14.6%
1983	2,663.1	16,805.0	1,335.7	14.7%
1982	2,265.6	14,743.9	1,446.3	14.0%
1981	1,866.2	12,665.0	1,393.8	13.3%
1980	1,544.1	11,788.6	1,219.3	11.9%

Notes: Ratio calculation includes R&D: Intramural and extramural company-financed domestic U.S. R&D expenditures for human-use and veterinary-use pharmaceuticals divided by sales. Reporting basis in net domestic U.S. sales plus U.S. exports (includes exports to other firms as well as intrafirm exports).

(PhRMA, 1999. Reprinted with permission from Pharmaceutical Research and Manufacturers of America)

Figure 9.2. Pharmaceutical R&D expenditure in Europe, 1980–1997



(EFPIA, 1999. Reprinted with permission from EFPIA)

Rational drug design: Uses computer-aided molecular modeling to design new entities that will bind a known receptor ligand like a "lock and a key."

Combinatorial chemistry: Uses automated sequencers to synthesize thousands of new molecular combinations and then screens them in test systems.

Virtual drug design: Based on medicinal chemistry/biochemistry knowledge, hypothetical molecules are computer-designed and tested on virtual models for binding affinity and reversibility, chemical interaction, and the potential to influence intracellular processes.

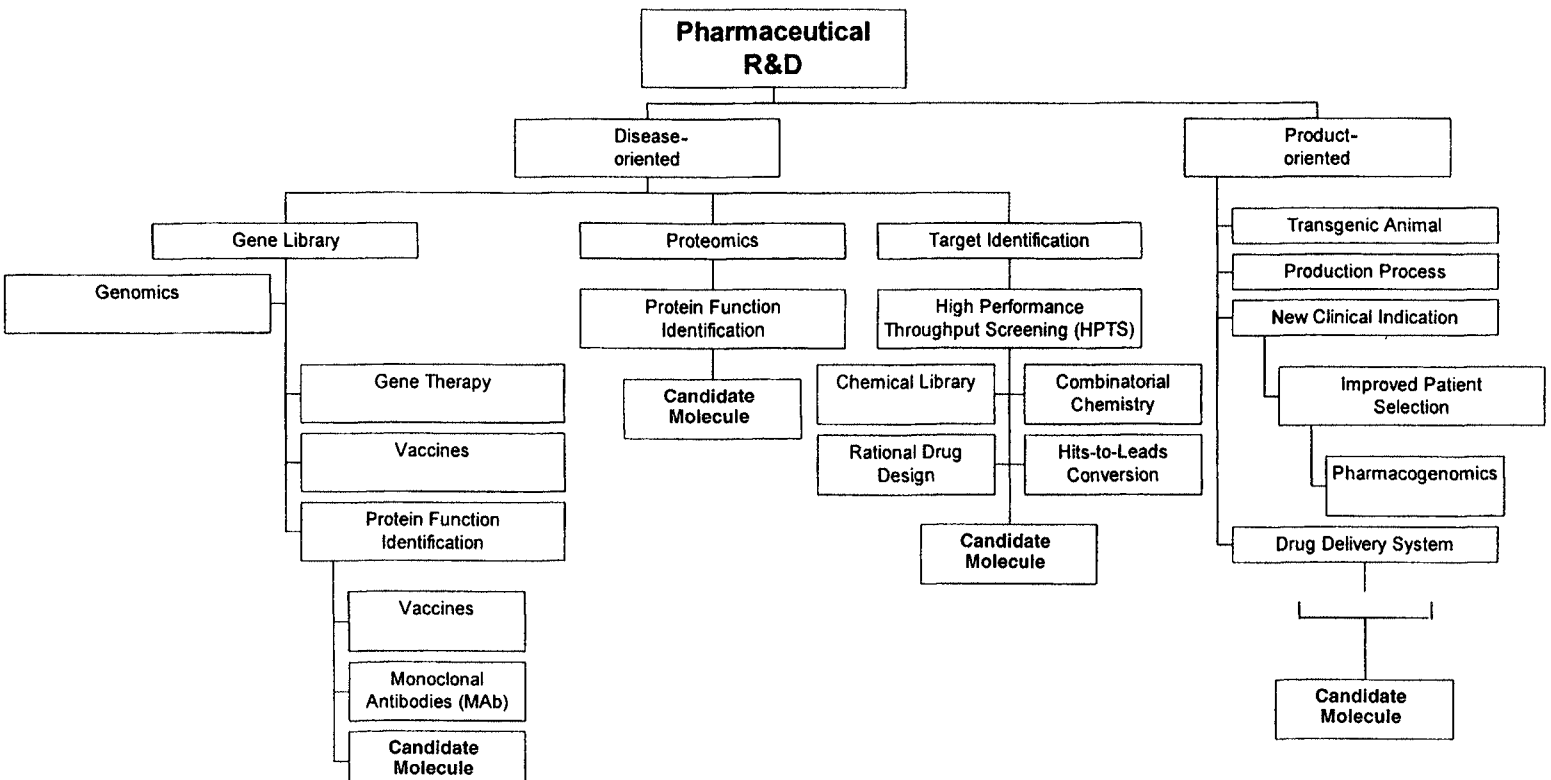
Pharmaceutical R&D approaches can be directed toward the disease or a pharmaceutical product. Figure 9.3 shows the classification of drug discovery methods according to a disease or product focus.

THE ROLE OF INNOVATION

Most experts would agree that in order for pharmaceutical R&D to continue to be innovative and effective, five key elements must be fostered and strengthened. These essential elements for success are a robust R&D strategy, improved processes, the availability of enabling technologies, the presence of the proper organizational culture, and effective knowledge management.

Of these critical R&D success factors, *innovation* plays a very significant role. Innovation is defined as the sum of invention and exploitation. Experts have repeatedly observed that global industry leaders have consistently outperformed their competition in product innovation and shorter times to market. However, the global

Figure 9.3. Disease- and product-oriented approaches of pharmaceutical R&D



pharmaceutical industry has recently been experiencing a worldwide political and regulatory climate change. Certain industry players would also argue that the initiating factors to such a change were long-standing criticisms against the industry that came from various sources. For instance, the pharmaceutical industry has been criticized for excessively high profit margins, mediocre innovation relative to other industrial sectors (such as information technology), or failing to introduce truly innovative new pharmaceutical products.

The combined long-standing effect of such accusations, coupled with the increasing global political forces aimed toward increasing national competitiveness and productivity and decreasing expenses, has directly, or indirectly, forced the pharmaceutical industry to take an adaptive role. In response, the industry attempted to focus on revolutionary NCEs, prove their cost-to-benefit ratios through the use of pharmacoeconomics, and simultaneously defend against the rising problems of generic substitution, parallel exports, and cost-minded reimbursement environments. However, these political and market forces have decreased the rate of introduction of NCEs, as evidenced by comparing global R&D expenditures to new regulatory approvals. The phenomenon already has been labeled as a shortage of innovation, which has strained the financial stability of former industry giants who have turned to mergers and acquisitions as a profit-protecting and financially stabilizing force. Simultaneously, R&D departments of worldwide industry players are being structurally reorganized, new enabling technologies are being introduced, and previous paradigms are being shattered in the constant pursuit of R&D innovation. Some of the most important factors that most industry analysts consider necessary for innovation in pharmaceutical R&D are listed in Table 9.2.

THE NEW DRUG DEVELOPMENT PROCESS

The new drug development process is an arduous, time- and resource-intensive procedure that takes several years from initial drug discovery to product commercialization. The process is summarized in Figure 9.4. In general, the identification of unmet therapeutic needs leads to new drug design, a long clinical trial and marketing concept testing phase, a regulatory approval phase, and eventually the product launch and its life cycle management.

Ideally, a successful new product development procedure is focused on three factors: achievement of internal R&D standards, the satisfaction of external regulatory standards, and customer satisfaction from a product designed to satisfy their needs and wants. Table 9.3 summarizes the main characteristics of a new pharmaceutical product development, namely, idea generation, idea screening, business analysis, development, and commercialization. Each of these phases are presented in detail.

Idea Generation

The idea generation process for new pharmaceutical products is based on the identification of unmet therapeutic needs. This is based on the availability of large amounts of epidemiological and therapeutic area market data, currently commercially available online or through CD-based databases, as well as from primary customer data collected through syndicated market research or by sales, marketing, and medical affairs

Table 9.2: Factors Important for Pharmaceutical Innovation

Internal	
Strategy	Portfolio assessment and management, outsourcing.
Market share leadership	Learning curve and economies of scale.
Financial resources	Large R&D investments.
Organizational resources	Human capital, strive for innovation, creativity-fostering, R&D organization, marketing input.
Life cycle	Product decline or patent expiration necessitate a continuous innovation focus.
Discovery processes	Pharmacogenomics and virtual testing offer significant possibilities.
Enabling technologies	High throughput screening, combinatorial chemistry, compound libraries, assay development, pharmacogenomics, robotics.
Information technologies	Knowledge management, competitive intelligence gathering, IT strategy, IT specialists, IT architecture, Web technologies.
Globalization	Access to new markets and opportunities fosters innovation.
External	
Alliances	With academia, biotech, other pharmaceutical companies.
Competitive pressure	Innovation is the most promising among all offensive competitive strategies.
Government regulation/deregulation	Tightening government regulation or regulatory harmonization may significantly influence the rate of innovation.
Unmet therapeutic needs	Previously unmet and new therapeutic needs drive innovation.
Intellectual property protection	Strong protection is a prerequisite for investing in innovative research.
International trade barriers	Trade barriers may hinder the global diffusion of innovation.
Government support of academic research	Academic research may play a significant role in pharmaceutical R&D.

professionals. Armed with this knowledge, pharmaceutical marketers select a therapeutic area with an unmet therapeutic need, a significant potential for sales, and company knowledge (see Figure 9.5). They then construct a product target profile, as shown in Table 9.4. The process of unmet needs analysis, target profililing, and profile-based development is called *label-driven development.*

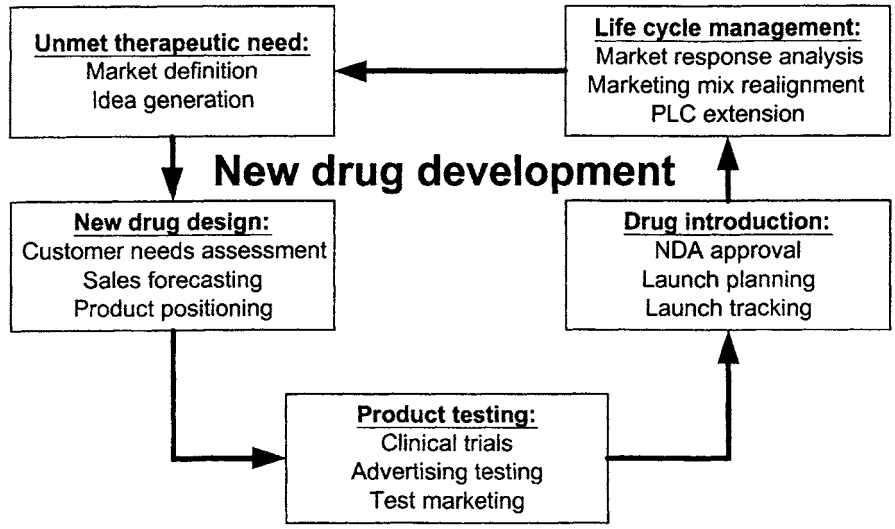
Idea Screening

Idea screening is the critical evaluation of numerous new product ideas based on a precise corporate strategy. New product ideas are exhaustively screened for their attractiveness based on various equations and models. The attractiveness index equation is expressed as:

$$I = T \times C \times P/D$$

where I = index of attractiveness, T = probability of technical success, C = probability of commercial success, P = profit if successful, and D = development cost.

Figure 9.4. The new drug development process



Furthermore, Table 9.5 shows a new product-screening model based on predetermined internal benchmarks.

New product feasibility study

One commonly used new idea screening tool is the product's feasibility analysis. Table 9.6 gives a detailed example of a new pharmaceutical product feasibility study, while Figure 9.6 depicts an R&D portfolio risk assessment model.

Figure 9.5. The magnitude of therapeutic need compared to market size portfolio model

		Magnitude of therapeutic need		
		Low	Medium	High
Market size	Small			
	Medium			
	Large			

Table 9.3: Stages of New Pharmaceutical Product Development

Idea Generation	Idea Screening	Business Analysis	Development	Commercialization
Definition: The systematic search for new ideas that may lead to a new product	*Definition:* Critical evaluation of numerous ideas based on a precise corporate strategy	*Definition:* The comparison of sales, costs, and profit forecasts to corporate objectives	*Definition:* The development of a new therapeutic idea into a pharmacological entity, and its efficacy and safety testing	*Definition:* Deciding on when, to whom, where, and how to introduce the new pharmaceutical product
Steps involved: Unmet therapeutic need identification Creation of idea Databasing of idea Creation of proposal	*Steps involved:* Establish criteria Check idea vs. criteria Concept testing	*Steps involved:* Estimate sales Estimate costs and profits	*Steps involved:* Patent Preclinical Clinical NDA	*Steps involved:* Prelaunch Launch Postlaunch evaluation
New idea proposal: Executive summary Present situation Product description Market analysis Product development plan Marketing plan Financial analysis Supporting documents	*Criteria used:* Fit within existing product mix Patentability Risk of competitive entry Ability to sell via existing distribution Compatibility with strategic plan Acceptable return on investment (ROI) period Growth potential Cost of new production facilities Compatibility with core technologies	*Criteria used:* Market size and trend Market share (with or without) Sales projections Cost assumptions Profit projections Risk factors Cash flow implications Investment appraisal	*Preclinical steps (Models/Test animals):* A. Chemical Development Synthesis, Purification, Identification of impurities, Characterization of active substance, Identification/analysis method development B. Formulation and Packaging Dosage forms, Packaging, Methods validation C. Pharmacology/Toxicology (Phase 0) Lethal Dose 50 (LD50), Acute animal tests, Subacute animal tests (up to 3 months), Chronic tests (0 to 18 months), Reproductive studies	*Prelaunch activities:* Positioning, Targeting, Profiling Distribution Pricing Promotional campaign Sales and Market share objectives Budgeting Sales force organization Training

Table 9.3: Stages of New Pharmaceutical Product Development (continued)

Idea Generation	Idea Screening	Business Analysis	Development	Commercialization
Techniques used: Attribute listing Segmentation studies Need identification Gap analysis Trend projections Parallel market identification Brainstorming Idea incentives and rewards	*Index of Attractiveness (I):* I = (% technical success) × (% commercial success) × (profit if success)/(Cost of development)		*Clinical Phases (Humans):* Phase I: Toxicity, Metabolism, Pharmacokinetics, Pharmacodynamics, Safe dose range Phase II: Controlled trials for effectiveness and additional safety experience Phase III: More patients exposed, less adverse events reported, more physician experience Phase IV: Postapproval study of risks, benefits, and optimal use	*Launch activities:* Finalize marketing mix Roll-out strategy Launch symposium Launch communications
New product idea sources: Internal (Sales, Marketing, R&D) Prescribers, Pharmacists, Patients, Competitors, Distributors, Suppliers			*New Drug Application (NDA):* Summary of pharmacology/toxicology findings, active substance properties, formulation, manufacturing, testing, labeling, packaging, stability testing, and clinical trial findings.	*Postlaunch activities:* Monitoring and feedback Plan refinement

Table 9.4: New Pharmaceutical Product Target Profiling

Indication	Psychosis.
Population	1% of world population, relatively stable across different nations.
Route of administration	Oral.
Formulation	Taste-free, colorless syrup to be diluted in milk or juice.
Duration of action	24 hours.
Efficacy	At least as effective with current world market leader.
Tolerability	Well tolerated, no significant adverse events, such as muscle rigidity.
Interactions	Limited interactions with dopamine agonists and hypotensive agents.
Pregnancy warning	Continuation of pregnancy to be decided by physician.
Price	20% premium over existing market leader.
Key markets	United States, Germany, United Kingdom, France, Italy, Spain, Japan.
Launch projections	NDA submitted July 2000, approved July 2001, launched in 7 top markets by January 2002.
Other	Disease management program to be available by time of launch.

Business Analysis

Business analysis is the comparison of sales, costs, risks, and profit forecasts to corporate objectives. A variety of assessment criteria are used in the process, such as galenic form, tolerability, efficacy, interactions, economic dossier, or drugs of reference. Table 9.7 shows a new product financial projection grid.

Development

This phase refers to the development of a new therapeutic idea into a pharmacological entity, and its preclinical and clinical efficacy and safety testing.

The clinical testing of experimental drugs is normally performed in three phases, with each successive phase involving a larger number of people. Once the FDA has approved an NDA, pharmaceutical companies conduct postmarketing or late Phase III/Phase IV studies (Figure 9.7). The test subject and time requirements of each testing phase are described in Table 9.8. Overall, the new drug development process may last up to ten years and cost more than 300 million U.S. dollars to complete. These facts, together with the usual patent exclusivity period lasting up to twenty years from

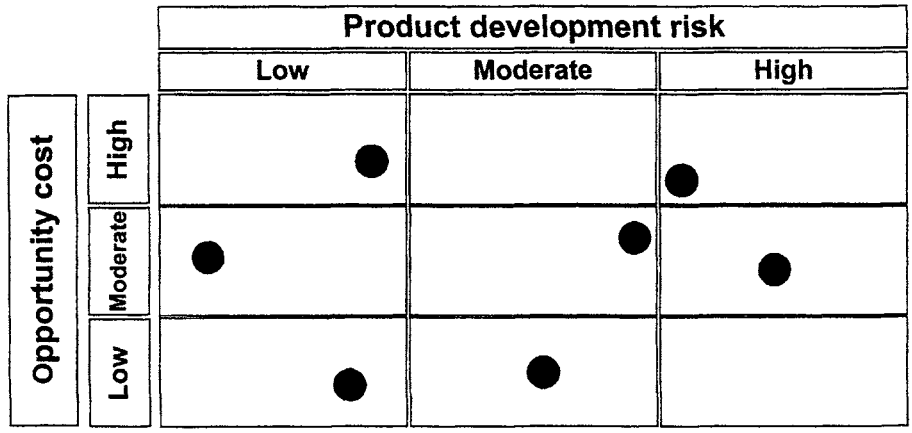
Table 9.5: Screening New Pharmaceutical Products with an Index Scoring System

Product Success Factor	Importance Factor	NCE Fit with Internal Company Competencies										Idea Rating
		1	2	3	4	5	6	7	8	9	10	
Company strategy	5							■				35
Financial resources	4					■						20
R&D	3						■					18
Purchasing and supplies	1								■			8
Manufacturing capabilities	2									■		18
Marketing expertise	3								■			24
Distribution channels	1										■	10
Total scoring												133

Table 9.6: New Product Feasibility Analysis

Parameter	Question	Data Sources
Disease epidemiology	What is the disease incidence and prevalence? Is there a seasonal disease manifestation? Are there any geographical area irregularities?	WHO, Organization for Economic Cooperation and Development (OECD), International scientific associations, National medical associations, Medical journals
Market size and growth	What is the market size (in patients, treatment cycles, units, and values) and evolution?	IMS Trade publications
Satisfaction with existing therapies	Are prescribers, patients, patient families, and health personnel satisfied with existing therapies?	Opinion leader input, market research, Web site feedback, press, sales force feedback
Competition	Who are the prescription, generic, and OTC competitors? What are their number, size, and specialization?	Marker research, management consultants, financial analysts, suppliers, sales force
Therapeutic category acceptance and penetration	What is the acceptance of this therapy among prescribers and patients? What is the life cycle stage and penetration rate of the treatment?	Customer feedback, market research, Web site feedback
Development costs	How much will it cost to develop 10 preclinical/4 clinical leads? Do we have the know-how and resources? Do we possess the necessary technologies?	R&D department, management consultants, CRO organizations
Expected sales	How can we forecast our future sales (units and values)? What was the market penetration rate of previous competitive launches?	IMS Managed care/government hospital data
Category expertise of company	How many years have we been active? What is our product portfolio depth? How many NCEs have we introduced in the category?	Internal data (R&D, marketing, past sales)
Company image	How do our stakeholders perceive our company and our products? How do we rate in customer satisfaction, patient quality of life improvement focus, animal testing, environmental sensitivity, and community relations?	Market research Customer service department feedback Sales department feedback Web site feedback

Figure 9.6. R&D portfolio risk assessment grid



the patent award date, make new pharmaceutical product development an extremely expensive and risky procedure.

R&D STRATEGIES

In the pharmaceutical industry, *research* is defined as the science and technology applied to the discovery of NCEs, and *development* as the activities following the preliminary NCE selection, including the detailed characterization, purification, formulation, toxicity, pharmacokinetic, and pharmacodynamic evaluation of the test entity. Different pharmaceutical/generics manufacturers employ various R&D strategies, that can be either **proactive** (continuous performance improvement, value for money, and product proliferation) or **reactive** (responsive, defensive, imitative, and not truly pioneering but safer or more efficacious). Most experts agree, however, that continuous performance improvement is the optimal approach for long-term innovation and profitability.

Figure 9.7. Steps of pharmaceutical research

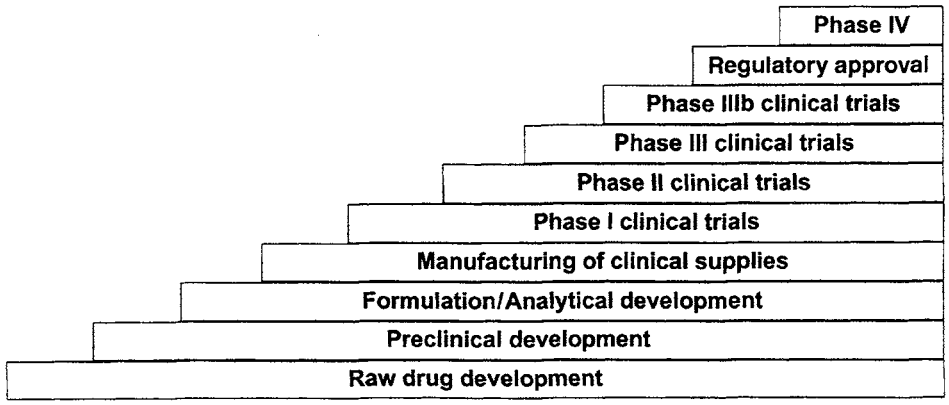


Table 9.7: New Product Financial Projection Grid

Parameter		Estimate	Year –5	–4	–3	–2	–1	1	2	3	4	5
Product:												
Market:												
Analyst/Date of analysis:												
Launch year	early											
	target											
	late											
	probability											
Launch year unit price (exfactory price in local currency)												
Unit used												
Total market sales	units											
	values											
Unit sales	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Value sales	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Market share postlaunch	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Price changes	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Sales calls	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Sales call	priority 1											
	priority 2											
	priority 3											
Sales costs	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Clinical trial costs	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Advertising costs	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											
Promotional costs	low (pessimistic)											
	target (realistic)											
	high (optimistic)											
	probability											

Table 9.8: New Drug Development Phase Requirements

Parameter	Basic Research	Preclinical	Phase I	Phase II	Phase III	Phase IV
Success parameter		Efficacy and safety in animals	Pharmacokinetics and tolerance in humans	Efficacy and optimum dosage in humans	Efficacy and long-term safety, comparative	Safety in large populations
Sample subjects	Test models (in vitro, ex-in vivo, in vivo)	Laboratory and animal testing	100–300 healthy volunteers	300–1,000 consenting patients	1,000–5,000 consenting patients	Thousands of patients
Number of compounds	5,000–10,000 screened	250 enter preclinical	5 enter clinical	3 enter Phase II	2 enter Phase III 2 are submitted	1 is approved
Phase duration	2–10 years	4 years	2 years	2 years	3 years	Several years
Decision points	Suitable portfolio candidate (SPC)	Entry into Man (EIM)		Complete development (CD)	New Drug Application (NDA)	New dosage New indications

The strategic objectives of pharmaceutical R&D are threefold (see Figure 9.8): to bring the current pipeline to market, to shorten the time-to-market, and to launch NCEs.

Outsourcing

Recently, the industry has seen an increase in outsourcing, indicating the need for pharmaceutical organizations to focus on their core competencies and minimize their costs. This phenomenon has been increasingly evident within the R&D field too, which has been viewed traditionally as a critical and internal-only industry activity. Due to this increasing trend, research-related organizations (such as the contract research and site management organizations) have enjoyed phenomenal growth in the last decade. The decision to outsource or maintain the internal control of pharmaceutical R&D is a critical one. Factors influencing such a decision are listed in Figure 9.9.

R&D BENCHMARKING

Almost all industry players are currently involved, in one way or another, in trying to make their R&D activities more efficient and focused. An important tool in monitoring the efficiency and productivity of R&D departments is *R&D benchmarking*, that is, the constant comparison of internal parameters to those of industry leaders. Experts and consultants in search of useful benchmarks have monitored several variables across the industry. Current R&D benchmarks are either qualitative or quantitative.

Qualitative benchmarks include regulatory agency commentary about protocols, nature of regulatory agency queries related to protocol flaws, and reasons for approval cycles. Quantitative benchmarks include protocol approval time, clinical development time, number of patents filed, number of INDs and NDAs filed, number of scientific publications and their bibliographic citation index, number of approval cycles, regulatory agency approval time, experts' survey of the level of trial protocol quality, experts' survey rating the efficiency and effectiveness of the approval process, pipeline size at various preclinical/clinical stages, project attrition rate, portfolio contents, and R&D spending as a percentage of company sales.

Figure 9.8. Strategic objectives of pharmaceutical R&D

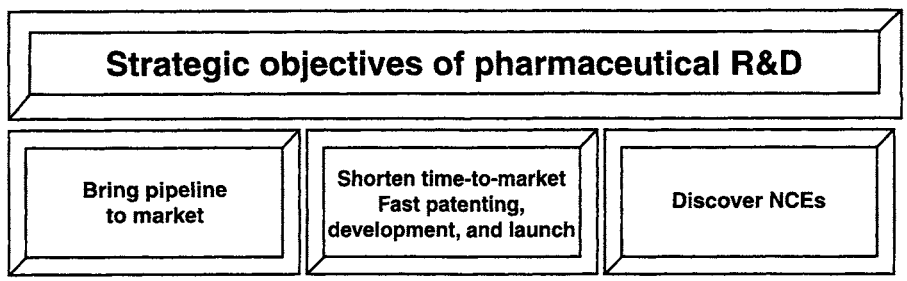
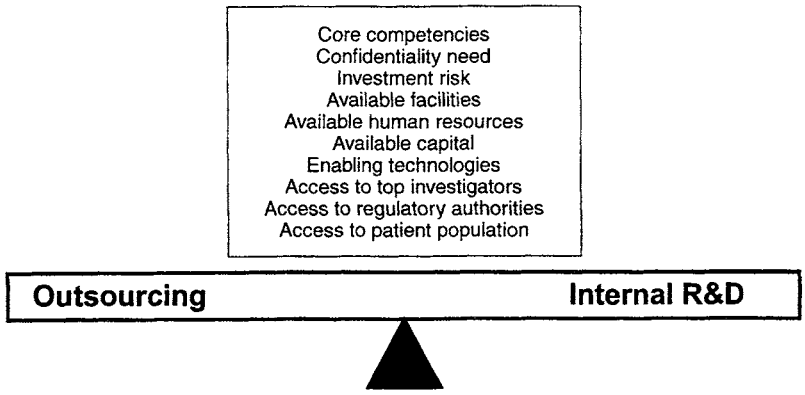


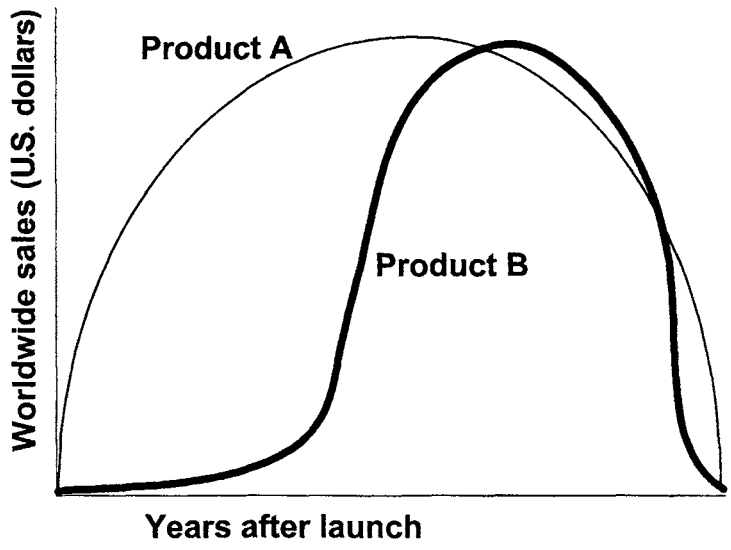
Figure 9.9. The internal R&D outsourcing dilemma



IMPORTANCE OF TIME-TO-MARKET

As mentioned earlier, one of the strategic objectives of R&D is to shorten the time-to-market. Indeed, arriving first to the product launching pad is necessary for maximum commercial success in the marketplace. As Figure 9.10 shows, the first entrant (product A) is able to maximize commercial returns, whereas the second entrant (product B) finds steep competition at the time of launch and takes years to reach its maximum potential, while its patent exclusivity protection is quickly expiring. The importance of shortening the time-to-market has become evident through concurrent drug development phases and other industry initiatives.

Figure 9.10. Importance of time-to-market



Methods of reducing the time-to-market include accelerated development path, early customer input, cross functional R&D teams, enabling technologies that reduce time required, flexible manufacturing, strategic alliances, and efficient premarketing.

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10

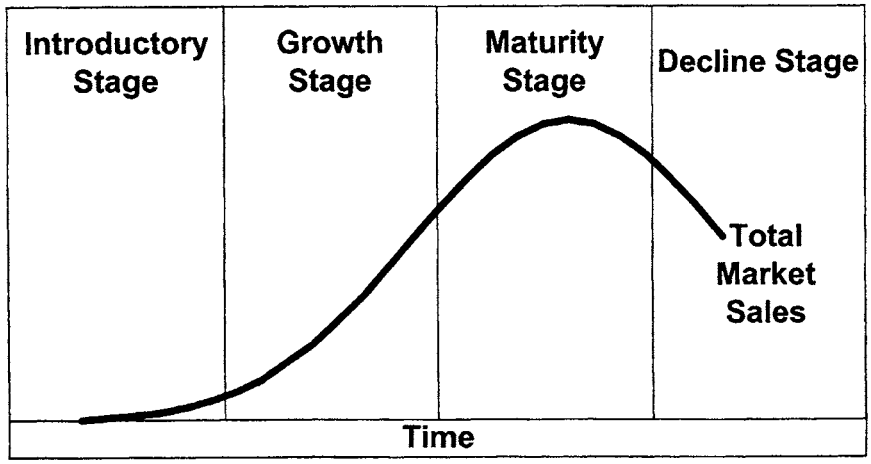
Product Life Cycle and Portfolio Management

> In the past two years alone, pharmaceutical companies have added more than one hundred new treatments to the nation's medicine chest.
>
> PhRMA, 1998

Pharmaceutical products follow the same course as consumer products, that is, a rise, plateau, and eventually a fall of sales, in a phenomenon which has been described as the *product life cycle* or PLC. There are multiple reasons behind a product's life cycle changes including the following: (a) different customers buy the product at different stages (diffusion of innovation); (b) evolving competitive structure of industry; (c) evolving internal product portfolio priorities; (d) evolving cost structure of the product; (e) evolving dosage strength and formulation of the product; and (f) evolving design and manufacturing of the product. Due to these and other reasons, every product needs a differentiated marketing strategy throughout its PLC stages. Industry marketers should master the art of life cycle management in order to maximize the product's life cycle and profits. The distinct phases of a product's life cycle are depicted in Figure 10.1.

Occasionally a consumer may find pharmaceutical products that were originally launched in the world marketplace several decades ago and now have seemed to reach immortality (aspirin, penicillin, cisplatin). There are two reasons behind the apparent immortality of these substances. Either the products were significant therapeutic

Figure 10.1. The product life cycle



breakthroughs at the time of their launch and are considered reference drugs, or there has not been any significant therapeutic innovations in their respective indications and they remain the valid therapeutic choices today. This by no means indicates the sustained profitability of the original manufacturer, who may have abandoned the therapeutic area all together, bowing to the competitive pressures of myriad me-too products. This chapter, then, discusses the PLC management of product brands—the valuable assets of industry marketers during their years of patent protection.

PATENT PROTECTION

According to the U.S. Patent and Trademark Office, "a patent for an invention is a grant of a property right by the government to the inventor (or his or her heirs or assigns), acting through the Patent and Trademark Office. The term of the patent shall be twenty years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), from the date the earliest such application was filed, subject to the payment of maintenance fees. The right conferred by the patent grant extends only throughout the United States and its territories and possessions." The right conferred by the patent grant is, in the language of the statute and of the grant itself, "the right to exclude others from making, using, offering for sale, or selling" the invention in the United States or "importing" the invention into the United States. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention.

Because the patent exclusivity period starts the day the patent application is filed and many years are needed for the completion of a product's R&D phase (which can take as much as ten years), a pharmaceutical innovator is left with only a limited period in which to get a return on the huge R&D investment that was allocated to its discovery. The process of a drug's commercialization is a resources- and time-based approach that needs to be carefully designed and implemented in order to acheive the

expected returns. In this chapter, the whole process—from the drug discovery and patent application to its launch, sales growth, maturity, and decline—is presented, together with the requirements for success at every stage.

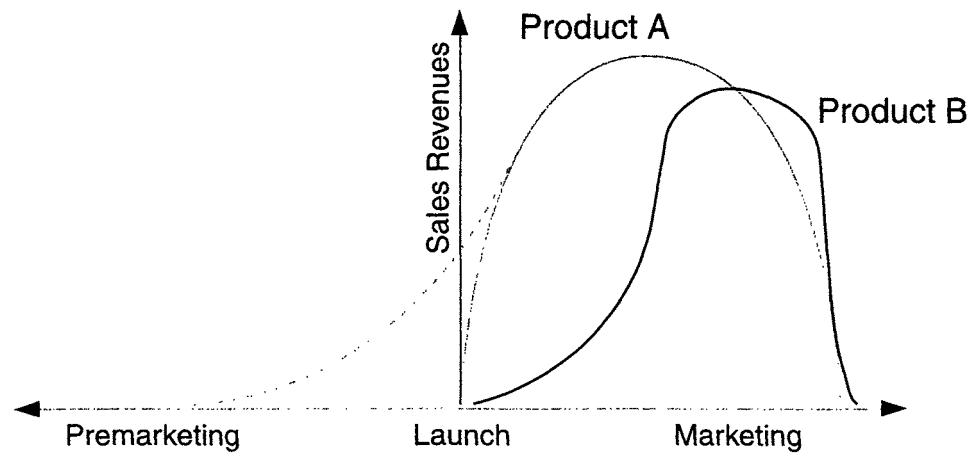
A patent for a pharmaceutical invention may have different legal statuses. For example, it may be valid for certain geographical regions only or for a large number of remote countries that depend on the existence of a mutual patent protection agreement. Furthermore, the market exclusivity provided by a patent may be strictly enforced by some national authorities, while others may not have the resources or the political will to enforce it. In such situations, the marketplace doors are wide open to me-too manufacturers, and the return-on-investment of the original manufacturer becomes a difficult goal. Industry professionals are aware of areas where patent protection is lax and foreign pharmaceutical innovations are easily copied. However, trade associations of the negatively affected industries have been conducting strong lobbying campaigns for the stricter enforcement of patent protection laws. Significant success has been achieved in the last few years.

CONCEPTION AND PRODUCT DEVELOPMENT

The product conception and development phase was extensively presented in Chapter 9. As stated earlier, this phase begins with basic research, and then gradually moves through a series of preclinical and clinical research phases that lead to a new drug application (NDA). This is a long and risky period of resource-intensive activities and no product sales, thus a prolonged negative-profitability period.

One of the most important aspects of a product's life cycle management is maximizing product revenue during the very limited period of remaining patent exclusivity at the time of launch. A typical product introductory period will take several months, or even years, to reach its growth levels, provided that the product's promotional effort starts at launch. However, as Figure 10.2 shows, pharmaceutical marketers can use a very significant business tool called premarketing to raise consumers'

Figure 10.2. The need for premarketing



awareness before the product becomes available. The introductory phase becomes shorter and revenue is maximized.

How is premarketing conducted? Table 10.1 summarizes the reasoning, methodology, strategy, and key activities of pharmaceutical premarketing. In general, premarketing should be initiated at least two years prelaunch, or at the beginning of Phase III of clinical research. The activities needed for premarketing require significant human and financial resources. Early commitment to the potential new pharmaceutical product from the company's management is essential. Some organizations assign the design of premarketing strategy to the product managers who will eventually take responsibility of the marketed product. However, this often takes time and energy away from other product priorities. Alternatively, premarketing activities are directed by specialized marketing managers, often called new product development or new market development managers. These managers either transfer the responsibility of the product to the brand manager or continue with it as a full-time responsibility.

INTRODUCTION PHASE

During the introductory phase, a pharmaceutical product's sales revenues are small and exhibit a slow growth (see Table 10.2). The manufacturer is trying to gain product acceptance from the prescribers or patients. The overall marketing strategy behind this stage is to attract the therapeutic area opinion leaders, who are essential in communicating the product's benefits to their colleagues through the pyramid of influence cascade. The product is offered only in a limited number of dosage strengths and formulations, while the prices are often high and stable (provided the product is an innovative one).

During this phase the industry marketers' main information need is market data that helps them define the product's optimal targeting, positioning, and profiling. In

Table 10.1: The Case for Premarketing

Reasoning	Methodology	Strategy	Key Activities	Internal Activities
Faster market penetration	Create a demand	Positioning	Market research	Demand forecasting
Higher market shares	Develop a user pool	Targeting	Clinical trials	Manufacturing
Higher long-term profits	Build company image	Profiling	Congresses	Logistics
	Build awareness	Promotion	Publications	Product management
		Formulation	Develop OLs	Medical marketing
		Packaging	Advisory Board	Sales force
		Pricing	Develop global campaign	Regulatory support
		Comarketing	Branding	PR
		Budgeting	Training	
			Public relations	
			Advertorials	
			Mailings	

Table 10.2: Characteristics and Marketing Objectives of the Different PLC stages

Characteristics	Introduction	Growth	Turbulence	Maturity	Decline
Revenues	Small	Moderate	Large	Large	Moderate
Sales growth	Slow	Rapid	Slow	None	Negative
Costs	High fixed, High variable	Moderate fixed costs	Low fixed, Low variable	Low fixed, Low variable	Rising fixed costs
Profits	Negative	Increasing	Maximum	High	Decreasing
Customers	Innovators	Early adopters	Early majority	Late majority	Laggards
Competitors	0–2	Many	Fewer than before	3–4	Fewer than before

Marketing Objectives	Introduction	Growth	Turbulence	Maturity	Decline
Information needs	Positioning, targeting, profiling	Life cycle management		Life cycle management	Life cycle management
Overall strategy	Attract OLs	Expand distribution		Maintain advantages	Harvest/Terminate
Product mix	Basic model	Expand line	Product extensions, service	Full line	Best sellers
Product changes	A few	Many	Insignificant	Insignificant	Insignificant
Product offerings	Basic benefits	Major features	Major features	Secondary characteristics	Basic benefits
Pricing objective	Penetration/Skimming	Fight competition	Protect position		Maximize profits
Price	Stable	Declining	Declining	Stable	Declining
Distribution	Stable	Increasing	Decreasing	Stable	Decreasing
Advertising	Informative	Persuasive		Competitive	Informative
Sales force	Large, Targeted	Large, Wide-focused		Key account management	Reduced

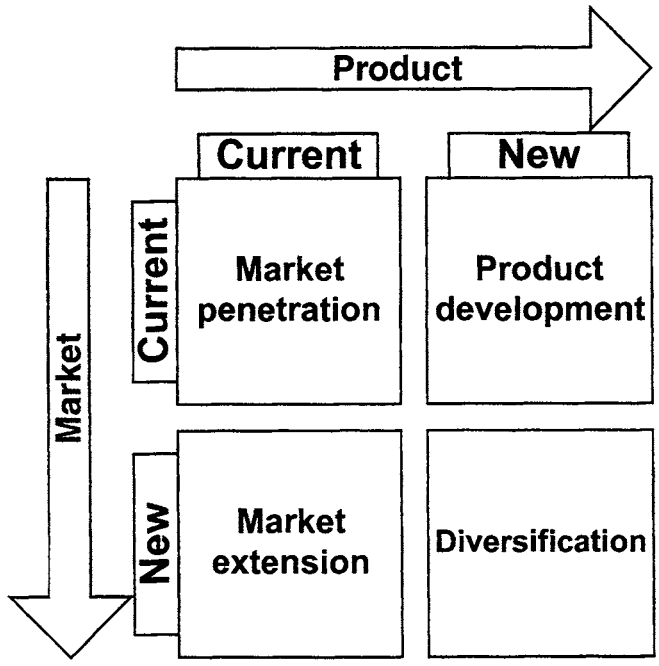
order to increase consumer awareness and willingness to buy, the following activities can be implemented: (1) offer clinical trial experience; (2) include physicians and patients in long-term treatment; (3) develop opinion leaders; (4) develop media spokespersons (such as successful patient testimonials); (5) sampling or couponing, (6) risk reduction; (7) adapt promotional mix; (8) broaden product offerings; and (9) modify marketing channels. Furthermore, the ability to prescribe and/or buy can be increased by the following activities: (a) penetration pricing; (b) adequate distribution; (c) liberal payment terms; (d) wholesaler consignment stocks; and (e) compatibility with existing medical supplies and equipment.

When a new product is introduced in a current therapeutic area, the company is said to be active in *product development*, as opposed to entering a new therapeutic segment with an existing product—a strategy called new *market extension*. Additionally, when a new product is introduced into a new therapeutic segment the company is pursuing a *diversification* approach (see Figure 10.3).

GROWTH PHASE

In the growth (or expansion) phase, a product's sales revenues are moderate but rapidly growing and its profitability is increasing, while more competitors are entering the stage. The marketer's main objectives are to expand the distribution breadth and product line by offering new product benefits and forms. Furthermore, the increasing competitive intensity is driving product prices down. As far as the product's promotion is

Figure 10.3. New product versus market development



concerned, the messages are now persuasive and often comparative to competition's (where comparative pharmaceutical advertising is allowed). The sales force is expanding, reaching more and more customers, often shifting its priority from the few medical specialists at the beginning to the large number of family physicians or general practitioners throughout the national markets.

At the peak of the growth phase, some marketing scholars have proposed the existence of a separate phase called the *turbulence* (or shake-out) phase. This period is when product sales plateau and signifies the imminent entrance into the maturity phase. Some of the characteristics of the turbulence phase are the slowing of the sales growth, fewer competitors than before, and a stabilizing distribution base.

MATURITY PHASE

At some point in a product's life cycle every product reaches maturity, that is, a phase characterized by a stabilized sales performance, with low costs and high profits. At this stage, marketers are occupied with maintaining the product's advantages, often fighting competitive new product launches with new features and benefits. A full product line is now available, offering a wide spectrum of product dosages, administration route possibilities, and formulations. Both price and distribution are now stable. The pharmaceutical manufacturer is conducting competitive advertising. An important feature of this phase is the shifting of the sales force focus from the "blanket coverage" of every active prescriber to the "key accounts," or those physicians with the highest prescription potential and the highest profitability for the company. The task of key account management is fully explained in Chapter 17.

DECLINE PHASE

Eventually, the product enters its decline phase, with decreasing sales, rising fixed costs, and an eroding profitability. Now, pharmaceutical marketers are faced with the dilemma of further "harvesting" the product, that is, prolonging its sales as long as posible or terminating the product and introducing a replacement. The product's advertising becomes a reminder and sales force time and effort are reduced.

PRODUCT WITHDRAWAL

After a pharmaceutical product has reached its decline phase, the decreased profitability may necessitate the product's withdrawal from the marketplace. Common reasons for a pharmaceutical product withdrawal include the following: low profitability, stagnant or declining sales volume or market share that would be too costly to build up, risk of technological obsolescence, entry into a mature or declining phase of the product life cycle, or product line conflicts. A variety of withdrawal strategies exist, which are characterized by the varying speeds of the product's elimination from the market. Possible withdrawal strategies are (a) harvesting, (b) line simplification, and (c) total-line divestment.

THE DIFFUSION AND ADOPTION PROCESSES

A product's *diffusion* process is based on its acceptance by the population. It depends on product characteristics such as relative advantage, complexity, compatibility, communicability, trialability, risk, and so on. Diffusion increases with standardized technology, leads to lower manufacturing costs, and translates into lower prices. A product's *adoption* is a customer's internal process, involving awareness, interest, evaluation, trial, and adoption (Figure 10.4). It has been observed that people vary in their propensity to try new products. Rogers (1976) has differentiated types of consumers according to their speed of adoption of new products. These different population groups, including the innovators, early adopters, early and late majorities, and laggards, have been shown to play a role in the adoption of most consumer products and pharmaceuticals. Figure 10.5 illustrates the average adoption process curve. The characteristics of the different prescriber groups, according to their pharmaceutical product adoption, are listed in Table 10.3.

Some of the factors influencing the speed of new pharmaceutical product diffusion among prescribers and patients are the following: (a) relative product advantage (NCE); (b) type of advantage to be gained (antacid versus oncological product); (c) compatibility with one's self (experiences, beliefs, values); (d) complexity (once monthly depot injection versus inpatient continuous infusion); (e) trialability (medicines often have to be included in a hospital formulary before an innovator physician may prescribe them); (f) observability (immediate pharmacodynamic effects or dissolution of disease symptoms will increase product adoption); and (g) past experience (a previously tried bitter tasting syrup formulation). Pharmaceutical development teams should take these factors into account early in the process, and test their product concepts with customer experimentation.

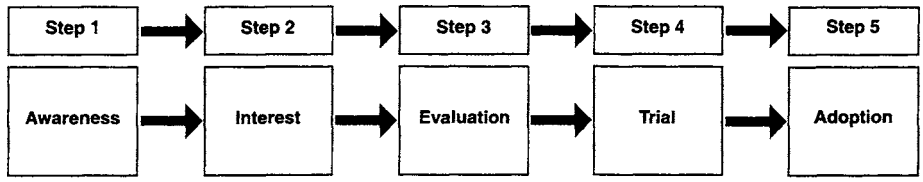
STRATEGIES FOR MODIFYING EXISTING PRODUCTS

Very often a successful product life cycle needs to be prolonged, either because the product can continue to be a significant revenue-making engine for the organization, or because the existing product pipeline does not guarantee a promising blockbuster in the near future. There exist a variety of possible product modification strategies, some of which are listed in Table 10.4. Once again, the customer needs, market and competition characteristics, and the company's own resources and expertise will dictate the use of one or more of these strategies.

Table 10.3: The Prescription Decision Adoption Model

Innovators	Early Adopters	Early Majority	Late Majority	Laggards
Adventurous	OLs	Longer decision process	Very cautious	Older age
Well-educated	Literature readers	Follow the leaders	Follow peer pressure to adopt	Long-past medical education
Forty-somethings	Localized in major centers		Practice setting must allow innovation	Limited networking
Handle risk well	Wide networking			Very suspicious

Figure 10.4. Product adoption steps



A company's product portfolio mix can be plotted in a two-dimensional model of the products' relative competitive position versus their life cycle stage, indicating the product's focus on innovation and present competitive position in the marketplace (see Figure 10.6).

THE REGULATORY LIFE CYCLE

A product's life cycle management requires not only good marketing and sales strategy planning, or changes in its distribution or pricing. Additionally, there has to be a robust and proactive regulatory plan, spanning the product's life cycle that allows new product modifications or indications to be introduced at the right phase. A regulatory life cycle plan used in the pharmaceutical industry is shown in Figure 10.7.

PORTFOLIO MANAGEMENT

The preceding chapters discussed the importance of new product development, the inherent risks involved, and the magnitude of company resources needed. We have also observed and analyzed the increasing globalization of the pharmaceutical industry players in their quest for long-term profitability and growth. These are only some of the factors that underlie the resource intensity and risks involved in the industry. They,

Figure 10.5. The adoption process curve

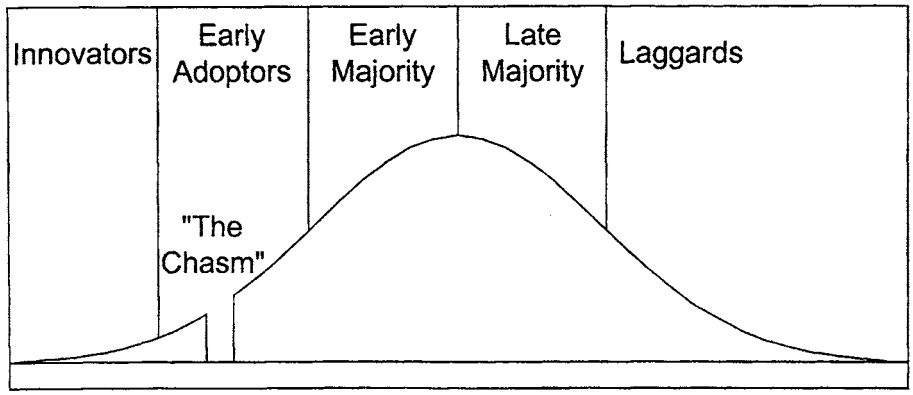


Table 10.4: Product Modification Strategies

#	Strategy	Example
1.	Product modification	A molecular structure change resulting in higher efficacy.
2.	New therapeutic areas	A new clinical trial indicating its efficacy in a new indication.
3.	New uses	An antibiotic now available in a pediatric form.
4.	New dosage strength	A halving of the previous strength allowing individualization.
5.	New formulation	An injection now available in tablets and nasal spray.
6.	Relaunch	New promotional drive for maturing product.
7.	Cost reduction	A temporary rebate or permanent price reduction.
8.	Rx-to-OTC switch	Switching to OTC status and selling it through grocery chains.

in turn, make the following questions critical: Are we getting the maximum return on investment and is the company doing all it can to maintain a long-term profitability? Do the therapeutic areas, geographical regions, and projects pursued have a strategic fit with the company's core competencies? And do the initiatives undertaken show a balance between therapeutic areas, short- and long-term or new and old products? These questions are in every international company's boardroom and are best addressed by portfolio management, which is discussed next.

What Is a Product Portfolio?

A *product portfolio* is all marketed products and all products currently in R&D that a pharmaceutical company is involved with on a global scale. In other words, it includes all marketed product lines, brands, dosages, or formulations, and all those compounds currently in basic research, preclinical or clinical testing, and in every national market in which the company is operational. Therefore, a product portfolio is similar to an investment portfolio that includes all financial forms of investment worldwide. The portion of its product portfolio currently in R&D may also be called a *pipeline*, a metaphorical reference to the process that carries a pharmaceutical product from discovery to market.

Figure 10.6. A product portfolio model of competitive position versus life cycle stage

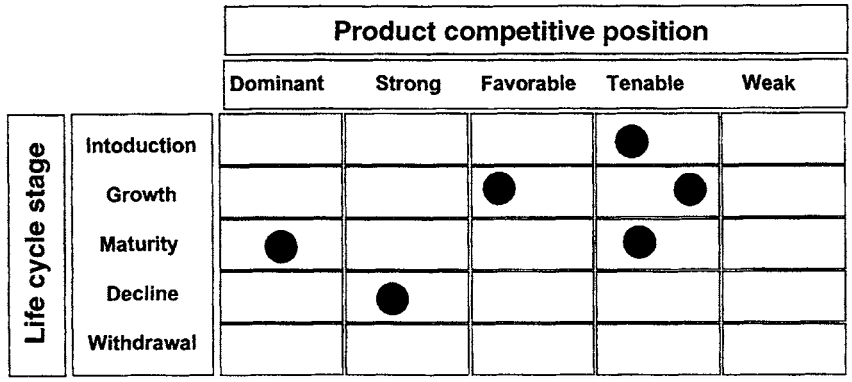
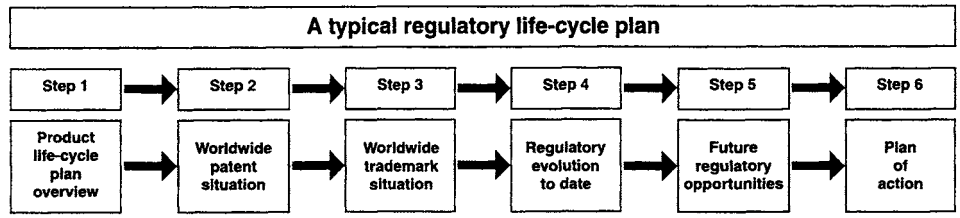


Figure 10.7. A typical regulatory life-cycle plan



Why, then, is it important to look at portfolio management? Because this provides essential answers to the following dilemmas: Which therapeutic areas will allow the organization to build and sustain a competitive advantage? How much investement should be allocated to each product (at the expense of the others)? What is the ideal performance attainable from each product? And how do you allocate resources across portfolios, including new and older portfolio members?

The three main goals of portfolio management are shown in Figure 10.8. They include the critical tasks of ensuring portfolio value maximization, strategic fit, and balance.

Portfolio Selection

The portfolio selection framework is shown in Figure 10.9. Potential projects are first prescreened, and, after a proper project analysis enter the screening phase. Suitable projects are selected and pursued. After any required divestments, they become part of the company's portfolio. This portfolio is in constant change because the parameters of value maximization, strategic fit, and balance may be better satisfied by incoming portfolio ideas. New portfolio inclusion and other portfolio divestment or discontinuation are a constant reality in today's pharmaceutical industry environment.

Figure 10.8. Pharmaceutical portfolio management goals

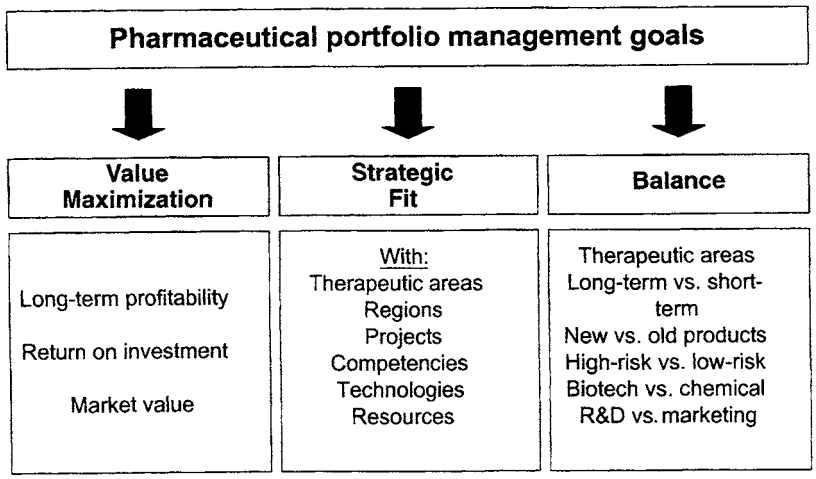
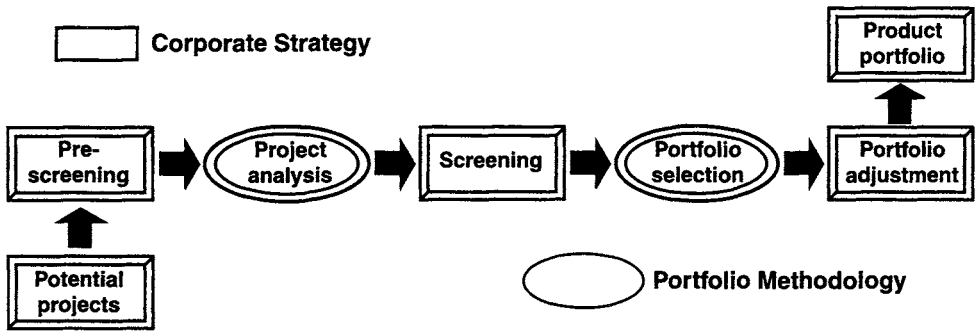


Figure 10.9. The portfolio selection framework



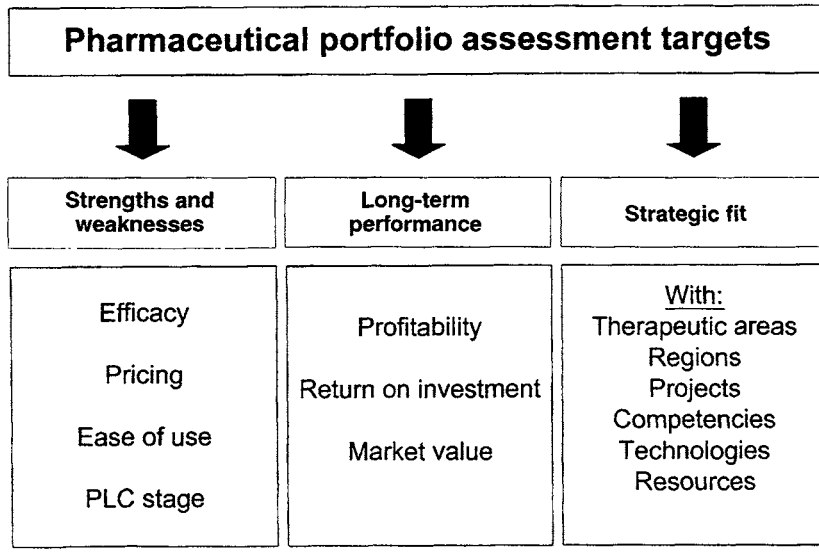
Portfolio selection may occur at any stage of the R&D process and is discussed later. The general portfolio selection criteria are: (a) risk, that is, probability of success, (b) exposure, that is, cost of failure relative to firm's size, and (c) reward, that is, potential profits if successful.

Portfolio Assessment

Pharmaceutical portfolio assessment has three distinct targets (see Figure 10.10). First, it is involved is assessing the project's strengths and weaknesses in relation to customer needs, market characteristics, and competitor's offerings. Second, it attempts to ensure the project's long-term profitability. Third, it checks the project's strategic fit with the company's core competencies.

Several experts have proposed a wide spectrum of portfolio assessment tools that can be used by pharmaceutical industry managers. Figure 10.11 shows the five major types

Figure 10.10. Targets of pharmaceutical portfolio assessment



of these assessment tools, namely, economic return models, risk analysis, various portfolio models, benefit/cost analysis, and market research. The first three types will be presented in this chapter, while market research was presented earlier, and the benefit/cost analysis is the subject of pharmacoeconomics discussed in Chapter 14.

Idea assessment tools

The initial idea assessment (prescreening) is based on several potential market criteria, such as the market size or unmet therapeutic needs. Some of the most commonly used techniques are the following: (1) *perceptual mapping*, which identifies areas of unsatisfied customer demand; (2) *consumer choice modeling*, such as conjoint analysis, which identifies measures of consumer value for each product attribute, allowing the firm to custom design a preferred product; and (3) *cluster analysis*, which identifies logical groupings of products and customers.

Concept screening tools

Concept screening is based on a more in-depth analysis of the concept's characteristics and risks, such as the research risks, research and development costs, strategic fit, market potential, economic return, and life cycle. Table 10.5 provides a detailed pharmaceutical product concept screening grid.

Table 10.6 shows a hypothetical product portfolio assessment of two therapeutic classes. The variables used are the following:

- Therapeutic Class A compared to Therapeutic Class B
- Each therapeutic class has two indications, 1 or 2
- Each indication can be treated with two formulations, a or b

Figure 10.11. Portfolio assessment techniques

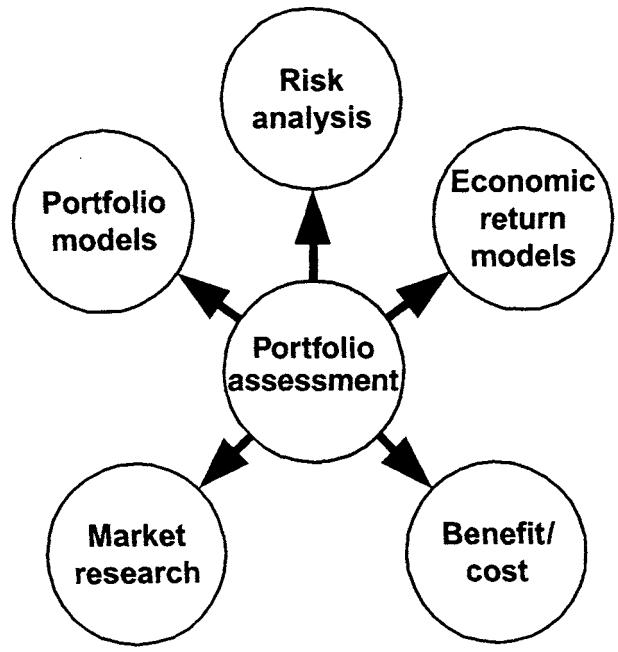


Table 10.5: Portfolio Concept Screening Grid

Parameter	Measure	Weighing	Rating	Score
Research risk analysis (Probability of technical success [PTS])	Efficacy, safety, tolerability, interactions, contraindications, formulation, approval Decision tree method			
R&D costs	Capital investment, research, regulatory, marketing, sales, head count, overhead			
R&D time	Basic research Preclinical testing Clinical testing Development phase			
Strategic fit	Financial, core competencies, human capital, manufacturing capacity, manufacturing equipment, raw material, distribution channel,product line fit/cannibalization			
Market potential	Satisfaction of unmet therapeutic need Disease prevalence and incidence Market value Patients aware, diagnosed, treated, and compliant Treatment duration First 5-year product sales Time from launch to peak sales Product sales at peak year			
Economic return	Internal Rate of Return (IRR) Return on Investment (ROI) Net Present Value (NPV) Economic Value Added (EVA)			
Life cycle	Market size Changing customer needs Unique competitive advantage Present and future competition Future line extensions			

In addition to the visual grid (Table 10.6), there are a variety of mathematical models used to estimate a concept's profitability. These include the following.

The Net Present Value (NPV) method

$$ECV = [(NPV \times Pcs - C) \times Pts - D]$$

where $ECV = Expected commercial value of the project; Pts = probability of technical success; Pcs = probability of commercial success (technical success is given); $D = development costs remaining in the project; $C = commercialization (launch) costs; and $NPV = net present value of the project's future earnings (discounted to the present) (see Figure 10.12).

The probability of success can be estimated with the following methods: (1) **Delphi method**, which is attempting to reach experts' census, and (2) **Matrix method**, which is plotting market newness and competitive advantage gained (see Figure 10.13).

Table 10.6: Product Portfolio Assessment of Two Therapeutic Classes

	8 possible portfolio alternatives							
Parameter	**A-1-a**	**A-1-b**	**A-2-a**	**A-2-b**	**B-1-a**	**B-1-b**	**B-2-a**	**B-2-b**
Know-how available	•	•			•	•	•	•
Personnel available		•			•	•	•	
Development time (years)	4	4	6	6	5	5	8	8
Qualitative ranking	# 3	# 1	# 6	# 6	# 2	# 2	# 4	# 5
Investment required (U.S. dollars)	20	25	30	30	15	16	22	24
Sales expected (U.S. dollars)	100	150	80	60	200	250	50	75
Financial ranking					# 2	# 1		

The ECC version of the model incorporates the strategic importance of the project, as follows.

$$ECC = (NPV \times SI \times Pcs - C) \times Pts - D$$

where NPV = net present value of 10-year cash flow, after launch (inclusive of all project costs); SI = strategic importance index (high, medium, low = 3, 2, 1 respectively); Pcs = probability of commercial success (0.2 to 1.0, increments of 0.2, according to internally established criteria); C = commercialization (launch) costs (capital, marketing); Pts = probability of technical success (0.2 to 1.0, increments of 0.2, according to internally established criteria); and D = development costs.

The productivity index method

$$PI = [ECV \times Pts - R\&D]/R\&D$$

where PI = productivity index and R&D = R&D expenditures.

Figure 10.12. NPV portfolio assessment method

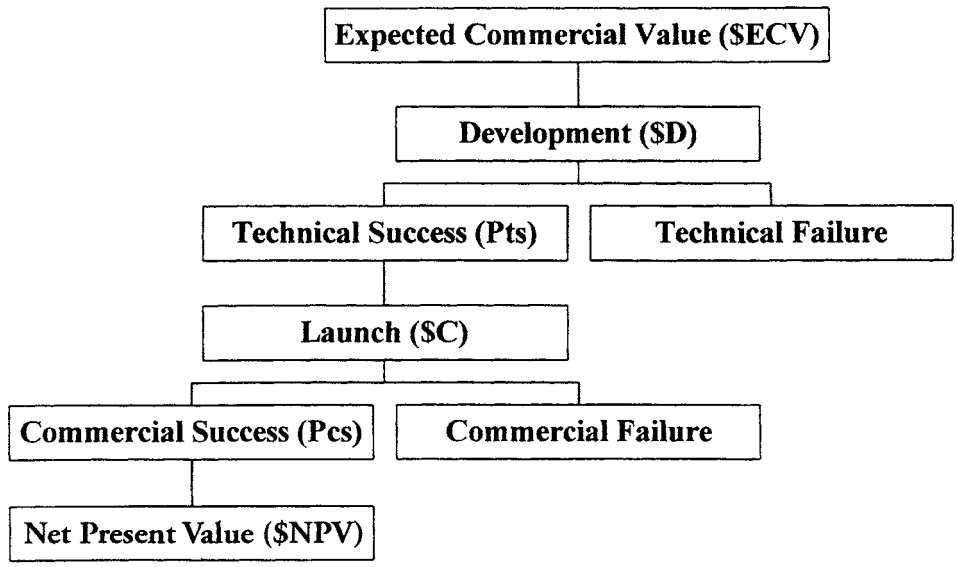
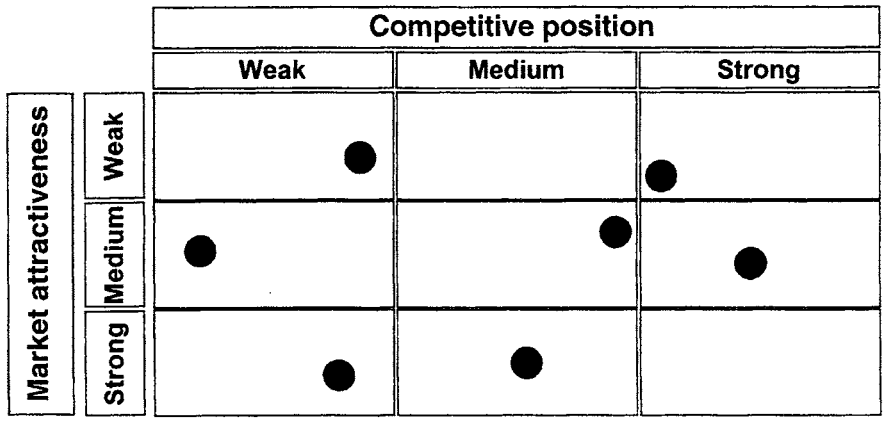


Figure 10.13. The Matrix method for estimating a project's probability of success



Clinical research decision points

The following are critical pharmaceutical research decision points, evaluation parameters, and relevant criteria for a Go/No Go decision:

1. Lead identified
   Evaluation parameter: biomarker. Criteria: pharmacologic activity, in vitro and in vivo potency and selectivity, metabolic resistance, viable synthesis and production, and patentability.
2. Enter development
   Criteria: in vivo activity in disease model, pilot toxicity data, preliminary metabolism data, and estimate of synthesis costs.
3. First in man (FIM) administration
   Criteria: adequate rationale and data from animal models to suggest beneficial effect in disease target, and adequate safety margin in animal models to enter clinical testing.
4. Proof of concept (POC) principle (Phase I to II transition)
   Evaluation parameter: surrogate marker. Criteria: pharmacologic activity in humans, acceptable therapeutic index, and competitive advantage.
5. Phase II to III transition
   Evaluation parameter: clinical benefit. Criteria: pharmacologic effect shown, dose-response shown, acceptable therapeutic index, acceptable competitive advantage (similar to target profile, see Chapter 9), acceptable synthesis costs, and viable manufacturing.
6. Regulatory submission
   Criteria: proof of efficacy and safety and active substance and pharmaceutical product manufacturing process validation.

Portfolio risk analysis

A project's risk analysis is designed to evaluate the project-related costs versus the probability of success at any step of the discovery-to-commercialization process. Figure

10.14 depicts a project risk analysis decision tree often used in the pharmaceutical industry.

The results of several projects' risk analyses are then plotted in a two-dimensional risk analysis model (see Figure 10.15). This helps marketers prioritize among several R&D projects.

The probability of technical success can also be plotted against financial reward measurements (for example, NPV) in a two-dimensional matrix, as shown in Figure 10.16. The Arthur D. Little consulting firm has labeled the four resulting matrix quadrants, as pearls, oysters, bread and butter, or white elephants. These quadrants indicate various degrees of the project's probability of success versus the expected returns.

Finally, others have plotted the probability of technical success against the project's NPV in a two-dimensional risk–reward bubble diagram. The shape of the resulting diagram bubbles helps visualize the forecasted ranges of these two parameters (see Figure 10.17).

Figure 10.14. Portfolio project risk analysis decision tree

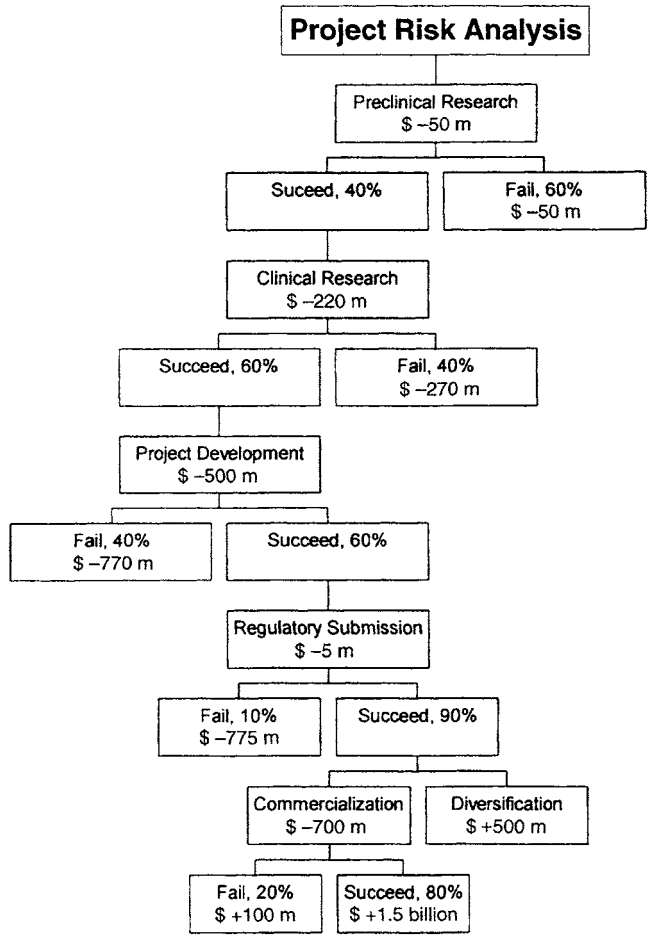
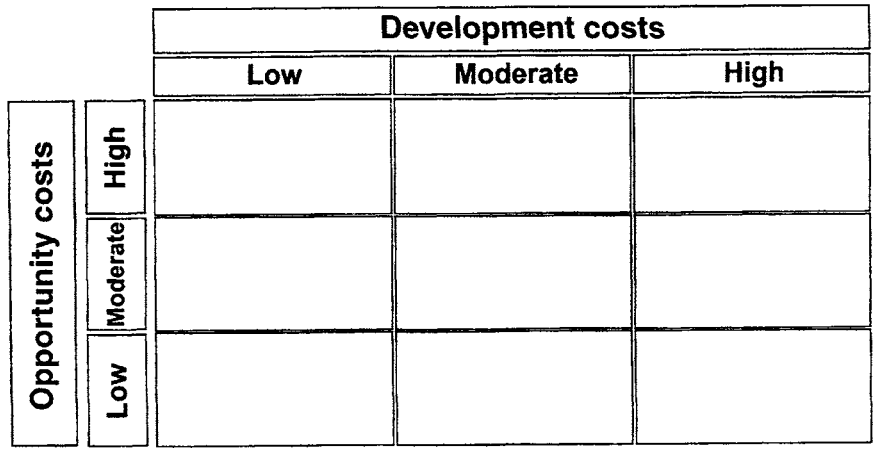


Figure 10.15. Portfolio risk analysis model



Standard Portfolio Models

The Boston Consulting Group (BCG) grid

One of the most famous portfolio models, developed by the BCG consulting firm, plots a company's products' relative market shares against the respective market growth rate (see Figure 10.18). The four diagram quadrants contain products that have been

Figure 10.16. The importance of a balanced portfolio (Arthur D. Little)

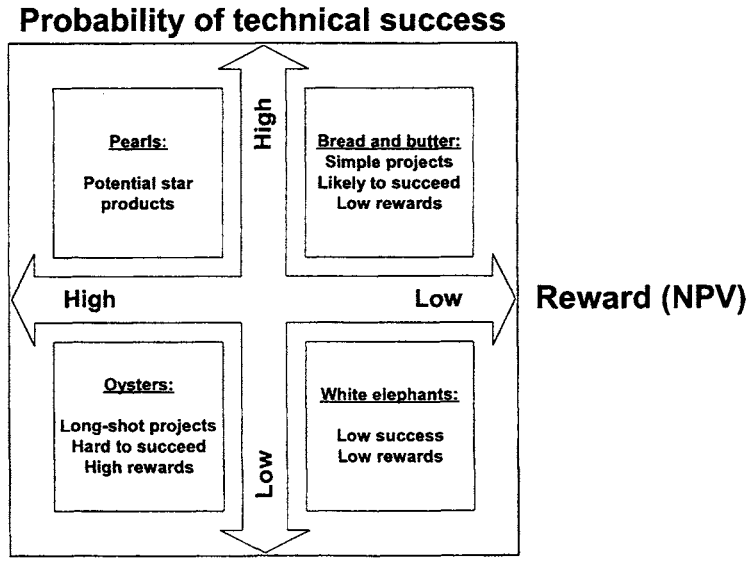
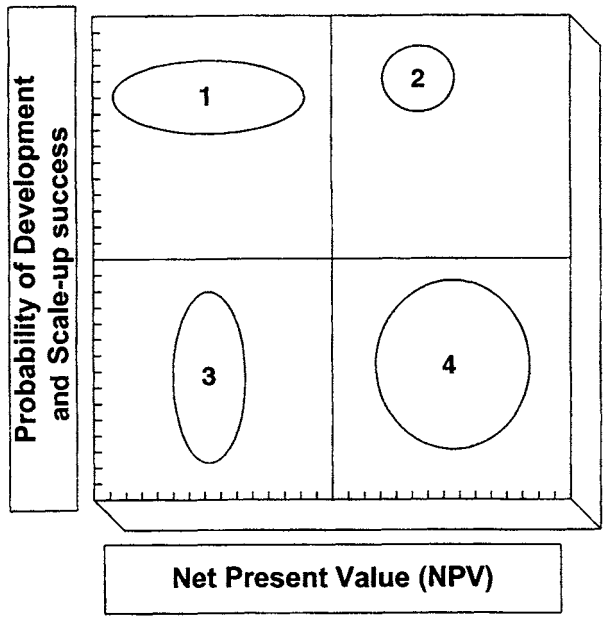


Figure 10.17. Risk-reward bubble diagram (3M)



labeled as stars, cash cows, question marks, and dogs, which imply respective build, milk, or divest strategies, based on the two analyzed parameters. Henderson (1973) has proposed strategic implications of the BCG model, which are summarized in Table 10.7.

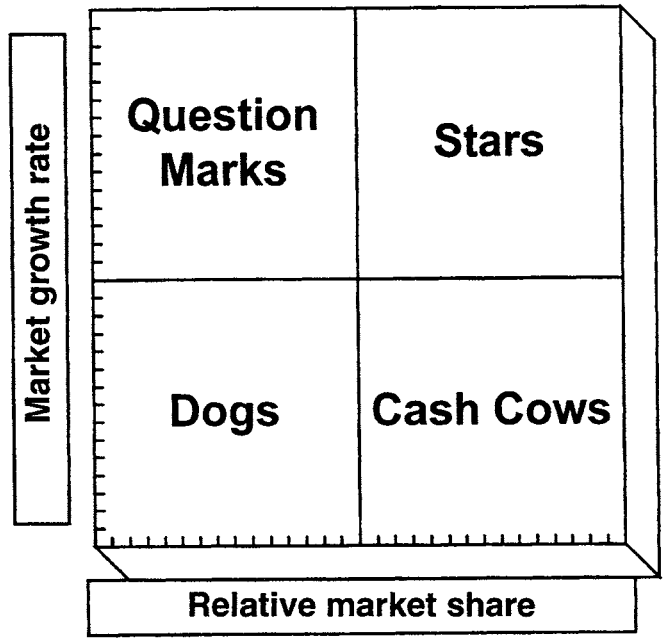
Although the BCG model has offered significant contributions to portfolio analysis, it has certain limitations. These include: (1) it is focused on only two criteria; (2) it assumes a portfolio is in cash balance; (3) it neglects the need to defend market share leaders; and (4) there is no assurance that resource allocation toward stars and question marks leads to increased market share.

Table 10.7: Strategic Implications of the BCG Model

	Stars	**Cash Cows**
Status	High share/high growth market	High share/low growth market
Strategy	Build and invest	Manage for profit and cash generation
	Question Marks	**Dogs**
Status	Low share/high growth market	Low share/low growth market
Strategy	Pick the winners and drop the losers	Niche Harvest: cut costs or increase prices Withdraw: sell rights or delete

(Henderson, 1973)

Figure 10.18. The BCG portfolio model

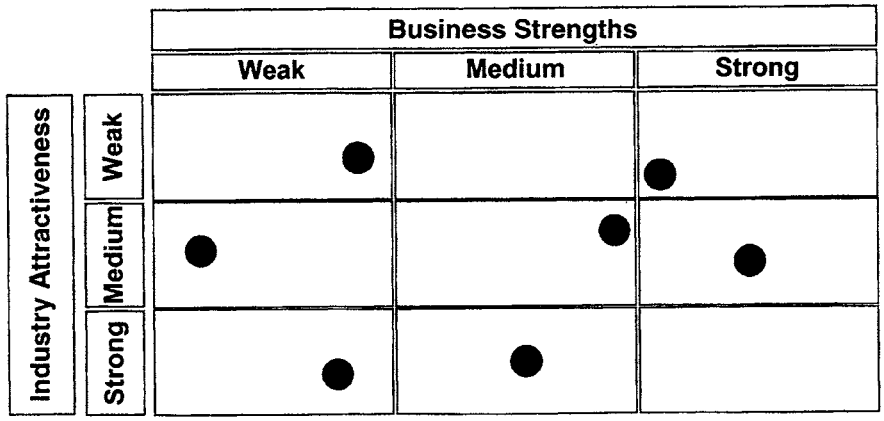


The market attractiveness model

The market attractiveness model (GE matrix) plots the various product portfolio members on a two-dimensional matrix of their business strengths against the industry attractiveness (see Figure 10.19). This model allows wide selection of measures relevant to the specific industry sector under study.

For example, a pharmaceutical market attractiveness model would use the following parameters of business strengths and industry attractiveness.

Figure 10.19. The market attractiveness portfolio model (GE Matrix)



(Rausch, 1982)

Business strengths: Relative product quality, market share, positioning, image, efficiency, market knowledge, management, marketing, distribution strengths, labor and government relations, cost, technology, capacity, patent situation.

Industry attractiveness: Reimbursement mix and coverage, regulation, competitive intensity, price elasticity, buyers' power, substitution threats, technology utilization, market size, market growth, life cycle, cyclicality, stability, scale economies, learning curve.

The directional policy matrix model

The directional policy model (Shell matrix) plots the product portfolio members in a two-dimensional matrix of their competititve capabilities against the prospects for sector profitability (see Figure 10.20). Market segments (or therapeutic areas) of strong competitive capabilities and attractive segment profitability can be easily visualized by industry marketers.

The strategic condition matrix

The strategic condition matrix plots a portfolio's products in various life cycle stages according to their actual or forecasted relative market share (see Figure 10.21).

The product value map

A product value map (see Figure 10.22) plots a product's cost against its benefits. Product B has an average benefit to cost ratio, while product A has an exceptional value (high benefits and low costs).

Strategic fit analysis

A strategic fit analysis compares a project's characteristics to the company's strategic direction. As stated in Chapter 4, all of the company's departments and individual employees should be focused on the common strategic vision of the corporation. Thus,

Figure 10.20. The directional policy matrix (Shell matrix)

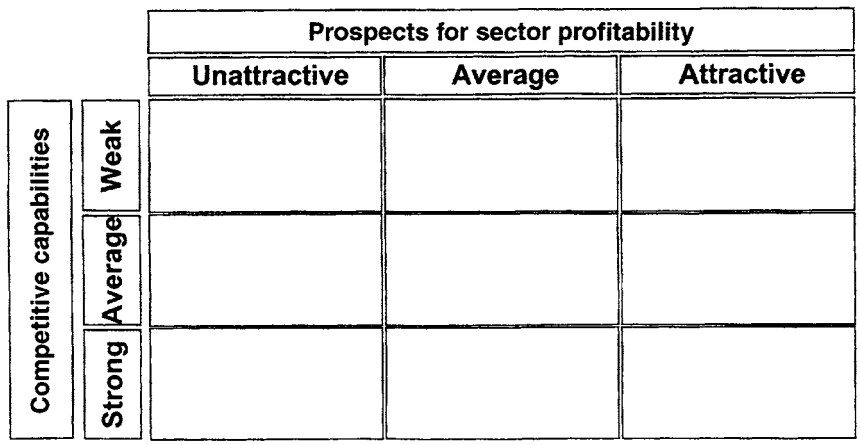
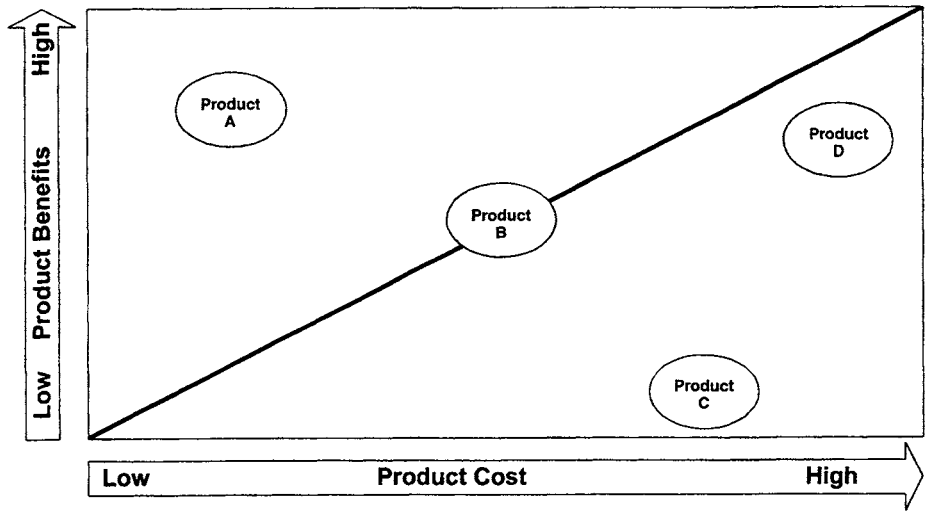


Figure 10.21. The Arthur D. Little strategic condition matrix as applied to the pharmaceutical industry

Competitive position (relative market share)	Life cycle stage									
	Preclinical	Phase I	Phase II	Phase III	Launch	Rapid growth	Shake-out	Mature	Decline	Withdrawn
Weak										
Tenable										
Favorable										
Strong										
Dominant										

(Wright, 1974)

Figure 10.22. Product value map



every potential new project needs to first display a strategic fit with the company's mission. Table 10.8 depicts a strategic fit analysis applicable to the pharmceutical industry.

The strategic intent model

The strategic intent diagram plots several portfolio projects in a two-dimensional matrix showing strategic intent across various market segments. The size of the diagram bubbles indicates the anticipated project costs (see Figure 10.23).

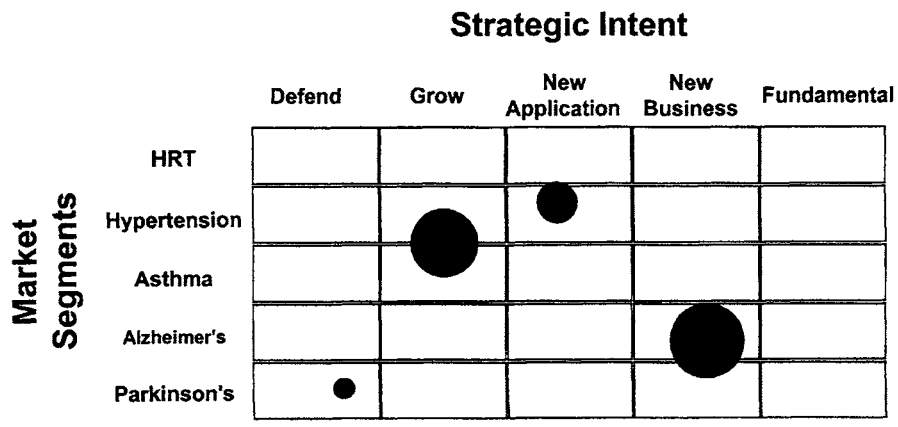
Portfolio Management

Portfolio management is the design, planning, implementation, and controlling of every company's activity that ensures the three principles of a successful portfolio (namely, value maximization, strategic fit, and balance). As Figure 10.24 shows, the activities of product management can be categorized as strategic or operational. The strategic aspect deals with the therapeutic category focus, selecting market segments with significant potential, allocating resources across various projects, assessing development risks, and comparing the project's fit with internal competencies. Project prioritization,

Table 10.8: Strategic Fit Portfolio Analysis

	Strategic Value		Financial Value	
SBU	Cost-sharing or skill transfer translate into competitive advantage or added profitability	Fits with corporate strategic direction	Contributes significantly to corporate performance	Enhances corporate overall worth
A				
B				
C				

Figure 10.23. The strategic intent diagram (Rohm and Haas diagram)



(Cooper, Edgett, and Kleinschmidt, 1998)

progress monitoring, operational resource allocation, and licensing activities are some of the operational tasks of portfolio management.

Portfolio management steps

There are five distinct portfolio management steps (see Figure 10.25). Entering a promising field, building a strong competitive presence, maintaining the captured market shares, managing the portfolio's life cycle, and evaluating the need for the portfolio's divestment are the main steps of portfolio management.

The importance of a balanced portfolio

As previously mentioned, one of the goals of portfolio management is to achieve balance across therapeutic areas, geographical regions, short- and long-term growth, new and older products, and low- and high-risk, as well as each of the company's departments and functions versus the others (R&D versus marketing, and so on). Why is

Figure 10.24. Strategic and operational portfolio management

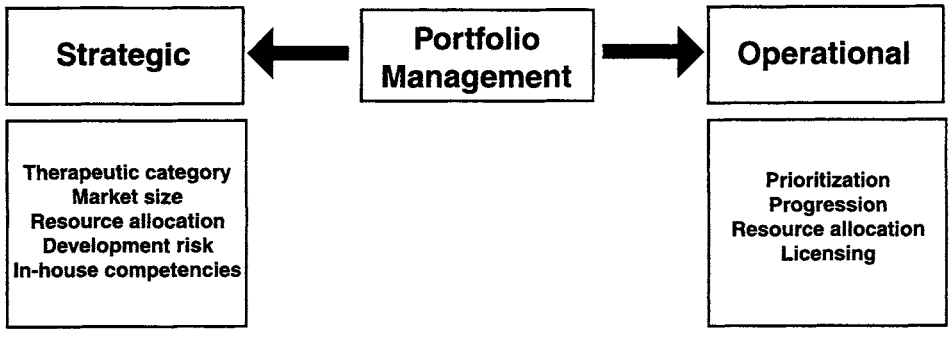
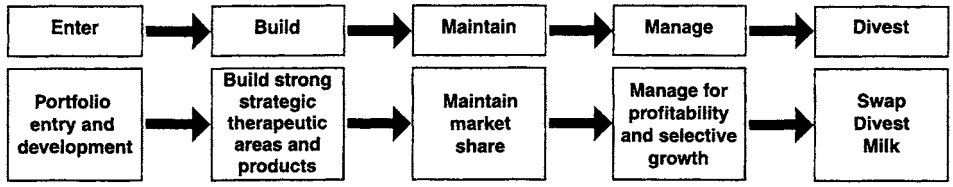


Figure 10.25. Portfolio management steps



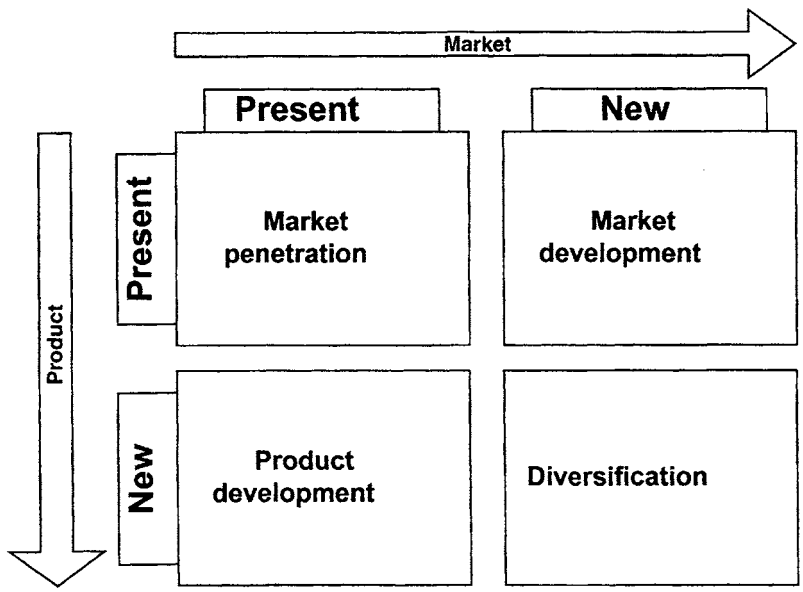
such a balance critical for the long-term growth and viability of the company? There are several reasons, such as risk minimization, efficient resource allocation, maximum return on investment, avoiding conflict, and adjusting to a dynamic market environment. Therefore, industry executives are forced to establish sound portfolio benchmarks, and must constantly evaluate the company's performance against these standards. Making frequent portfolio changes is standard practice in the healthcare environment, now and in the future.

Portfolio strategies

There are multiple portfolio entry strategies available to industry marketers. Figure 10.26 shows some commonly used generic portfolio strategies.

Alternatively, portfolio strategies can be classified according to the number of products in a marketed portfolio or the number of market segments chosen (see Table 10.9).

Figure 10.26. Ansoff's growth matrix



(Ansoff, 1957)

Table 10.9: Typical Pharmaceutical Portfolio Strategies According to Number of Markets/Products

Single market	Parkinson's disease only
Multiple markets	Parkinson's and Alzheimer's diseases of the CNS
Total market	All CNS market segments
Single product	One brand, one formulation
Multiple products	Several brands, dosages strengths, formulations
System of products	Drugs, disposables, and diagnostics in a disease "package"

Resource allocation

Resource allocation is the cornerstone of product portfolio viability and balance. Some of the typical allocation methods used divide resources according to familiarity indices, geographical areas, product lines, project types, strategic goals, technology platforms, and therapeutic categories. The choice of any of these methods is influenced by the resource intensity, and customer, market, and competitor characteristics, as well as a company's preferred practices.

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11

Competitive Strategies

> In 1994, patented prescription medicines accounted for only 3.3 percent of healthcare expenditures in Canada.
>
> PMAC, 1998

Competition in the pharmaceutical industry has been steadily intensifying over the last decades. Currently, there are very few market niches (among hundreds of distinct therapeutic areas) that have remained relatively protected from competition or are competition-free. The vast majority of therapeutic segments and national markets are occupied by several strong competitors who fiercely compete with each other for market share. Additionally, the intensifying regulatory environment, coupled with the lack of innovation and the shortening of product life cycles, has left the competing players with an even more challenging marketplace. This is the operating environment for most industry marketers, who are becoming more focused on competition in their market segments. This chapter discusses the essence of competitive strategy and the tools available for industry players situated in different market shares and with different product life cycle stages.

WHAT IS A COMPETITIVE STRATEGY?

A competitive strategy is the design, planning, and implementation of all a company's activities designed to combat the competition. This strategy's concepts are

closely related to the product and marketing strategy concepts discussed in earlier chapters. Competitive strategy influences product and marketing strategies in such a way that the company will win a *competitive advantage.* Figure 11.1 illustrates competitive strategy, that is, the company develops programs designed to satisfy customer needs, which are then evaluated by the customers, producing a perception of product value. If the product's perceived value is superior to competitors' the product will gain a competitive advantage—the main element of the product's commercial success.

Therefore, gaining a competitive advantage is the essence of every competitive strategy. Furthermore, the competitive advantage must be sustainable over a significant period of time and must not be easily copied and marketed by imitators. Sustaining a competitive advantage depends on resources and capabilities that are durable, nontransferable, and not able to be replicated by other companies. Nevertheless, sustainable competitive advantages (SCAs) erode due to competitive attacks or market evolution. The elements required for gaining an SCA are shown in Figure 11.2. They include superior company resources, superior market position, and superior knowledge and relationships in the marketplace.

Which of the product characteristics or benefits can serve as bases for sustainable competitive advantage? The following is only a small list of potential product differentiation: value, reputation, image, location, access, speed, people, circumstance, size, low cost, legal protection, and competitive weakness. Why is a sustainable competitive advantage so important? Because it ultimately contributes to these two types of company gains: (1) customer attraction and (2) defending against competitors. Both of these gains lead the company to higher profits (see Figure 11.3).

Let us now focus on the competitive strategy framework (Figure 11.4). A company possesses certain strategic assets and strategic skills. Leveraging its assets (such as its product brands and customer base) offers the company one or more alternative bases for differentiation (value, cost, or segment focus). It also influences the competitive strategy the company may follow when holding different relative market share positions. On the other hand, the leveraging of strategic skills (such as enabling R&D technologies or marketing skills) will offer certain competitive alternatives over the industry's life cycle or may influence the choice of its commercial strategies. Before studying the wide spectrum of available competitive strategy possibilities, first consider the various types of competitive market structures.

Figure 11.1. The basis for competitive strategies

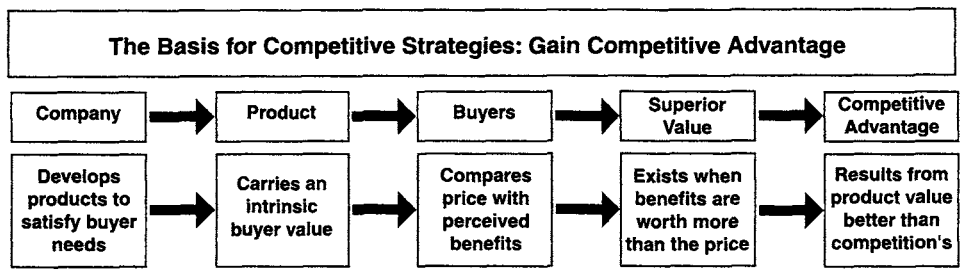
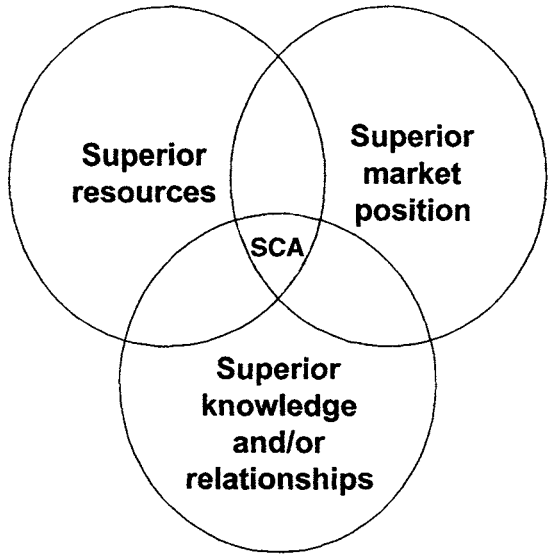


Figure 11.2. Elements of SCA



COMPETITIVE MARKET STRUCTURES

Different therapeutic or geographical areas can present one of four potential competitive market structures. They are pure competition, monopolistic competition (where the sellers mandate product prices in a low regulation market), oligopoly (with few sellers), and monopoly. Table 11.1 summarizes the number and power of sellers, differentiation, price elasticity, and government regulation present.

Figure 11.3. The benefits of a competitive advantage

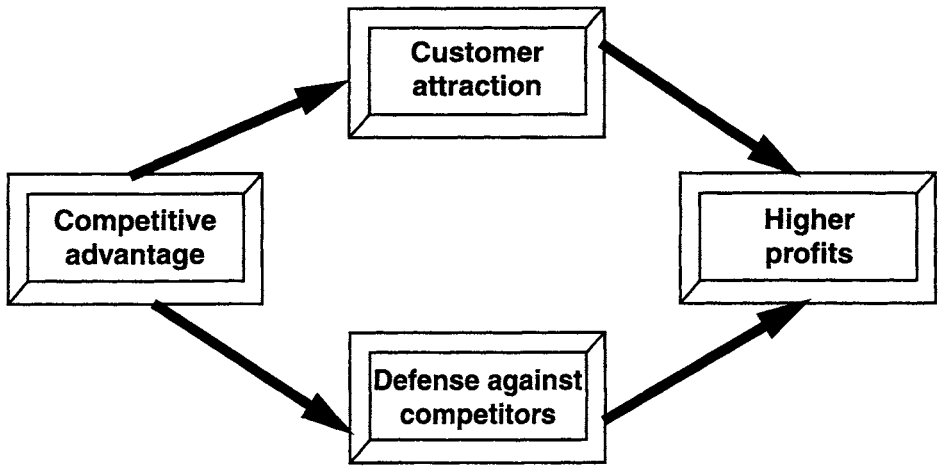


Table 11.1: Characteristics of Competitive Market Structures

	Pure Competition	Monopolistic Competition	Oligopoly	Monopoly
Buyers	Many	Many	Many	Many
Sellers	Many	Many	Few	One
Differentiation	Yes	Yes	Difficult	No
Price setter	Market	Sellers	Sellers	Sellers
Price elasticity	Low	High	High	High
Regulation	Low	Low	Significant	High

COMPETITIVE FORCES

Porter (1985) created the widely accepted model of the five competitive forces acting within every industry. These forces include internal rivalry, the threat of new entrants, suppliers' bargaining power, buyers' bargaining power, and the threat of substitute products (mainly generics in the pharmaceutical market). Adapting this model to the pharmaceutical industry, several experts have added a sixth force—the intense regulation of the industry (see Figure 11.5).

Table 11.2 summarizes the main characteristics and influencing factors of the pharmaceutical industry's competitive setting.

Internal Rivalry

The pharmaceutical industry's rivalry is growing due to globalization, elimination of trade barriers, innovation and technology advances from small- and medium-sized firms, and communication advances that allow easier coordination across foreign markets. Some of the strategic alternatives available to the industry members are value management, science and technology, marketing power, and customer service.

Figure 11.4. Competitive strategy framework

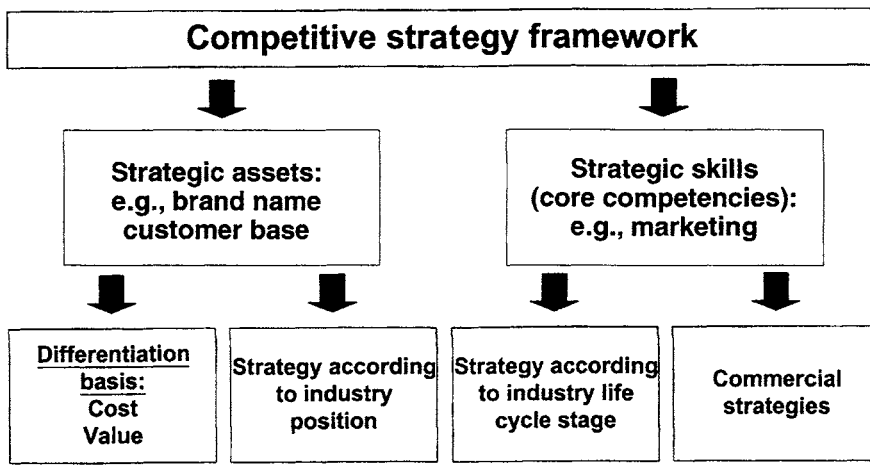
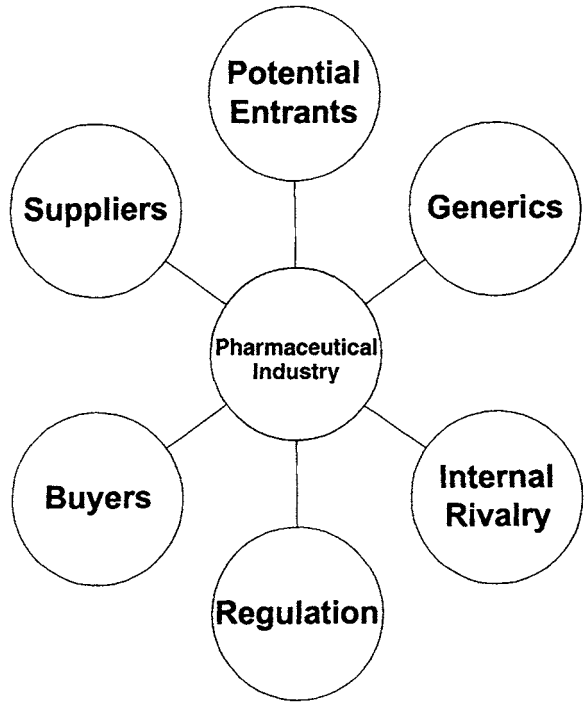


Figure 11.5. Pharmaceutical industry's competitive forces



GENERIC COMPETITIVE STRATEGIES ACCORDING TO WEAPON USED

Figure 11.6 depicts a wide spectrum of competitive strategy alternatives.

Porter (1980) has proposed three main strategic alternatives, namely, differentiation, cost leadership, and focus. In this model, the intensity of cost and differentiation focus may vary, as shown on the two-dimensional matrix of competitive scope and competitive advantage (Figure 11.7).

This book focuses on six potential competitive strategies commonly used in the pharmaceutical industry. They are (1) best value for the money, (2) low cost, (3) broad differentiation, (4) focus based on cost, (5) focus based on differentiation, and (6) vertical integration. The characteristics and respective examples of these strategies are shown in Table 11.3.

GENERIC COMPETITIVE STRATEGIES ACCORDING TO INDUSTRY POSITION

The competitive strategy a company should implement against companies of varying sizes and capabilities is strongly influenced by its relative market share position. The potential strategic options are illustrated in Figure 11.8 and are presented in detail.

Table 11.2: Competitive Forces within the Pharmaceutical Industry

#	Force	Threat	Influencing Factors	Characteristics
1.	Pharmaceutical Industry	Internal rivalry	Several firms equal in size and capability Slow market growth driving market share wars Low profit margins Product standardization Switching costs Exit barriers	Weapons: price, quality, innovation, patents, warranties, distribution channels, promotional campaigns. Trend: rivalry will intensify due to: untapped potential of world's untreated population, increasing globalization, and diminishing trade barriers and open-door investment policies.
2.	Potential Entrants	Threat of entry	Economies of scale Access to specialized technology Product differentiation, customer loyalty Capital requirements Switching costs for buyers Ease of access to distribution channels Existing preferential agreements Regulation Expected retaliation Experience curve barriers	High entry barriers have inhibited the entry of new players into the field. Biggest threat comes from associated industries, through forward (chemical industry) or backward (distributors) integration.
3.	Suppliers	Bargaining power	Supplier concentration Forward integration Industry importance as a customer Product differentiation	They have a bigger impact when their supplies are responsible for large proportion of the product's cost, are essential to the production process, and significantly affect quality. Have impact through price increases. Today's focus: value-added partners and value chain analysis.

Table 11.2: Competitive Forces within the Pharmaceutical Industry (continued)

#	Force	Threat	Influencing Factors	Characteristics
4.	Buyers	Bargaining power	Concentration of buyers Alternative sellers Level of purchase cost for the buyer Backward integration Product standardization Switching costs Profit margins Buyers' concerns about quality Buyers' access to information	They are demanding reduced prices, improved quality, and added services. Individual consumers (patients) and their families and advocacy groups have changing characteristics (e.g., due to aging), increased needs, and a strong voice. Organizational consumers (primary providers and HMOs) are cost-minded, outcomes-driven, and have huge bargaining power.
5.	Generics	Threat of substitution	Better price/performance compared to name brands Competition among generic manufacturers	Imposes ceiling on industry's profitability. Limits price flexibility.
6.	Authorities	Regulation/ Intervention	Political situation Economic situation International collaborations/guidelines/restrictions	Stricter worldwide regulatory environment due to cost-containment measures, political rhetoric, and a negative industry image.

(Adapted from Porter, 1979)

Figure 11.6. Strategic focus

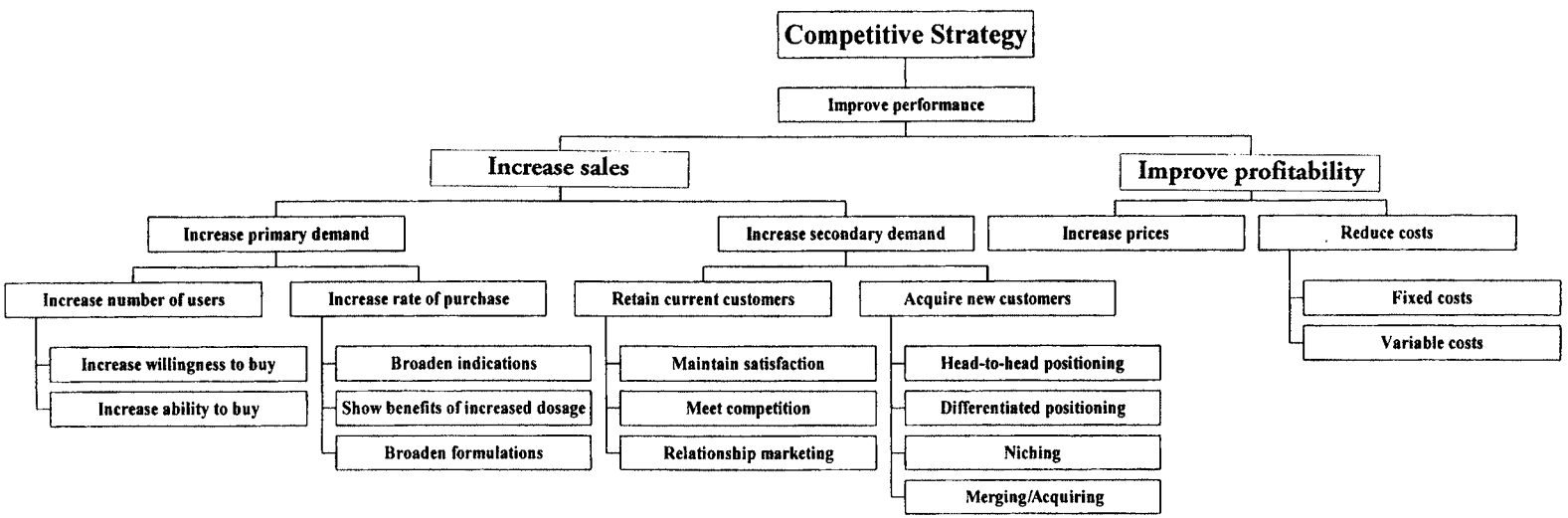
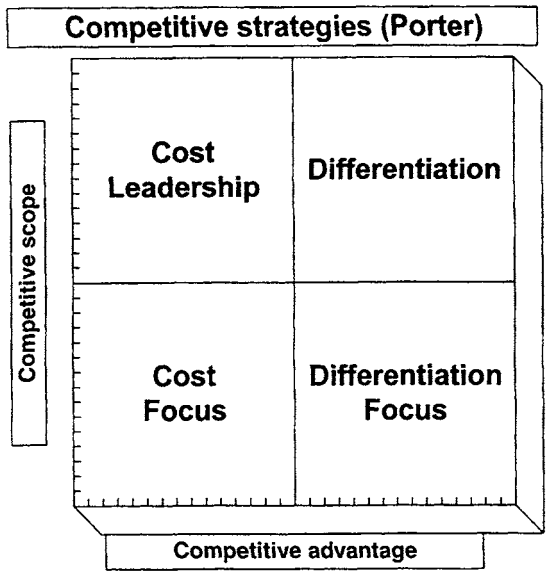


Figure 11.7. Competitive strategies

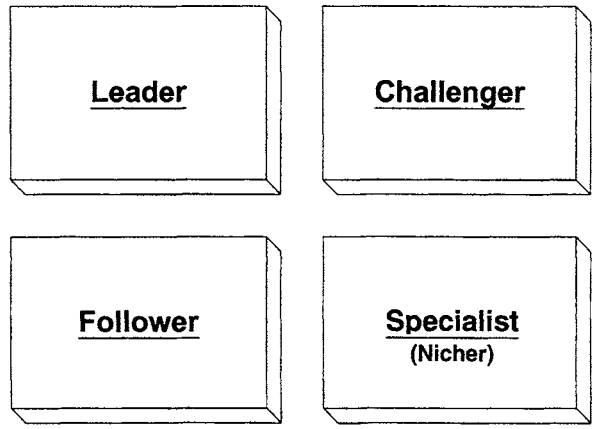


(Porter, 1980)

Table 11.3: Generic Competitive Strategies According to Weapon Used

#	Strategy	Description	Prerequisites
1.	Best value for the money	Improve quality and reduce costs	Stringent quality control and cost analysis reduction.
2.	Cost leadership	Lower the price Increase the profit margin	Mind the costs across the organization, create no-thrill facilities, be thrifty on employee compensation, improve production yield, monitor purchasing activities, re-engineer/diversify under-performing activities.
3.	Differentiation	Therapeutic categories, products, formulations, packaging, customer service	Advanced technology or customer service (core competencies).
4.	Focus based on cost	Target niche segments	Beat the competitors in this segment on costs. Segments must be large enough to be profitable, growing, not crucial to competitors, manageable with own resources, and defensible.
5.	Focus based on differentiation	Target niche segments	Beat the competitors in this segment on providing something different.
6.	Vertical integration	Backward (supply side) Forward (end-user side)	Large volume to cover efficiencies of scale, technological know-how, large capital requirements.

Figure 11.8. Competitive strategies in the pharmaceutical industry



(Kotler, 1994)

Leader

A market leader is the company currently holding the highest market share, even though this market share may not be dominating. For example, there exist different market segments where the biggest competitor may hold a 60 percent market share, while in other, fiercely contested, fragmented markets, the segment leader may hold a 20 percent share. The leader tends to dictate some market characteristics such as prices, promotional intensity, distribution channels, and sales force size. Smaller contestants try to follow these benchmarks when challenging the leader's position.

A pharmaceutical company's market share leadership refers to the national pharmaceutical market as a whole, to leadership within a therapeutic area (such as CNS), to a disease area (such as psychosis), or to therapeutic alternatives of a single formulation type. The competitive strategic objectives of a market leader follow.

Expand the market

- **Attract new users** (market penetration, market development). Example: A public awareness campaign driving postmenopausal women to seek HRT therapy.
- **Discover new uses** (market development). Example: A new clinical trial showing beneficial effects in a new indication.
- **Encourage more usage** (market penetration). Example: New clinical data showing increased clinical benefits at a higher dosage.

Expand market share

- **Increase satisfaction.**
- **Increase loyalty.**
- **Increase repeat purchase** (product modification, market modification, marketing mix modification). Examples: New dosage strengths and formulations; increasing patients' medication compliance; and intensifying advertising or medical detailing.

Defend market share

- **Fixed position defense** (defending present position, a potentially risky approach). Example: Marketing a monotherapy while new competitors market combination treatments.
- **Flanking defense** (limiting competitor possibilities to attack main product). Example: Ensuring long-term contracts with organizational buyers.
- **Preemptive defense** (launching a counterattack before being attacked). Example: A massive sales force expansion, price cut, or new product launching.
- **Counter-offensive defense** (the strategic choice of market leaders when being attacked). Example: Launching a product similar to the competitors' new products, attacking their products on their weak efficacy, or aggressively attacking their cash cow.
- **Mobile defense** (expanding the product line width). Example: If intravenous formulation is attacked, reply with launching a convenient new oral formulation.
- **Contraction defense** (consolidating market segments). Example: Discontinuing the anti-asthma product line and focusing on the cardiovascular line.
- **Erecting barriers to entry**. Examples: Increase promotional spending, increase sales force spending, increase manufacturing capacity, fill product line, block access to distribution channels, strengthen channel relationships, block access to suppliers, raise prescribers' switching costs (via training time or product-device bundling), fill clinical trial centers with own program, increase economies of scale, acquire rights to alternative technologies, protect internal know-how, convert OLs into own product champions, influence regulators via lobbying, negotiate long-term exclusivity contracts, signal commitment to defend, signal high barriers to entry, and lower profit expectations.

Despite the wide possibilities, most experts have expressed the view that investing in R&D is the best market share-defending strategy of pharmaceutical market leaders.

Challenger

A challenger is a competitor with a smaller market share, but similar resources and capabilities. If other product priorities or available resources allow the challenge of the market leader, then a challenger's strategic objective is to gain market share by attacking the target.

The tactics used are the following:

- **Frontal attack** (if weak brand preference, and strong challenger resources). Example: Offer similar new formulation at better price.
- **Leapfrog** (offer better, differentiated product). Example: Launch a previously unavailable treatment combination or administration device.
- **Flank** (go after segment with unmet needs). Example: While the leader is targeting the entire market, go for the elderly segment.
- **Encircle** (go after small untapped segments). Example: Target the pediatric segment.

- **Guerilla** (sporadic attacks on geographic or therapeutic market weak points, through sales promotions, local advertising blitzes, or legal action). Example: Maintain competitive intensity in the U.S. but aggressively pursue the Latin American market.

Follower

A market follower is a competitor who either does not have the resources to attack the leader (but remains innovative and competitive), or someone who is merely focused on survival. The competitive strategies available to followers are:

- **Clone**. Example: A generic pharmaceuticals manufacturer focusing on cost leadership.
- **Imitate**. Example: A manufacturer offering identical strengths and formulations.
- **Adapt**. Example: A manufacturer offering a slightly improved injection device.

Specialist (Nicher)

A market specialist focuses on a specific, small market segment chosen on the basis of cost or innovation differentiation. The competitive strategy, then, is **choosing a niche and differentiating within**. The advantages of this strategy include: (a) reduced rivalry; (b) ability to compete with limited resources; (c) reduced pressure from substitutes; (d) perception by niche customers as affording superiority because of focus; and (e) mass customization (see Table 2.2, page 28). However, a specialist strategy presents the following pitfalls: (a) attracting larger competitors and (b) dependence on a single market.

GENERIC COMPETITIVE STRATEGIES ACCORDING TO INDUSTRY'S LIFE CYCLE STAGE

Generic competitive strategies according to the industry's life cycle stage are described in Table 11.4. Essentially, these are strategies that have been discussed for market leaders, challengers, followers, and specialists/nichers; however, their selection is influenced by the product's life cycle stage.

Generic Commercial Strategies

In addition to the competitive strategies described in Table 11.4, some of the available generic commercial strategies can be classified as shown in Figure 11.9. These include external growth (acquired products), internal growth (products coming from the internal pipeline), and various commercial collaboration alternatives such as product licensing, comarketing, copromotion, or renting an external sales force for increased promotion.

MARKET SIGNALING

Often a competitor does not wish to get involved in a costly defensive battle because of other product priorities. The competitor may decide to use a technique called *market sig-*

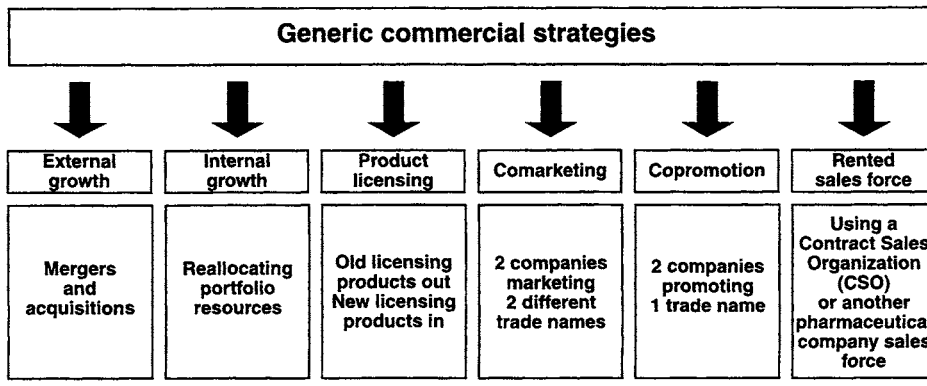
Table 11.4: Generic Competitive Strategies According to Industry's Life Cycle Stage

#	Stage	Strategies
1.	Emerging	Capture new customers.
		Capture new uses.
		Capture new geographical regions.
2.	Maturing	Limit the product line.
		Reduce costs.
		Purchase competitors exiting the industry.
		Expand to foreign markets.
3.	Declining	Focus on specific segments.
		Outsource.
		Re-engineer.
		Consolidate units.
		Diversify units.

naling. This refers to issuing market messages, or "signals," aimed at current competitors or potential new entrants, who disclose their own intentions in case of an attack. Typical reasons for using market signaling include: (1) to gain something bigger than the anticipated costs; (2) to warn the competition; and (3) to define competitive standards of conduct.

A market signal may discourage competitors from imitating a new technology, distribution system, pricing structure, or manufacturing capacity. Examples include: "We can undercut any competitive price reductions"; "We are committed to the region/therapeutic area/product line"; "We do not seek to merge, but are constantly looking for corporate alliances"; "We believe there is a place in the market for generic equivalents, but any penetration over 10 percent will be met by our swift action"; and "We consider our product reimbursement important, but do not plan to leave the market if reimbursement does not materialize." However, market signaling has some associated risks; it gives away information, it causes product line cannibalization, it affects firm's reputation, and it causes antitrust litigation. Therefore, caution and weighing of all competitive strategy alternatives should be employed at every level.

Figure 11.9. Generic commercial strategies



ETHICAL PHARMACEUTICALS VS. GENERICS

One of the hottest industry issues in the 1990s was the increasing industry market share held by generic pharmaceuticals. This clearly represents the threat of substitutes Porter included in his model of competitive forces. In order to evaluate the magnitude of this competitive battle and discuss the competitive strategy choices of the two sides—ethical and generics manufacturers—we will discuss the reasoning behind the phenomenon of therapeutic substitution, the drivers of generic growth, and the most commonly used antigeneric and generic strategies.

Why Substitution?

Therapeutic substitution refers to a patient's course of treatment, other than the prescribed therapeutic treatment that may or may not be pharmacologic, effective, or widely accepted. Who is responsible for therapeutic substitution? The responsible party may be a physician who is copying the patient's original prescription for therapy continuation or is involved in determining if the initial medication belongs to a national or institutional list of "approved" drugs (formulary). The responsible party often may be an institutional pharmacist also charged with checking formulary conformity of the prescribed choice or a retail pharmacist who elects to substitute the prescribed medication with one she or he stocks in the pharmacy. It also can be the patient choosing to selfmedicate with an OTC alternative. Furthermore, it can be the patient's family members who may not believe in the prescribed drug's efficacy or safety characteristics.

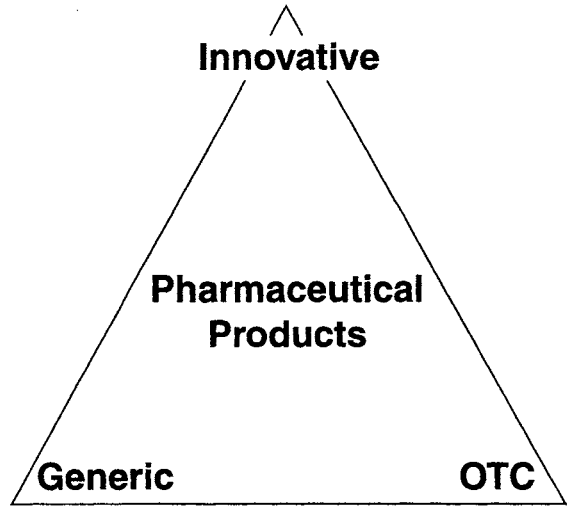
Types of Substitution

There are various types of substitution. A prescribed drug may be substituted by **another original medication** (for example, other therapeutic class, other brand within class, and other formulation within brand), or **a generic pharmaceutical** (for example, generic equivalent brand, other therapeutic class, other brand within class, and other formulation within brand), or even **a nonpharmacologic treatment** (for example, diet, physical exercise, psychotherapy, alcohol, naturopathy, religion, acupuncture, surgery, hypnosis, chiropractic, massage therapy, and homeopathic interventions). The results of therapeutic substitution may be of a different efficacy or safety compared to the original or even may be dangerous for the patient's life. The focus of this chapter is on only one of the many substitution alternatives—that of an innovative, or "ethical" pharmaceutical product (referring to the significant R&D effort that went into its discovery) by a "generic" equivalent (a product with equivalent efficacy and bioavailability of the original, which, however, was developed and approved in an abbreviated manner). This chapter attempts to objectively present the arguments of both sides, explaining the prerequisites of competitor's success and the strategic choices of both sides.

ETHICAL VS. GENERIC INDUSTRY

Figure 11.10 shows the three broad classifications of pharmaceutical products, namely, ethical, generics, and OTC. Ethical pharmaceuticals can be further classified into

Figure 11.10. Pharmaceutical product classes



innovative or commodities (according to their degree of innovation), while generic pharmaceuticals can be prescription or OTC.

Table 11.5 shows the main differences between ethical innovative and commodity products, and generics. One of the main points illustrated in this table is that innovative pharmaceuticals are relatively higher priced, due to their high R&D costs, while generics are usually lower priced, but also can be differentiated in other areas, as shown later in this chapter.

As a measure of their respective market penetrations, Table 11.6 lists the top twenety brand and the top twenty generic pharmaceuticals in the United States prescription market in 1998.

Table 11.5: Comparison of Portfolio Characteristics of Innovative, Commodities, and Generic Pharmaceuticals

Variable	Innovative	Commodities	Generics
Competition	Low	High	High
Competitive advantage	High	Moderate	Low
Development costs	High	Moderate	Low
Initial investment	High	Moderate	Low
Manufacturing costs	High	Low	Low
Market growth	High	Stable	Low
Market penetration	Fast	Moderate	Moderate
Price	High	Moderate	Low
Price competition	Low	High	High
Profitability	High	Low	Low
Promotional cost	Low	High	Low
Risk	High	Low	Low
Skills required	High	Moderate	Low
Target customers	OLs	Prescribers	Administrators, Pharmacists

Table 11.6: Top 20 Brand and Top 20 Generic Drug Sales in the United States

	Brands		Generics	
Rank	**Trade Name**	**Total Rx Retail Unit Sales**	**Trade Name**	**Total Generic Retail Unit Sales**
1.	Premarin Tabs	41,282,000	Hydrocodone/APAP	51,587,000
2.	Synthroid	34,907,000	Trimox	29,928,000
3.	Prilosec	23,981,000	Furosemide Oral	27,151,000
4.	Prozac	23,860,000	Atenolol	27,143,000
5.	Lipitor	22,607,000	Cephalexin	24,996,000
6.	Norvasc	21,067,000	Albuterol Aerosol	24,344,000
7.	Claritin	20,292,000	Propoxyphene-N/APAP	24,220,000
8.	Lanoxin	19,922,000	Amoxicillin	23,898,000
9.	Zoloft	19,364,000	Acetaminophen w/Cod.	23,232,000
10.	Paxil	17,773,000	Alprazolam	22,123,000
11.	Prempro	17,140,000	Ibuprofen	21,785,000
12.	Zestril	16,731,000	Triamterene w/HCTZ	20,007,000
13.	Augmentin	16,375,000	Hydrochlorothiazide	17,089,000
14.	Vasotec	16,158,000	Trimethoprim/Sulfa	16,955,000
15.	Glucophage	16,042,000	Prednisone Oral	16,169,000
16.	Zocor	15,950,000	Lorazepam	15,913,000
17.	Zithromax Z-Pak	15,239,000	Amitriptyline	15,374,000
18.	Coumadin Tabs	14,579,000	Glyburide	13,016,000
19.	Cipro	12,655,000	Ranitidine HCl	12,694,000
20.	Caldizem CD	12,159,000	Metoprolol Tartrate	12,336,000

MARKET EROSION BY GENERICS

Generic pharmaceuticals are products with the same bioequivalence and biovailability as their original counterparts. As Figure 11.11 shows, they also possess good quality and a relatively lower price than their original competitors.

How are these products developed then? Figure 11.12 illustrates the typical steps involved in generic drug development. The patent expiration of a successful name

Figure 11.11. Essentials for introducing a generic pharmaceutical

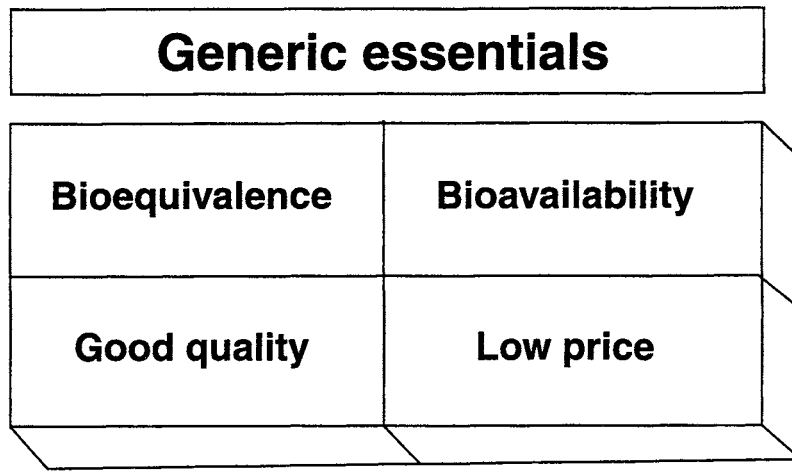
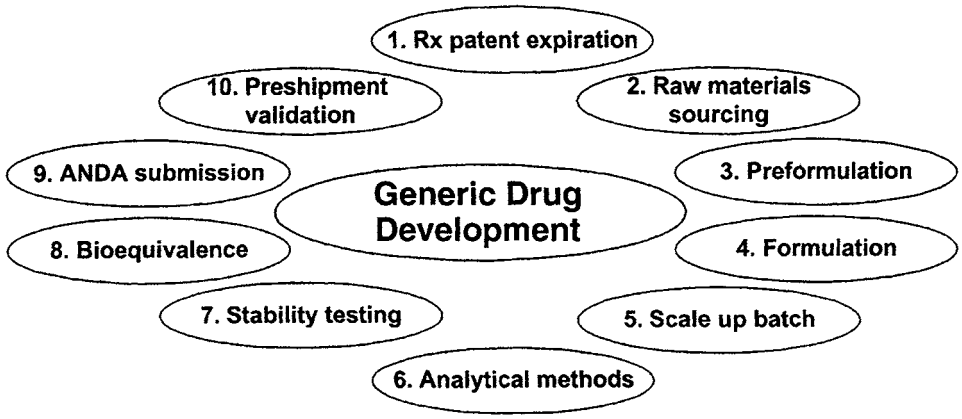


Figure 11.12. Steps in generic drug development



brand product is usually the signal to initiate a generic drug development. In some countries, this development can only start after the actual expiration of the original's patent. However, in others, the development process can actually start at a much earlier point, with the marketing authorization awarded to the generic only after the original patent expires. The second scenario is obviously beneficial to generic development and is a strong opposition point between innovative pharmaceutical manufacturers and the governments that allow it.

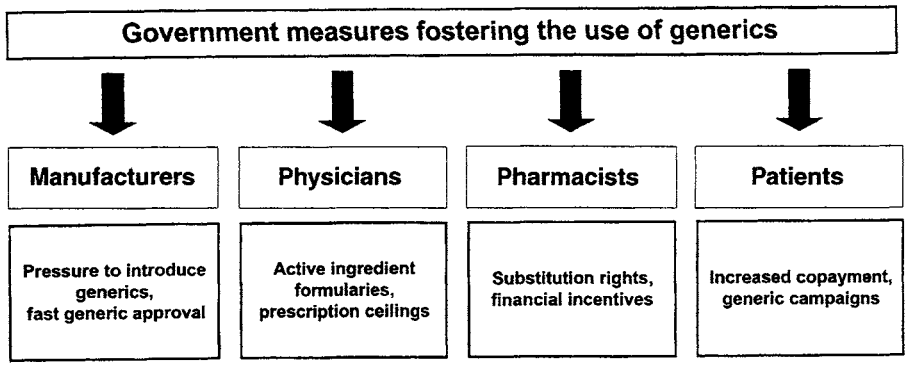
DRIVERS OF GENERIC GROWTH

What, then, are some of the main reasons for the gradually increasing market penetration by generic pharmaceuticals? These include: aging population consuming more medicines on limited finances; managed care growth; government factors (abbreviated regulatory approval policies, pricing policies, reimbursement policies, substitution policies); price competition; value-added benefits (formulation, packaging, labeling); high patient copayment; influencers (physicians, pharmacists, healthcare payers, patient bodies); parallel importing; slow rate of ethical R&D; patent expiration of major ethical blockbusters; and ethical industry's entry into the generics field.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Act) stated that generic drug manufacturers only have to show that the generic product, containing the same active ingredient, is bioequivalent to the branded product, thus reducing their introduction time by six years.

One of the important influencing factors of generic growth is the governmental fostering of generics in several markets for reasons of cost-containment. This increases the competition level among the pharmaceutical industry players and establishes a true managed care environment, where all stakeholders involved are both fiscally responsible and accountable for their healthcare decisions. Figure 11.13 illustrates the main government measures supporting the use of generics today.

Figure 11.13. Government measures fostering the use of generics



GENERICS STRATEGIES

The typical competitive strategies used by generics manufacturers today are actually a case study of Porter's model of competitive strategies, which was discussed in Chapter 10. The tools against innovative manufacturers are cost leadership, differentiation, or focus. Indeed, as Table 11.7 describes, manufacturers employ a variety of tactics in gaining a competitive advantage. Obviously their competitive approaches are working because their market shares in various national markets are growing.

Nevertheless, their marketing efforts are not without obstacles. Generic products often have to face a variety of negative customer perceptions, government restrictions, or image problems that are obstacles to their continuing growth. Table 11.8 lists some problems that are challenging the generics industry to become even more customer-focused and innovative.

ANTIGENERIC STRATEGIES

Faced with increasing regulatory restrictions and a strong competition within the industry and from generics manufacturers, innovative manufacturers are greatly challenged. They see their market shares eroding and that their long-term profitability and survival are in danger. Under these circumstances, they are trying to defend against

Table 11.7: Generics Strategies

#	Strategy	Factor
1.	Cost leadership	Limited R&D requirements.
		Minimum regulatory resource and time requirements.
		Global sourcing of active ingredients.
		Manufacturing economies of scale.
2.	Differentiation	Galenic developments.
		Sophisticated distribution networks.
3.	Focus	Specific therapeutic areas.
		Specific national markets.
		No need to be global to survive.

Table 11.8: Obstacles Generic Products Have to Overcome

#	Stakeholder	Description
1.	Government	Mandatory lower prices than originals squeeze profit margins. Antisubstitution laws or barriers. Barriers to develop and register before patent expiration of originals. Brand-name patent extending regulation (e.g., the General Agreement on Tariffs and Trade [GATT] effective since 1995).
2.	Physicians	Low price is key to patients, not prescribers. Doubt about therapeutic merit. Political pressures to quote original products in publications/ presentations. Reduced sponsorships and services compared to ethical manufacturers.
3.	Pharmacists	Lower prices mean lower profits. May not have substitution rights.
4.	Patients	When reimbursement is full, price is not an issue. Ethical pharmaceuticals possess high brand image.
5.	Segment rivalry	Price erosion. Extreme market comodification (fifty generic equivalents may coexist). Competition for pharmacy space.
6.	Segment image	Negative image of imitators. Isolated counterfeiting cases have tarnished industry image.

generic competition by one of the four strategies described in Figure 11.14. Erecting higher entry barriers, hurrying to develop replacement products, extending their product lines, or entering into the generic arena are some of their approaches. Another method used is aggressive branding. Some of the benefits of a pharmaceutical brand are shown in Table 11.9.

The following list describes some of the antigeneric strategies used by the innovative pharmaceutical industry players (see also Figure 11.14). The innovative industry players should realize that strong environmental factors influence the success of either of the two competitive forces. Furthermore, they should realize that adapting to the new marketplace realities, continuing to provide innovative products with distinct competitive advantage, and packaging strong pharmacoeconomic arguments and disease management programs with new product offerings will give them a strong push forward in the fierce competitive race.

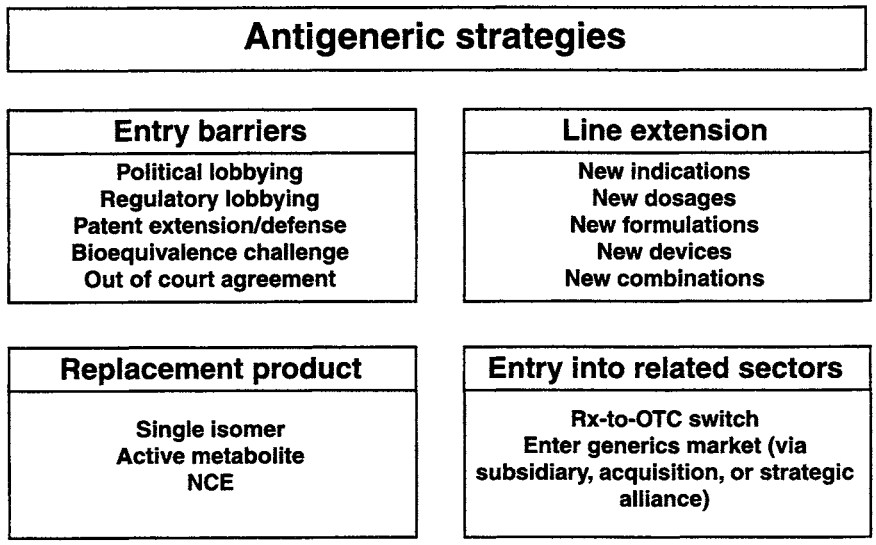
Erect entry barriers: political lobbying, regulatory lobbying, OL lobbying, patent extension/defense, bioequivalence challenge, out of court agreement, establish differential advantage, aggressive branding, aggressive product line "gap" filling, product bundling, lower price.

Replacement product: single isomer, active metabolite, NCE.

Table 11.9: Benefits of a Pharmaceutical Innovative Brand

For Buyers	For Sellers	For Society
Quality	Easier to access/administer	Higher and consistent quality
Efficiency	Protects from copying	Increases innovation
Draws attention to new products	Builds loyalty and profits	Increases customer efficiency
	Assists segmenting	

Figure 11.14. Common antigeneric strategies



Line extension: new indications, new dosages, new formulations, new devices, new combinations.

Entry into related sectors: Rx-to-OTC switch, launch "ultragenerics," or enter generics market (via subsidiary, acquisition, or strategic alliance).

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Part 3

Distribution Strategy

12

Overview of Pharmaceutical Distribution

PMAC members have increased employment by more than 3,300 since 1987, of which, 2,150 are in high-tech medical R&D.

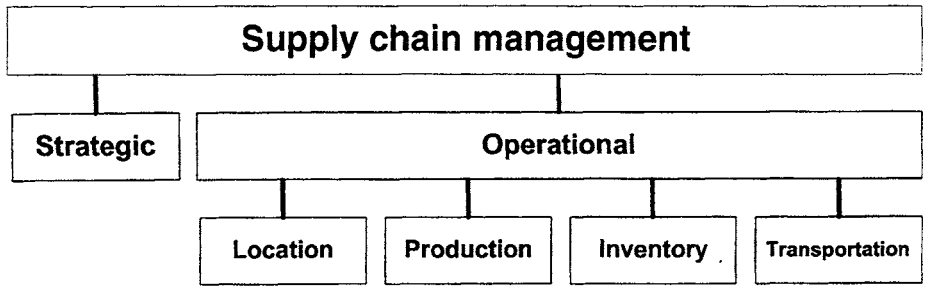
PMAC, 1998

The distribution of pharmaceutical products is of vital importance in their marketing. Indeed, whatever a product's characteristics or benefits are and whatever its pricing or promotional strategies have achieved in other markets, the product's availability at the right time and in the right place is critical to its penetration and long-term success in any given market.

Before discussing the avenues and methods used for distributing pharmaceutical products from manufacturing site to final customers, let us first define some related terms. *Supply chain* is a network of facilities and distribution options that procures materials, transforms these materials into intermediate and finished products, and distributes these finished products to customers. *Supply chain management* is designing, implementing, and controlling efficient supply chain systems. It is used in both strategic (designing, evaluating the outcome, and realigning) and operational (location determination, production, inventory, and transportation of goods across the chain) management (see Figure 12.1).

The tasks of supply chain management are purchasing, sales forecasting, production control, material handling, inventory management, distribution, and customer service.

Figure 12.1. Supply chain management



Logistics is the process of planning, implementing, and controlling the efficient and effective flow and storage of raw materials, in-process inventory, finished goods, and related information from point of origin to point of consumption for the purpose of conforming to customer requirements (Council of Logistics Management, www.clm1.org).

It is now apparent that physical distribution of goods is only one of several tasks of supply chain management. As far as physical distribution is concerned, a *distribution channel* is a group of independent firms composed of manufacturers, wholesalers, and retailers designed to deliver the right set of products to the customers at the right place and time. A *distributor* carries pharmaceutical products from the manufacturing site to either wholesalers or pharmacies (hospital and retail), for a fee. An *agent* brings sellers and buyers together, for a commission. A *broker* is an agent that does not have a continuous distribution relationship with the seller. A *wholesaler* buys pharmaceutical products from the manufacturer and sells to retail pharmacists. A *retail pharmacist* buys pharmaceutical products from the wholesaler and sells to the public.

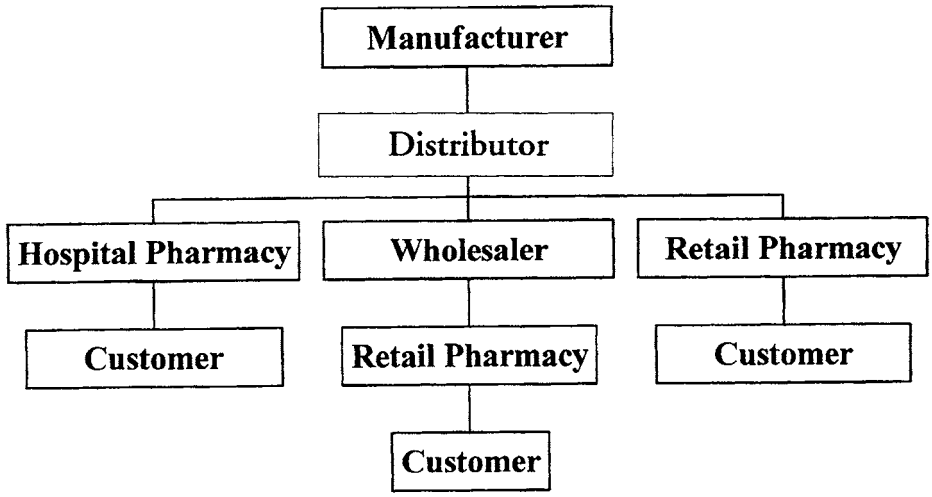
Distribution channels in different markets of the pharmaceutical industry are characterized by varying degrees of integration. In the order of decreasing vertical integration one can identify fully integrated corporate distribution systems, distribution franchises operating under various contractual arrangements, administered systems (where a single mass distributor may have disproportionate power over the remaining distributors), and also the commonly encountered system of multiple distributors and wholesalers.

ETHICAL DISTRIBUTION CHANNEL MEMBERS AND EXCHANGES

Ethical distribution describes the distribution process of ethical prescription pharmaceuticals, that is, the products of ethical manufacturers (those involved in developing new prescription medicines through original R&D) (see Figure 12.2). Alternative routes of pharmaceutical distribution are those used for OTC products or the newly emerging Web distribution, which is discussed later in this chapter.

The main characteristic of ethical distribution is the overwhelming use of distribution intermediaries. Distribution intermediaries are involved with the physical distribution of ethical pharmaceuticals from their manufacturing site to a large number of wholesalers or pharmacies within national, and sometimes international, markets. The main benefit

Figure 12.2. Ethical pharmaceutical distribution channels



of using a distribution intermediary is the reduction of manufacturer transactional contacts with the customers (as shown in Figure 12.3). Additional benefits, as identified by the U.S. National Wholesale Druggists' Association (NWDA), are listed in Table 12.1.

The ethical pharmaceutical distribution channel intermediaries are broker, carrier, contract distributor, depositary, distribution agent, mail distributor, parallel importer, self-distributor, Web distributor, and wholesaler. Furthermore, the ethical pharmaceutical

Figure 12.3. Ethical pharmaceutical distribution interactions

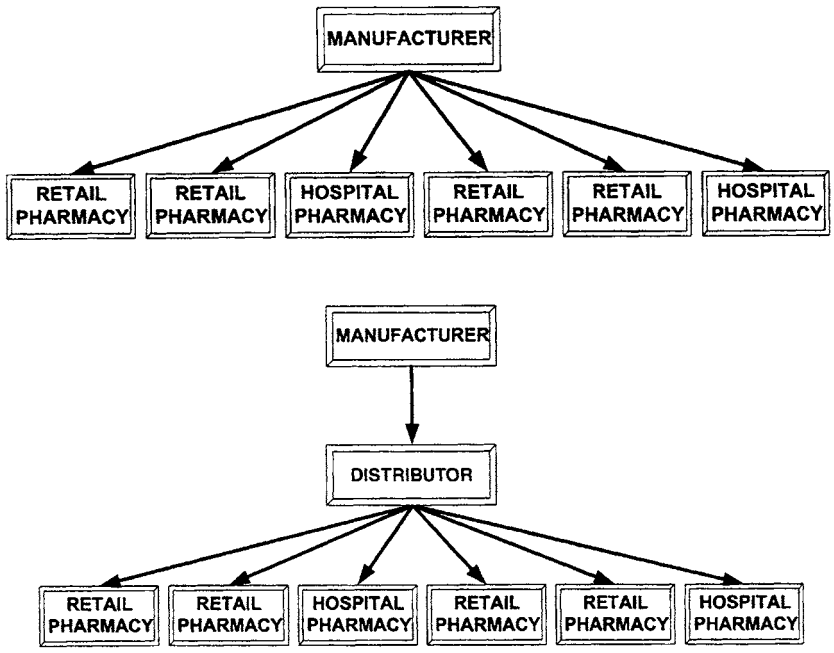


Table 12.1: Advantages of Using Pharmaceutical Distribution Intermediaries

1.	Reduced number of contacts
2.	Efficient performance
3.	Economies of scale
4.	Reduced margins for consumers
5.	Lower expenses for consumers
6.	Warehouse licensing and standardization
7.	Environmentally controlled and secure warehouses
8.	Availability of real-time product information

(Copyright 1999 National Wholesale Druggists' Association.)

distribution customer types are cooperatives, hospital pharmacies, pharmacy chains, retail pharmacies, supermarket pharmacies, and voluntary trading groups. Table 12.2 shows the ethical pharmaceutical sales and market shares in the U.S. market by class of customer. The ethical distribution intermediaries and their customers exchange a wide variety of goods and services, the main types are shown in Figure 12.4.

ETHICAL DISTRIBUTION CHANNEL FUNCTIONS

Distributors

As previously discussed, distributors carry the products from the manufacturers to a large number of customers (wholesalers and pharmacies). During this phase, distributors do not actually take control of the products' ownership, but instead perform their function on a distribution fee basis—either as a distributed unit-related fee or as a percentage of manufacturer's value sales to wholesalers and pharmacies. The services offered by a distributor to the manufacturer vary widely, setting apart low-priced logistic subcontractors and high-end, value-adding integrated distributors. In general, these services may fall into three broad categories, namely, logistic, transactional, and facilitating. Main examples of each are summarized in Figure 12.5.

Wholesalers

As previously mentioned, a wholesaler buys pharmaceutical products from the manufacturer and sells them to hospital and retail pharmacies. In contrast to the distributors,

Table 12.2: Ethical Pharmaceutical Sales by Class of Customer, U.S. Market

Class of Customer	Sales (U.S. millions)	Market Share
Wholesalers	54,714.6	78.4%
Retailers	9,640.5	13.8%
Private Hospitals	1,458.1	2.1%
Practitioners	1,258.6	1.8%
Manufacturers, Repackagers	1,423.8	2.0%
Federal Hospitals	570.2	0.8%
Other Federal Government	317.8	0.5%
State and Local Government Hospitals	415.2	0.6%
Total	69,798.9	100.0%

(Reprinted with permission from Pharmaceutical Research and Manufacturers of America)

Figure 12.4. Ethical pharmaceutical distribution channel exchanges

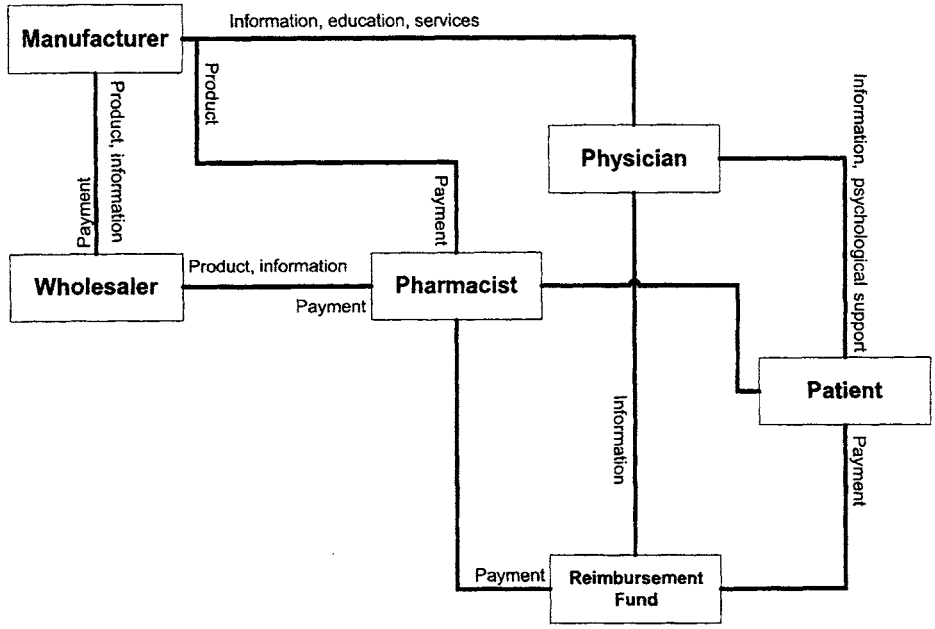


Figure 12.5. Services offered by ethical pharmaceutical distributors

Services offered by ethical pharmaceutical distributors

LOGISTIC	TRANSACTIONAL	FACILITATING
Assortment Storage Sorting Bulk breaking Transformation Order picking Repackaging Regulatory labelling Inventory control Warehouse climate control Retailer stocking Transportation Distribution Sample distribution Literature distribution Reverse distribution Customs clearance Insurance Security	Order taking Invoicing Administration Payment collection Risk taking Factoring Negotiation Marketing (e.g., local advertising) Sales (e.g., in-store displays)	Financing Training Information Quality control Marketing research Complaint gathering Local government lobbying After sales

wholesalers take hold of products ownership and resells them to pharmacies and charges a wholesale margin. Wholesalers can be categorized as full-line (selling all product lines of pharmaceutical manufacturers) or short-line (often engaging in the sale of selected product lines, such as hospital products, opthalmologicals, and so on). Furthermore, they may be multichannel wholesalers (selling to hospitals, retail chains, retail independents, and mail-order pharmacies) or short-line (covering select retail channels only).

Retail Pharmacies

Retail pharmacies belong to large pharmacy chains that span across nations or small-sized independent retail pharmacies. They are characterized by the regulatory requirement of staffing at least one board-certified professional pharmacist, while large-chain pharmacies also employ several pharmacy assistants or technicians. In contrast to distributors or wholesalers, pharmacists are healthcare professionals coming in direct contact with consumers, and thus, require an advanced professional education and continuous training. Strict regulatory requirements apply to the layout and facilities needed for a retail pharmacy. The profession is even a closed system in some countries; meaning that a pharmacy-operating license can only be transferred by a retiring pharmacist to a new one in order for the number and operating standards of that country's pharmacies to be protected.

Hospitals

Hospital pharmacies share several common characteristics with retail pharmacies. They both require the presence of qualified pharmacists, have special storage and security facilities, and so on. Nevertheless, under the healthcare reform environment, these pharmacies do not have the same freedom when ordering and dispensing pharmaceuticals because institutional committees closely monitor their budgets. Usually there are institutional pharmaceuticals' buying committees, which follow strict formulary criteria and cost-containment guidelines. Their mode of operation was presented in Chapter 2.

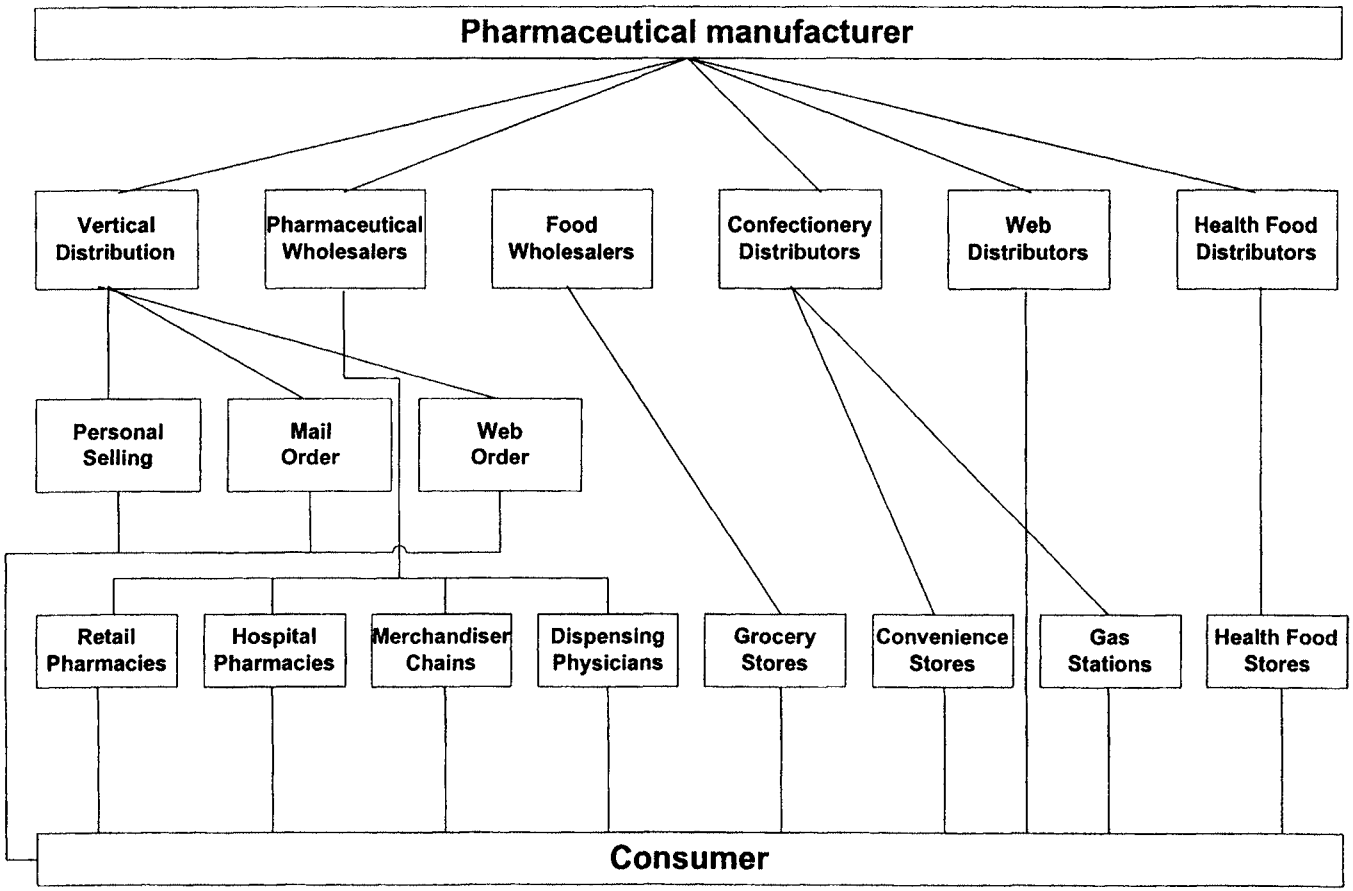
Dispensing Physicians

One of the dying methods of pharmaceutical dispensing around the world is physician dispensing. This method is based on the drug dispensing, and therefore profit-making, rights given by few national governments to their physicians for either historic reasons or necessity mandated by vast rural areas. Japan and China are two countries that allow physicians to dispense pharmaceuticals. Obviously, the presence of this type of pharmaceutical dispensing presents certain disadvantages, for example, the tendency of these physicians to dispense high-priced products or to overprescribe. The system may be mandated by national conditions, and, as such, it may continue to operate in some markets.

OTC DISTRIBUTION

OTC distribution is a network closely resembling ethical prescription pharmaceuticals' distribution. But, based on the relaxed regulations concerning the sale of OTC medications, it is a much wider network, which includes food wholesalers, health

Figure 12.6. OTC distribution channels



food distributors, confectionery distributors, grocery stores, convenience outlets, gas stations, or health food stores (see Figure 12.6).

Whether or not the sale of OTCs is allowed outside the traditional pharmacy setting differs from country to country. Countries with strong pharmacists' trade associations have often protected their right to exclusively market pharmaceuticals to the final consumers, arguing that even nonprescription pharmaceuticals need to be properly marketed and explained to the persons in need.

WEB DISTRIBUTION

The expansion of the World Wide Web revolution around the globe has given rise to a new pharmaceutical dispensing method: patients receiving their medications by contacting a Web-based, or "virtual," pharmacy and having their prescription medications shipped to their home. The number of operating virtual pharmacies is expanding quickly to meet customer needs for increased convenience, privacy, and speed of prescription filling. Some of the different drug dispensing scenarios appearing around the globe are: (1) pharmaceutical manufacturer-operated Web pharmacies; (2) medical Web sites offering information, education, prescribing, and dispensing; (3) Web pharmacies offering cutthroat drug prices; and (4) selfmedication medical sites offering medical advice, computerized diagnosis of selected diseases, and pharmacy referrals.

Nevertheless, there are still several unsolved ethical aspects that need to be addressed by the relevant healthcare ethical and legislative bodies so that several potential problems are averted. For example, prescription authentication is almost impossible by a foreign-based virtual pharmacy; dispensing of unregistered products to the ordering patient's country presents serious regulatory problems; and getting prescription pharmaceuticals without a prescription or with a virtual prescription presents problems. These are issues that need to be resolved soon by the setting of a legal framework. The reader may find more insights into the Web revolution in Chapter 20.

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13

Distribution Strategy

> Spending by PMAC member companies in universities and hospitals created up to 3,800 research jobs in 1995.
>
> PMAC, 1998

The design, implementation, and control of distribution strategy are some of the most important tasks of the overall marketing strategy. This strategy is a part of the overall logistics strategy that involves both inbound materials and products and outbound materials, parts, or finished products logistics. The outbound materials, parts, or finished products go to their customers (either the final consumers or finishing manufacturing sites) adding the final step in the manufacturing, processing, and packaging of the products).

This chapter presents an overview of the key channel decisions, the criteria for selecting a distributor, and a brief presentation of the various logistic functions and costs, as well as a discussion of the important issue of parallel exporting, which greatly affects pharmaceutical marketing strategies in certain regions.

KEY CHANNEL DECISIONS

What, then, are the main channel decisions a distribution manager is called to properly evaluate and decide upon? The five most important issues are: (1) channel

intensity, (2) channel length, (3) channel integration, (4) key distribution functions, and (5) channel conflicts.

Channel intensity refers to the number of distribution intermediaries and retail outlets a manufacturer is using in order to reach the final customers, an issue that is discussed later. *Channel length* refers to the levels of a distribution network covered by any single channel, that is, whether the channel reaches the final customer or only mediates the distribution of products between the manufacturer and another intermediary (for example, a wholesaler). *Channel integration* is an indicator of distribution activities' consolidation within a single player (such as pharmaceutical manufacturer). It also indicates whether or not the manufacturer is using various contractual schemes to outsource the distribution function. Recent years have witnessed the increasing vertical integration of manufacturers, namely, the acquiring of external distribution networks and their integration into the manufacturer's supply chain. The managed care reform and the desire of the manufacturers to "control their destiny" (or contain their costs in a fiercely competitive market) mandated such moves. Nevertheless, the little experience gathered does not overwhelmingly support such an integration, especially when outsourcing of noncore competency areas are a must for manufacturers trying to focus on innovative R&D in their therapeutic area niches.

EXTENT OF DISTRIBUTION

The extent (or breadth) of the distribution decision determines the number of wholesalers, and, ultimately, retail outlets that will be carrying the product. As far as prescription pharmaceuticals are concerned, most countries have pharmaceutical distribution laws that mandate the full and uninterrupted availability of all prescription medicines at all retail pharmacies throughout the country. Therefore, it is not up to the manufacturer to decide which retail pharmacies to use, but only to decide on the number of distributors who will supply these pharmacies. A common phenomenon is stocking as many retailers as possible with a new pharmaceutical during its launch period because this is required before the territory's prescribers can prescribe the product to their patients. The decision to stock or have it delivered just-in-time is a critical decision for the pharmacist too, because a critical case (e.g., a life-threatening infection) cannot wait for a distribution delivery to the pharmacy and the patient's family may decide to search for it at another location. A frequently chosen strategy is the manufacturer (or a wholesaler) contacting its collaborating retail pharmacies, informing them of the new product launch, and offering special introductory payment terms if the pharmacists stock the new medicine. The continuation of this policy depends on the prescribers' and patients' acceptance of the new medication, which ultimately makes the product available in more outlets and eliminates the need of special terms offered to select pharmacies.

In contrast to prescription medicines, OTC medicines are items with a low customer decision involvement and a high switch rate if a specific product is not available at the point of purchase. Therefore, they require wide availability in as many points of sales as possible, and an intensive distribution strategy is indicated. Table 13.1 shows some of the advantages and disadvantages of the various intensity distribution breadths.

Table 13.1: Breadth of Distribution

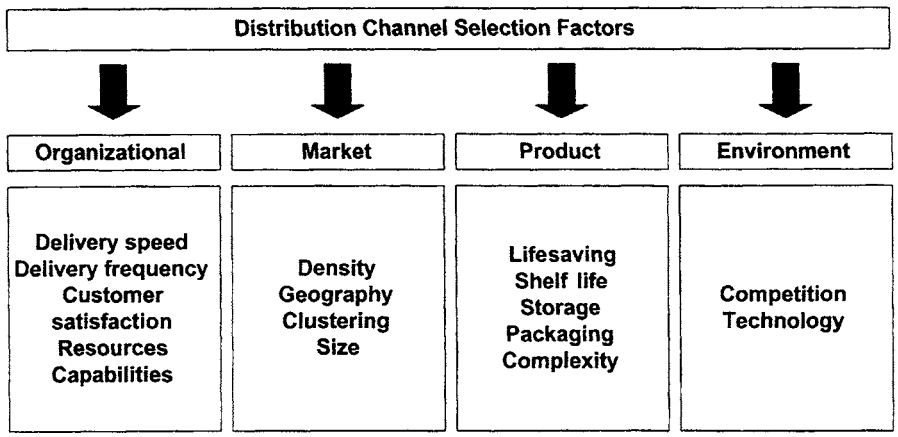
	Intensive	Selective	Exclusive
Advantages	Easy to select	Specialty items	High service support
	Frequent purchases	Carefully chosen outlets	High prices
Disadvantages	Price competition among outlets	Requires retailer effort	Reduced purchases

SELECTING A DISTRIBUTOR

The decision to select a distributor is a critical one for the organization. It requires careful strategic planning from the organization, delicate negotiations with the potential distributor (often with current distributors fearing their profit margin erosion) and painful and time-consuming changes if a distributor has not met the company's expectations. There are a variety of selection factors for a new distributor. These factors can be categorized as strategic or operational, or as organizational or market-, product-, and environment-related (see Figure 13.1). **Strategic factors** are those having to do with the desired distribution intensity, the frequency and speed of distribution, or the required level of customer satisfaction. On the other hand, market-, product-, or environment-related factors are those imposed by the intrinsic characteristics of these three forces. **Organizational factors** are strategy-related, mandated by the company's intended level of service, desired customer satisfaction level, and internal resources and capabilities. These issues are very closely related to the work of marketing and product managers who have determined the required levels of customer service and satisfaction for the company's products to gain a competitive advantage. Furthermore, the tools of situation and competitor analysis, which are both described in following chapters, can help determine the internal resources and capabilities, as well as the required KSFs in the field of distribution.

Market characteristics such as size, density, geography, clustering, urbanization, and infrastructure largely affect distribution decisions and are critical to the overall commercial success of pharmaceutical products. A variety of technological tools are

Figure 13.1. Distribution channel selection factors



available today from third parties that can precisely describe geographical territory characteristics, monitor the progress of a distribution shipment, and provide on-line data for fast decision making.

Distribution strategy-related product characteristics include their lifesaving potential, their shelf life and storage requirements, and their packaging and distribution complexity. Obviously, lifesaving, hospital products require frequent and fast deliveries, while special storage needs require special facilities along the supply chain. Furthermore, a product's packaging may require protective repackaging for shipment or may render standardization difficult (e.g., ability to palletize), which increases the complexity of distribution. Additionally, competitive supply chain strategies and the availability of technological tools along the distribution path are significant factors in a product's distribution strategy or in selecting its distributors.

In conclusion, the selection of distributors should be a carefully designed process, involving a multidisciplinary team of experts—internal and external to the organization—working to optimize the distribution function and achieve higher customer satisfaction.

LOGISTICS FUNCTIONS

The company's logistics functions involves both inbound and outbound functions. The first deals with materials and resources coming into the organization for manufacturing, processing, or finishing, and the second deals with any activity related to the handling of manufactured goods to their customers. Figure 13.2 shows the main logistics functions. The next few pages are devoted to only a brief overview of these activities.

Materials Management

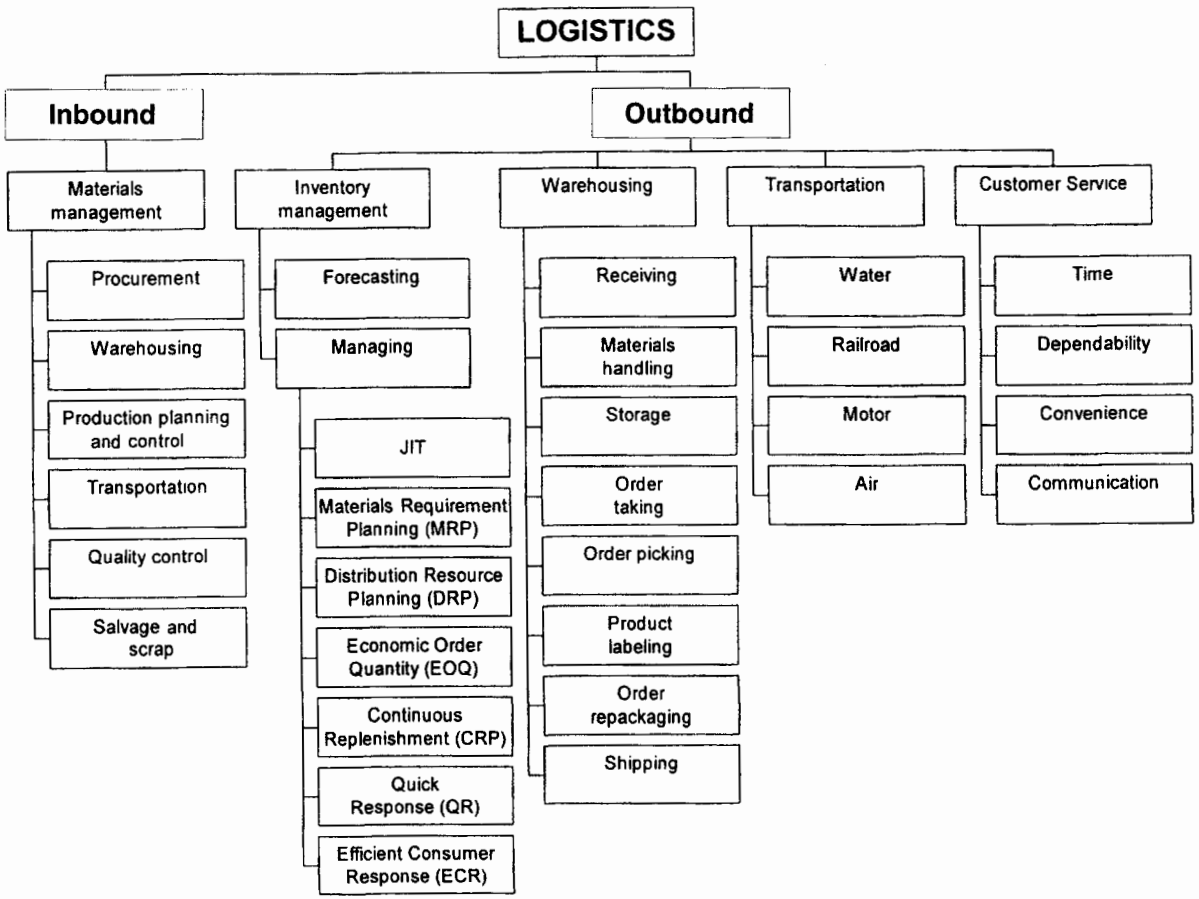
Inbound logistics are involved with the management of inbound materials. It includes the planning of production needs, procurement of the required raw materials, quality assurance (adhering to strict internal standards), transportation to the manufacturing site, and salvaging or scrapping quantities unused by manufacturing. Each of these steps plays a critical role in the uninterrupted supply of high-quality products, and should be managed by pharmaceutical manufacturers effectively and efficiently.

Inventory Management

The management of the finished goods inventory is probably one of the most sensitive issues in the industry today because of accusations of creating excessive overhead costs or being responsible for costly stock-outs in times of unpredicted high demand. Nevertheless, despite the high costs involved, maintaining a sufficient inventory is essential for the following reasons: purchase economies, transportation savings, safety stock, speculative purchases, seasonal supply, maintenance of supply, production savings, and substitute supply.

The strategic decisions of defining the optimal inventory level and containing its costs are central to a company's supply chain management. The levels of inventory are related to the product characteristics (customer type, lifesaving potential, storage requirements, expiration date) or various market characteristics (size and growth,

Figure 13.2. The main logistics functions



influencing trends, demand cyclicality and seasonality, tender bidding, retailer demands, and so on). All of these factors should be factored efficiently when estimating each product's future demand. This process is called forecasting, which is discussed in detail in Chapter 21.

Warehousing

A host of tasks and activities are associated with product warehousing, such as receiving and storing, collecting customer orders, picking, labeling, and repackaging the ordered goods, and making them ready for physical transportation to customers. These activities are shown in Figure 13.2.

There are several types of warehouses used by the pharmaceutical industry. They range from vertically integrated facilities to fully outsourced warehouses kept by third parties. Some types of warehouses include: (1) **private**: kept by sole firm; (2) **public**: with own, as well as other companies' stock; (3) **bonded**: avoiding taxes and tariffs until product is ready to be sold; (4) **field**: when a firm requests receipt of goods in warehouse (i.e., to use as loan collateral), value is negotiable; and (5) **contract**: kept by third party. Selecting any given type depends on the company's strategic intent, its internal resources and capabilities, and specific market conditions that exist in every national market (such as the evolutionary stage of third-party warehousing facilities, special legislation, profitability issues, and others).

Materials handling during warehousing involves the unloading and loading of product, transferring to and placing in their storage place, and transporting them within the warehouse for labeling, bar coding, and repackaging purposes. This handling can be manual or mechanized. Some of its important issues are movement, quantity, time, and space.

Repackaging involves placing product goods and product information (e.g., patient information leaflet) together into one package. It also includes special labeling of the outer packaging in country-specific manners, placement of the individual customer-ordered quantities in their shipping containers along with the accompanying shipping documents, and bar coding for easier processing. Some important issues for repackaging are the following: interior packaging (e.g., PIL, patient information material), exterior packaging, packaging materials (type, recyclability, size, variance, transportation mode, palletization), and corporate branding.

Transportation

Physical distribution, or transportation, involves the shipment of the finished and repackaged goods to customers via water, railroad, motor, and air. Powerful shipping specialists exist in almost every market. These agents are subcontracted by the manufacturer or its distributors using one of the following legal arrangements: common, contract, exempt, and private. In addition to the integrated or mode-specific shippers, there are a variety of other transportation intermediaries, such as small-package carriers, freight forwarders, brokers, and intermodal (between various modes, e.g., between water and air) marketing companies.

An important component of the shipment is the accompanying document commonly known as the *bill of lading,* which describes the origin of shipment, receiver's

address, and transportation contract terms. It also serves as a receipt of goods and a certificate of title of the goods.

When selecting a transportation agent, a manufacturer/distributor should pay attention to the following: (a) transportation rates, (b) minimum weight requirements, (c) loading and unloading, (d) packaging and blocking, (e) damage in transit, and (f) special services (e.g., payment collection, reverse transportation).

Customer Service

One of the most important issues in pharmaceutical distribution is the degree of customer service provided by the various supply chain members. The strategic importance of this issue is clear in view of the fiercely competitive marketplace conditions existing in major markets, as well as the need for customer satisfaction in building a sustainable competitive advantage. Table 13.2 lists some customer service variables in ethical pharmaceutical distribution.

Defining the minimum required customer service level, as well as ensuring each member of the supply chain meets that level is a challenging task for pharmaceutical manufacturers. Nevertheless, a multidisciplinary team is helpful in setting the standards, while specialized customer service personnel should evaluate and control channel member performances. The latter can be enforced by using contract term or brand leverage by the manufacturer.

REVERSE DISTRIBUTION OF EXPIRED QUANTITIES

Reverse distribution of pharmaceuticals refers to the product distribution from its final customers back to the manufacturer's warehouse for reasons of product expiration or product recall. This activity represents a significant cost in both expired/discarded quantities and reverse distribution costs. Therefore, it should be managed efficiently by the manufacturer. Increased information and reminders to retailers or high manufacturing QA standards, play a significant role in reducing reverse distribution.

DISTRIBUTION-ASSOCIATED COSTS

Costs related to a product's distribution activities arise from a variety of sources. Table 13.3 lists some of the most common ones.

The detailed measurement of each distribution-associated cost and a continuous effort to increase the distribution system's efficiency are two of the most important aspects of supply chain management. Enterprise-wide systems and other information technology tools help manage the supply chain.

Table 13.2: Customer Service Variables in Ethical Pharmaceutical Distribution

Condition of delivered goods	Order size	Order convenience	Delivery terms
Invoicing accuracy	Claims procedures	Order cycle time	Order status information
Inventory availability	Delivery reliability	Delivery consistency	

Table 13.3: Common Pharmaceutical Distribution-Associated Costs

1.	Direct Sales	Order processing and shipping and handling costs of directly shipped products.
2.	Sales Discounts and Allowances	Costs related to offering discounts, rebates, and allowances.
3.	Credit Extension	Costs resulting from delayed customer payments, especially state hospitals.
4.	Market Research	Market research costs associated with assessing customer service levels and so on.
5.	Warehousing and Handling	Capital, human, insurance, and maintenance expenses for warehousing.
6.	Inventory Levels	The cost of inventory kept, expiration costs, and so on.
7.	Packing, Shipping, and Delivery	Repackaging, labeling, IT, insurance, and shipping costs.
8.	Order Processing	Order taking, invoicing, payment collection, and communication costs.
9.	Customer Service	Information, training, added service, and communication costs.
10.	Returned Merchandise	Expired or recalled merchandise reverse distribution and destruction costs.

PARALLEL EXPORTS

One of the most controversial issues within the pharmaceutical distribution framework is the phenomenon of parallel imports, which is seen mainly within the boundaries of the European Union. The origin of this phenomenon may be attributed to the free competition and antimonopolistic policies of the European Union initially expressed in the Treaty of Rome. Essentially, the work of parallel importers is triggered by price differentials among the member states and is protected by the Treaty. Thus, they buy pharmaceuticals from countries with low prices and import them into countries with higher prices, bypassing the manufacturers' local pricing strategies and pocketing the price difference. Obviously, the practice of parallel importing represents a serious threat to manufacturers' profitability, who are actively seeking new and effective ways of limiting this problem. The following list contains some of the factors influencing the parallel trade of pharmaceuticals in Europe.

Sustaining Factors: national price controls and bargaining power of parallel traders.

Limiting Factors: *Pricing counter-measures:* Pan-European pricing strategies, direct negotiations with parallel importers, and discounting in parallel-import prone areas; *Nonpricing counter-measures:* Pan-European launch, product differentiation among different markets (formulations, strengths, packaging, labeling), attach added value to locally purchased quantities, restrict sales in certain countries to their needs, refuse delivery to suspect wholesalers; *Other:* self-erosion due to competition, regulatory barriers, political solution, legal measures, exchange rate fluctuations, and introduction of the Euro.

Manufacturers influenced by parallel exports, should carefully evaluate the above strategies and implement those suitable on a country-by-country basis.

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Part 4

Pricing Strategy

14

Pricing Concepts

> While Canadian prices of patented medicines are strictly controlled by the Patented Medicine Prices Review Board (PMPRB)—and have increased at half the rate of inflation since 1988—other factors, such as utilization and an increasingly aging population, also affect total drug costs.
>
> PMAC, 1999

Pharmaceutical marketers trying to define a proper price for a new product have a variety of pricing tools available from other industries. Nevertheless, pharmaceutical products bear distinct differences from consumer goods in their price-setting considerations. First, the patient often does not pay for his or her medication, which instead is reimbursed by national governments with varying price sensitivities. Second, activists and politicians alike often complain of "ever escalating drug prices," without giving any consideration to the R&D costs involved or even to their own expectations from their pension fund that invested in pharmaceutical company stocks. Third, all patients deserve the best possible treatment for their disease, regardless of actual cost if the drug is reimbursed or "symbolic" cost if it is not. Finally, the notion of health care as a social good that must be universally provided criticizes private pharmaceutical manufacturers who must address the needs of their stockholders, in an ever more competitive environment.

This chapter attempts to place the pharmaceutical pricing issue within the perspective of healthcare regulation, reimbursement, and pharmacoeconomics, and evaluate the importance of these parameters in the successful pricing and marketing of pharmaceutical products.

ELEMENTS OF PRICE

Price is the value attached to a product or service. Price has many names: fee, price, rent, tuition, taxes, and fares. In the business world, price is one of the main elements of the marketing mix. Thus, is both closely related to and supportive of the other marketing mix variables. Price is also directly related to company revenues. Therefore, the pricing decision is very important. These are discussed in the following chapter. *Value* is a buyer's perception on the worth of the seller's offering. This value is affected by three factors: the seller, the buyer, and the competing sellers. Thus,

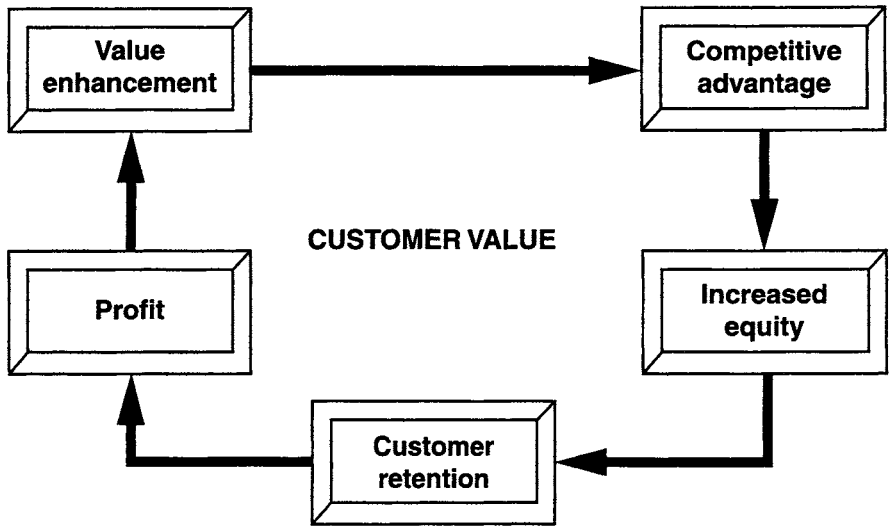
$$\text{Value} = \text{Perceived benefits} - \text{Acquisition cost}$$

Customer equity is the value of the customer to the company.

Figure 14.1 shows the customer value cycle that exists in all industry sectors, including pharmaceuticals. Value enhancement of the company's product offerings leads to a competitive advantage and this leads to increased brand equity. This, in turn, leads to customer retention, which generates profits that complete the cycle by perpetuating the value enhancement process.

Profit is generated when the selling price exceeds costs. Profit making is often criticized by many as unnecessary seller's greed. The public images of obscure billionaires leading extravagant lives on the profits of a trivial consumer good irritate most hard-working people around the globe. Thus, large profits create a negative image of those

Figure 14.1. Customer value cycle



organizations, eventually giving the respective industry sectors a certain "aura" of profiteering and waste. Such feelings, however, arise from ignorance about the significance of business profit in free enterprise economies. Indeed, sustainable profit is the only factor responsible for long-term viability of a company. It offers the resources required to invest, acquire new technologies, develop new products, enter new markets, and, overall, remain competitive in a dynamic business environment. This is the notion of the operating profit, and should not be confused with profiteering or personal greed of the seller.

The pharmaceutical sector is a profit-driven enterprise. The industry customers, namely, prescribers and their patients, are largely unaware of the huge investment costs and years of R&D required to introduce a new pharmaceutical product to the market. In addition, wellness and health are considered basic human rights. Thus it is often considered that pharmacological treatments necessary for life should be offered free to the consumers. The high cost of a long-term pharmacological effect, even produced by a tiny quantity of medicine, makes the comparison to consumer goods' or luxury items' pricing impossible and irrelevant. Furthermore, in an era of increased worldwide regulation of the pharmaceutical industry and cost-minded governments, industry profits are often under criticism, negatively affecting the industry's public image.

Price as a Marketing Mix Variable

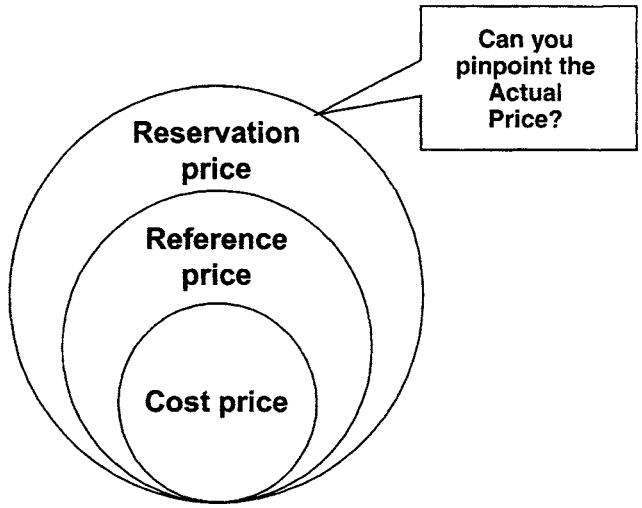
As mentioned earlier, price is an important marketing mix parameter. Together with the other variables, it is related to sales volume and, ultimately, to the company's profits. Furthermore, price is the final determinant of the value customers will attach to the product, and must reflect product characteristics and benefits very closely. Some of the characteristics of price are the following: (1) it is a comparable measure; (2) it is a signal of quality and value; (3) it affects the image; (4) it is a competitive weapon; and (5) it affects the sales volume.

While customers see only the product's value in the price, marketers see more elements to it. As Figure 14.2 shows, a product's price structure includes such terms as cost price, reference price, and reservation price. *Cost price* is the price level that allows the company to merely cover its costs with sales revenue or break even. *Reference price* is the price level relating to a set reference, such as the initial product's launch price or a national price or the price of the product as related to a well established product. Furthermore, *reservation price* is a price at a higher, "reserved" level. Setting the actual product price is related to the company's pricing strategy, which is discussed in Chapter 15.

Price in the Economy (Supply and Demand)

A product's price affects the quantity that will be purchased by customers as well as the quantity that will be produced by the seller. Furthermore, a high price will probably make the product only available to the affluent, while a low price will make the product available to the masses. Two important terms often studied by marketers are supply and demand. *Demand* is the quantity that consumers are willing and able to pay for a given product at a given price. As the product's price increases there is relatively less demand

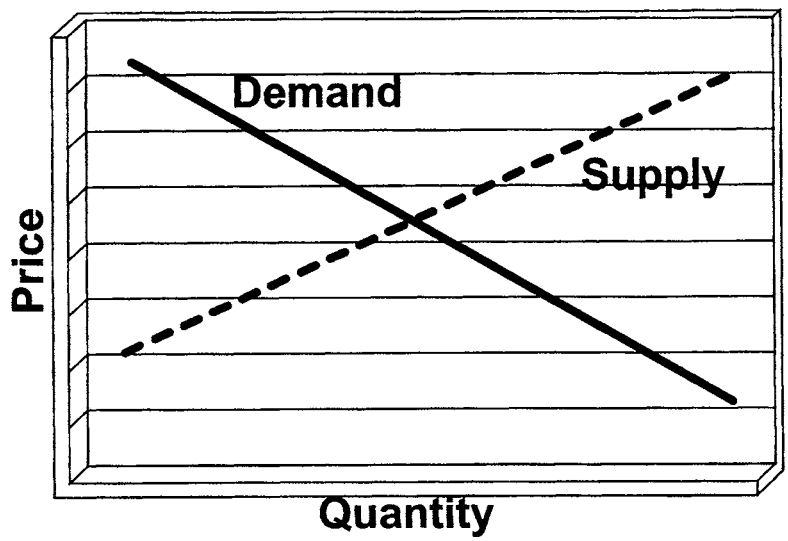
Figure 14.2. A product's price structure



(see Figure 14.3). *Supply* is the quantity of a product that a seller is willing and able to sell at a given price. As product prices go up, so does supply. In Figure 14.3, the intersection of the Supply and Demand curves indicates the market size at a market price.

Close study of the relationship between the price charged and the quantity purchased (demand) is essential in the setting of the actual price level, and thus a main focus of a pricing strategy.

Figure 14.3. The Supply and Demand curves



MULTIPLE PHARMACEUTICAL PRODUCT PRICES IN A SINGLE MARKET

Due to the complexity of healthcare systems and the government regulations surrounding the price of pharmaceuticals worldwide, pharmaceutical multinationals may need to set multiple price levels in different markets. In addition, due to the variety of different purchasing customers of pharmaceutical products in a healthcare system, there can be a wide spectrum of prices across the supply chain. The following list explains some of the different price levels found within a single national market.

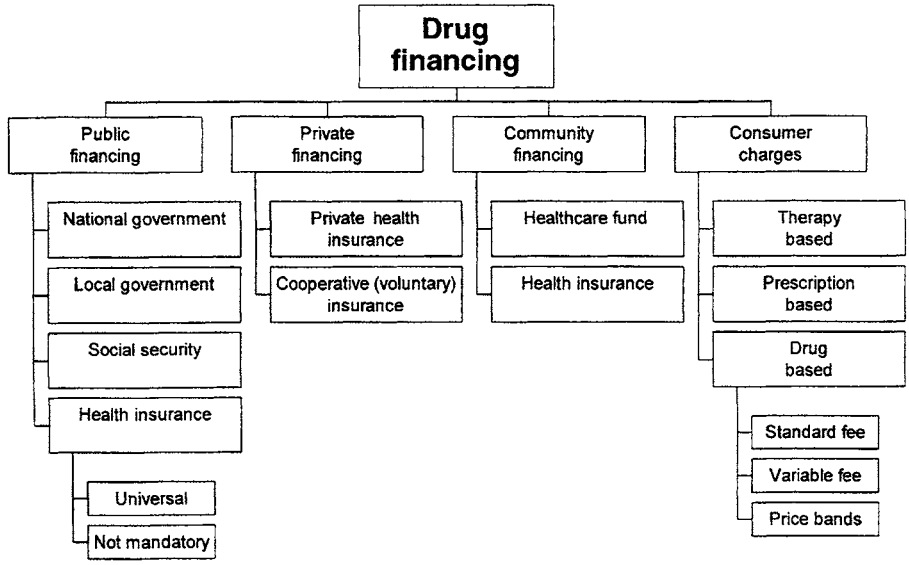
Cost price: the price equivalent to the costs required for the product's manufacture. This changes according to the quantity produced due to the existence of fixed and variable cost centers. *Discount price* (where allowed): the reduced (from the regular price level) price offered by any member of the pharmaceutical supply chain. This is a closely regulated concept in most countries to avoid price wars within a healthcare system. *Hospital price:* the price of pharmaceuticals the hospital charges its inpatients or discharged patients (or their insurance agency). *FOB price* (Freight on Board or Free on Board): a price charged by a pharmaceutical manufacturer to an importer that includes the shipping charges up to a prespecified point of shipment. This point is not the importer's warehouse, but the original point-of-entry into the country. *Import price:* a price inclusive of manufacturing and shipping costs, as well as import taxes. *Net-to-hospital price* (ex-factory-to-hospital or Average Selling Price [ASP] to Hospital): the price a pharmaceutical manufacturer charges a hospital pharmacy. This is usually a highly regulated price. *Net-to-physician price* (where allowed): the price a pharmaceutical manufacturer charges the dispensing physicians (a practice limited to few countries today). *Net-to-wholesale price* (ex-factory-to-wholesale or ASP wholesale): the price a pharmaceutical manufacturer charges the wholesalers. *Retail pharmacy price* (public purchase price [PPP] or public price): the price the retail pharmacy charges the public. *Tender price:* the price offered by a pharmaceutical manufacturer in a sealed bidding to a hospital or government tender. It may be significantly reduced from the average net-to-hospital prices. *Transfer price:* a price charged by a foreign manufacturing site to its local subsidiary entity. It is directly related to the subsidiary's profit margins and has important tax implications. *Wholesale price:* the price the wholesaler charges its retail pharmacy customers.

PHARMACEUTICAL DRUG FINANCING

An industry marketer involved in setting the price of his or her company's products needs to be very familiar with the drug financing system in the respective markets. This is due to the fact that many discrepancies exist in the way and level of drug financing across national markets or even geographical regions of the same market. Furthermore, the substantial price increases of new, innovative products often are the focus of cost-minded politicians who are looking for ways to reduce the healthcare bill—looking first at the price of pharmaceuticals and last at the inefficiency costs of healthcare institutions.

The main methods of drug financing in most countries are shown in Figure 14.4. These are broadly based on a long-term financing scheme (insurance, social security, and so on) or a fee-for-service consumer copayment. The level of national healthcare spending is often a hotly contested issue and is usually in the 5–8 percent of the gross

Figure 14.4. Drug financing methods in different healthcare systems



domestic product range in most industrialized countries. On the other hand, the patient copayment level is an important determinant of the adoption rate of new pharmaceutical products. Therefore, both standards are very important for setting a marketing strategy and must be carefully considered in industry's business planning.

GOVERNMENT PRICE CONTROL

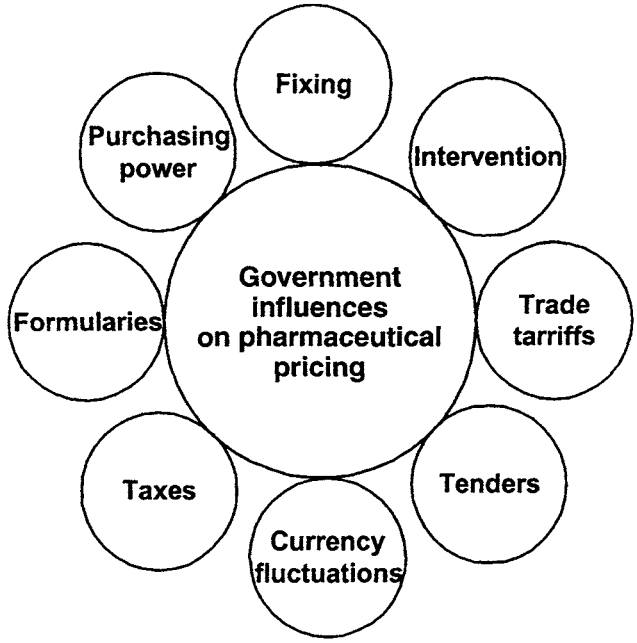
National or local governments significantly influence pharmaceutical prices around the global market environment. Figure 14.5 shows some of the government influences on pharmaceutical pricing.

Industry leaders have taken diverse stands on the issue of government intervention; that is, some elect a low-profile approach, while others opt to confront the issue. Regardless of the final outcomes, it remains extremely important for the industry to stand behind the relevant trade associations to protect its profitability and long-term viability. Conversely, the industry's fragmentation and opposing agendas will only weaken its position against its competitive forces (remember Porter's Five Competitive Forces) and will lead to a long-term detrimental effect.

REIMBURSEMENT

Reimbursement refers to the level of government or private payors' financial coverage of healthcare products and services used by consumers. In the case of pharmaceutical products, this coverage comes from one of the existing drug financing methods discussed earlier. In general, healthy citizens (receiving vaccines, mothers in delivery, and so on) and patients are charged by their primary provider (physician, hospital, and so on) for health services and products, which are wholly or partly covered by the payor

Figure 14.5. Government influences on pharmaceutical pricing



(state or private) and partly by the consumer. The contribution of the latter is also called the consumer's copayment.

Different healthcare systems are characterized by different levels and systems of healthcare reimbursement. This characterization is related to the economic strength of the state payor, the contribution structure of the private payor, the severity and duration of the disease covered, or the costs of the product or services utilized. The four most common systems are (a) the standard percentage system (all medical interventions reimbursed with the same percentage); (b) variable percentage (disease states categorized according to severity and duration, where the most severe is reimbursed the highest); (c) price bands (medical interventions reimbursed up to a certain percentage based on price); and (d) price ceilings (where all interventions are reimbursed up to a certain fixed price ceiling). Typical disease reimbursement levels are 100 percent for chronic and severe diseases (cancer, AIDS, multiple sclerosis), 75–90 percent for less severe but chronic diseases (asthma, osteoporosis), and 50–75 percent for other ailments. Faced with the growing healthcare costs, several payors are gradually lowering their copayment levels, which automatically raises the patient copayment contributions.

Another very important issue in pharmaceuticals reimbursement is the issuing of state reimbursement formularies or "lists," which include products reimbursed by the state. When these lists include those reimbursed products they are called *positive reimbursement lists*; lists of nonreimbursed or excluded pharmaceuticals are called *negative lists*. Under these circumstances, it is critical for the commercial success of any given product to be included in the list of reimbursed pharmaceuticals because the insured or covered part of the population is usually the majority of the population.

The inclusion method, then, is the predetermining factor for a product's inclusion or exclusion into the reimbursement lists. Different governments have instituted a wide spectrum of inclusion methods, ranging from the all-inclusive automatic systems, to the long and hotly debated reimbursement negotiations between the government reimbursement committees and the pharmaceutical manufacturer. Some of the most common reimbursement inclusion systems follow.

Automatic, across the board: Resource-rich nations opt to offer complete reimbursement of all new pharmaceutical products. The reimbursement's date of effect can be simultaneous with local registration, or local pricing (in countries with split registration-pricing systems), or a certain time after launch (one year, five years, and so on). *Automatic, but coverage related to disease state:* All new products are reimbursed but only up to a percentage of price according to the degree of disease severity. For example, anti-cancer products are fully reimbursed, while NSAIDS are reimbursed 50 percent. *Automatic, but coverage up to a maximum ceiling:* All new products are reimbursed up to a certain price ceiling. For example, an economic anti-allergy medication is reimbursed 100 percent because it is below the ceiling, while an expensive oncological is reimbursed 50 percent because it is priced at double the price ceiling. *Daily treatment cost based:* New pharmaceutical products are compared on a daily treatment cost basis, figured by multiplying the recommended daily dosage by their unit price. All drugs below a therapeutic class average are reimbursed while those above are not reimbursed. This system ignores the total treatment cost differences and the overall decrease of morbidity caused by an apparently expensive product as opposed to a less effective cheaper alternative. This system supports the use of older, lower-priced or generic pharmaceuticals. *Therapy cost based:* New pharmaceutical products are compared according to their total therapeutic cost, or, if chronically used, according to their annual costs. Only those costing below a set average are reimbursed within each therapeutic category. *Outcomes based:* New products are thoroughly compared to an existing "reference" drug on the basis of extensive clinical outcomes data (over a long period of time and with a large number of patients). Data on new products are collected during their clinical trial phases, while existing drugs use clinical trial and postlaunch treatment data. The comparison is done with the use

Figure 14.6. The role of pharmacoeconomics

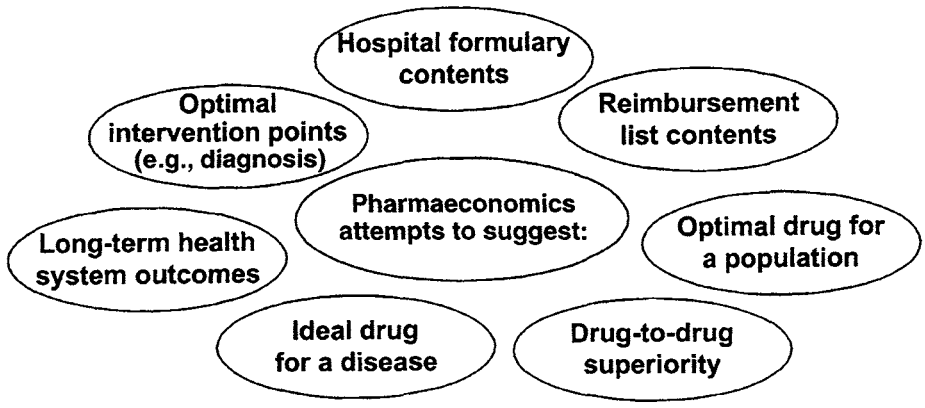
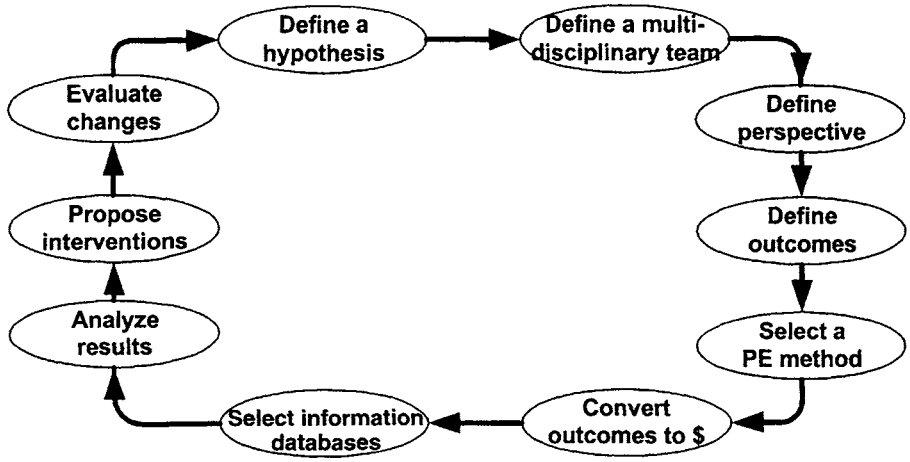


Figure 14.7. A pharmacoeconomic study process



of special analytic tools, which are developed by the modern science of pharmacoeconomics, presented next.

PHARMACOECONOMICS

Pharmacoeconomics is the systematic analysis of pharmaceutical product and care services' costs and their impact on patients, healthcare systems, and society. Increasingly, it is being used in healthcare environments around the globe. Therefore, use of this

Table 14.1: Major Pharmacoeconomic Techniques

Cost-analysis	Studies the total costs of a medical intervention: direct (medical and nonmedical), indirect (lost income), and intangible (degree of suffering). Also determines the cost of illness, identifies cost savings, and predicts cost impact. It does not study the outcomes.
Willingness-to-pay analysis	Evaluates the patient's willingness to pay for alternative medical procedures with different costs.
Outcomes analysis	Typical clinical trials involved in studying efficacy and safety, or quality of life. Does not study costs.
Cost-benefit analysis (CBA)	Studies the relation between costs and benefits of a project, and compares similar projects on the basis of these results. Both costs and benefits are evaluated in dollar amounts and are compared.
Cost-effectiveness analysis (CEA)	Divides the per-unit-benefit by the per-unit-output when a project involves multiple modules of basically the same service. Benefits are not evaluated in dollar amounts, but, instead, compares the costs of alternative means of achieving the same benefit.
Cost-minimization analysis (CMA)	Attempts to identify the least costly alternatives in providing health care.
Cost-utility analysis (CUA)	Studies the quality-adjusted life years or other utilities associated with the chosen medical intervention.

analysis by the pharmaceutical industry is required for success. Figure 14.6 shows the main role of pharmacoeconomics.

Pharmacoeconomics' focus is on the direct, comparative, and indirect costs of pharmaceutical product and care services among large numbers of individuals. A typical pharmacoeconomic study process includes the components described in Figure 14.7.

The analysis of pharmacoeconomic data is performed by the use of special techniques, such as cost-benefit, cost-effectiveness, cost-minimization, and cost-utility analyses. A description of these analytic tools is given in Table 14.1.

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15

Pricing Strategy

> The failure to have prescriptions dispensed and/or refilled has resulted in an estimated cost of 8.5 billion U.S. dollars for increased hospital admissions and physician visits—nearly one percent of the U.S. total healthcare expenditures.
>
> APhA, 199

Before describing the pricing objectives and strategies pharmaceutical companies follow, consider the following two scenarios. A patient suffering from hay fever needs a decongestant and plans to spend some personal money to buy an OTC product from the local supermarket pharmacy. At the same time, a hospital pharmacist is looking to replenish some of her antibiotic inventory by using hospital funds for ordering a product included in the managed care hospital formulary. Both the individual patient and the pharmacist have a therapeutic need, varying degrees of product knowledge, and access to money needed (their own or the hospital's budget). Therefore, they are both potential buyers of a pharmaceutical product.

Proper pricing involves matching the price to buyer value. Costs are only partly involved in the pricing process. If the buyer's perceived value is low, the price offered by the seller may seem much higher and thus, low product sales may be inevitable. However, if the buyer's perceived value is high, the offered price may seem low in the eyes of the buyer, and this results in high volume sales. Therefore, a product's

perceived value should be known in advance, and the ideal price should be matched to the value. Lowering the price to match the value may be limited by high manufacturing costs, and the price setting should include the detailed analysis of fixed and variable costs. This cost analysis may even create dramatic savings by reducing a single cost, leading to increased profit margins. On the other hand, the perceived value or other market conditions may allow a high price, maximizing the profit. Competitive pricing is another important factor because comparative product prices and their perceived value may lead to the product's success or market demise. Finally, after a product's price is set using its own perceived value and other competitor and market factors in its launch market, different national market and pricing environment conditions will demand their own complex considerations. After these are done, does the price of a product remain the same throughout its life cycle? The answer is definitely no. For instance, government tenders may require fiercely competitive pricing, or large customers may require special prices, or sagging demand may mandate short-term price discounts.

This chapter discusses the different price-influencing factors, explains the price elasticity principle, and presents the most commonly used pricing strategies for new and established pharmaceutical products.

PRICE-QUALITY STRATEGY

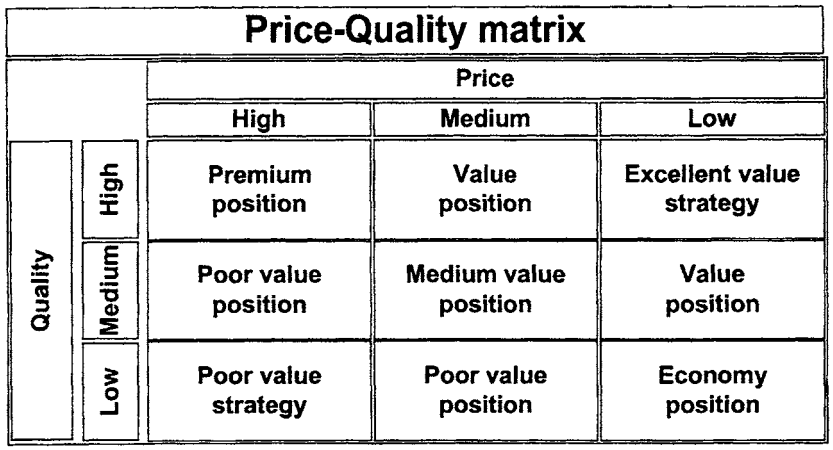
As previously mentioned, pricing involves matching the price to a buyer value. What does the value of a pharmaceutical product represent to a prescriber/patient then? It may represent the product's high efficacy and safety, good tolerability, lack of drug interactions, ease of administration, fast onset of action, no dependence, no need for hospitalization, no days lost from work, sales location convenience, and so on.

After determining a product's value, how does a customer decide what price he or she will pay? A customer determines a price by comparing the relevant value of the product's characteristics and benefits to the alternatives, and then decides what this difference represents to him or her. Obviously, if a new product holds a differential advantage over the existing alternatives, then the customer attaches a higher value to this product and is willing to pay a higher price for it. If, on the other hand, the product is no better or less efficacious than the existing alternatives, or it is equal in all characteristics and benefits but the customer must drive fifty kilometers to find it, then the new product is of a lesser value to the customer. He or she may be willing to pay only a lesser price than for the easily found alternative.

If the manufacturer estimates the relative values a customer is attaching to the different product alternatives and prices his product according to its perceived value, then the product will have a good sales performance. The different relationships that may exist between the final price and the relative values the customer is attaching to each of the product characteristics and benefits are illustrated in Figure 15.1. If the product possesses a characteristic of high customer value and has a low price, then the manufacturer is said to follow an excellent value strategy.

The customer value of pharmaceutical products can be evaluated through various market research techniques, described in Chapter 5. The determined relative value of the various product alternatives are compared using a value analysis ranking shown in Table 15.1.

Figure 15.1. The price–quality matrix



Furthermore, the estimated value index of alternative product substitutes can be plotted against their actual price in a two-dimensional map. This helps visualize products that have better value-to-price ratios than their competition (see Figure 15.2).

Figure 15.3 shows the different price-setting steps. A company's marketing team sets the pricing objectives of the organization, assesses customer demand, sets the pricing policies and strategy, and, finally, sets the price range, which may be adjusted periodically.

SETTING A PRICE OBJECTIVE

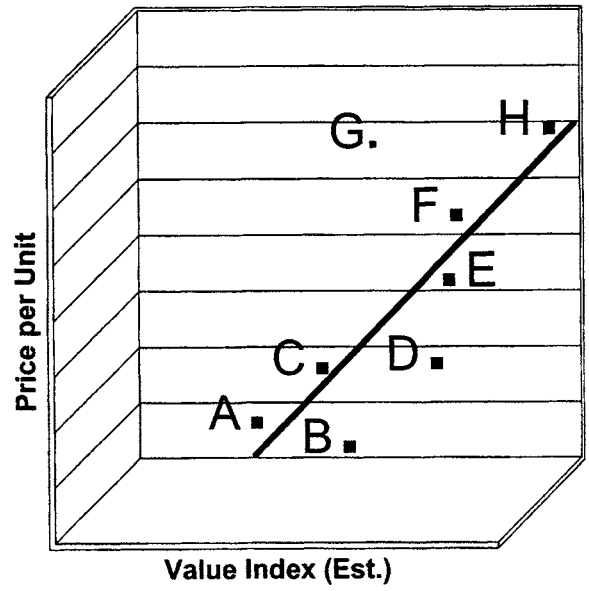
A company's pricing decisions should closely reflect the company's pricing objectives. Pricing objectives, together with the organization's product, distribution, and promotion objectives, constitute the organization's marketing objectives (which are part of the overall company objectives). Which can be the organization's pricing objectives then? As Figure 15.4 shows, the organization may be determined to fight the competition, establish an image, increase its revenue income, and so on.

Selecting a distinct pricing strategy helps the organization achieve its pricing objectives, which are a part of its overall objectives. Table 15.2 gives a detailed listing of how different pricing strategies can help attain the organization's objectives.

Table 15.1: Determining the Customer Value of Pharmaceutical Products

			(5 = high, 1 = low)					
Product	**Your Prescribers**		**Competitor A**		**Competitor B**		**Competitor C**	
Attribute	**Importance**	**Value**	**Importance**	**Value**	**Importance**	**Value**	**Importance**	**Value**
Efficacy	5	3						
Safety	4	5						
Tolerability	4	3						
Adverse effects	3	4						
Onset	2	2						
Other								

Figure 15.2. A value-to-price product comparison map



Based on the different potential price-to-value and price-to-objectives relationships, a product's final price level can be placed in one of the four quadrants of the price-to-value or price-to-objectives matrix (see Figure 15.5).

ASSESSING CUSTOMER DEMAND

There is a wide spectrum of influencing factors that may affect pharmaceutical product pricing. Table 15.3 lists several of these factors, which are demand side, supply side, or environment related.

The first step in assessing customer demand is to measure the product price and product demand relationship. Typically, customer demand decreases as a function of an increasing price. Figure 15.6 depicts a typical demand and revenue curve as they relate to the product's price. At an optimal price-to-demand relationship, the company's sales revenues are maximized.

Figure 15.3. Overview of pricing steps

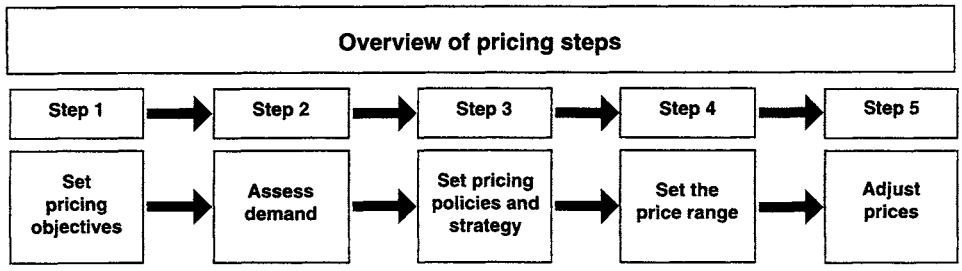
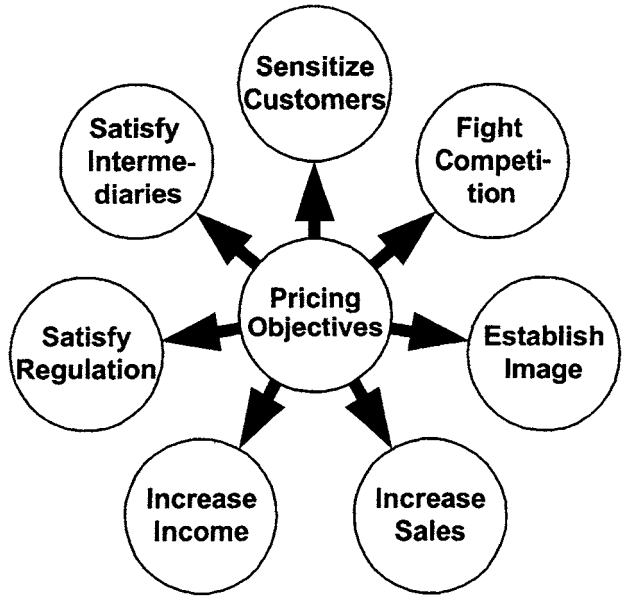


Figure 15.4. Different pricing objectives



PRICE ELASTICITY OF DEMAND

Having studied the price-to-demand relationship, a marketer has to determine exactly how a given change in price affects the quantity of the demand. This parameter is described by the term *elasticity of demand*, defined as:

Price elasticity of demand = % Change in Quantity/% Change in Price

Figure 15.5. Product pricing versus objectives value grid

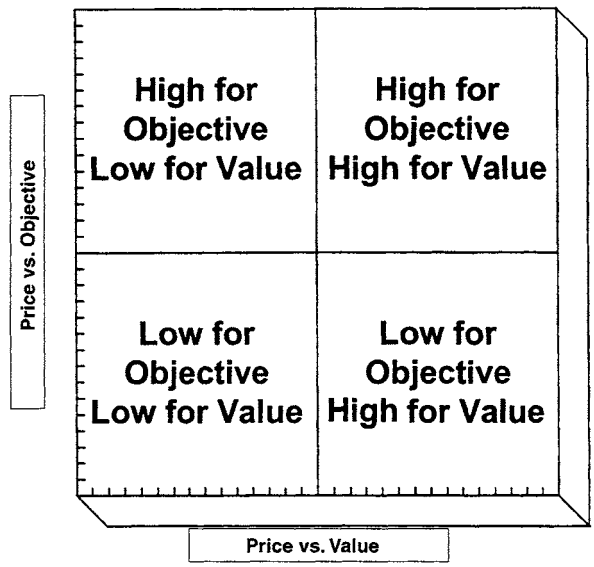


Table 15.2: How Pricing Can Help Attain Certain Organizational Objectives

Competition	Customer
Meet competition	Sensitize to price
Avoid competition	Desensitize to price
Undercut competition	
Set up entry barriers to competitors	
Force out of business	
Be the price leader	
Maintain market price stability	
Be the lowest price supplier	
Image	**Income**
Become the quality leader	Achieve a target return on investment (ROI)
Underline product differentiation	Maximize profits
Enhance branding	Limit the payback period
Behave ethically	Achieve product portfolio balance
Maintain employment	Achieve product bundling
	Increase cash flow
	Achieve survival
Intermediaries	**Regulation**
Maintain MCO satisfaction	Abide to state pricing laws
Protect distributor/wholesaler margins	Avoid trade barriers
	Achieve reimbursement
	Achieve formulary inclusion
Sales Volume	
Skim the market	
Foster sales growth	
Maintain market share	
Gain market share	
Expand market size	

As previously mentioned, a decrease in price leads to an increase in demand. Figure 15.7 depicts two potential demand curves. By comparing their respective slopes for the same price decrease, observe that the one to the right of the diagram is more responsive to the price change and is called *more elastic*. In contrast, the one to the left is less reactive; that is, a smaller demand increase follows the price decrease and is called *less elastic*. Furthermore, the term *cross-elasticity of demand* refers to the change in a product's demand following a price change of another product.

What are the factors influencing a product's elasticity of demand? Some of the most important factors include: product positioning strength; product differentiation strength in the eyes of the prescriber/consumer; number of competitors (ethical and generic); competitor brand awareness; other forms of substitution; product use within a combination treatment scheme; importance of product for treatment (antipyretic versus anticancer); and absolute price of the product (generic analgesic pill versus biotechnological anticancer treatment). In general, the broad pricing strategies as related to elasticity are (a) if elastic, decrease prices and (b) if inelastic, increase prices. Finally, how do costs impact price elasticity? Costs impact price

Figure 15.6. The demand curve

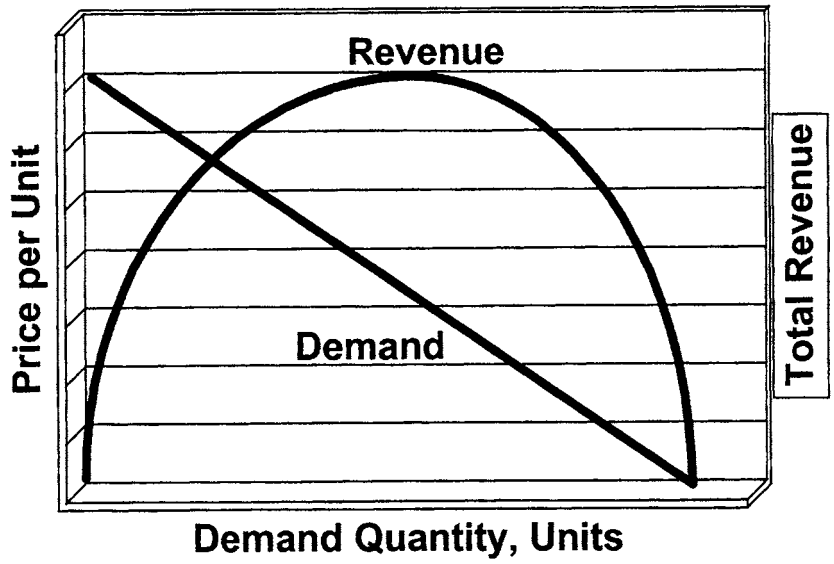
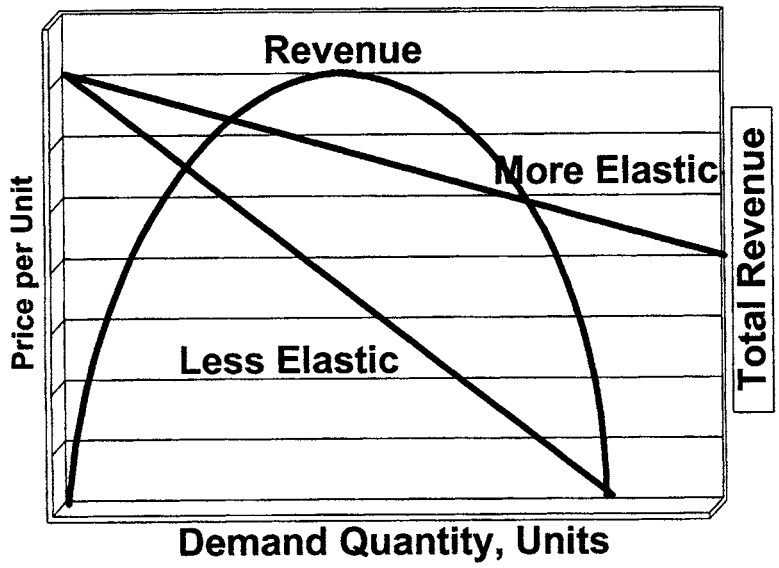


Table 15.3: Pharmaceutical Price Influencing Factors and Their Variables

Demand	Supply	Environment
Competitive pricing	Additional product portfolios	Gross Domestic Product
Competitive product characteristics	Company market position	Healthcare spending
Customers' adoption rates	Competition intensity	Import taxes
Distribution strategy	Corporate objectives	Inflation
Elasticity of demand	Customer service costs	Manufacturing site licensing
Formulary inclusion	Disease management costs	Parallel imports
Hospital pharmacy buying power	Distribution costs	Patent protection
Market life cycle stage	Financial costs (loans and foreign currency)	Patient compliance to prescription
Patient segment buying power	Formulations available	Patient perceptions and expectations
Prescriber specialty	In-house technology know-how	Per capita income
Primary demand (i.e., for therapeutic category)	Manufacturing costs	Prescription switching
Product characteristics	Patent protection	Regulatory environment
Product cost structure	Product differentiation	Social attitudes on disease
Product life cycle stage	Promotional costs	State economic status
Promotion strategy	R&D costs	State reimbursement
Regional market size	Raw material availability	Trade barriers
Reimbursement coverage	Regulatory approval	
Secondary demand (i.e., for a given company's products)	Sales taxes	
Supplemental therapy costs	Threat of new entrants	
Therapeutic category size		
Total treatment cost		

Figure 15.7. The price elasticity of demand curve



elasticity through (a) relationship of fixed costs and variable costs, (b) economies of scale, and (c) cost structure versus those of the competitors.

KNOWING YOUR COSTS

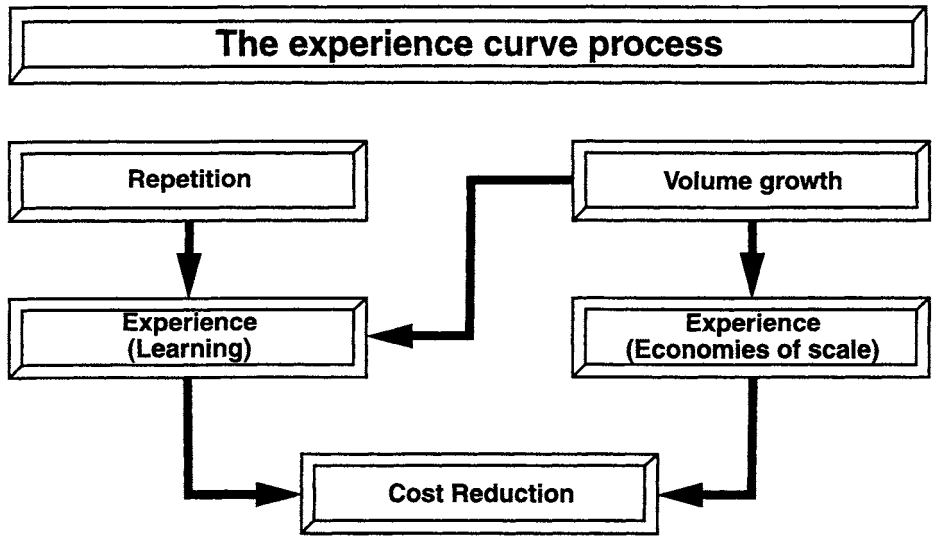
Costs provide an indispensable background for the design of a pricing strategy. They include: (a) fixed manufacturing costs, (b) variable manufacturing costs (raw materials), (c) advertising and promotional costs, (d) distribution costs, and (e) sales force costs, and so on. Costs are broadly categorized as *fixed costs* (those remaining stable as the quantity produced rises, e.g., those coming from manufacturing site utility costs, or workers' compensation) or *variable costs* (those increasing as the quantity produced increases, e.g., due to higher distribution and promotional costs). *Total costs* are the sum of fixed and variable costs.

Another important aspect of a product pricing strategy is the development of the experience curve process. As Figure 15.8 shows, manufacturing repetition leads to **learning** (due to improved machinery, improved yields, improved labor efficiency, product standardization, product redesign, or alternative materials sourcing), while the volume growth leads to **economies of scale**. Both of these lead to increased experience and reduced costs.

Eventually, as the accumulated unit volume is increased, the resulting cost per unit is decreased (see Figure 15.9).

Now evaluate the cost-to-output relationship. The combined effects of the price-to-demand relationship and the experience curve are plotted in Figure 15.10. As the quantity produced increases, total costs rise, while total revenues rise to a maximum profit level (revenue minus cost), and then decrease due to the supply exceeding demand.

Figure 15.8. The experience curve process



SETTING PRICING POLICIES

Pharmaceutical marketers have a large armamentarium of different pricing policies to choose from. These policies are broadly categorized in five groups.

1. *Differential pricing* indicated for markets with a diverse customer mix
2. *Competitive pricing* aimed to fight the competition

Figure 15.9. The experience curve

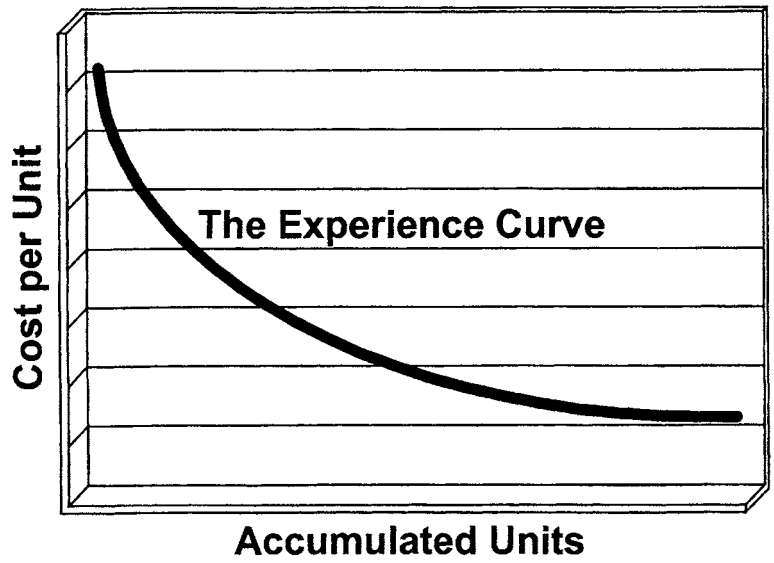
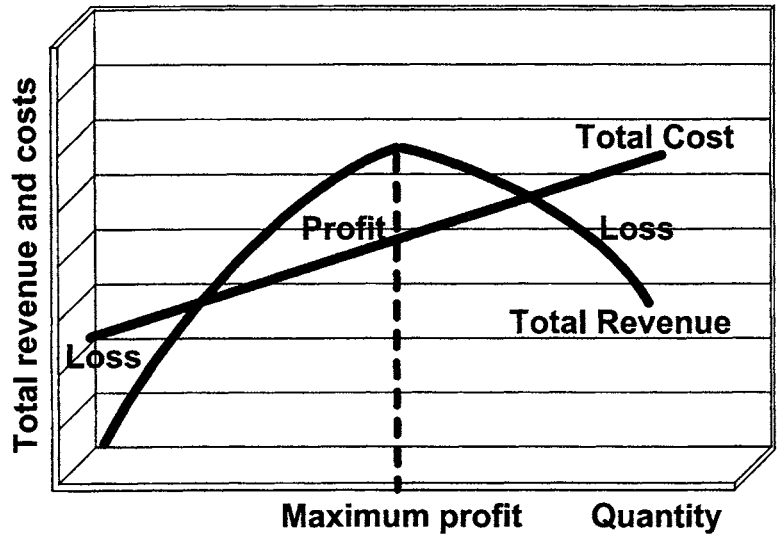


Figure 15.10. Costs versus revenues as demand and quantity produced change



3. *Product-line pricing* aimed at optimizing profits for the product line as a whole
4. *Psychological/image pricing* aimed at setting a company's image, and
5. *Distribution-based pricing* related to various distribution routes

The most common policies within each of these broad categories are listed and explained in Table 15.4.

SETTING THE PRICE RANGE

Armed with the knowledge of corporate pricing objectives and the company's product cost structure, as well as the evaluation of customers' perceived values and price-to-demand relationships, a pharmaceutical marketer then proceeds to set the product's price range (see Figure 15.11).

Figure 15.11. The price-setting framework

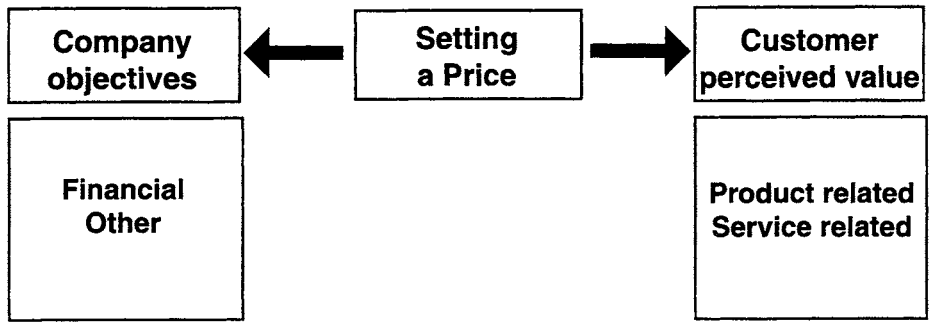
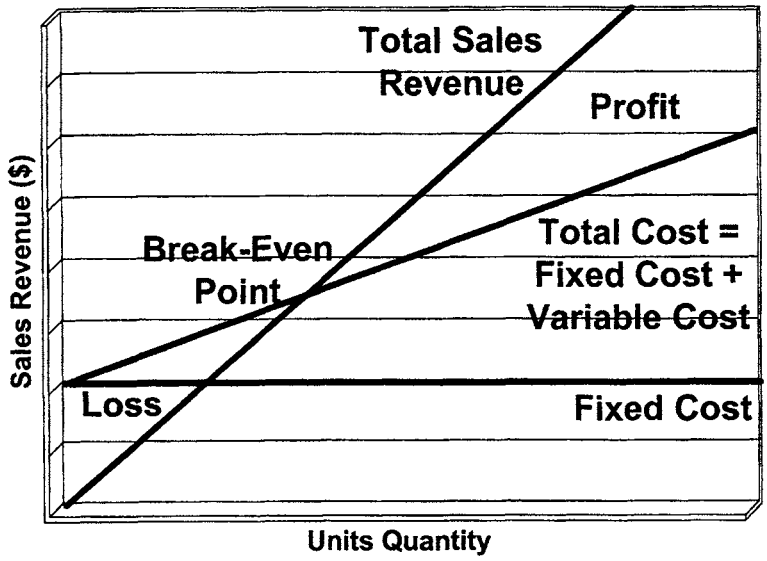


Table 15.4: The Basic Pharmaceutical Pricing Policies

Differential pricing	**Explanation**
Variable pricing	Set different prices in different markets, due to local regulations.
Second market discounting	If primary market covers fixed/variable costs, enter second market with lower price.
Skimming	Set initial prices high, then lower gradually.
Periodic discounting	Lower prices at periodic intervals (e.g., seasonally).
Random discounting	Lower prices unpredictably and infrequently.
Competitive pricing	
Competition-meeting pricing	Offer products priced at the same level with competition. Avoid price wars.
Competition-undercutting pricing	Offer prices lower than competitors' to try to gain market share.
Price leadership	Capitalize on competitive advantage (e.g., unique formulation) to set high prices.
Following the leader pricing	Adjust prices according to the market leader's pricing moves.
Penetration pricing	Offer initial prices below cost, planning to capitalize as experience curve rises.
Predatory pricing	Set initial prices low to eliminate competitors, then raise them.
Traditional pricing	Set according to historic price of "reference" drug (e.g., the first NSAID).
Inflationary pricing	Adjust prices downward if inflation rises (lower purchasing power).
Product-line pricing	
Total-profit pricing	Sacrificing an item's price so that store traffic and, thus, total profit increase.
Captive pricing	Price a basic unit low, with its necessary supplies high.
Leader pricing	If the market leader, add a price premium on preferred product.
Value pricing	Set prices according to customer perceived value.
Bait pricing	Offer an OTC priced low, planning to switch the customer to something higher.
Price lining	Instead of a wide range, offer three product classes at $5, $20, and $100 per unit.
Price bundling	Offer discounts for buying a product package.
Multiple-unit pricing	Bundle products in large quantities and low prices (economies of scale).
Psychological/image pricing	
Reference pricing	Offering a low priced generic next to an expensive "reference-priced" original.
Odd and even pricing	Odd prices (e.g., $4.99) indicate low price, while even prices (e.g., $200) indicate prestige.
Prestige pricing	Set very high prices to match a luxury item's prestigious image.
Distribution-based pricing	
FOB pricing	"Free on Board" means an all-inclusive price up to a destination point.
Delivered pricing	Price of a product delivered at the customer's warehouse (e.g., hospital pharmacy).
Zone pricing	Prices set according to regional zones (e.g., north, south, central).
Uniform delivered pricing	Mail order pharmacies charge a uniform price across the country.
Basing-point pricing	A manufacturer sells to a wholesaler in Paris, with a London delivery-based price.

Figure 15.12. Break-even analysis



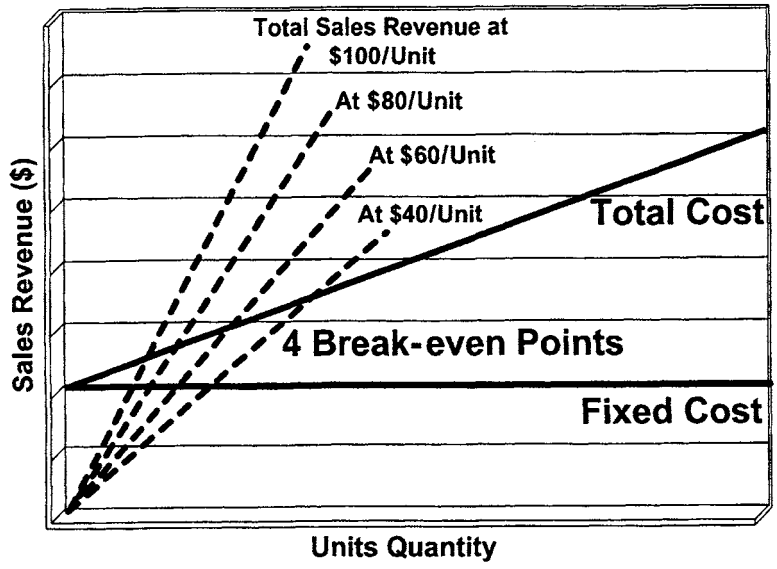
Pricing the new products may present problems due to the following facts: (a) benefits may not be well known; (b) reference products may not exist; (c) if a mistake is made, it is easier to lower than to raise the price; and (d) product innovation may have value, but eventually disappears. Some of the most commonly used price setting methods follow.

Markup on selling price: a simple pricing method that sets a fixed markup as a percent of the final selling price (e.g., a 25 percent markup on selling at a price of $100 represents a cost of $75). *Markup on cost:* similar to the markup selling price method, with a markup expressed as a percentage of cost (e.g., a 25 percent markup on a cost of $75 sets the selling price at $93.75). *Cost-plus method:* estimates the total costs required for a quantity to be produced and then adds a reasonable profit margin to set the final price. Similar to the markup on cost where item cost is known. *Average cost method:* applies a desired profit margin on the average cost (i.e., the total costs divided by the total quantity produced). Unfortunately, if only a portion of the

Table 15.5: Common Price Discounts in the Pharmaceutical Distribution Chain

Manufacturer Discounts	To Distributor	To Wholesaler	To Retailer	To Hospital
Cash discount		•	•	•
Volume discount		•	•	•
Free delivery	•	•	•	•
Promotional allowance	•	•	•	
Price hold		•	•	•
Extended credit	•	•	•	•
Lower/zero interest	•	•	•	•
Sale or return		•	•	
Package deals		•	•	•
Retrospective rebates		•	•	•

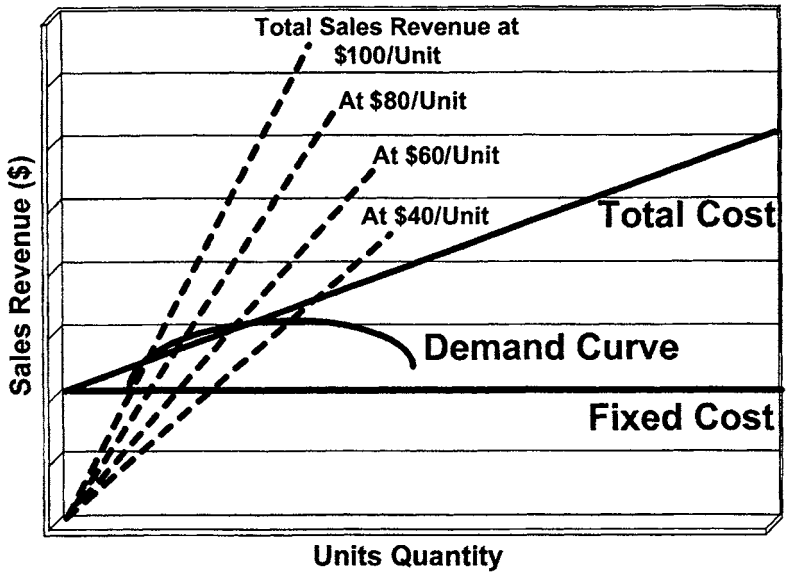
Figure 15.13. Modified break-even analysis



produced quantity is sold, final profit margin is severely eroded. *Target return pricing:* After identifying the fixed level cost for a given quantity, a target return is added, setting a target price for the given quantity. Variable costs are then added to each unit to arrive at the final unit price.

Break-even analysis is a pricing technique that determines the product quantity the firm must sell at a given price in order to cover total costs. As Figure 15.12 shows, the

Figure 15.14. The demand curve at various price levels



break-even point is the intersection of the total sales revenue line with the total costs line. At the respective unit quantity, the company is breaking even. *Modified break-even analysis* is a slightly modified technique that determines consumer demand at a variety of prices. It determines the product quantity the firm must sell at a variety of prices in order to cover total costs, and then compares these quantities to the respective expected sales at those prices (see Figures 15.13 and 15.14).

ADJUSTING PRODUCT PRICES WITHIN THE PHARMACEUTICAL SUPPLY CHAIN

A variety of price discounts may be implemented along the pharmaceutical supply chain. Table 15.5 summarizes some of the most common adjustments. Whether or not these discount options can be exercised may be regulated by government restrictions on pharmaceutical pricing.

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Part 5

Communication Strategy

16. Integrated Communications
17. Personal Selling
18. Advertising
19. Public Relations (PR) and Sales promotion
20. The Internet

16

Integrated Communications

> In 1994, patented prescription medicines accounted for only 3.3 percent of healthcare expenditures (Industry Canada). The remainder was composed of nonpatented and OTC drugs, generic drugs (which, in 1996, accounted for 40 percent of prescriptions), dispensing fees, and retail and wholesale markups.
>
> PMAC, 1999

Pharmaceutical companies, like companies in every other industrial sector, put forth great effort when identifying their customer needs and wants. They then invest in R&D hoping to discover and launch innovative products that will both satisfy the customer needs and hold a significant advantage over competitive product offerings. After the product has been developed and approved by the relevant regulatory authorities, it is then launched in world markets to compete in the marketplace. However, before a new pharmaceutical product wins its first prescriber or patient, the prescribing or buying customer must be aware of the characteristics and benefits in order for the product to capture their attention and interest. It has been proven across different therapeutic or geographical area boundaries that pharmaceutical products depend on a successful communication effort from the seller to the consumer for a significant market penetration. Is it the same communication techniques and tools with those of consumer goods that pharmaceutical product marketers use in their markets? They can

be similar in their approaches, however the pharmaceutical industry is heavily regulated, as seen in earlier chapters.

Part 5 of this book is devoted to the discussion of the pharmaceutical communications effort, which includes various approaches and tools for reaching the industry's diverse audiences. This chapter presents an overview of this multifaceted communications effort, called *integrated communications*. In the process, it discusses the elements of communication and the prescribing decision, and presents the elements of a communication strategy, the promotional mix, and the importance of promotional planning.

THE PROCESS OF COMMUNICATION

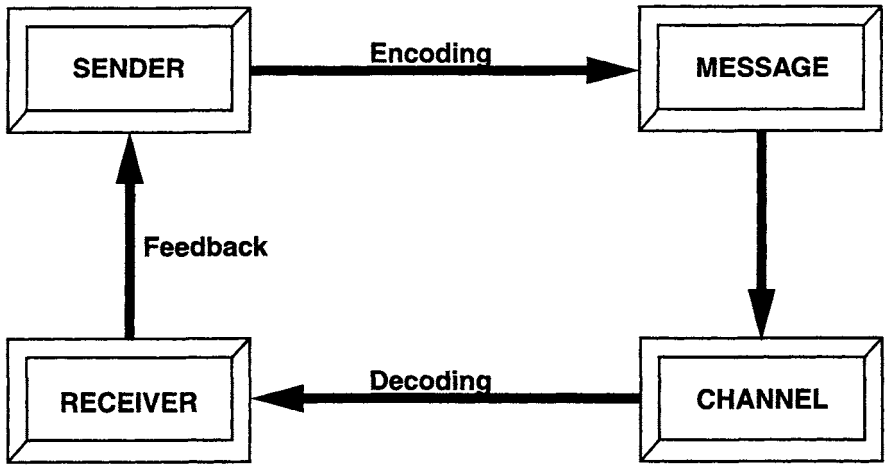
Communication refers to the process of exchanging a message and carrying a meaning to others. This meaning has to be identical to both sides for communication to be successful. The sender of the message may use any of the available communication methods, such as words, pictures, gestures, or sounds that will attract the attention of the message recipient and convey the desired message. However, messages are not always conveyed properly and communication can be faulty or misleading. It remains the responsibility of the message sender to ensure that the recipient has received it and has understood the meaning the message was intended to convey. Proper communication is not an easy task.

Figure 16.1 shows the steps involved in the communication process. The sender may want to transmit a fact, an idea, or a feeling. He or she decides to choose the most convenient way of transmitting the message, via words, gestures, or by using physical items (pictures, and so on). The process of converting the original fact or idea to a message is called *encoding*, that is, attempting to include the desired meaning in the communication method chosen. Whether or not this encoding will be successful depends on the skills and experiences of the sender, including having knowledge of the receiver's characteristics and method of understanding. For example, a working mother communicates with her colleagues and her one-year-old daughter in two completely different ways because she knows the different characteristics or communication powers of each receiver.

Once the message has been encoded, the sender then selects a communication channel, or the *medium*, for transferring the message. Word-of-mouth is one method of transmission, while other means include the telephone, television, printed material, billboards, and so on. After the message reaches the receiver, she or he attempts to decipher it, or *decode* it. In other words, based on the receiver's characteristics, skills, and experiences, the message is decoded to a meaning, which may or may not be the same as what the sender intended. Occasionally, after receiving the message, the receiver gives some response or feedback to the sender. Using the last example, the woman's colleague may voice an agreement with her business proposal or her daughter may indicate the desire for less food. In pharmaceutical industry communications, a prescriber may tell a sales force representative of her enthusiastic approval of the new medication, while television viewers may call the company's customer service line to ask about the new drug.

In an ideal situation, the message reaching a receiver carries an identical meaning with that intended by the sender. In business communications this is absolutely essen-

Figure 16.1. How communication works



(Schramm, 1954. Reprinted with permission of the University of Illinois Press)

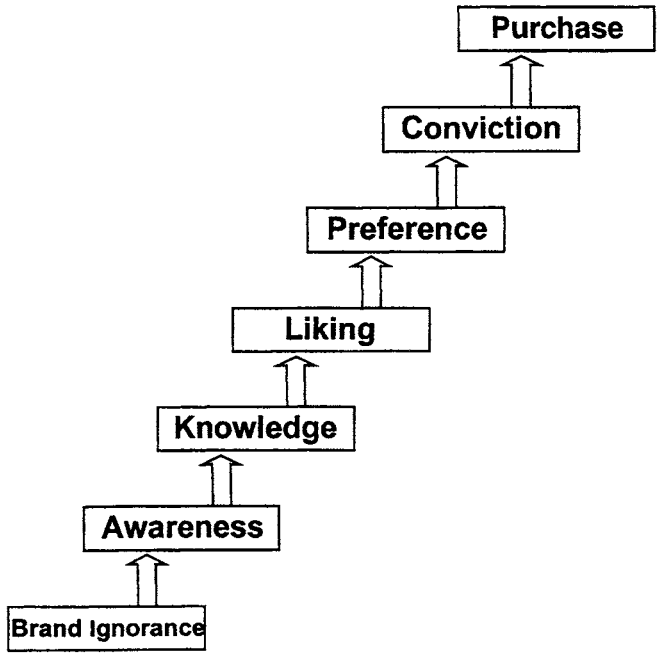
tial. Thus, marketers wishing to communicate their product benefits to their customers need to have a thorough understanding of their characteristics and communication preferences. For example, it would be a waste of marketing resources to employ TV advertising for a new hospital product that only can be prescribed by one hundred specialists around the country. Therefore, considerable attention is given to the channels and methods of industry communications with its customers in the following few chapters.

THE PRESCRIBING DECISION

We have just discussed the importance of integrated communications in transmitting a product's benefits to its audiences. In the pharmaceutical industry, the primary audiences are the product prescribers and patients. How, then, can a physician's prescribing process or a patient's purchasing process can be influenced by industry communications? The answer can be found by studying the prescribing or buying decision and identifying the processes that can be influenced by a communication strategy. Because both processes have similar characteristics, focus will be on the distinct elements of the prescribing decision.

Figure 16.2 shows the steps involved in the prescribing decision process. A prescriber may have no knowledge of a given pharmaceutical product very early in its launching phase. At this point, the company's marketing and sales departments begin a product's promotional campaign through print, television, or direct sales calls in an effort to raise the prescriber's awareness of the new product. The prescriber, who is always in search of new and effective medications, will naturally seek information about the product, through the company's sales force, at the hospital library, or through a trusted colleague. Having evaluated the available knowledge, he or she may initially like the new product characteristics, and later realize that some

Figure 16.2. The prescribing decision



of them carry an advantage over the previously available medications. When the brand preference is turned into a conviction, the prescriber is then ready to prescribe the new medication and collect personal clinical experience about the new drug. The rate a prescriber moves through the different steps of the prescribing ladder until he or she finally decides to prescribe a product is described by the adoption process discussed in Chapter 10. Indeed, an innovative physician would have studied the clinical trial results and have been eagerly anticipating its regulatory approval and launch. A "laggard" may take several years after the product's launch until all of his or her colleagues have switched to the new medication before he or she decides it is safe enough to prescribe. The following paragraphs describe the objective and subjective factors influencing a prescribing decision, as well as the prescribers' motives behind this decision.

Brand Ignorance

Brand ignorance may be encountered at the beginning of the product's life cycle. A company's size, market share leadership, or marketing and sales force effectiveness limit the time of the prescriber's complete ignorance of the product. Innovative physicians have a fairly good awareness of most new products at the time of their launch, while laggards operate in ignorance for several years. Also, the brand ignorance time will be longer for physicians operating in rural areas, as opposed to medical center or metropolitan area physicians. As shown later on, there are different communication channels for reaching this diverse spectrum of audiences.

Awareness

During the awareness phase, physicians will start coming in contact with the manufacturer's promotional activities, for example, through medical journal advertisements, the first sales force visits, or scientific announcements at medical congresses. The awareness process may represent an internal or external information search by the prescriber. As Table 16.1 shows, an *internal search* is usually based on the prescriber's clinical practice experience, academic and continuing education, memory, and needs. It is also associated with a low disease severity, which allows the prescriber to depend on past experiences for deciding the course of patient's treatment. On the other hand, an *external search* is usually conducted if there is an internal "gap" or lack of information due to inadequate past education or experience. The disease to be treated will most likely be one of high severity, where careful consideration of all options is needed. Furthermore, a prescriber conducting an external search will probably seek the advice of medical experts, that is, the OLs, thus giving rise to the "pyramid of influence" that is described later. Furthermore, a prescriber conducting an external search will primarily be an innovator who is always looking for knowledge, as opposed to the laggards who prefer to depend on old and trusted products.

Knowledge

In the knowledge phase, a prescriber intensifies his or her information search for maximum awareness. The search reflects internal and external needs, as shown in Table 16.2. Internal needs include passive or "low-intensity" communications, such as an advertisement read in a medical journal. External needs include the desire to be influenced by others (and indirectly pay respect to the OLs) or the search for direct marketing communications, that is, the physician calling on the manufacturer to ask for a sales call.

Liking

In the liking phase, a prescriber has been thoroughly informed of the product's characteristics and benefits, and begins to be convinced of the product's superiority. During this period, previously existing alternatives are compared to the new product, and conclusions start to favor the new alternative. This evaluation of product alternatives can be externally influenced by marketing communications. Before this is achieved, however, perceptual mapping is needed to compare the competitive positions of all alternatives. The attitudinal strategies used by marketing communications at this phase are: (1) *create,* for example, "this NCE sets a new standard in treating the disease"; (2) *reinforce,* for example, "combination treatments are clearly superior in treating this disease"; and (3) *change,* for example,

Table 16.1: Customer Awareness Process

Internal Search	External Search
Experience	Internal "gap"
Learning	Need for supplementation
Memory	OLs' advice
Past purchase	Marketing communications
Low disease severity	High disease severity
Need for self-assurance	Need for innovation

Table 16.2: Prescriber's Needs during an Information Search

Internal	External
Passive communication	OL influence
Incidental learning	Direct marketing communications
"Low dose" market communications	Emphasis on informing

"there is no need for your patients to suffer from so many adverse events because the new product is equally effective and much safer."

Some of the important aspects of pharmaceutical marketing communications during this phase are: (a) know the attitudes of prescribers and patients; (b) always focus on several attitudes; (c) competitive response; and (d) different segments. Marketing communications can (a) change a belief about the attribute, (b) add new attribute, or (c) change the importance of the belief.

Preference

The preference phase occurs when the prescriber realizes the new product's superiority over previously existing alternatives, and seriously considers using the product in the future. However, there is still a distance from the actual prescription or the patient's purchase.

An important aspect every marketer should be familiar with is the degree of switching within the given therapeutic area. Therefore, patient medication histories need to be investigated in an effort to gain insight into the therapeutic area characteristics and preferences. Such data are commercially available via omnibus surveys of physician prescribing habits or patient surveys conducted within a hospital or at points-of-sale (e.g., a grocery chain's OTC section).

Conviction

During the conviction phase, prescribers are convinced of the product's superiority and ready to prescribe. The rate at which a prescriber moves from the preference phase to the conviction phase also can be significantly influenced by persuasive marketing communications, showing that the new product has changed the disease treatment for good, that more of the physician's colleagues are switching to the new medication, that now is the time to prescribe because of introductory prices or rebates, or that he or she should not be left behind in the competitive private practice market.

Purchase

During the purchase phase, the emphasis is placed on stimulating the action. In personal selling this is equivalent to closing the sale. Marketers can bundle the actual prescribed volume with additional services (e.g., patient videos available for the physician's waiting room), two-for-one rebates, diagnostic test subsidy by the pharmaceutical manufacturer, and so on.

Postpurchase

After a prescription has been given to a private patient or a hospital pharmacy has purchased the medication on the prescriber's recommendation, industry marketers and sales professionals can closely monitor and facilitate the sales with postpurchase customer service. Some of the essential activities include: (a) check delivery quantities and dates; (b) thank the prescriber or pharmacist for the decision to use their product; (c) provide training to health personnel; (d) check satisfaction; (e) handle complaints; and (f) provide continuous customer service.

THE PYRAMID OF INFLUENCE

As previously mentioned, the prescribing decision is strongly influenced by the pyramid of influence; namely, the cascading influence exerted from medical OLs to hospital clinic directors/department heads, to clinical specialists, and then to family physicians or general practitioners (see Fig. 2.4, pg. 32). This phenomenon is present in almost all medical specialties in every national market and has tremendous implications on pharmaceutical marketing approaches. Therefore, industry marketers should always try to capture the attention, liking, preference, and conviction of the respective therapeutic area leaders early so that they become the product speakers or endorsers through medical congresses, physician meetings, clinical rounds, or medical education. The optimal way to gain an OL's backing is by giving him or her early access to the product's clinical trial program, by including them in the Phase II or III studies, giving them access to a limited quantity for named-patient use, or donating a small drug supply (where sampling is allowed) for their own personal use.

Alternately, an OL may be invited to serve as a member of an experts' committee, advisory board, or medical think-tank that designs a disease's optimal treatment guidelines or health system changes. This indirectly gives industry's professionals access to the top OLs in the field. A word of caution, however, advisory board initiatives and expert committees need to represent true clinical practice improvements. A camouflaged marketing activity may alienate the committee members and cause long-term animosity and opposition.

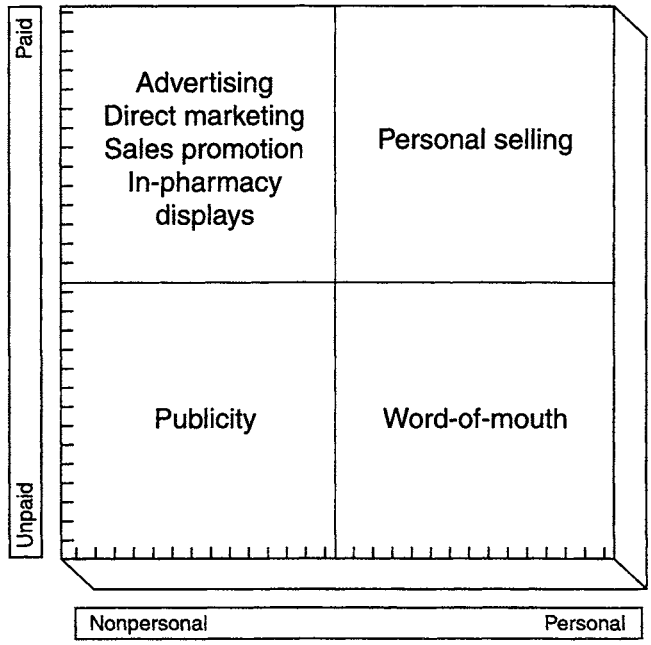
COMMUNICATION STRATEGY

What are the main channels of an integrated communications strategy? Figure 16.3 shows the main channel alternatives, ranging from nonpersonal to personal, and unpaid to paid.

The next few chapters discuss in detail the main activities of pharmaceutical marketing communications, namely, advertising, personal selling, public relations, and sales promotion, as well as Web communications. These activities are collectively called the *promotional mix*. They have a triple purpose: (1) to provide information, (2) to persuade, and (3) to remind.

Furthermore, a *communication strategy* is the design, planning, implementation, and controlling of integrated communication activities. As Figure 16.4 shows, this strategy is involved with four different aspects of communication, namely, the selection of the

Figure 16.3. Communication tactics



message, target, medium, and frequency most suitable to the particular pharmaceutical product.

PROMOTIONAL MIX

The main elements of the promotional mix have been mentioned earlier. *Advertising* is defined as a nonpersonal, paid communication about an organization, product, or idea by an identified sponsor. *Personal selling* is direct communication with customers to generate a response and/or a transaction. *Public relations* is the evaluation of public attitudes and the execution of plans to gain public understanding and acceptance. Furthermore, *sales promotion* is providing extra value or incentive to customers to purchase a product. The characteristics of each of these promotional channels as they

Figure 16.4. Elements of communication strategy

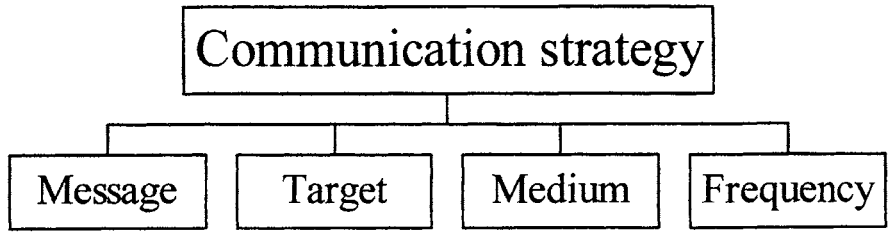


Table 16.3: Characteristics of the Four Elements of Pharmaceutical Promotion

	Personal Selling	Advertising	Public Relations	Sales Promotion
Mode of communication	Direct contact	Indirect	Direct and indirect	Indirect
Communication objective	Indirect sales through prescribers by specialized representatives	Boost image (brand/corporate), inform, persuade, remind, sell	Gain public understanding and acceptance	Provide short-term incentive to prescribe/ purchase (trial/repurchase)
Regular and recurrent activity	Yes	Yes	Yes	No
Message flexibility	High	Low	High	Low
Direct feedback	Yes	No	No	Yes
Marketer control over message	High	High	High	Low
Sponsor identified	Yes	Not always	Not always	Yes
Cost per contact	High	Low	Low	Low
Market environment	Customer needs more information; product is complex; service is important after sales	Dispersed customers; information and service not critical	Different stakeholder needs; negative industry/ company image	Competitive; price sensitive; high switching
Advantages	High credibility and impact; sale can be closed	Massive reach; proactive planning	Diverse audiences; large impact	Direct influence on usage; effect on final customer
Disadvantages	High cost; inconsistency in message delivery	High overall cost; inflexible message	No immediate effect; diverse audience needs	Significant logistical needs; may cause discount war

relate to the pharmaceutical marketing are summarized in Table 16.3. They are discussed in detail in the following chapters.

PROMOTIONAL PLANNING

The promotional planning process involves the following activities: (1) identify target audience, (2) determine desired response, (3) decide on the messages, (4) select media, and (5) evaluate responses. A promotional campaign's target audiences may include academic professors, prescribers, hospital administrators, pharmacists, nurses, patients, the media, and the general public. Identifying the exact audience requires a thorough knowledge of customer needs, market characteristics, competitive activities, and the product's own characteristics. Thus, the collection of secondary and primary data is paramount to this decision. Furthermore, the selection of a push versus a pull approach (see Chapter 18), the customers' adoption stage, and the product life cycle are some of the important aspects of target audience selection.

Determining each audience's desired response also comes from the knowledge of their needs, wants, and purchasing behaviors. Multifunctional teams of a pharmaceutical organization, including marketing, sales, market research, and medical marketing professionals, should evaluate these responses with each member. Deciding on promotional messages is also related to the customers, market, product characteristics, and promotional objectives. The latter may be image building, the product's differentiation or positioning, or a direct customer response. This process, as well as media selection and promotional effectiveness evaluation are presented in detail in Chapter 18.

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17

Personal Selling

> In 1998 there were 30,000 chain store pharmacies and 20,000 independents, which employed together 128,000 pharmacists in the U.S. market.
>
> National Association of Chain Drug Store (NACDS), 1999

Personal selling is one of the basic elements of integrated communications and the promotional mix. It refers to the direct communication between a seller and the prospective customer. Within health care, as in other industrial sectors, there are four major types of personal selling. First, *retail selling* of pharmaceuticals from a licensed retail pharmacy or a grocery store department selling OTC products. Second, *field selling* of pharmaceuticals by a sales representative visiting potential prescribers. Third, *telemarketing*, which is mostly used in the consumer goods sectors, but also applied in the healthcare field for health insurance, HMO participation, and pharmacy purchasing of OTCs. Fourth, *inside selling* by a medical disposables sales representative permanently located within a medical center who caters to that center's orders. This chapter solely focuses on the field sales of pharmaceuticals to prescribers via specialized sales forces, which focus on informing and persuading the physicians to prescribe a pharmaceutical product.

Despite misconceptions about pharmaceutical marketing—especially field sales, which was addressed in Chapter 3—medical detailing is an approved, regulated, and

widely accepted means of pharmaceutical marketing communications found in every major national market. Furthermore, despite the growing number of mergers and restructurings seen in the industry and the increasing use of new technologies such as the internet, the use of pharmaceutical sales representatives continues to be considered the core marketing activity of the pharmaceutical industry. Additionally, the number of employed representatives is growing. Why, then, is the personal selling of pharmaceutical products (via medical detailing) so important to pharmaceutical marketing? Some of the reasons for its importance include: (1) optimal customer targeting; (2) optimal message adjustment; (3) maximum informational content; (4) mutual flow of information; (5) optimal evaluation of customer perceptions and needs; (6) marketing research; and (7) competitive intelligence gathering.

Before focusing attention on the specific tasks and activities of medical detailing, let us first discuss some of its characteristics. First, the profession offers qualified individuals a significant degree of professional flexibility, which allows them to design their own daily detailing schedule, as well as an interesting working environment away from the daily office routine. Second, medical detailing is all about relationship building, especially with high-caliber healthcare professionals. This leads to a continuous increase in personal knowledge and the number of professional acquaintances for the sales professionals. Third, the professionals encounter challenging sales targets, which demand training and traveling and the possibility of rejection. Aspiring pharmaceutical sales professionals should talk with sales veterans and study the available literature, as well as this chapter, when trying to become more informed and prepared for a challenging but rewarding career ahead.

PERSONAL SELLING TASKS AND ACTIVITIES

Medical detailing tasks and activities can be categorized as those preceding a sales call (commonly referred to as *prospecting*), those occurring during a call, and those that follow a sales call. A detailed description of their respective tasks, activities, and relevant examples is provided in Table 17.1.

Others express the view that medical detailing, like personal selling in every other industrial sector, is all about providing sales support. Thus, a medical sales representative is involved in supporting the prescribing decision, managing the implementation, dealing with prescriber or organizational buyer dissatisfaction, and constantly enhancing the relationship through postpurchase customer service, asking for referrals, and so on. The main activities associated with the different types of sales supporting efforts are listed in Table 17.2.

Different industrial sectors display a spectrum of personal selling modes. These include the following: (1) **transactional** (e.g., receiving customer orders and transmitting them to the company's warehouse), (2) **consultative** (e.g., trying to identify the customer needs and offer solutions), and (3) **enterprise** (e.g., selling a diverse product portfolio to a diverse audience). The pharmaceutical industry is dependent on a consultative approach, based on a variety of prescriber and patient needs. Additionally, this approach includes explaining and discussing the significant

Table 17.1: Common Pharmaceutical Personal Selling Tasks and Activities

Timing	Tasks	Activities	Example
Precall			
	Prospecting	Sales visits	Seeking names of prospects via directory listings, referrals, or door-to-door.
	Uncovering customer needs	Questioning	Discovering if the prescriber is looking for efficacy, safety, onset of action, and so on.
	Product detailing	Presenting	Using promotional material to inform customer.
	Identifying key accounts	Data gathering	Evaluating customers according to academic status, patients basis, prescription volume, or treatment preferences.
	Arranging higher contacts	Networking	Bringing customers together with the company's marketing, medical marketing, R&D, and so on.
During call			
	Informing customers	Oral and written, Phone detailing	Oral detailing, promotional, clinical literature.
	Product demonstrating	Group meetings, Exhibitions	Presenting the product features, explaining its usage, and mentioning nontangible attributes.
	Persuading	Active listening, Objection handling	Presenting a superior value proposition and handling customer objections.
	Monitoring competition	Data gathering	Collecting customer's information on competitive clinical trials, planned product launches, new formulations, and promotional levels.
	Maintaining relationships	Being cordial, Showing empathy	Showing empathy to prescribers—a feeling that you "really care." Remembering personal details, joys, or problems.
	Project managing	Active listening, Record keeping	Checking customer satisfaction with ongoing therapies, promotional material, information, company services, and own visit frequency.
After call			
	Product demonstrating	Group meetings, Exhibitions	Often needed by the healthcare personnel after a hospital buying decision or a patient's follow-up visit.
	Checking deliveries	Company and customer contacts	Making sure that the quantity ordered was delivered at the right quantity, right time, and right invoice payment terms.
	Evaluating satisfaction	Customer contacts	Evaluating the prescriber's and patient satisfaction with the pharmaceutical product.
	Asking for referrals	Probing	Asking the customer to refer you to other colleagues, pharmacists, or patient groups.
	Request gathering	Data gathering	Attracting customer requests for more information, education, training, or sponsorships and transferring them to the right company person.
	Complaint gathering	Active listening	Understanding, recording, and transferring customer complaints to relevant company personnel.
	Personalizing the relationship	Caring	Making a successful professional relationship into a first name basis friendly relationship.
	Inviting to company functions	Extending invitations	Inviting customers to company functions, congresses, open houses, and patient gatherings.

Table 17.2: Elements of Sales Support

#	Element	Activity
1.	Support buying decision	Reduce buyer anxiety. Make a follow-up call. Ask for feedback.
2.	Manage the implementation	Assist with approval process. Introduce support resources. Monitor and report progress.
3.	Deal with dissatisfaction	Empathize with the buyer. Respond to problems. Anticipate buyer concerns and expectations. Reinforce benefits.
4.	Enhance the relationship	Be available. Arrange continuous communication. Maintain quality of products/services. Provide updates and progress reports. Provide information, help, and ideas. Grow the business internally. Ask for referrals.

informational content about the product to prescribers. Next, we will evaluate all potential selling styles and then focus attention to the style recommended by most sales professionals. Individual therapeutic or national market areas may utilize more that a single selling style.

SELLING STYLES

The most common personal selling styles are shown in Table 17.3. The majority of pharmaceutical sales representatives operating across different national markets rely on the top three approaches, namely, a need-satisfying, problem-solving, or consultative approach.

How, then, can an industry sales representative achieve a high sales performance and satisfy both the prescriber/customers and the company's management? Possible answers are provided by the "art and science" of offering solutions to customer needs, as shown in Table 17.4.

The sales process that identifies and satisfies prescriber needs is described in the structured sales interview section, which is next. In general, a successful sales call can be based on five distinct elements, as shown in Figure 17.1. These include deep product knowledge, an extraordinary service, the art of establishing relationships, persuasion skills, and special education and training for offering solutions to therapeutic needs.

Table 17.3: Common Personal Selling Styles

#	Style	Description
1.	Need-satisfying	Help the buyer identify the need and then offer the product.
2.	Problem-solving	Develop alternative solutions to satisfy customer needs.
3.	Consultative	Help buyer reach goals through products, expertise, and so on.
4.	Friendly	Create a personal bond with customer.
5.	Stimulus-response	Perform actions in order to elicit desired response.
6.	Mental states	Lead the buyer through specific mental steps (attention, interest, desire, action [AIDA]).
7.	Prior experience	Repeat previously successful selling routine.
8.	Take it or leave it	Depend on hard product characteristics to self-sell.
9.	Hard selling	Take control of customer until he surrenders (buys).

Table 17.4: The Art and Science of Pharmaceutical Sales Offering Solutions (S) to Customer Needs (N)

N:	My cancer patients often present with frequent disease relapses.
S:	Using our high dosage drug combination, you will achieve the longest possible disease-free interval.
N:	My young patients react to the idea of a daily injection.
S:	Our new needleless auto-injector does not cause any pain and even can be used during the child's sleep.
N:	My elderly, retired patients cannot afford such a high price for a medication.
S:	Our product will save your patients money through fewer lab tests, disease complications, and hospital days, and offer higher quality of life.
N:	The patient family should be better informed about their relative's disease condition and treatment.
S:	Our product is included in a comprehensive disease management program, offering education and compliance training to families.
N:	I am afraid of discontinuing my patient's anti-anxiety treatment because of withdrawal symptoms.
S:	Our wide dosage strength range allows you to gradually reduce their dosage to avoid withdrawal symptoms.

THE STRUCTURED SALES INTERVIEW

The structured sales interview procedure refers to the classroom training, role practicing, and implementing of a predefined series of sales activities that have been specifically designed to identify therapeutic needs and offer solutions. The major components of the structured call include the opening, exploring customer needs, presenting product benefits, handling customer attitudes, and closing the sale. The major requirements for each sales interview component are shown in Figure 17.2. Industry veterans will agree that all essential interview components must be present and skillfully executed for maximum effectiveness. Detailed skills training in the industry's classrooms and long hours of practicing the routine in front of experienced colleagues or in the field are required before a pharmaceutical sales representative becomes successful.

The structured course of a medical detailing call can be sidetracked by various prescriber objections (see Table 17.5). The important thing to remember is that, in most cases, no matter what the objection may sound like, it is not a personal attack on the sales representative (provided she or he is not hard selling). Instead an objection is usually a prescriber's reaction to something specific such as the limited time available, prior experience with another product, or ignorance of the new therapeutic entity.

Figure 17.1. A successful sales call

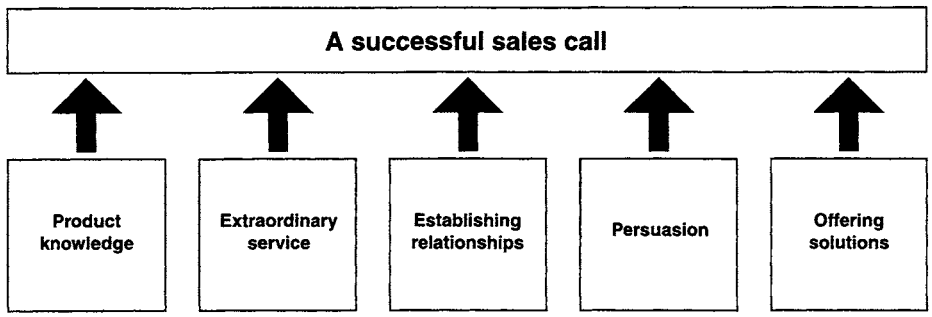
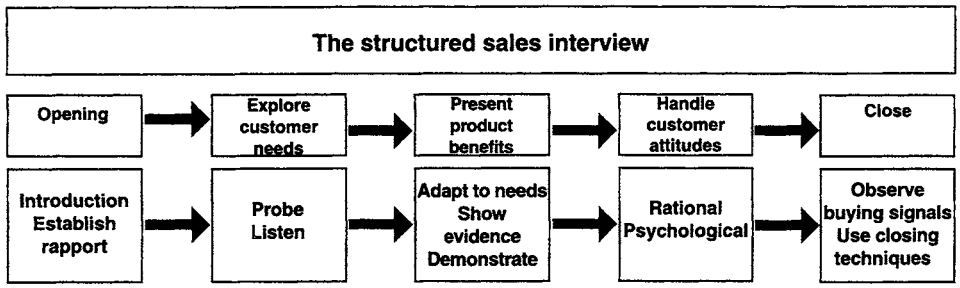


Figure 17.2. The structured sales interview



Learning to handle initial rejection and continuing to offer solutions to needs will undoubtedly lead to a successful sales career.

SALES FORCE MANAGEMENT

Sales management is the planning, implementation, and control of a sales force's personal selling activities designed to achieve the sales objectives of a firm. The task of sales management is a multifaceted and challenging one. The main components are shown in Figure 17.3, as well as presented next.

Sales Management Tasks and Responsibilities

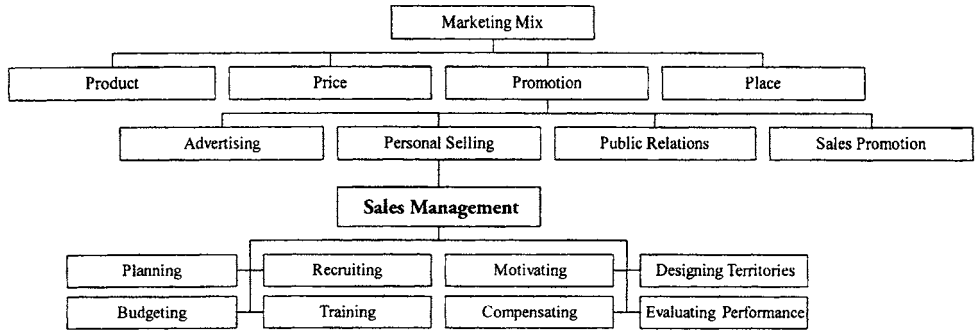
Figure 17.4 depicts the sales force cycle. Sales force recruiting and selection are followed by training and motivating, organizing, planning and budgeting, and finally by performance evaluation, compensating, and rewarding. The last part of the cycle leads to sales force satisfaction and retention or additional recruiting.

Figure 17.5 shows a pharmaceutical subsidiary's sales department organization, led by a national sales manager. He or she supervises a team of regional sales managers, sales analysts,

Table 17.5: Typical Prescriber Objections to Pharmaceutical Personal Selling

#		Reason Example
1.	Company	Lack of variety of dosages. Strengths and formulations offered by the competitor.
2.	Product	Limited elimination halflife mandates frequent dosage.
3.	Service	No patient information materials to give my patients.
4.	Pricing	I am not sure if such pricing for a contraceptive pill is ethical.
5.	Sales representative	Late for our appointment and forgot to bring me the literature I requested.
6.	Not competitive	Product's marginal advantage does not justify the increased therapy costs.
7.	Delivery delay	After placing the order, we found out there was no inventory.
8.	Patient can't afford	My patients are low to medium income, unable to afford this new medication.
9.	Patient doesn't need	Patient is satisfied with intramuscular injections and does not need an oral formulation.
10.	Adverse events	I have noticed an increased frequency of adverse events in my hospital patients.

Figure 17.3. Responsibilities of sales management



sales administration managers, and customer service managers. Frontline medical sales representatives are categorized as senior sales representatives, sales representatives, product specialists, or account managers, according to their seniority or account specialization.

Recruiting

The process of recruiting sales professionals involves the following elements: (1) recruiting and selecting policies, (2) analyzing sales function, (3) describing sales job, (4) recruiting candidates, (5) selecting prospects, and (6) evaluating the process. Potential sources of qualified pharmaceutical sales representatives include the competition, within the organization, other companies' sales people who call on the company, hospitals, physicians' waiting offices, pharmacies, medical congresses, pharmaceutical representative association meetings, relevant schools (biology, pharmacy, chemistry), sales training courses, personnel selection agencies, customer referrals, and sales managers' referrals.

Figure 17.4. Sales force cycle

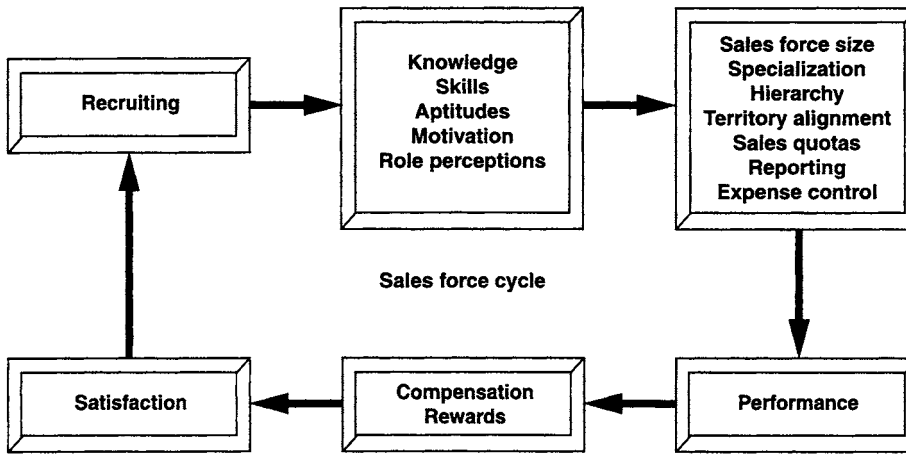
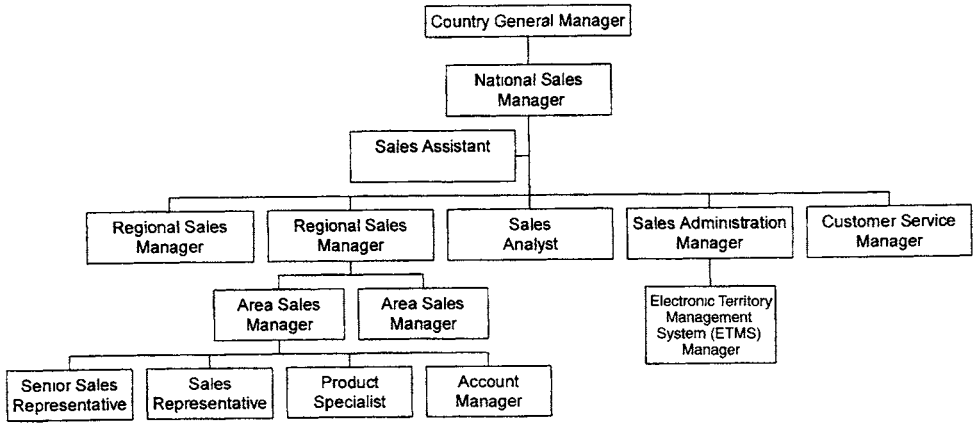


Figure 17.5. A national subsidiary's sales department organization



When recruiting sales professionals it is important to consider carefully who will interview the top applicants and what capabilities or traits are desirable. It has been repeatedly proven that the selection process must be a well designed activity including interviewing promising applicants by an interdisciplinary team that includes the area sales manager, regional sales manager, national sales manager, and product manager, as well as the human resources or general manager. Additionally, a consensus should be reached about who to hire. In general, the interviewers should be looking for the following sales representative attributes: knowledge, honesty, professionalism, empathy, persistence, self-assurance, verbal communication skills, and enthusiasm.

Training

Sales force training is a one of the most critical aspects of success in the marketplace. Multinational pharmaceutical companies have realized this fact and have gone to great lengths to ensure the high quality of their training procedures and materials. Some even have set up corporate "sales universities," where internal and external experts train incoming and experienced sales representatives. The main reasons for relying on a thorough training process are: (1) control (consistent message), (2) improved customer relations, (3) increased productivity, (4) increased sales, (5) better management of demanding accounts, time, and territory, (6) improved morale and confidence, and (7) reduced turnover. Table 17.6 describes the multiple sales force training settings. These include classroom and field training, and even distance learning, which capitalizes on the power of new technology such as multimedia or the internet.

At the end of each training session it is important to conduct an official appraisal of the training quality and quantity of materials covered. The appraisal can include any or all of the following activities: self-appraisal, supervisory appraisal, trainee feedback, customer appraisal, and actual sales results.

Table 17.6: Common Pharmaceutical Sales Force Training Settings

Setting	Description
Classroom training	Initial in-house training on disease, products, company, software, and skills.
Field training (on-job-training [OJT])	Initial field training with trainer, supervisor, and manager.
Double calling	Sales calling with senior colleague, supervisor, or manager.
New product classroom training	Additional training before new product, formulation, or dosage launch.
Reminder training	A training coinciding with regular sales cycle meeting as a refresher course.
Internal training at corporate headquarters (HQ)	Sales specialist teams invited to corporate HQ for training and motivation.
External training	Selling techniques or computer or presentation skills training by consultants.
Distance learning	Correspondence or Web-based training on business administration, biology, and so on.

Motivating

Motivation is defined as the drive to act and the intensity and persistence of this effort. It comes as internal (personal fulfillment) or external (compensation and rewards). The increased need for constant sales force motivation is associated with the following factors: (1) direct improvement of sales presentation, (2) indirect performance improvement, (3) frequent rejection, and (4) separation from the team. How, then, can a pharmaceutical company motivate its sales employees? There are a variety of methods, some of them monetary and others psychological, such as the following: compensation, sales award, job title, company car, mobile phone, task force inclusion, direct contact with company executives, recognition in company newsletter, or secretarial support. The important thing to remember is that motivation needs to be continuous, not sporadic or subjective, in order to avoid decreased morale or feelings of managerial bias toward some of the sales force members.

Compensating

An industry sales force compensation survey would invariably show the existence of a variety of compensating schemes used, including: straight salary, straight commission, commission with draw, quota-bonus plan, salary plus commission, salary plus bonus, salary plus commission plus bonus, and nonfinancial (promotion, redeployment, sense of accomplishment, opportunity for personal growth, recognition, job security, star clubs).

Whether or not a company chooses one of these schemes is largely dependent on the desired sales force objectives. Some compensation schemes work better than others for individual sales force objectives. Sales force objectives include: increased total sales; increased market shares; increased sales of profitable products; increased sales of new products; increased sales of products during their low sales seasons; balanced sales portfolio; reduced direct selling costs; new segments; new accounts; competitor account conversion; account retention; account satisfaction; product presentations in clinics; hospital formulary inclusion; patient inclusion in postmarketing studies;

increased sales call numbers; increased customer bibliography requests satisfied; competitive intelligence gathering; increased disease, product, market, or competition knowledge level; and improved sales technique application. Furthermore, attention must be given to designing sales force objectives so that both the organizational and sales force objectives are achieved. Some of the important issues are: Submission Management and Review Tracking (SMART) objectives, transparent objective setting, company-specific incentive schemes (new versus old products), incentives as a percentage of total compensation, and incentive ceiling for top performers.

Organizing

Organizing the sales force involves determining the required sales force size, specialization, territory alignment, setting sales quotas, sales force reporting, and expense control (travel, meals, hotel, car rental, phone/fax, minor gifts to customers, and miscellaneous such as tips or baggage handling).

As Figure 17.6 shows, there are three different ways of determining the required sales force size, namely, the workload, breakdown, and incremental method.

After determining their size, sales forces need to be carefully deployed. Table 17.7 describes how a sales force size is determined by the workload method, and then deployed to the field.

Territories must be realigned constantly due to changes in selling strategy (key account instead of all accounts, restructuring, merger); change in product portfolio (new launches or withdrawals); demand growth (increased demand for anti-obesity medications); hospital consolidation; change in prescriber number (relocations, retirements, or deaths); sales force turnover changes in competition (sales force specialization, new launches, new promotional campaigns); changes in government regulation; and new intelligence sources.

Another important sales force issue is their specialization type. Pharmaceutical sales forces are most often specialized according to one of the four methods listed in Table 17.8, namely, by customer, product, task, or region.

Occasionally, other product priorities or a product launch date moved forward due to an unexpectedly fast regulatory approval process necessitate rapid deployment of a specialized and trained sales force to capitalize on opportunity. In this case, an increasing number of global pharmaceutical players rely on the services of a CSO with a large

Figure 17.6. Determining the required sales force size

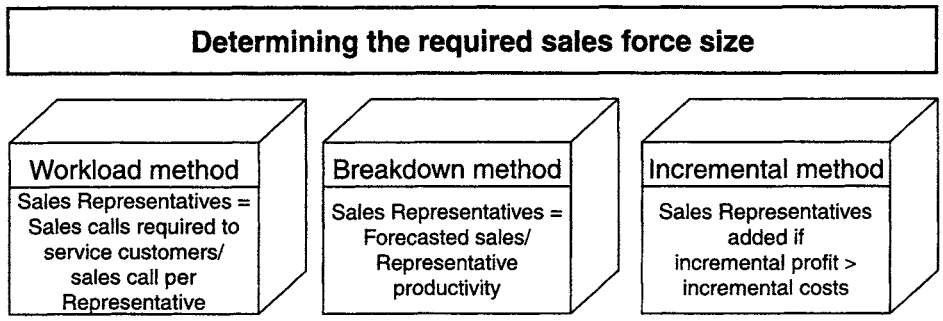


Table 17.7: Pharmaceutical Sales Force Deployment

Task	Parameter to Be Determined	Number
Allocation of sales effort (i.e., how many calls needed to cover the target).	Number of prescribers (accounts and prospects). Average sales call frequency. Total sales effort required (2,000 × 10 = 20,000)	2,000 10 times per year 20,000 calls per year
Sales force size (i.e., how many representatives needed).	Average daily sales call frequency by a representative. Average number of representative working days. Average number of calls per year per representative (10 × 200 = 2,000) Number of representatives required (20,000/200 × 10 = 10)	10 calls per day 200 days per year 10 representatives
Territory creation (i.e., how many territories are needed).	10 territories are needed to ensure proper coverage. In most countries, pharmaceutical companies define territories in IMS territory equivalents (see Chapter 5). If 30 IMS territories in country, (30/10 = 3).	10 Territories 3 IMS territories per representative
Actual territory design (i.e., which territories per representative).	The sales force must be given balanced territorial groups, which are grouped according to number of territories, number of customers, value size of district, and growth potential of district. Determining factors are salesperson's home, number of large accounts, and number of metropolitan areas.	Representative A in North sectors Representative B in Central sectors Representative C in South sectors 3 territories each sector

and flexible team of sales force professionals. The obvious benefits in collaborating with a CSO include fast deployment, ROI maximization, customization to a client or territory, risk minimization, outsourcing the difficult task of sales force management, more control than a potential copromotion agreement, and cost effectiveness for companies not vertically integrated (e.g., biotech startups).

KEY ACCOUNT MANAGEMENT

Key account management is based on the fact that all accounts are not created equal. In other words, individual prescribers or organizational buyers may have a different patient base, different prescribing habits, diverse formulary limitations, and so on that make them quite different from each other. Vilfredo Pareto, an Italian sociologist, devised the *80/20 Principle,* which states that 20 percent of human events usually result in 80 percent of the

Table 17.8: Sales Force Specialization Types

	By Customer	By Product	By Task	By Region
Example				
	Hospital Private Practice Key Account Pharmacy	Immunosuppressant Hemopoietic factor Anti-emetic	Initial sales Follow-up (e.g., training) Promotion efforts	Capital city North region South region
Advantage				
	Consistent with market driven strategy Representatives are customer experts	Focus of sales effort High expertise	Task specialization	Less complicated Less travel time Less conflict
Disadvantage				
	High costs	High costs Duplication of sales calls to prescribers	Duplication of sales calls	No product specialization

outcomes. His theory has found wide acceptance in the business world, and is even applicable in medical prescribing or organizational buying. Today's pharmaceutical sales forces are moving away from the indiscriminate and resource-intensive medical detailing of the past, and moving into sophisticated key account management; namely, the identification, needs satisfaction, and profitability monitoring of the top key accounts.

Planning

Two of the most important sales force planning activities include efficient sales call schedule planning and setting sales quotas.

Sales call planning

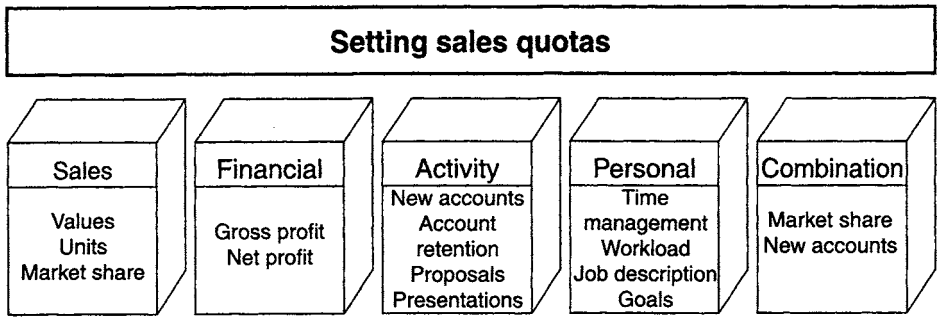
Sales call planning is determined by each prescriber's importance ranking, which then determines when sales force time is allocated. Modern sales force planning software efficiently creates sales call plans based on large prescriber information databases, past purchases, and so on.

Setting sales objectives (quotas)

Primary emphasis should be always on maintaining physicians' interests in prescribing. Enhancing the product or company image, distributing information, collecting market information, or customer service should follow. Typical sales objectives include the following: units/values information, market shares, formulary inclusion, call targets/target rating, sales cycles, target call frequency, average time per sales call, and dividing representative time among product lines.

Setting a sales quota is one of the most demanding activities of a sales force manager. This is because achieving both company sales objectives and individual representative's quotas (and their compensation and rewards) are dependent on a skillful and objective quota setting procedure. Figure 17.7 presents some of the types of selling quotas used by industry sales forces.

Figure 17.7. Setting sales quotas



Budgeting

Budgeting involves the allocation of resources to a sales force organization, in the form of recruiting, training, equipping, compensating, rewarding, and covering expenses.

Evaluating Performance

Evaluating the performance of a sales force is critical for both the organization and the sales person. There are a variety of potential measures currently used by the industry, such as: individual sales performance reaching target sales, individual business objectives, team sales results, team objectives, account-specific objectives, territorial objectives, company results, individual competencies (product knowledge, sales techniques, objection handling), and customer satisfaction.

MARKETING TO SALES INTERACTION

The marketing to sales interaction is a critical interface within the pharmaceutical industry. Table 17.9 shows why such an interface is important and how it should be conducted on a regular basis.

Table 17.9: Pharmaceutical Marketing to Sales Interaction

Why	What	How
To mutually educate	Positioning, targeting, profiling	Area meetings
To exchange product, customer, market, and competitor information	Promotional strategy and tactics	Electronic reports
To align	Competitor activity	Monthly reports
To focus	Key accounts	National meetings
To motivate	Regulatory environment	Double calls
To discuss	Market research	Sales training
To share	Opportunities and threats	Campaign planning Brainstorming

FUTURE SALES MANAGEMENT TRENDS

Finally, pharmaceutical sales forces are currently experiencing the beginning of future trends that are slowly changing the industry. Some of the prevailing trends are the movement from transactions to relationships, individuals to teams, sales volume to productivity, management to leadership, and local to global. Sales force managers should closely monitor these trends and adjust their structures and processes accordingly.

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18

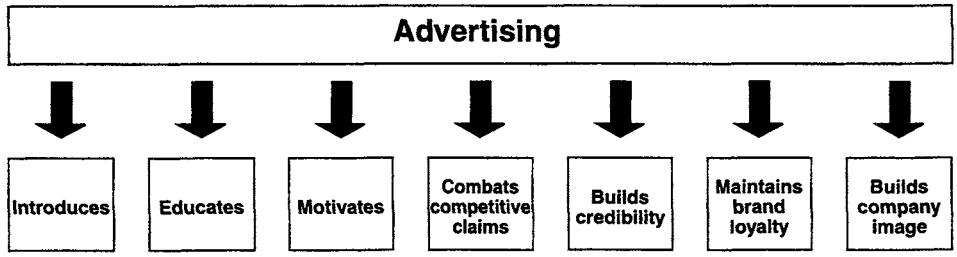
Advertising

> In recent years, the U.S. retail prescription drug industry has grown dramatically. The number of retail prescriptions dispensed each year increased from 2.0 billion in 1992 to 2.6 billion in 1997. This represents a 23 percent increase in just five years.
>
> NACDS, 1999

In a previous chapter, advertising was defined as a nonpersonal, paid communication about an organization, product, or idea by an identified sponsor. Advertising is one of the elements of the pharmaceutical promotional mix. Figure 18.1 shows the principal effects of advertising.

Nevertheless, advertising *does not* sell products of inferior value. In the pharmaceutical market, it is always the prescribers' and patients' personal experiences that determine if a new pharmaceutical product achieves a significant market penetration and long life cycle. Conversely, those same experiences determine if it will only capture a small market share and quickly be withdrawn. This chapter focuses on the idiosyncrasies of pharmaceutical marketing and the available channels and activities, as well advertising planning and development over a product's life cycle.

Figure 18.1. Effects of advertising



IDIOSYNCRASIES OF PHARMACEUTICAL ADVERTISING

Pharmaceutical advertising has several similarities to and some distinct differences from the advertising of consumer goods. The characteristic idiosyncrasies of pharmaceutical marketing are the following: advertising is directed to the prescriber, not the final consumer; the target audience is identifiable; the company image is important; scientific journal reputation is key; rational appeals dominate primary prescribing decision, while nonrational appeals dominate secondary prescribing decision; medical advertisement readership is higher than for consumer products; the summary of product characteristics (including weaknesses) must be attached; and there is a medical pyramid of influence. Understanding these differentiating factors is important for pharmaceutical marketers because it significantly influences their advertising strategy choices, as shown later in this chapter.

PHARMACEUTICAL PROMOTION IS REGULATED

The major international regulatory bodies closely regulate pharmaceutical advertising. For example, the FDA's pharmaceutical advertising regulation includes Section 502(n) of the Federal Food, Drug and Cosmetic Act specifying that advertising include: (1) the product's established name, (2) its formula, and (3) a brief summary of its side effects, contraindications, and effectiveness. Some important aspects of pharmaceutical advertising regulation are presented below.

- Drug advertisements mentioning the product's uses and effectiveness must contain information on contraindications, adverse events, and interactions (since the 1960s).
- The FDA requires that drug advertisements are not "false or misleading," mention only approved uses of the drug, and present a "fair balance" between beneficial and detrimental effects (Kessler and Pines, 1990).
- The FDA has selfdefined its regulatory jurisdiction as including "all information-disseminating activities by or on behalf of a prescription drug manufacturer" (Kessler and Pines, 1990). However, its limited staff cannot properly monitor all pharmaceutical advertising activities.
- Although they have limited reach and power, various European national regulatory bodies require the pre-approval of any pharmaceutical advertising.
- The FDA, with the American Medical Association (AMA) and the Accreditation Council for Continuing Medical Education (CME), has tried to

regulate drug company-supported CME (Randall, 1991, Kennedy). However, lawsuits from both physicians and the industry stopped these measures (Editorial, 1994, *Medical Marketing & Media Journal).*

- Members of the U.S. Congress (Senator Ted Kennedy and others) held hearings on pharmaceutical marketing in 1974 and 1990, which led to the adoption of advertising and gift-giving guidelines by both the AMA and the drug industry (U.S. Senate, 1990).
- The AMA included in its 1990 *Code of Ethics* the following pharmaceutical advertising regulatory statements:

  > Gifts from drug companies should not be expensive and should somehow have the potential of being used for the benefit of the patients. Gifts may not be contingent on physician behavior, in particular on prescribing practices.
  >
  > Support of CME meetings should consist of funds disbursed directly to the course director and not to individual attendees. In some cases drug companies may still control who speaks at CME meetings.

In addition to international government agency regulation, there is a significant degree of industry self-regulation of pharmaceutical advertising, both at the national and international level. The IFPMA defined its pharmaceutical marketing code in 1994.

PHARMACEUTICAL ADVERTISING CHANNELS AND ACTIVITIES

There are a variety of advertising channels available to industry marketers. These can be broadly categorized as mass media (broadcast, print, publicity, congresses, and others) or direct (print, phone/fax, electronic, and others). Examples of these categories, together with their advantages and disadvantages and related considerations are summarized in Tables 18.1 and 18.2.

The managed care environment has created an even more diverse audience for pharmaceutical advertising. Now pharmaceutical companies have to appeal to employers, insurance fund administrators, and hospital administrators. Furthermore, the growing patient advocacy movement has strengthened the decision power and voice of patient groups. These results necessitate the use of DTC advertising in those countries where allowed (currently allowed in the U.S., but not in Europe). Two other important recent trends are the public demand for health economic data and more value-added components.

Push and Pull Strategy

Pharmaceutical advertising uses two different approaches to reach its target audiences: *push and pull strategies* (see Figure 18.2). In the push strategy, pharmaceutical company marketers design a variety of marketing items (product brochures, congress stands, medical journal advertisements, multimedia CD-ROMs) that are carefully aimed at their target prescriber segment to increase product awareness and liking. These activities may, in turn, lead to prescribers' convictions and preferences. This leads to prescribing the company's products to their patients.

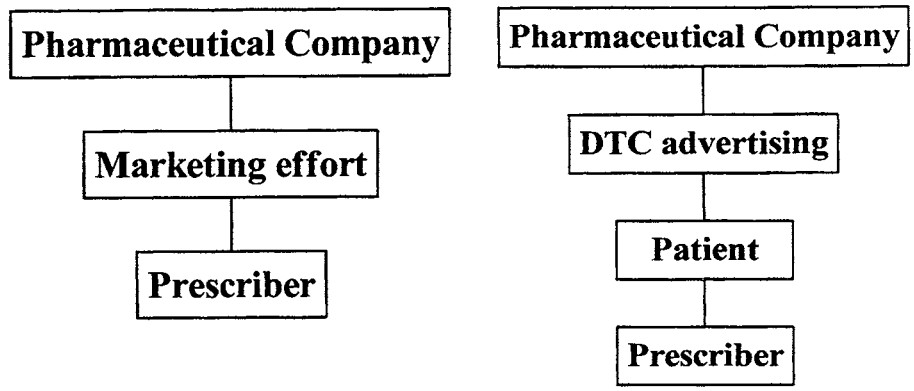
Table 18.1: Pharmaceutical Advertising Channels: Mass Media

Media	Advantages	Disadvantages	Considerations
Broadcast Media			
Radio	High frequency, broad audience, low cost.	Too many stations, short message duration, sound only.	Run of station (ROS).
Broadcast Television	Mass coverage, high speed, impact, and credibility, product demonstration, timing flexibility.	High prices, short message duration, no targeting.	Day and time zone.
Interactive Television	Targeted audience, possibility for feedback.	Expensive investment, limited coverage.	Databasing and managing feedback.
Closed-Circuit TV	Targeted audience.	Expensive investment.	Programming subjects, objectivity,
Print Media			
Medical Journals	Medical specialty selectivity, credibility.	Infrequent, low readership.	Page rate, color rate, cover rate.
Lay Magazines	Demographic selectivity, color print quality, long life, high reader interest.	Long lead time, high costs, low geographic coverage.	Page rate, color rate, cover rate.
Lay Newspapers	High ad print quality not required, coverage of all demographic segments, geographic selectivity, short lead time, inserts, coupons.	Local coverage, short life-span, no audience selectivity, low print quality.	Position, column inch rate, color rate, insert rate.
Physician Directories	Thorough coverage.	Low readership.	Ad rates, distribution.
Publicity			
Press Conferences	Corporate image building.	High costs, high newsworthiness needed.	Venue, timing, spokesperson media savvy.
Press Releases	Credibility.	High newsworthiness needed.	Recipient list.
Congresses			
Medical Congresses	Attendance, credibility, product demonstration, market research possibility.	Rising costs, large scale planning needed.	Congress stand costs, booth rental costs, labor costs.
Other			
Product Tie-ins	Direct response.	Price discounting.	Timing, location, evaluation.
In-pharmacy Display	Stimulate impulse buying.	Pharmacy chain bargaining power.	Retailer negotiation.
Outdoor	Frequency, mass audience, creativity, flexibility.	Local coverage, decreasing impact, high cost, long-term contract, difficult verification.	Poster size, traffic count.
Kiosks	Interactivity.	High costs, limited use.	Technology, Web connection.

Table 18.2: Pharmaceutical Advertising Channels: Direct Media (continued)

Media	Advantages	Disadvantages	Considerations
Printed Media			
Sales Literature	Promote sales call.	Frequent updates.	Creative charges, print charges.
Prescription Pads	Constant prescriber reminder.	Physicians' acceptance.	Creative design.
Direct Mail	Chosen audience, long message, smaller scale testing possible.	Low readership.	Address lists, postage rate.
Phone/Fax			
Telecommunications	Mass reach, possibility for feedback.	Customer annoyance.	Telemarketing costs, phone lists.
Electronic/Interactive			
Web Site	Instant flexibility, interactivity, massive information, huge audience.	No targeting, proprietary areas are difficult to visit.	Friendliness, electronic visit monitoring, site design.
Audio	Flexible, low cost.	Decreasing impact.	Text, announcer.
Video	High impact, wide use.	High video taping costs.	Messages, actors, studio.
E-mail	Very convenient and fast.	Increasing volume of junk mail.	E-mail lists, readership.
Multimedia CD	High impact.	High costs.	Design.
Other			
Reminder Items	Promote usage through reminding.	Decreasing impact due to competition.	Innovation, costs.

Figure 18.2. Push versus pull advertising strategies



In the pull approach, industry marketers target the patient audience directly by using a set of different promotional activities. For example, they may insert lay newspaper advertisements or use radio and TV advertising, or use magazine coupons and shopping mall signs. How can this approach lead to the commercial success of pharmaceutical products? In the case of OTCs, the customer is free to visit the neighborhood pharmacy or grocery store and seek the advertised brand. In the case of prescription medicines, a patient will visit a physician and discuss the disease treatment requirements, the risks and benefits of various treatments, and very often, the advertised brand itself with her or him, thus influencing the prescriber to prescribe it. In other words, the patient is acting as a company's sales representative, reminding the physician of a product's benefits and asking for its prescription.

The pull approach (where the prescriber is "pulled" by the patient, instead of being "pushed" by an advertisement) is used increasingly in the marketing of both innovative and generic products. This approach is called DTC.

DTC Advertising

DTC advertising is taking the pharmaceutical promotion campaigns by storm. In those countries allowed, it is used for a wide variety of prescription or OTC products, with significant influence on the product's sales performance. Industry experts have described the role of DTC as follows: DTC creates brand name awareness in the minds of the public; it seeks to indirectly increase product demand and sales by driving patients to influence physicians' prescribing decisions; it challenges the efforts of MCOs to impose restrictive drug formularies; and it tries to influence patients to pay higher copayments for DTC-marketed products. In designing a new DTC campaign, marketers follow these steps: (1) target identification, (2) identify unmet therapeutic need, (3) direct the patient to see a physician, and (4) influence the patient to ask for the product.

DTC tactics are diverse and may utilize several media. Some of the typical DTC activities include product advertisements appearing as lay press testimonials, drug cost assistance, internet, mail samples, patient information, patient videos, press releases,

radio or TV advertising, rebate coupons for prescription drugs, see-your-doctor coupons, and toll-free telephone lines. Therapeutic categories most commonly advertised by DTC are those with a strong element of patient participation in the treatment selection. Strong patient participation may be due to the chronic nature of the disease, multiple physician opinions sought, multiple brand switches, lifestyle implications, or low past compliance with the prescribed medications (for example, antidepressants, cholesterol-reducing agents, contraceptives, hormone replacement therapy, migraine, respiratory diseases, and ulcer). Table 18.3 shows the top spending DTC brands in the U.S. market during the first eleven months of 1998.

ADVERTISING PLANNING AND DEVELOPMENT

Pharmaceutical advertising activities include the following: (a) objective setting, (b) budget definition and allocation, (c) message decision, (d) media selection, (e) production, and (f) evaluation. Some of their most important characteristics and aspects are described in Table 18.4.

Objective Setting

Advertising objective setting is a critical step in advertising strategy creation. Some of the most common advertising objectives are shown in Table 18.5.

Based on their specific message objectives, pharmaceutical advertising approaches can be categorized as informative, persuasive, and mnemonic (reminder). Typical examples of each of these advertising approaches are provided in Table 18.6.

Determining which approach to use is dictated by prescriber and customer characteristics, the therapeutic area, and competitor, as well as product aspects. In general, the advertising objectives of most pharmaceutical products seem to be influenced by their product life cycle stage, as shown in Table 18.7.

Table 18.3: Top Spending U.S. DTC Brands January through November 1998

Rank	Brand/ Family	DTC Dollars Jan.–Nov. 1998	Percent change from 1997	Advertising to Physicians Dollars Jan.–Nov. 1998	Percent change from 1997	Total Dollars Jan.–Nov. 1998	Percent change from 1997
1.	Claritin	182,938	170	74,974	18	257,912	96
2.	Propecia	82,386	N/A	18,051	N/A	100,437	N/A
3.	Zyrtec	74,094	45	51,307	–20	125,401	9
4.	Pravachol	59,243	–19	47,400	–3	106,643	–13
5.	Allegra	52,437	–18	57,108	31	109,545	2
6.	Zyban	48,502	47	19,772	7	68,274	32
7.	Prilosec	45,184	23	47,950	90	93,134	52
8.	Zocor	42,124	–14	41,986	–10	84,110	–12
9.	Evista	39,153	N/A	48,918	N/A	88,071	N/A
10.	Prozac	39,099	98	54,566	–3	93,665	23

(IMS HEALTH and Comparative Media Reporting)

Table 18.4: Pharmaceutical Advertising Planning and Development

Objective Setting	Budget Definition and Allocation	Message Decision	Media Selection	Production	Evaluation
Objectives Target market, response sought, reach and frequency	Budgeting approaches Breakdown Build-up	Important attributes AIDA	Steps involved Major category, vehicle, timing		Evaluation methods Measure recognition/recall, measure attitude changes, generic inquiries
Important factors Product, market, customer-focus, environment, budget, marketing mix	Budgeting methods Affordable Percentage-of-sales Competitive basis Objective-and-task	Steps involved Generation, evaluation and selection, execution	Category criteria Target audience, product, message, cost		Important components Copy testing, media testing, expenditure testing
Target market Physicians, specialists, patients, public		Message hooks Product related, physician related, clinical use, patient, manufacturer related, nonrational	Category types Mass media: Broadcast, print, outdoor, in-pharmacy, other Direct media: Printed, phone/fax, electronic/ interactive		Copy-testing methods Pretesting: Direct ratings, portfolio tests, laboratory tests Posttesting: Recall tests, recognition tests
Response sought Inform, persuade, remind		Message themes Rational, emotional, moral	Vehicle criteria Cost-per-thousand, target audience reach		
Reach and Frequency Few specialists or large population			Timing criteria Seasonality/burst, continuous, intermittent		

Table 18.5: Common Pharmaceutical Advertising Objectives

1.	Establish awareness within target market: Promote corporate image / therapeutic category leadership
2.	Influence consumer perceptions (prescriber, pharmacists, patients): Establish product image, modify product positioning, educate, eliminate misconceptions.
3.	Influence consumer preferences
4.	Influence consumer behaviors: Develop intend to prescribe/purchase, encourage switching, promote new uses, new strengths, new formulations.
5.	Influence health personnel, administrators.

Budget Definition and Allocation

The allocation of financial resources to pharmaceutical advertising can be done with various methods. Some of the typical methods include: historically based (or same as the last time) all you can afford, breakdown method (or percentage-of-sales budget), competitively based (equal to or bigger than competitor's), build-up method (end objective), per unit allocation, and research approach. Which method is appropriate depends on the availability of past data, competitive benchmarking, resource strength, or time limitations. Marketers should make an effort to benchmark and question their advertising budgets as often as possible.

Message Decision

As previously mentioned, pharmaceutical advertising messages can be informative, persuasive, or reminding. The advertising vehicle may be product-related, physician-related, clinical use-based, patient-related, manufacturer-related, or nonrational. Examples of these different approaches are provided in Table 18.8.

Table 18.6: Pharmaceutical Advertising Message Objectives

Informative	Persuasive	Mnemonic (Reminder)
New therapeutic products	Pharmaceutical brand preference	Mature products
New therapeutic indications	Growth products	Product availability
New strengths, formulations, packagings	Attitudes toward product benefits	First choice
Low adverse events	Talk to sales representative	Most widely prescribed medication
Educational services	Long-term cost-effectiveness	Low price
Disease management	Prescribe/try now	Purchase more for home/office use
Company image: therapeutic category expertise, global leadership, vision and ethics	Brand switching from competitive products	
Administration instructions		
Compliance promotion		
Eliminating fears of adverse events		
Switch to OTC status		

Table 18.7: Advertising Objectives over the Pharmaceutical Product Life Cycle

	Pre-introduction	Introduction	Growth	Maturity	Decline
Promotional Objective	Set objectives, design tactics, set budgets	Establish awareness, enhance demand	Support product liking and preference	Maintain loyalty, encourage switching	Promote new uses, new strengths
Advertising Strategy	Concept testing, media selection	Develop intention to prescribe/buy, inform trade	Increase spending, increase intensity, fight competition	Promote repeat purchases, remind and differentiate	Decrease spending if withdrawal, advertise replacement
Message Objective	Tease, prepare market	Inform	Persuade	Remind	

Agency Selection

The advertising agency selection should be done early in the advertising planning process. Some useful criteria for selecting an advertising agency in pharmaceutical marketing include: market segment specialty (therapeutic area and geographic region expertise), location, track record, compatibility, business ability, type of help required, and size.

Media Selection

Media selection is an integral part of the overall advertising planning. In general, the criteria for selecting an advertising medium are campaign objectives, budget, geographic focus, target audience, competitive environment, and timing.

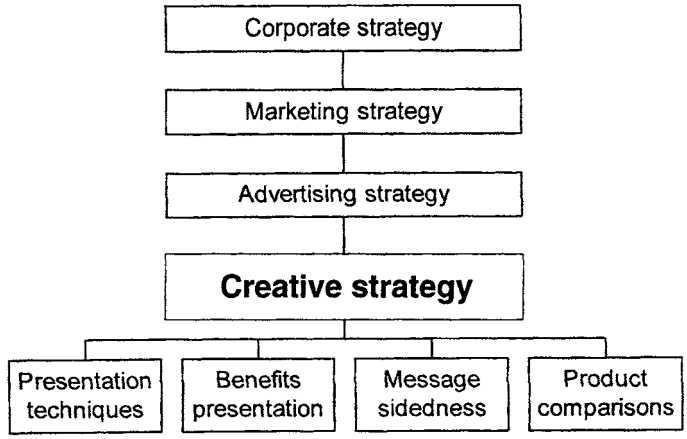
Production

Production refers to designing the creative strategy, its concept testing, and final creation of the desired medium (black and white, four-color processing, and so on) to be used for reproduction purposes. Figure 18.3 describes the main elements of an advertising creative strategy.

Table 18.8: Pharmaceutical Advertising "Hooks"

1.	Product-related	Efficacy, safety, innovation, mechanism of action, route of administration, cost-effectiveness, formulation, packaging.
2.	Physician-related	Specialists involved in clinical trials, publications, advisory committee recommendations.
3.	Clinical use	Safety, tolerability, dependability, clinical illustration, before and after.
4.	Patient-related	Compliance, quality of life, preference, patient group endorsement.
5.	Manufacturer-related	Leadership, innovation, image, history, patient orientation, services.
6.	Nonrational	Empathy, humor, curiosity, unusual image, self-gratifying, patriotism.

Figure 18.3. The elements of a creative strategy



Advertising Effectiveness Evaluation

The evaluation of pharmaceutical advertising effectiveness can be done either directly (through market research among prescribers, patients, the public, and so on) or indirectly (by measuring its effects on a product's sales and marketing activities, actual sales results, and so on). Figure 18.4 describes some of these evaluation methods.

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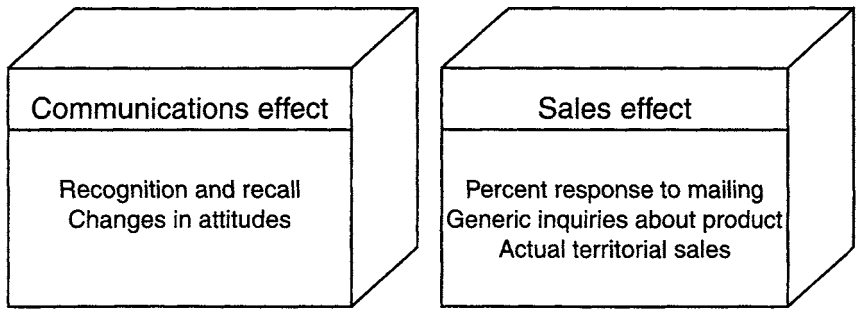
Figure 18.4. Advertising effectiveness evaluation



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19

Public Relations (PR) and Sales Promotion

U.S. chain pharmacies have annual sales of prescription drugs, OTC medications, and health and beauty aids of $135 billion.

NACDS, 1999

Most experts agree that the worldwide pharmaceutical environment is rapidly and substantially changing. Multiple reasons are often quoted for these changes. Government and regulatory changes in different nations are an attempt to implement stricter regulations, cost cutting strategies, industry profitability ceilings, ever more complex reimbursement considerations, and a strict outcomes-based approach. Managed care organizations impose strict formulary inclusion criteria, encourage generic substitution, and demand detailed pharmacoeconomic data. Prescribers are deluged with medical information, which makes it more difficult for the industry to attract their attention and adoption. Also, patients are more informed, demand participation in the decision-making process, and are combining their individual voices in powerful advocacy groups. Finally, industry players are consolidating, focusing on core therapeutic areas, and becoming fiercely competitive.

Operating under this competitive environment, pharmaceutical industry players are constantly reassessing their communication approaches toward diversified audiences, such as prescribers, regulatory authorities, administrators, pharmacists, health personnel, patients and their families, the media, and the public. A critical, yet often misunderstood,

communication approach is public relations. This chapter presents the main aspects of this powerful medium, describes how it differs from advertising or personal selling, and offers practical advice on planning, implementing, and evaluating a successful corporate public relations program within the pharmaceutical sector.

WHAT ARE PUBLIC RELATIONS?

Public relations attempts to create a mutual understanding of key messages among an organization, the organization's stakeholders, and the community as a whole. The most powerful element of a public relations program is credibility. Imagine the impact of a company or product presentation in the pages of *Newsweek*, or *Stern*, or the *Asahi Shibun*, as opposed to a classified ad in a medical journal or a sales pitch given by a pharmaceutical sales representative to a busy physician. Furthermore, think of the impact that a TV documentary about a revolutionary, soon-to-be-released biotech product for treating child leukemia had on you, an industry specialist. Such a "news item" carries a powerful, subliminal message of creditworthiness, breaking news importance, and global impact.

Now think of the potential impact that such a news presentation would have on prescribers and patients around the world, including the company's investors or financiers. Indeed, precisely targeting and delivering such a newsworthy message to a diverse audience is the principle behind pharmaceutical public relations programs currently implemented by the industry.

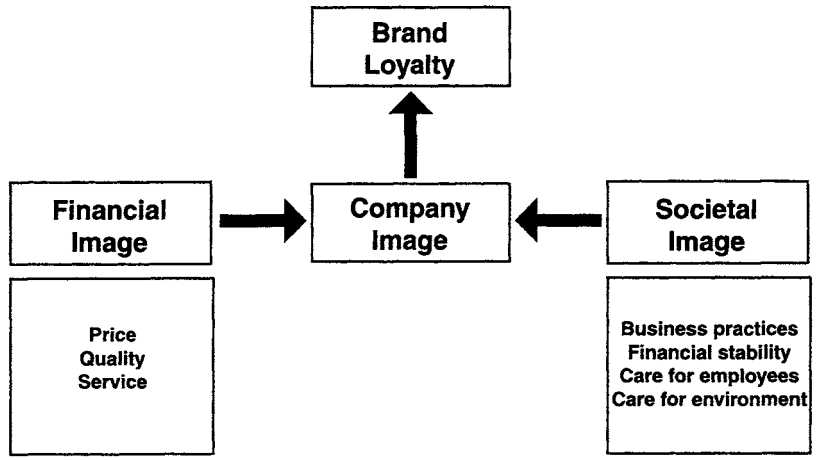
Consider for a moment what constitutes a company's image (see Figure 19.1). This is composed of a commercial image among its customers (based on product quality, price, service, innovation, and increasing the patients' quality of life) and a more general societal image (based on business practices, financial stability, care for its employees and the environment, and community relationships). Both of these parts contribute to the overall company image. This, in turn, has a direct relation to brand loyalty. This definition also applies to the pharmaceutical industry. Pharmaceutical PR people deal with the industry's commercial and societal image in every national market. The goal of public relations is to strengthen and improve these two images, leading to the overall success of the company.

Another definition given to public relations' goals is shown in Figure 19.2. Public relations aim at constantly creating value for shareholders and stakeholders. Obviously, the commercial success of the company brings value to shareholders in the form of stock dividends or long-term stability, while the company's good societal standing brings value to stakeholders in the form of customer or employee satisfaction or environmental sensitivity.

How, then, can corporate public relations programs bring value to stakeholders and shareholders? This can be achieved by pursuing one of the following objectives: communicate programs and policies, enhance greater recognition, stand apart from competition, build confidence, develop positive image, communicate with stakeholders who are not visited by sales force, influence policy makers, and manage publicity crises.

An important fact that needs to be emphasized is that public relations is *not* advertising. Indeed, PR is bigger than advertising; it relates to all the communications of the company. Advertising refers more to marketing. PR is *not* free advertising. Every organization is involved in PR in one way or another but not all organizations adver-

Figure 19.1. The company's public relations path to brand loyalty



tise. PR embraces everyone and everything related to the company. And finally, PR expenses are related to consultant fees, while advertising costs are related to media and production costs.

PHARMACEUTICAL PR INITIATIVES

Pharmaceutical PR initiatives can be based on a variety of types and themes. As Figure 19.3 indicates, the most commonly used types include corporate, financial, brand or product, crisis, personality, political, or community activities, as well as lobbying. Each of these types utilizes many different themes or angle points that are

Figure 19.2. Public relations' goal is to create value for shareholders and stakeholders

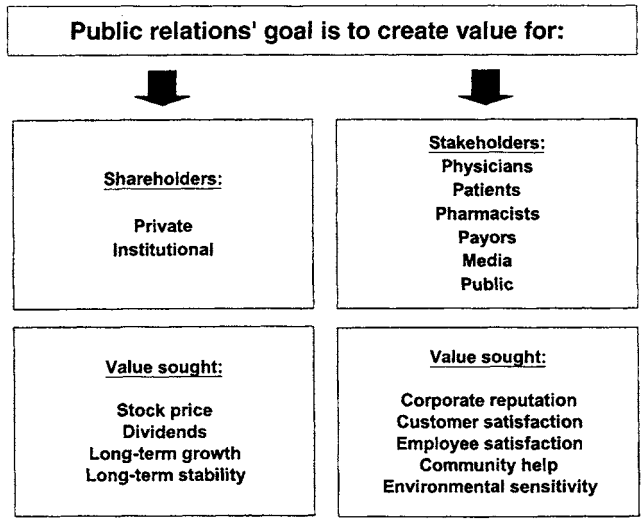


Figure 19.3. Pharmaceutical public relations themes

discussed later. Nevertheless, the common quality of each type is newsworthiness, that is, those characteristics that make a PR theme contain valuable media content by being interesting and attention-grabbing to the viewers, listeners, or attendees. What follows are some of the most commonly used themes of pharmaceutical public relations programs.

Corporate PR themes: great company; pride of the community or nation; large size; market leader; high-tech; high trust; and investing opportunities. *Financial themes:* positive financial results; exceeding last year's financial results; quarterly results according to target; getting approval for a significant bank loan; outstanding stock price performance; stock listing at a large stock exchange; stock dividends exceeding expectations; building of a new high-tech R&D or manufacturing facility; three new potential blockbuster drugs in pipeline; or new acquisition of a company adding synergy. *Pharmaceutical brand/product themes:* was discovered and/or produced with breakthrough technology; is a treatment breakthrough; is the focus of a major study announced in a prominent medical publication; is the focus of a presentation at a major international medical congress; has received the endorsement of a famous researcher, institute, or medical association; helps cut medical costs; is devoid of similar therapies' adverse events; helps patients improve their quality of life; or has helped a celebrity live a better life and he or she is willing to tell about it. *Crisis themes:* accidental death; adverse event reported in the media; black market; competitor action; environmental pollution; manufacturing plant accident; patient or family member's legal action; patient suicide; product contamination; product tampering; or theft from hospital. *Personality themes:* dynamic, overachieving Chief Executive Officer (CEO); Chief Financial Officer (CFO) just hired from a large bank; forward-looking Chief Investment Officer (CIO); new worldwide sales and marketing manager hired; R&D scientists receiving an innovation award; chief medical affairs man-

ager to give a public lecture; number of MDs, PhDs, and MBAs working within a team; Chief Operating Officer (COO) succeeding in completion of supply chain reengineering; board of directors visiting a local hospital to make large donation; or departing company founder leaves legacy behind. *Political themes:* company supports government initiative to increase healthcare spending; local government tax break required for long-term viability; company's position on reimbursement environment; new manufacturing site to be inaugurated by prime minister; foreign dignitaries visiting the board of directors to discuss company's investment; foreign ambassador visiting manufacturing facilities; or company supports opposition in its plight for universal health coverage. *Community themes:* building or expansion of local manufacturing unit; new hospital tender award leading to long-term growth; community donation to help build a new school; community work day for board of directors (road cleaning, tree planting, house painting); manufacturing facilities open house day; community sports day at local stadium; or new vacant positions at local facilities. *Lobbying themes:* registration; pricing; reimbursement; formulary; parallel exports; trade tariffs; antitrust; building permit; tender award; or state hospital receivables.

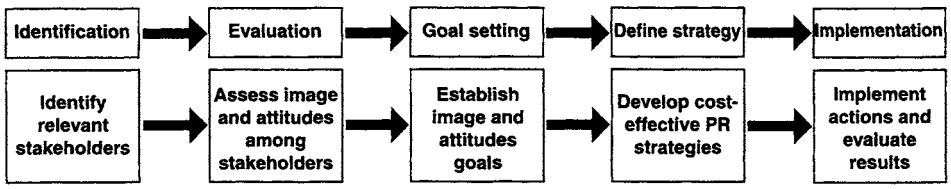
THE PR PROCESS

The PR process within an organization is depicted in Figure 19.4. First, the relevant stakeholders need to be identified and their attitudes and image of the company need to be assessed. An industry organization then sets the desired image and attitudes goals, which are in agreement with the corporate vision discussed earlier. Subsequently, cost-effective PR strategies are designed, implemented, and evaluated on an ongoing basis for all involved stakeholders.

Target Audience

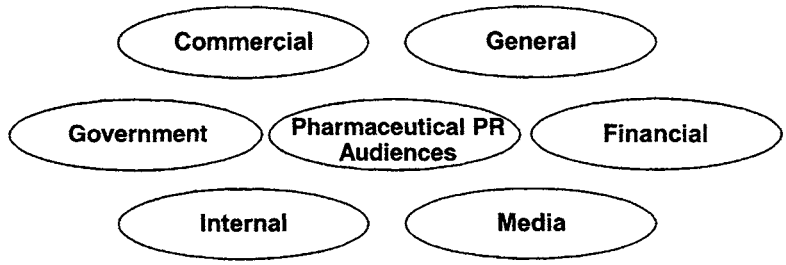
The industry's PR audiences are all related stakeholders. The characteristics of the most important stakeholder groups were discussed in Chapter 2. Figure 19.5 displays the main stakeholder categories that need to be targeted. The exact evaluation of their beliefs and attitudes uses the collection of secondary data available from several internal departments, or through primary research data collected via specially designed market research surveys (for more information see Chapter 5).

Figure 19.4. The public relations process



(Kotler and Clarke, 1987)

Figure 19.5. Pharmaceutical public relations audiences



PR Tools

There are a variety of PR tools that can be used by pharmaceutical PR professionals. The following list describes some of the most common tools.

Written material: annual reports; corporate magazines; corporate brochures; and planted article (advertorial). *Audiovisual material:* corporate video and corporate multimedia CD ROM. *Internal public relations:* corporate journal; newsletter; newspaper; intranet announcements; employee briefings; employee sports day; employee family day; and employee competitions and awards (best employee, photography, sculpture, car models).

Press relations: press release; press kit; press conference; press briefing; and press reception. Press relations are among the most important corporate PR activities. Industry marketers should always look for newsworthy stories. For example, a press release could announce the following: the discontinuation of animal testing; the sale of the vitamins division to another company; the purchase of a small biotech company; an international company campaign to eradicate malaria; a new biotechnology plant in the UK; the registration of a breakthrough anticancer agent; a new protein sequencing methodology; enabling new R&D possibilities; an infertile couple having a baby after hormonal treatment; hiring a new worldwide marketing director; or a donation to a local library.

Events: annual shareholder meeting; new subsidiary inaugural gala; new facility; inauguration; community open house day; or a community service day (tree planting, road cleaning, beach cleaning). *Exhibitions:* trade exhibition; international commercial expos; ethical manufacturer "innovation" exhibition; generics manufacturer shows; or foreign lobby exhibitions (e.g., American company subsidiaries operating in Italy or German manufacturers exhibiting in a Peking show). *Speeches:* school or university lecture; patient association lecture; public lecture; trade association speech; or congress speech. *Philanthropy:* financial support to patient association; community donation; university donation; hospital donation; or Christmas day hospital patient visit. *Corporate promotion:* TV or radio advertising; printed press advertising; road billboards; airport or athletic facility signs; or corporate gimmicks. *Sponsorships:* the arts (opera, dance, theater, photography, poetry, festival); sports (association, league, tournament, team, match); radio or TV shows (news, documentary, chat shows, drama or comedy series); hospital or clinic activities (blood drive, mass screening, door-to-door diagnosis); healthcare professional activities (physician galas, pharmaceutical expos); patient advocacy groups (office rent, destigmatization efforts, public service commer-

cials); community events (New Year's Eve celebration, new stadium inauguration); or education.

CRISIS MANAGEMENT

Crisis management (or damage control) could be defined as public relations under adverse circumstances. Its goals are to remove threats and regain control and to limit damage, and protect and maintain the company's reputation. Several potential industry crisis situations were described earlier. The essential methods to prepare for a PR crisis are: (1) create an internal mechanism, (2) distribute guidelines and crisis team contact numbers, (3) conduct training, and (4) make list of people to be contacted (authorities, OLs, medical societies, media, spokespersons, attorneys). Furthermore, at the time of the crisis, some useful items to remember include: (1) inform authorities if there are threats; (2) mobilize the predefined crisis team; (3) monitor the situation; (4) use official statements and dedicated spokespersons only; (5) crisis team may mobilize OL or regulatory authorities to contribute; (6) do not avoid confronting the media; (7) be strictly factual; (8) nothing is "off the record" in times of crises; and (9) beware of persons seeking scandals.

MEASURING THE EFFECTIVENESS OF PR

The effectiveness of pharmaceutical public relations can be measured, directly or indirectly, by conducting a variety of evaluations. Table 19.1 summarizes some useful methods.

INTERACTION WITH PR AGENCIES

The industry has relied on the PR expertise of both internal employees and external PR agencies, often working in tandem in pursuit of the company's PR objectives. The input of external agencies (preferably those specialized in health care) is invaluable, due to their powerful media relationships, large human resources size flexibility, expertise, and foreign market knowledge, as well as the essential diversity they add to internal

Table 19.1: Measuring the Effectiveness of Pharmaceutical PR

Budget	Awareness	Attitude	Media Coverage
Versus budget, last year, total promotion, competitors.	Pre- and post-PR awareness, liking, preference, conviction of customers.	Pre- and post-PR stakeholder attitudes about company, products, management.	Broadcast frequency, broadcast time, number of newspapers, media clippings.
Positioning	**Response Generation**	**Share Price**	**Sales**
Perceptual mapping of own company or products versus competitors.	Number of phone calls, faxes, or e-mails, new prospect leads, new patients treated.	Level, liquidity, range.	Units and values, new accounts, orders per account, order size per account.

thinking. However, the relationship between in-house and outsourced PR organizations needs to be managed closely and efficiently in order to achieve maximum synergy, inspiration, dialogue, and transparency. Some of the important aspects of this relationship are the following: PR *impact and credibility* are more powerful than any other marketing communications means; PR cannot force a desired *editorial content* on a news medium; PR attempts to deliver *few, clear, and consistent company messages* to its stakeholders through the media; PR *does not necessarily have an immediate effect* on company or product sales; effective PR should become a *corporate philosophy;* management or marketing's contribution to PR does not end with creating the message, but instead is a constant business philosophy, an approachability by the media, and a cultivation of *long-term relationships* with media professionals; PR agency input does not end with delivering the message to the media for publication, but is a constant business philosophy of *fine-tuning* it to each medium's needs, evaluating its usage, and informing the client; PR performance, although difficult to be quantified, is not a free-willing, open-spending endeavor, but a *carefully planned process* designed to offer long-term value to the industry client.

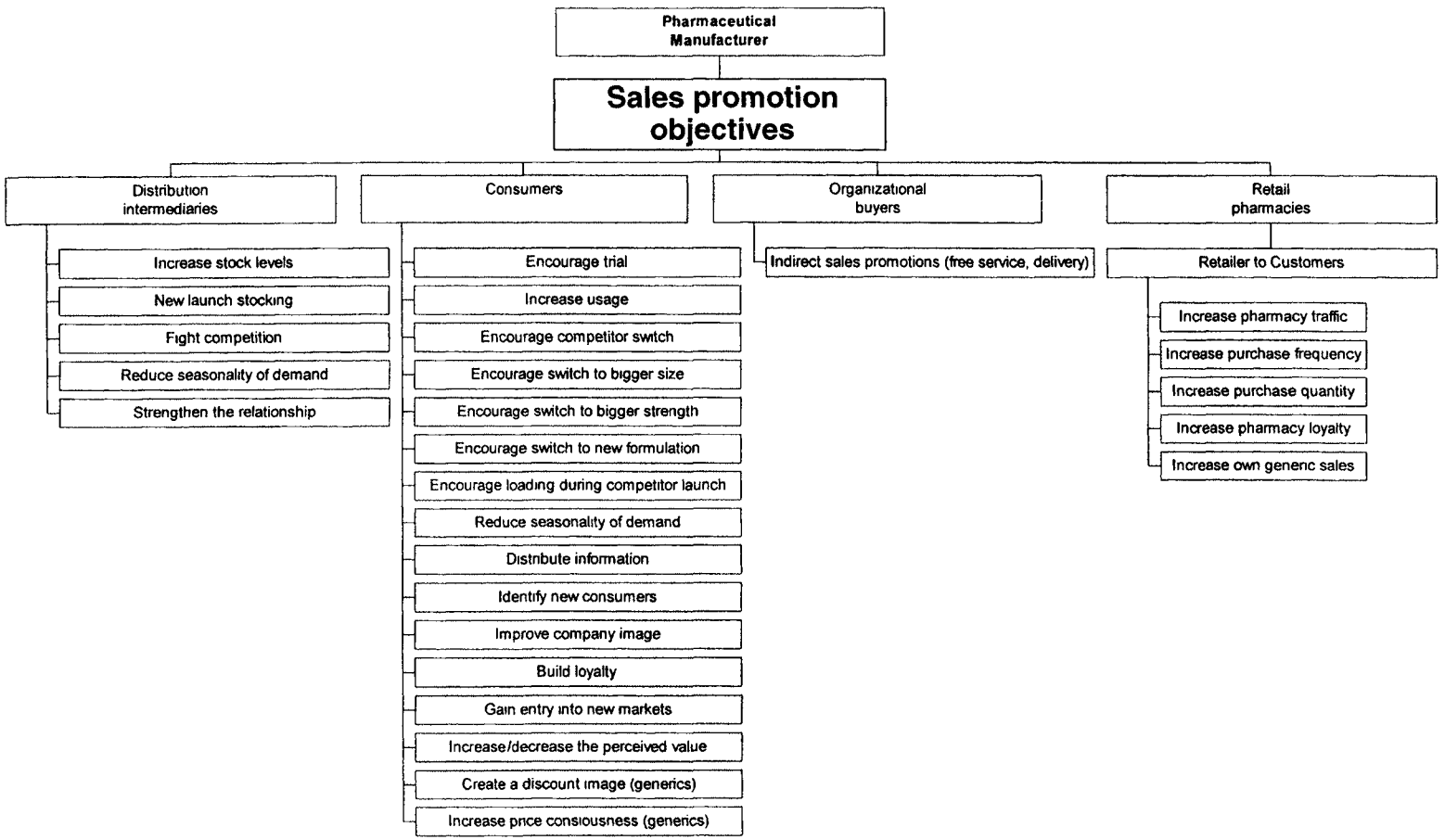
SALES PROMOTION

Sales promotion refers to the short-term offer of incentives to stimulate customer purchasing. This by no means implies that sales promotion should to be used as a last resort in times of sales slumps. In contrast, sales promotion is an organized, preplanned component of the overall promotional mix and should be used with the strategic promotional objectives in mind. Sales promotion can be utilized by a manufacturer to distribution chain intermediaries or organizational buyers or retailers, or by a retailer to customers. Figure 19.6 summarizes the main objectives behind the different sales promotion paths.

Table 19.2: A Pharmaceutical Sales Promotion Plan

Objective(s)	To encourage customer switch to a new, more profitable formulation. To attack competitive market-leading formulation.
Timing	Summer 2001.
Location	Middle East.
Resources required	International PM, Middle East Marketing Manager, Egypt PM, local agency.
Critical deadlines	February 2001: TV advertising campaign ready. March 2001: TV campaign aired in Egypt, Kingdom of Saudi Arabia, Arab Emirates. May 2001: Rebate coupons placed at pharmacies.
Budget	150,000 U.S. dollars for TV advertising campaign, rebate coupon printing, database.
Goal(s)	To increase regional sales by 40,000 new formulation units and capture additional 10% market share. To increase regional annual contribution by 3%.
Method of evaluation	Omnibus sales data, phone survey in 5,000 homes across the region.
Fit in overall creative strategy	Good penetration of new formulation in test region will support global launch.

Figure 19.6. Different sales promotion objectives



Some of the most common pharmaceutical sales promotion methods are: premium incentives, point of purchase displays, couponing, advertising specialties, promotional licensing, sponsored events, specialty printing, promotion fulfillment, interactive or telepromotions, refunds or rebates, customer contests or sweepstakes, loyal customer incentives, in-pharmacy marketing, product demonstrations (physicians, nurses, patients), and product sampling. Finally, a pharmaceutical sales promotion campaign needs to follow the overall promotional strategy—by satisfying the corporate objectives, following the pre-agreed budget, and so on. Table 19.2 shows a typical industry sales promotion plan.

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20

The Internet

An estimated 50,000 pharmaceutical company scientists are currently researching more than 1,000 new medicines for cancer, heart disease, AIDS, Alzheimer's, and many others.

PhRMA, 1999

Three decades ago, a few U.S. universities and the U.S. Department of Defense established an experimental electronic linkage between computers. This linkage allowed them to communicate and exchange information within their computer network, setting the basis for today's *internet*. That system gradually grew larger to include more educational institutions, and slowly included corporations and outside users. Eventually, the system crossed national boundaries. The growth of the internet was explosive during the 1990s. Today, the World Wide Web has more than 300 million users. This international computer network is based on a truly shared architecture, where there is no central computer administering the system. Instead, millions of individuals use personal computers to connect to *servers* (that hold information and data) via Internet Service Providers (ISPs) and communicate. Each of these countless personal computers, hosts, and servers has an identifying *electronic address* (IP, or Internet Protocol, address), which allows other systems to easily hook up to each other. They are all interconnected via a global system of electronic links called the *World Wide Web* (WWW or, commonly, the Web).

Individuals, educational organizations, associations, corporations, and governments are rushing to establish a presence on the Web because it is growing at phenomenal rates and is seen as the global communication medium of the Twenty-first Century. Furthermore, their combined presence on the Web has provided users with an enormous amount of information. And because most experts agree that access to this information will become one of the most instrumental business resources of the Twenty-first Century (see Figure 20.1), the explosion of the Web and its reach will be self-perpetuating for a long time.

These personal or organizational users create a set of computer files that collectively construct a *Web site*, or an electronic facade of their Web connection. This set of files is saved at one of the many international Web servers, and can be accessed twenty-four hours a day by any other computer user who knows their Web site address.

The electronic sites existing on the Web today serve an array of purposes. Some are informative, others are educational, others are used for electronic commerce (e-commerce). Some are used for financial services (e.g., banking, investing), advertising, recruiting and so on. Yet others are official government or corporate sites. The application of these new technologies and methods has significantly influenced the global pharmaceutical sector. Under the World Wide Web umbrella, regulatory agencies, pharmaceutical companies, distribution intermediaries, retail pharmacies (Web pharmacies), healthcare professionals, and patient associations interact with each other on a daily basis. The objective of this chapter is to discuss the ethical and commercial implications of marketing pharmaceutical products over the Web, present some important aspects of developing an interesting Web site, and also offer some useful insight on methods for evaluating the effectiveness of the Web.

PHARMACEUTICAL INDUSTRY AND THE WEB

The influence of the Web on the pharmaceutical industry has been overwhelming. Figure 20.2 summarizes some of the most important influences of this medium on the pharmaceutical value chain. It can easily be seen that the Web has diverse, beneficial influences on all components of the value chain, starting from the R&D of new products, to their regulatory approvals, their manufacturing and distribution, on to marketing and sales, customer service, human resources, and others.

The combined financial impact of these influences on the growth of the pharmaceutical and medical e-commerce have been estimated to surpass 44 billion U.S. dollars by the year 2003 (see Table 20.1).

Figure 20.1. Business resources in the Twenty-first Century

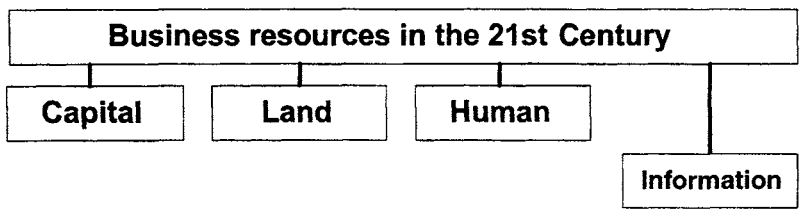

Figure 20.2. Pharmaceutical industry and the Web

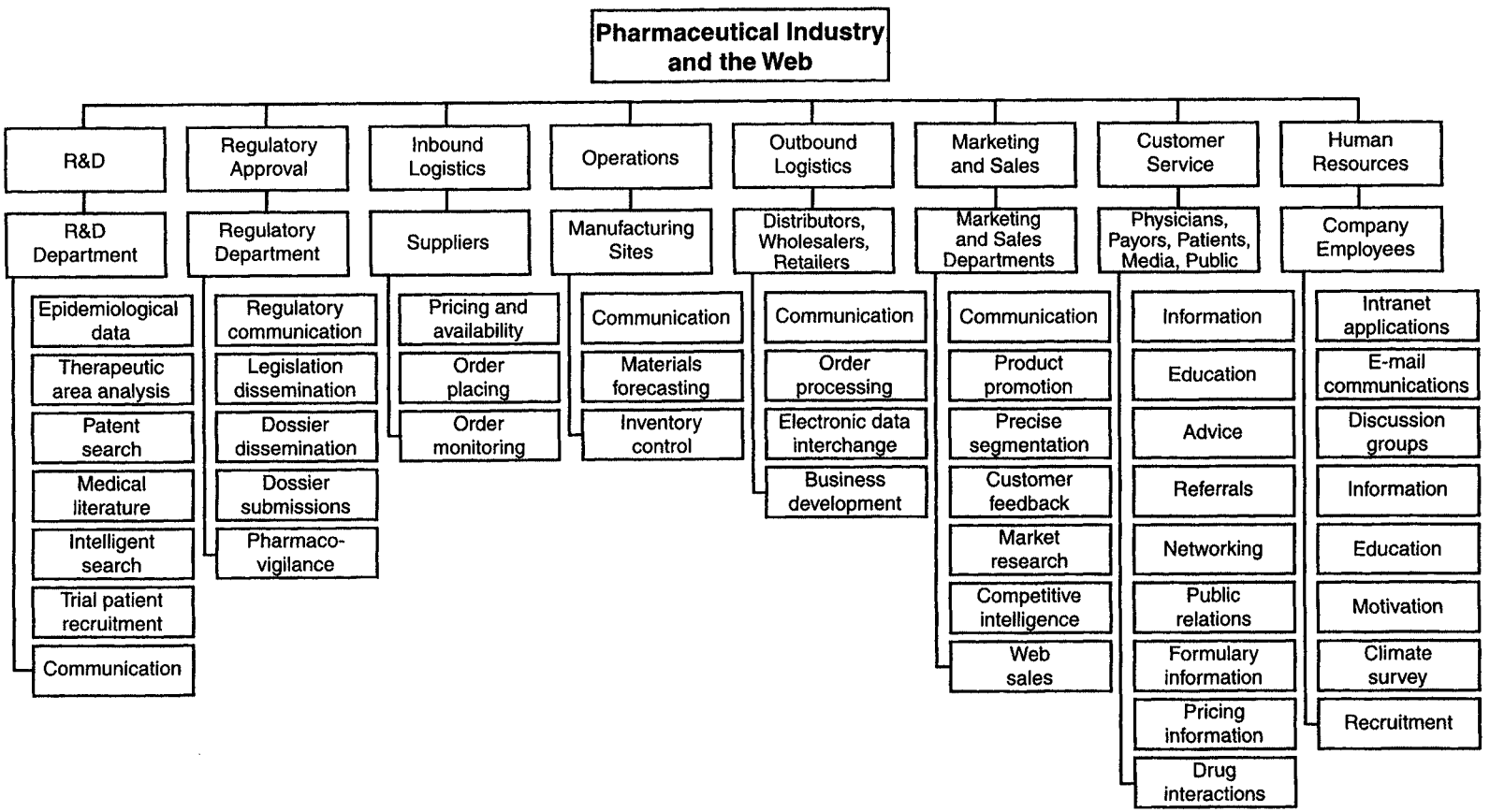

Table 20.1: U.S. Pharmaceutical and Medical E-Commerce Revenues (U.S. Dollars in Billions)

1998	1999	2000	2001	2002	2003
0.6	1.4	3.5	8.5	20.0	44.1

(Forrester Research, Inc.)

MARKETING PHARMACEUTICALS ON THE WEB

The Web has revolutionized several aspects of the traditional marketing mix for all products and services influenced by this medium, including pharmaceutical products. Table 20.2 describes the main consequences of this revolution on the four Ps of the marketing mix, namely, product, price, place, and promotion.

What, then, will be the main reasons that drive the pharmaceutical industry to conduct Web marketing in the future? The most important reasons are mass reach to all industry stakeholders; customer expectation; added customer service; not being left behind; cost sav-

Table 20.2: Web Marketing's Influence on Marketing Mix

Product	
	Larger product/service information content needed.
	New forms of information emerging.
	Mass customization of services.
	Branding is as strong as ever.
	Copyright protection critical.
	Reversal of traditional market exchanges: instead of offering a product at an asking price, ask the customers to set a minimum price and then offer a product or service.
	Niche market segments are precisely identified and targeted.
	Wider selection, lower price, and better service expectations reign.
	Virtual institutions lack the feel of traditional brick-and-mortar stores.
Place	
	Instant marketplace globalization.
	Physical space is replaced by virtual space.
	Products and services can be ordered online.
	In- and outbound logistics can be outsourced invisibly to the customer.
	Intermediaries are eliminated.
	Distribution margin is dwarfed.
	New digital intermediaries emerge (intelligent agents, search engines, auctions).
	Customers are redirected via links.
Price	
	New pricing and payment methods.
	Taxation is complicated.
	Markets become more efficient and even more competitive.
	Premium pricing is a thing of the past.
Promotion	
	Communication is no longer one-way, but two-way.
	New methods for push and pull strategies.
	Information is provided free, instantly, extensively, and customized.
	Virtual communities are formed (patient Special Interest Groups [SIGs], physician groups).
	Promotion strategies become flexible.
	Customer retention is key (acquisition, site traffic building, return hits).

ings; profitability; customization; flexibility; and competition. These reasons are driving the major industry players to create corporate Web sites in droves. However, the marketing strategies behind their internet campaigns differ. The varying information and services available at these Web sites include (a) company information only, (b) company, product, and service information, (c) after-service support information, (d) online ordering of product and service, (e) conducting e-commerce transactions, and (f) conducting complete sales cycles. Most pharmaceutical manufacturers today are involved in the first three Web marketing activities. Slowly, however, more and more pharmaceutical supply chain intermediaries are conducting e-commerce operations. We will study the progress and implications of drug dispensing of pharmaceuticals later in this chapter. Table 20.3 gives a detailed Web marketing tactical implementation framework.

Very often, Web marketing is aimed at internal audiences. Special networks that allow access only to internal employees are called *intranets*. Their main advantages are the following: (1) cost effectiveness, (2) easily updated, (3) ease of information delivery, (4) information customization, (5) secure, (6) easy to use and manage, (7) reduces paper costs and distribution time, (8) runs on all platforms, (9) internet portal, and (10) integrated with in-house databases.

Incorporating the Web into the Overall Marketing Strategy

Several Web-marketing experts have expressed the need for always incorporating the Web into the overall marketing strategy. Thus, a Web site cannot be isolated from physical marketing or be disassociated from the remaining elements of the promotional mix, that is, advertising, personal selling, and sales promotion. An industry's integrated communications strategy should efficiently combine the Web with all remaining elements and, ideally, make them self-depending. For example, the sales force tells the customer to look for more information on the corporate Web site or the company offers multimedia items and gimmicks only online. The ultimate goal of all Web-marketing efforts should be collecting large amounts of information about each customer and increasing the customers' lifetime equity—a strategy that has been called in other sectors "owning the customer."

DEVELOPING AN INTERESTING WEB SITE

Developing an interesting Web site is a large task by itself. Prior experience has shown that industry players should rely on the knowledge and training of experts. Experienced Web designers and managers (Webmasters) are available today in various national markets. Furthermore, studying the examples of Web pioneers from the pharmaceutical and other sectors is recommended.

Designing a detailed Web-marketing strategy and the related tactics are beyond the scope of this book. There are many Web marketing manuals available. In general, attention should be given to (1) targeting, (2) services offered, (3) response procedures, (4) security, and (5) monitoring. Furthermore, a variety of technical issues need to be addressed for creating and managing an interesting Web site. Some of these issues are naming, name registration, provider, mirroring, linking, technology, page design (idiosyncrasies of Web, layout, content, search engines, response to contacts), Web promotion, monitoring, and site management.

Table 20.3: Web Marketing Tactical Implementation Framework

Stakeholder	Activity	Physical Marketing	Web Marketing
Physicians	Information	Monographs, brochures, detail aids	Downloaded online and free
	Communication	Personal, phone, fax	Fast interactivity, e-mail
	Services	Guidelines, educational material	Downloaded online, 24 hours
Patients	Information	Patient information brochures	Huge content online, flexibility
	Education	Disease and compliance education	Downloaded online, 24 hours
	Referrals	Time consuming and complex	Fast, easy, anonymous
Retail Pharmacists	Pricing information	Phone, fax, price lists	Available online, always up-to-date
	Drug interactions	Complex contact with medical affairs	Vast online information, searchable
	Patient information materials	Limited quantity, manufacturer power	Available online, free
Hospital Pharmacists	Formulary information	Formulary books, pharmacopoiea	Available online, searchable
	Drug interactions	Complex contact with medical affairs	Vast online information, searchable
	Patient information materials	Patient information brochures	Huge content online, flexibility
Payors	Information	Official inquiries, sales representatives	Available online, cross-reference
	Pharmacoeconomics	Presentations, manuals, negotiations	Online access to outcomes databases
	Services	Required negotiations	Patient compliance training online
Suppliers	Pricing and availability	Phone, fax	Online 24 hours, always up-to-date
	Order placing	Phone, fax, inefficient and slow	Online order placing and verification
	Order monitoring	Impossible	Shipment tracking online
Marketing	Segmentation	Different materials for each segment	Different Web pages with huge content
	Market research	Agency selection, high fees, slow	Vast accessible audience online
	Customer feedback	Limited and unreliable	Constant and direct feedback online
Sales	Product promotion	Advertising, personal selling, PR	Vast opportunities online
	Product sales	Numerous intermediaries	Profitable Web sales, lifetime value
	After-sales support	Phone, sales force visit	Online services, satisfaction survey
Public Relations	Press relations	Expensive, slow, inflexible	Fast, up-to-the-minute, online material
	Audiovisual material	Expensive, low readership	Downloaded online on demand
	Corporate promotion	Small audiences, expensive	Vast audiences, flexible
Competitors	Competitive intelligence	Slow and inefficient process	Huge intelligence content online
	SWOT analysis	Limited data, subjectivity	Large amount of data, objectivity
	Benchmarking	Difficult	Fast

EVALUATING THE EFFECTIVENESS OF THE WEB

There is a wide availability of useful Web site monitoring tools used by industry's Web-marketing professionals. Figure 20.3 lists some of the most common.

DRUG DISPENSING VIA THE WEB

Before discussing the characteristics of drug dispensing via the Web, let us first consider the main advantages and disadvantages of e-commerce, as summarized in Table 20.4.

Most of these advantages and disadvantages apply in the e-commerce of pharmaceuticals (Web dispensing). This advanced form of Web marketing is not yet practiced by pharmaceutical manufacturers. However, entreprenurial Web pharmacies are being established on the World Wide Web. The catalysts behind this phenomenon are industry's deregulation, low distribution costs, and increased customer convenience.

Industry sources have predicted five possible scenarios for drug dispensing over the Web: (1) forward integration of pharmaceutical manufacturers into Web dispensing; (2) development of national Web-based platforms that interconnect physicians, pharmacists, regulators, insurance agencies, and patients, and provides fast and transparent dispensing; (3) development of medical Web sites that provide information and education, and allow prescribing and dispensing; (4) advent of Web pharmacies that utilize global economies of scale by offering cutthroat drug prices; and (5) creation of medical sites that provide medical advice, computerized diagnosis of selected diseases, and pharmacy referrals.

The beginning of the Twenty-first Century will be critical to the future evolution of drug dispensing on the Web. However, before major changes can be seen, multiple ethical and legal aspects need to be resolved. They include: **government regulation** (local pharmacy trade issues, Web dispensing licensing, foreign prescription authentication, Web prescribing, adverse event reporting, drug advertising, access to locally unregistered medications), **legal issues** (pharmacists' accountability, drug dispensing for unauthorized uses, parallel imports, pricing, customs clearance), **tax implications** (income reporting, currency restrictions), and **copyright implications** (advertising over the Web).

Figure 20.3. Web-marketing evaluation measurements

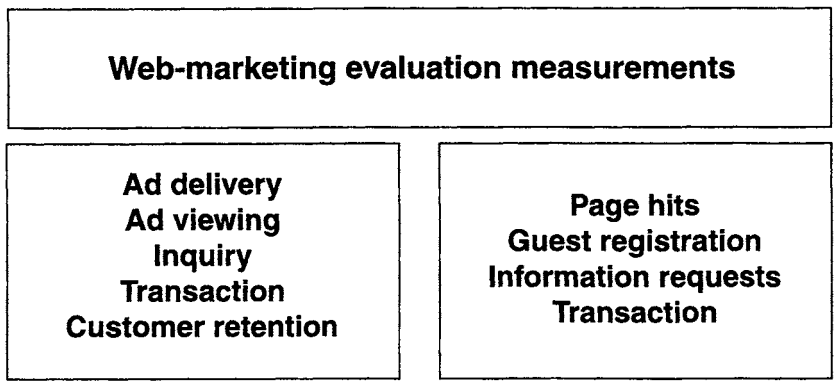

Table 20.4: Advantages and Disadvantages of E-commerce

Characteristic	Advantage	Disadvantage
Access	No travel required. No geographic barriers. 24 hours.	Computer knowledge and Web access required.
Information	Thorough and searchable. Free trial via downloading. Virtual demonstrations. Third party comments.	No physical demonstration allowed. No luxurious store fronts.
Customer Relations	More customized service.	No contact with sales people. Personal relationships not possible.
Security/Privacy	Electronic payments are easier. Outsourced secure servers exist.	Difficult to convince customers of security.

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Part 6

Forecasting, Planning, and Evaluating

21

Forecasting and Planning

> Average life expectancy at birth in 1955 was 48 years, in 1995 it was 65 years, while in 2025 it is expected to reach 73 years.
>
> WHO, 1998

Forecasting is defined as the prediction of future events used for planning purposes (e.g., the sales amount expected to be achieved within a set time under certain conditions). The most common forecasts are about sales, market shares, and profits. Other, less frequent forecasts include production resources, human resources, financial resources, costs, technology changes, economic conditions, and exchange rates. This chapter discusses the importance of forecasting to industry marketers, presents the different stages and types of forecasting, and compares various forecasting and forecasting evaluation methods.

THE IMPORTANCE OF FORECASTING

Pharmaceutical marketers are involved in designing, implementing, and controlling industry's marketing strategies. Two of the most important elements of these strategies are predicting each market segment evolution within the planning period and defining the future level of company sales needed to satisfy company objectives in the predicted market potential. These important marketing predictions are defined

as *market and sales forecasting* respectively, and are an integral part of every marketing strategy. The importance of forecasting lies in its ability to: (1) answer "what if" scenarios, (2) help define budgets, (3) provide a basis for a monitoring system, and (4) aid in production planning (avoiding stock-outs, excess production, or emergency production).

By conducting detailed forecasting, several company activities can be planned (see Figure 21.1). For example, the purchasing department can plan the required raw material purchases, manufacturing can produce the required quantities to satisfy demand and avoid stock-outs, operations can define the intensity and structure of the supply chain, R&D can efficiently decide on the best drug candidates to pursue, management can create and adjust the company's mission, human resources can be involved in recruiting or restructuring, and finance can base its future loan requirements on these forecasts.

Pharmaceutical forecasters most often look at the following parameters: units, values, time frame (week, month, quarter, year), therapeutic lines, products, formulations, number of orders, hospitals, territories (pharmaceutical sales representatives), regions, districts, and sales channels.

FORECASTING STAGES

Forecasting is conducted continuously in cycles (spanning a quarter of a year, a year, a three-year, or a five-year period). A typical forecasting cycle is categorized in six distinct steps, as shown in Figure 21.2. The forecasting process begins with assessing the overall market environment, which helps estimate the *market potential*, that is, the maximum market size if the regulatory, political, or other influencing factors all favor the market's growth. The estimation of the market potential helps define a realistic

Figure 21.1. The importance of forecasting

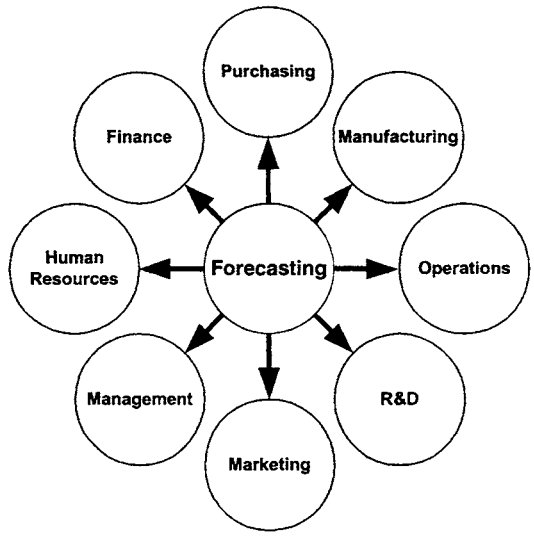
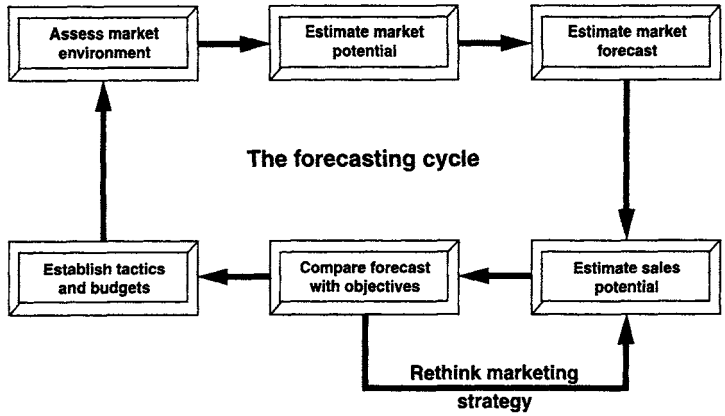


Figure 21.2. The forecasting cycle



market forecast, that is, the size of market under the current environmental forces and industry strategy.

After the prediction of the overall market size, the company's sales potential is forecasted. This sales forecast is compared to company objectives. If the forecast reinforces the objectives, it is accepted and included in the marketing strategy. The forecast is then considered when marketing tactics and allocating resources to projects. Occasionally, the company's sales forecast is below company objectives and it does not support the overall corporate objectives. In that instance, the marketing strategy is reevaluated, the product, pricing, distribution, and promotional mixes are analyzed, and adjustments are made in an effort to support a higher sales forecast that is in agreement with corporate objectives. At the end of the sales period, the actual sales performance is compared to the original sales forecast. Important conclusions are drawn on whether or not the applied tactics were appropriate and if the forecast was pessimistic, overoptimistic, and so on. These findings are then used in the next forecasting cycle to help set new goals, reach new sales levels, and evaluate the marketing strategy.

The actual forecasting approaches used in reaching market or company sales forecasts can be of two different types, namely, break-down and build-up. In the *break-down approach*, an indicator is used to forecast a large market, such as the government's planned healthcare spending for next year. This, in turn, is used to predict the total pharmaceutical market size. Breaking-down the total pharmaceutical market size determines the therapeutic segment forecast. In the *build-up* approach, the next planning period's purchases are estimated on an individual account basis, for example, on a per hospital basis across the country (based on their published patient admissions growth numbers). Then, the individual account order forecasts are "built-up" to a larger market segment (the hospital market). This is combined with the out-of-hospital market to determine the next period's sales forecast. Whatever the forecasting approach, these final two steps complete the forecasting cycle: (1) evaluation of influencing factors (planned activities, competitive activities, market changes, government measures, elections, adverse publicity) and (2) final check.

FORECASTING TYPES

The different forecasting types used by the pharmaceutical industry are shown in Figure 21.3. These are broadly divided into *market* or *company forecasts*. Both types of forecasts can give maximum potential or actual forecast estimates.

DIFFERENT FORECASTING SCENARIOS

Now consider the need for multiple forecasting estimates (or scenarios) for a given period. A forecast scenario planning considers different assumptions affecting the same time period, giving rise to pessimistic, average, and optimistic scenarios (see Figure 21.4). Why is this procedure helpful? It is helpful because several environmental factors can significantly influence the course of a product's sales within any market segment. For example, industry marketers working in Russia cannot possibly predict the course of the ruble in the next planning period. So, they make a pessimistic prediction for its devaluation (leading to low product sales), an average currency exchange prediction with respectively higher product sales, and so on. Furthermore, planning to receive product reimbursement or negotiating a high price with a government may serve as optimistic assumptions and give rise to optimistic forecasts. In general, forecast scenario planning (also called *conditional forecasting* or "what if" forecasting), allows the quick adjustment of the sales targets and marketing tactics, depending on the materialization of different assumptions.

FORECASTING METHODS

How is the actual forecasting performed? In general, the available data (past sales, primary, or secondary data) are entered into a suitable calculation (model, statistical method). The results of this calculation are combined with assumptions to create the final forecast. In general, forecasting methods are distinguished in three broad categories, namely, judgmental, relational, and analytical (see Table 21.1).

Figure 21.3. Forecasting types

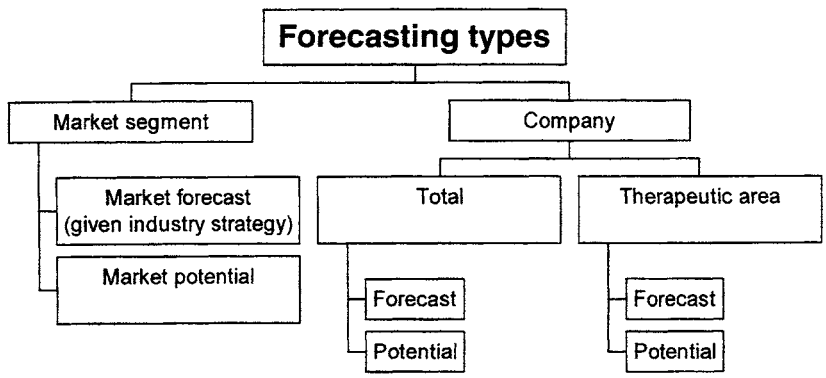


Figure 21.4. Forecast scenario planning

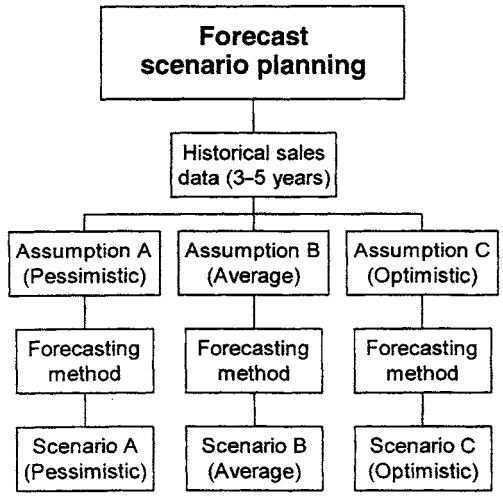


Table 21.1: Major Forecasting Method Categories

	Judgmental or Qualitative	**Relational (Associational) or Causal or Correlation-based**	**Counting or Compiled**	**Analytical or Quantitative or Time-series**
Characteristics	Subjective, based on intuition. Assumes someone knows the answer. Experience-based. May result in bias.	Assume cause and effect, and cause can be used to predict sales. Knowing one variable allows forecasting the other.	Tied to market research data.	Assume that historical data can be used to predict future demand. Look at historical data to reduce element of subjectivity.
Applications	Long-range forecasting (where technological and political factors play a role). Where data is limited (new product launch).			
Techniques	Naïve. Jury of executive opinion. Sales force composite. User's expectation. Delphi techniques. Scenario method.	Leading indicators (e.g., housing starts, births). Regression.	Concept-testing or intend-to-buy surveys.	Cumulative mean. Moving average. Exponential smoothing.

How does a marketer select a forecasting technique? Important things to be considered include accuracy, cost, precision, time span, and technical requirements. A detailed forecasting method selection framework is depicted in Figure 21.5.

A detailed analysis of the major forecasting methods is presented in Table 21.2.

New Product Forecasting

Because of the lack of historic sales data, the potential idosyncrasies of a new molecular entity, and the difficult-to-predict new product's diffusion rate new product sales forecasting presents some special problems. Nevertheless, a variety of forecasting techniques are used by industry marketers in forecasting the sales of new products. The most common techniques are presented in Figure 21.6. The judgmental, scenario planning, and testing methods have been discussed in this chapter, while the diffusion methods were presented in Chapter 10. We will now present two additional methods: *introduction modeling* and *epidemiological modeling.*

Introduction modeling uses the historic sales data of the last competitive product launches when forecasting the sales of our product. Thus, previous years' market sales data (available through omnibus surveys in most national markets) are used to estimate the demand of the product. This helps identify an average launch penetration rate or captured market share (e.g., 5 percent in the first year). This method neither predicts the outstanding demand for a truly innovative and advantageous product, nor predicts the sales performance of a new product. *Epidemiological modeling* is based on disease incidence/prevalence and recommended treatment dosage. This method is depicted in Figure 21.7.

Figure 21.5. Selecting a forecasting method

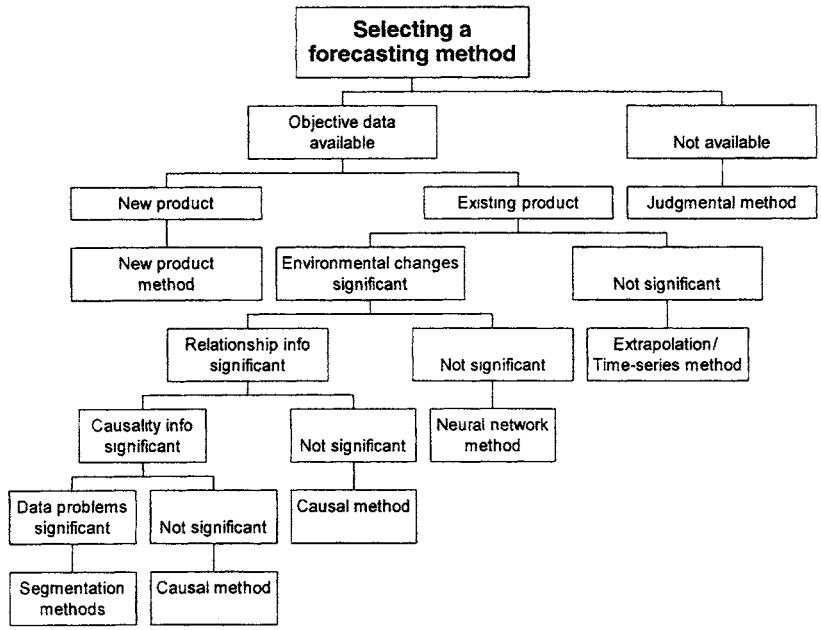


Table 21.2: Description of the Major Forecasting Methods

	Method	Description
Judgmental		
	Naïve Extrapolation	This period's forecast = last period's observation.
	Sales Force	Each sales representative is asked to predict his or her district sales, which are then combined into territory sales, and, finally, into national sales.
	Executive Opinion	The opinions and experience of one or more managers (e.g., GM, marketing manager, sales manager, logistics manager) are combined into a single forecast.
	Delphi	A process of gaining consensus from a group of managers while maintaining their anonymity. Each manager is asked to forecast individually and, after being informed of everybody else's forecasts, is asked to reconsider. After several revisions, a consensus is hopefully reached.
Compiled		
	Market Testing	Making the product available in a test market and measuring consumer demand, which is then extrapolated into a whole market forecast.
	Market Survey	Making a survey to determine consumer interest in a product, which is then used to estimate a forecast.
Analytical		
	Moving Average	This period's forecast = past n periods' observations, where n = 3, 5, 12, and so on.
	Weighted Moving Average	Similar to the moving average, but each time period is given its own weight.
	Exponential Smoothing	This period's forecast = last period's forecast + alpha (last period's actual observation – last period's forecast). This method gives recent demand more weight than earlier demands.
	Extrapolation	Data extrapolation on a straight line or a curve describing past evolution.
Relational		
	Regression	One variable (the dependent) is related to one or more independent variables by a linear equation. Y = a + bX where Y is the dependent, X is the independent variable, a is the line intercept, and b is the line slope.
	Correlation Coefficient	A causal method based on measuring the direction and strength of the linear relationship.
	Leading Indicators	Predicting a product or service demand based on a related indicator (e.g., new home construction based on the adulthood of baby boomers).
	Econometric	Predicting a product or service demand based on leading economic indicators (e.g., the growth of gross domestic product, inflation).

MARKET TRENDS ANALYSIS

A useful forecasting process is the thorough analysis of the prevailing market trends and their impact on company activities, including sales performance within a planning period. Although this is a heavily judgmental approach, it can help identify important opportunities or threats, prepare the organization to adapt to them, and also allocate resources to support or combat these trends. Some of the industry-related trends are described following.

Figure 21.6. New product sales forecasting

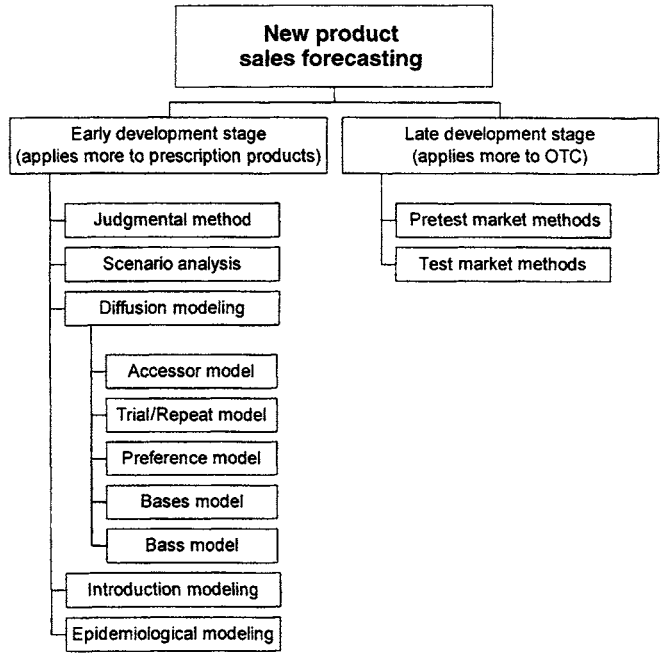
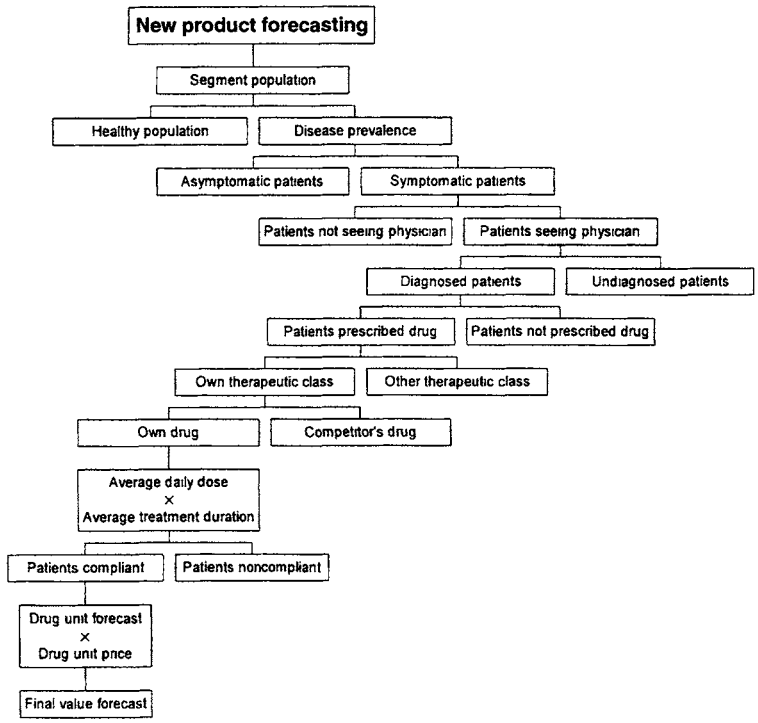


Figure 21.7. New product forecasting



Environmental trends: demographic shift, epidemiological changes, changing geopolitics, emerging ethical issues, healthcare system changes, regulatory changes, and state cost-containment. *Customer trends:* increased sophistication, increased copayment, more health conscious, consumerism, social changes, patient advocacy movement, and negative perception of industry. *Industry trends:* technology advances, economic pressure, shortage of innovation, diversification, increased rivalry, generic competition, virtualization, consolidation, partnerships, globalization, horizontal integration, vertical integration, disease management, pharmaeconomics, emerging markets, patent expiration, and DTC marketing. The detailed analysis of these trends leads to the assessment of their potential impact or to the allocation of internal resources in support or defense of them. A trend analysis grid is presented in Table 21.3. Trends that may affect the company positively are often called *upsides*, while negative trends are called *downsides*.

Furthermore, the forecasted impact of multiple trends can justify the long-term company sales forecast. Multinational pharmaceutical company subsidiaries, often submit their annual marketing plans to their headquarters for discussion and approval. These plans contain a long-term sales forecast and trend analysis grid, as shown in Table 21.4.

FORECAST EVALUATION METHODS

It is essential to periodically evaluate how close actual observations are to forecasts. One commonly used method is using the Mean Absolute Deviation (MAD) index. MAD is equal to the sum of absolute value of forecast errors over the number of forecasts (e.g., periods), as shown in the following equation:

$$MAD = \frac{[Actual_1 - Forecast_1] + [Actual_2 - Forecast_2] + [Actual_3 - Forecast_3]}{3}$$

CORE PLANNING CONCEPTS

The *marketing plan* is a written document that describes future tactics and resource allocations and their consequences in an operational and quantitative manner.

The Marketing Plan

The following pages provide a detailed marketing plan template. Examples of the tables referred to can be found in the various chapters of this book.

Table 21.3: Analysis of Key Market Trends Grid

#	Positive Trends (Upsides)	Probability (%)	Impact	Resources Needed
#	Negative Trends (Downsides)	Probability (%)	Impact	Resources Needed

Table 21.4: Forecasting the Impact of Key Trends

Geographical region:	**Japan**						
Therapeutic area:	**Asthma**						
Product:	**Brand ABC**						
Year:	**–3**	**–2**	**–1**	**Current**	**+ 1**	**+ 2**	**+ 3**
Market segment data (status quo)							
Market value size							
Market value growth (%)							
Average price							
Market volume size							
Market volume growth (%)							
Treated patient number							
Treated patient number growth (%)							
Market share (%)							
Market share growth (%)							
Market position							
Leading competitor market share (%)							
Key trends							
Increased patient awareness							
Improved disease prevention							
Improved disease diagnosis							
Disease eradication							
Vaccine launch							
National treatment guidelines							
Improved patient compliance							
Government pricing restrictions							
Reimbursement							
National formulary							
Competitor pricing reductions							
Competitive product launches							
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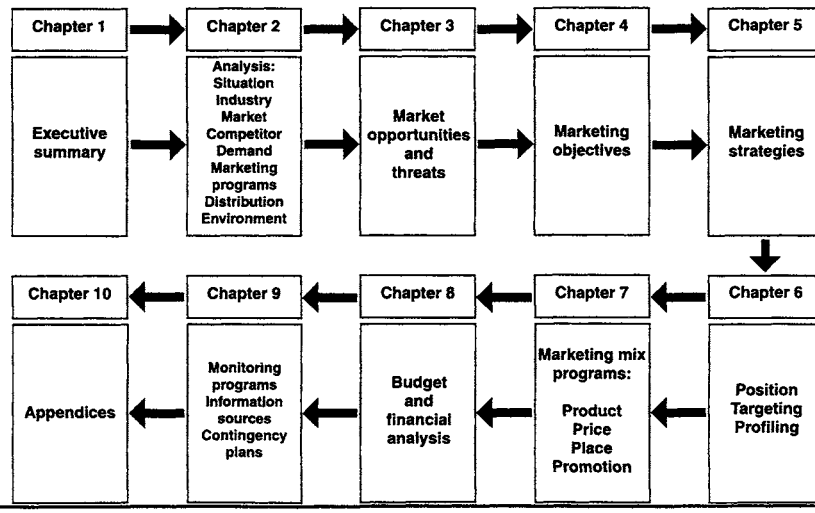
Figure 21.8. Marketing plan overview



DREAM PHARMA

FRANCE
BUSINESS PLAN 2001

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Summary

FURTHER READING

Cook, A. G. 1995. Navigating the intersection of forecasting, market research and pricing. *Pharmaceutical Executive* 15: 54–58.

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22

Evaluating Marketing Performance

> The value of UK pharmaceutical exports in 1997 was £5.5 billion—equivalent to more than £90,000 per employee.
>
> ABPI, 1998

Throughout the previous chapters the focus has been on the elements of marketing strategy in the pharmaceutical industry. We have discussed the planning and implementation of detailed product, distribution, pricing, and promotional strategies for different types of pharmaceutical products (innovative, commodity, and generics). These practices are part of the everyday work of all industry marketing managers, who painstakingly design and implement them for successful business cycles.

At the end of each business cycle, every industry player is involved in evaluating the actual company performance against the forecasted one and correlating these results with the planned strategy and tactics. The results of this thorough and periodic evaluation of marketing performance give useful insights to industry managers about what went right and what went wrong, what could be enhanced or prevented in the next planning cycle, and what overall changes need to be made to the company's marketing mix in search of a sustainable competitive advantage. Evaluating the company's marketing performance is called *marketing analysis* or *marketing audit.* This is a critical process that must be comprehensive, independent, periodic, and systematic. This

chapter focuses on the targets of marketing analysis, as well as the wide variety of analytical tools available to industry marketing departments.

THE MARKETING AUDIT PROCESS

Any marketing performed without marketing analysis will fail. Marketing analysis is an essential planning and evaluation tool. The main steps in evaluating the marketing performance are described in Table 22.1.

The marketing audit process is a systematic analysis of all major company strategies, tactics, and performance indicators in an independent and periodic manner. A detailed framework for conducting an extensive marketing audit is presented next.

Marketing Environment

Macroenvironment	Developments and trends.
Demographic	Company actions on developments.
Economic	International economic conditions. Developments in income, prices, savings, and credit. Company actions on developments.
Natural	Cost and availability outlook of natural resources. Cost and availability outlook of energy. Company actions on outlooks.
Technological	New technologies. Company's technological competency and resources. Potential generic substitutes of our product.
Political	Current and potential new government attitudes toward industry. New legislation under discussion. International, national, federal, state, and local laws. Regulation. Trade barriers. Pollution control, equal employment opportunity, product safety, advertising, price control. Access to authorities and lobbying activities.
Cultural	Ethics. Public attitudes toward industry.

Table 22.1: Steps for Evaluating Marketing Performance

1.	Establish standards	R&D benchmarks, manufacturing and distribution benchmarks, sales forecasts, human resources, financial resources, timing.
2.	Specify measures	Sales, market share, cost, profitability, contribution, variance, customer satisfaction analysis, profit and loss analysis.
3.	Collect data	Internal sales records, patent and regulatory approvals, partner satisfaction surveys, customer satisfaction surveys, sector analysis, financial reports.
4.	Analyze and monitor	Comparison of performance data to internal standards.
5.	Adjust strategy and tactics	Modify marketing mix, adjust resource allocation, change assumptions.

	Public attitudes toward company and products. Changes in consumer lifestyles.
Operating Environment	Markets. Market size, growth, geographic distribution, and profits. Segmentation and segment attractiveness.
Our Company	Basic values. Vision and mission. Balanced scorecard, benchmarking, and control. Product portfolio, balance, and resource allocation. Planning horizon, skills, and deadlines. KSFs identified. Culture and climate. Management skills and style. Organizational structure, SBUs, and communication. Internal resources (physical assets, financial, technological, human). Knowledge base, competitive intelligence, and information infrastructure.
Customers	Unmet therapeutic needs. Perception versus our company's or competitor's perception of product quality, service, sales force, and price. Buying decision processes of various segments. Satisfaction level.
Competitors	Who are they? Their objectives, strategies, strengths, weaknesses, sizes, and market shares. Future competition trends and new entrants.
Distribution Channels	Major channels, efficiency level, and growth potential. Electronic Data Interchange (EDI) confidentiality. Intrachannel conflict and backward integration.
Suppliers	Production resources availability outlook. Conflict, forward integration, and mergers.
Marketing Service Firms	Location, expertise, resources, and costs of advertising agency, PR agency, market research, CRO, and CSO.
Stakeholders	Who are they? Opportunities or threats. Company action on opportunities and threats.
Marketing Strategy	
Business Mission	Basic values. Mission clarity, feasibility, and compatibility with resources.
Marketing Objectives and Goals	Clarity and feasibility. Compatibility with corporate goals, resources, and competitive position.

Strategy	Clarity and feasibility. Resource availability and portfolio allocation. Resource allocation across the marketing mix.

Marketing Organization

Organization Structure	Authority and responsibility. Prioritization across functions, products, territories, and customers.
Functional Efficiency	Job descriptions and efficiency. Communication and working relations. Skill level and training.
Interface Efficiency	Communication with R&D, manufacturing, purchasing, finance, and sales.

Marketing Systems

Marketing Information System	Accurate, sufficient, timely, and open intelligence capabilities. Adequate and well-designed marketing research.
Marketing Planning System	Efficiency and timeliness. Realistic sales and market forecasting.
Marketing Control System	Availability of control systems. Periodic profitability and cost analysis.
New Product Development System	Support of innovation and creativity. Therapeutic category and concept analysis. New product idea collection, generation, and screening procedures. Enabling technologies. Prelaunch product and market testing.

Marketing Productivity

Profitability Analysis	Profitability analysis across market segments, products, territories, and distribution channels. New markets or market withdrawals.
Cost-effectiveness Analysis	Identification and reduction of wasting.

Marketing Strategy

Product	Product line depth and width. Product life cycles. Required quality, feature, or style modifications.
Price	Pricing objectives, policies, strategies, and procedures. Customer perceptions of price versus quality. Price promotion strategies.
Place	Distribution objectives and strategies. Market coverage, transportation, and warehousing. Capacity and inventory.

	Customer service. Distribution mix efficiency (distributors versus sales representatives versus Web).
Promotion	Advertising objectives, audiences, budgets, media, and campaigns. PR objectives, publics, budgets, media, and campaigns. Advertising and PR effectiveness evaluation.
Sales Force	Objectives, organization, specialization, and size. Recruiting, training, and evaluating. Motivating and rewarding. Sales force management.

The results of the detailed marketing audit described above can then be listed in marketing audit sheets, such as the one shown in Table 22.2.

THE MARKETING AUDIT TOOLS

A variety of marketing audit tools are available to the industry. These study various analysis subjects such as sales, market share, innovation, advertising effectiveness, cost, profitability, variance, contribution, competitive strength, resource utilization, and distribution. The main analytic tools in these categories are shown in Figures 22.1A and 22.1B.

Sales Analysis

Sales analysis is defined as the collection, comparison, and evaluation of a product, segment, or company sales data. Industry sales performance can be evaluated by one of the methods shown in Figure 22.2.

These methods can be broadly categorized as general-, geographic-, customer-, and product-based approaches. The major types of each are shown in Table 22.3.

Market Share Analysis

Market share performance can refer to a product, a product line's share of a therapeutic area segment, or to the company's share of the total pharmaceutical market. Product market shares can be expressed in value product sales (expressed in U.S. dollars, UK pounds, and so on), in units, number of prescriptions, number of defined daily dosages (sales of each competitor product divided by its recommended daily dosage), or number of patients (sales of each competitor product divided by the total treatment dosage). Furthermore, the market

Table 22.2: A Company Audit Sheet

Market segment:			**Rating**			
Company capabilities	**Weighing**	**1 (Low)**	**2**	**3**	**4**	**5 (High)**
	100					

Figure 22.1A. Marketing performance evaluation tools

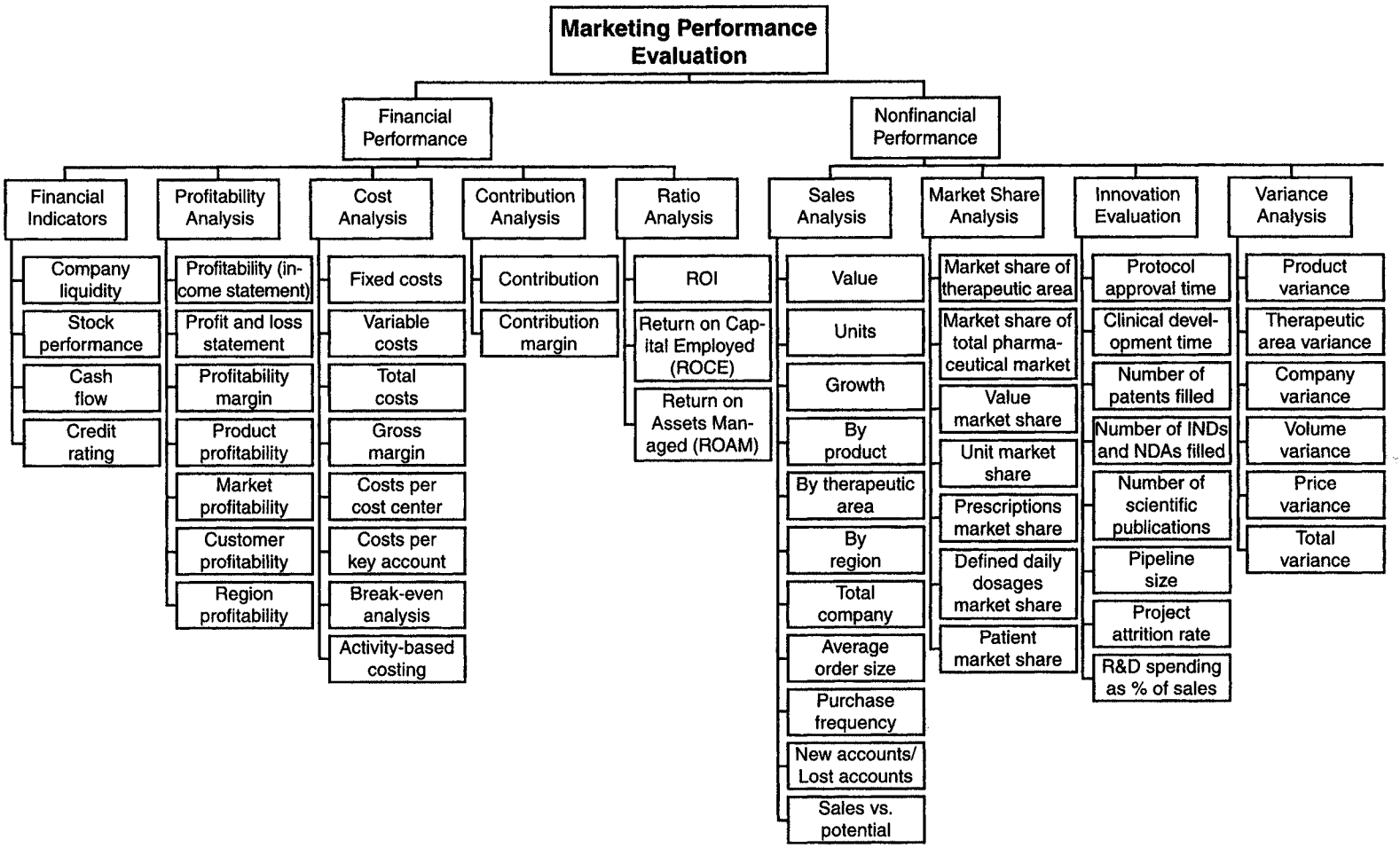


Figure 22.1B. Nonfinancial marketing performance evaluation tools

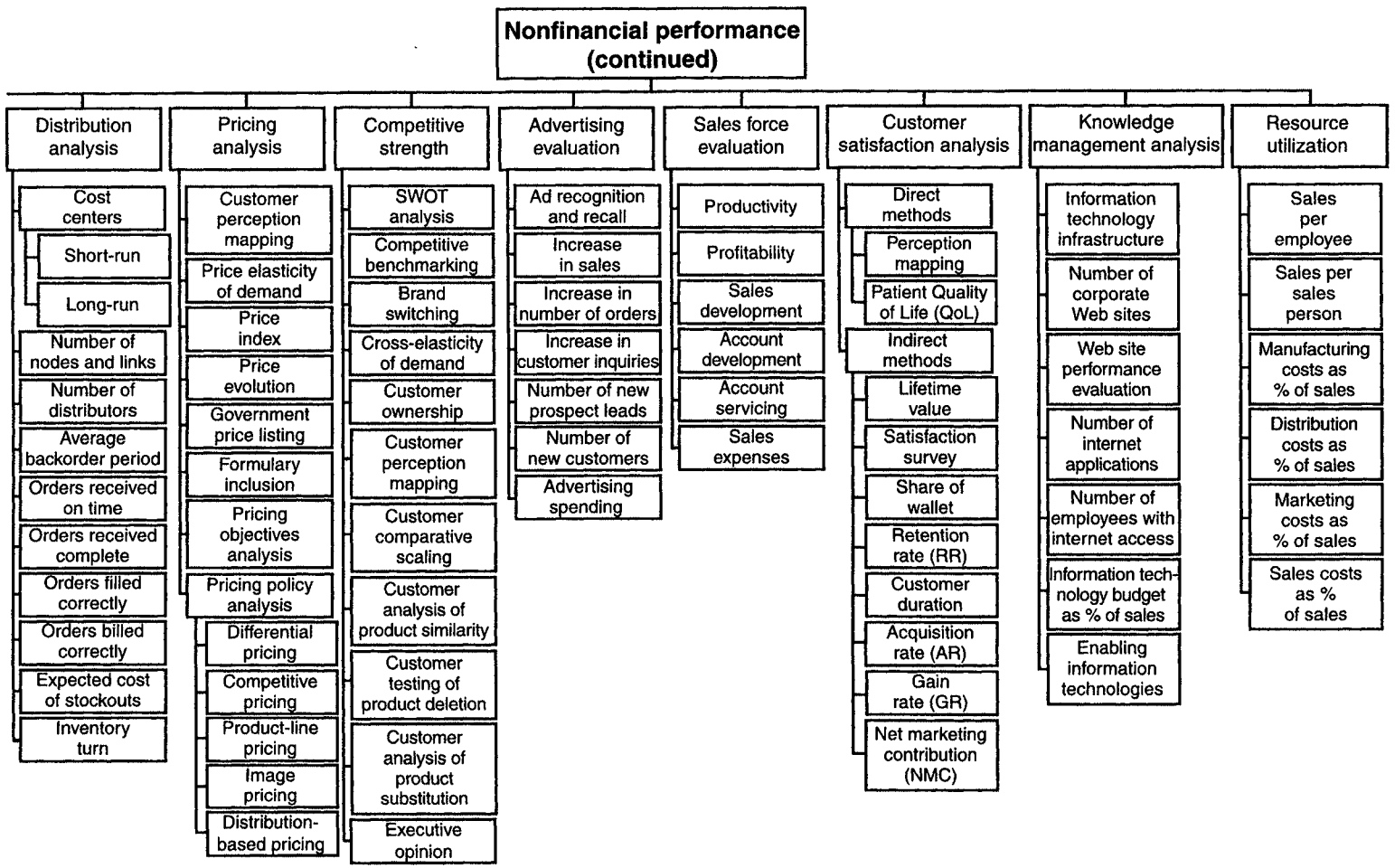
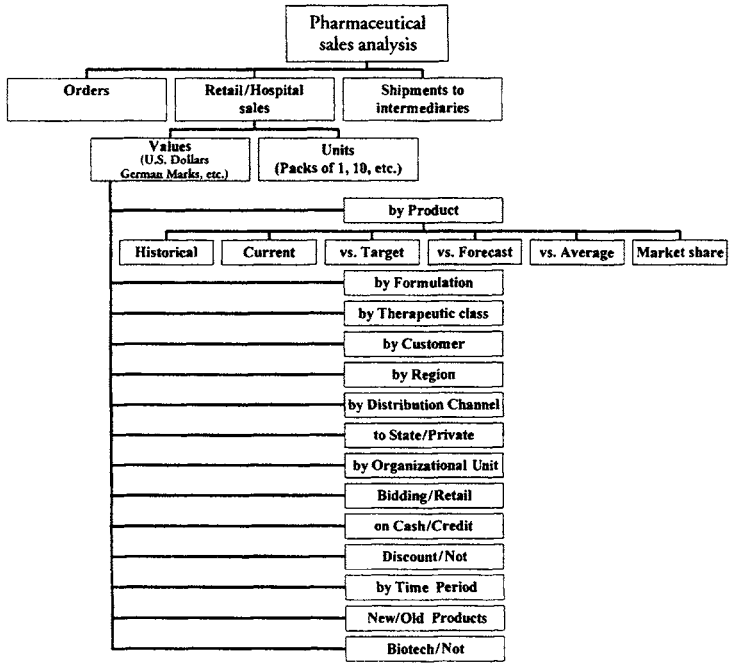


Figure 22.2. Types of sales analysis



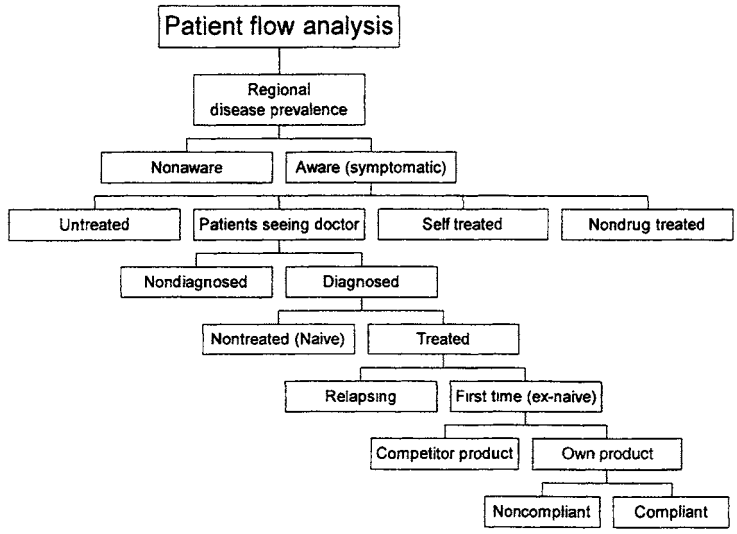
share of patients can be expressed in shares of the total number of patients diagnosed with the disease, those pharmacologically treated, naïve (previously untreated), or relapsing patients. These patient groups are shown in the patient flow analysis in Figure 22.3.

The competitors' relative market shares give rise to a variety of possible competitive strategies, as discussed in Chapter 11. Furthermore, several other strategy considera-

Table 22.3: Major Types of Sales Analysis

General Sales	Geographic Sales
Annual sales	Breakdown of state, city, zip code, and so on
Monthly sales	Sales territory
Comparative periods	Individual salespeople
Seasonal, cyclical, or irregular sales	Types of customers
Sales by product life cycle	Product types
Average order size	Sales dividend by quotas
Average back order period	Total sales per person per day
	Sales/calls
	Sales cost analyses
Customer Sales	**Product Sales**
Customer classes	Classes of products
Proportion of new vs. old customers	Product lines within classes
Standard Industrial Classification (SIC) of customers	Individual products within lines
Size of customer plants	Product attachments, accessories, and so on
Size of purchases	Packaging modes
Frequency of purchases	Pricing levels

Figure 22.3. A patient flow analysis (patient journey)



tions of a smaller scale are related to market share standings and need to be carefully planned, as shown in Table 22.4.

Cost Analysis

Cost analysis refers to the systematic evaluation of all costs related to products, activities (activity-based costing), cost centers (R&D, marketing, sales, and so on), key accounts, and so on. Costs are usually categorized as fixed and variable costs. *Fixed costs* stay the same as volume increases. However, if volume surpasses a given point

Table 22.4: Market Share Strategy Considerations

Market Segment: Country: Therapeutic category: Market value size and growth: Market volume size and growth	
Category Competitor Rankings: Market leader: Competitor #2: Competitor #3:	Competitor Market Shares:
Actions needed to advance own ranking by one position:	
Financial resources needed to advance own ranking by one position:	
Time needed to advance own ranking by one position:	
KSFs needed to advance own ranking by one position: KSF # 1: KSF # 2: KSF # 3:	
Benefits realized by advancing own ranking by one position: Benefit A: Benefit B: Benefit C:	Profit Value:

(break-even), they change inversely on a per unit basis. *Variable costs* do not change per unit when volume increases, but change as a direct result of volume increase.

Table 22.5 describes a typical pharmaceutical product's cost analysis.

A useful marketing cost analysis process is the estimation all company costs related to specific key accounts and subsequent comparison of account-servicing costs to product sales. This provides the estimation of individual account profitability levels. A cost analysis by account is described in Table 22.6.

Break-even analysis

Break-even analysis is a special cost-related analysis that estimates the minimum product quantity needed to be sold to balance its total costs with sales revenues (or break-even, generate zero profit). Any quantity sold in excess of the break-even point generates a profit, while any quantity smaller than break-even results in a loss.

$$\text{Revenues} - \text{Variable Costs} - \text{Fixed Costs} = \text{Profits}$$

$$\text{Break even units} = \frac{\text{Fixed Costs}}{(\text{Unit Price} - \text{Variable cost per unit})}$$

For example, a manufacturing plant has operating costs of 300,000 U.S. dollars monthly. The product unit price is 50.00 U.S. dollars and the unit variable costs are 10.00 U.S. dollars. Therefore, the break-even units would be:

Table 22.5: A Pharmaceutical Product's Cost Analysis (U.S. Dollars)

Category	Fixed	Variable	Total
Operating Expenses:			
Raw materials	47,000		47,000
Operations overhead		750,000	750,000
Direct labor	1,380,000		1,380,000
Direct administrative	356,000		356,000
Social benefits		510,000	510,000
Subtotal:	2,293,000	750,000	3,043,000
Nonoperating Expenses:			
Product development	213,000		213,000
Import taxes		23,000	23,000
Distribution		150,000	150,000
Advertising	189,000		189,000
Promotion	67,000		67,000
Sales force	432,000	75,000	507,000
Marketing	139,000		139,000
Marketing research	90,000		90,000
Disease management	110,000	25,000	135,000
Customer service	47,000		47,000
Postmarketing clinical trials (Phase IV)	39,000		39,000
Product samples	50,000		50,000
General and administrative (G&A)	70,000		70,000
Subtotal:	1,446,000	273,000	1,719,000
Total Expenses:	3,739,000	1,023,000	4,762,000

Table 22.6: Marketing Cost Analysis Steps

Selected Functional Accounts	Assignment of Costs to Individual Customers	Assigned Costs Regrouped by Sales District	Assigned Costs Regrouped by Size of Purchase (U.S. Dollars)
Credit extension expenses	A, B, C	A, C, F Eastern territory	B, I, E Less than 1 million
Office expenses	D, E, F	G, B, E Central territory	C, D, A, F 1–2 million
Order-handling expenses	G, H, I	D, H, I Western territory	H, G Over 2 million

$$\text{Break-even units} = \frac{\$300{,}000}{\$50.00 - \$10.00} = 7{,}500 \text{ units per month}$$

Easily verify the above calculation by reversing it:

Revenues:	7,500 units × \$50.00	= \$375,000
Variable costs:	7,500 units × \$10.00	= \$75,000
Fixed costs:		= \$300,000
Total costs:		= \$375,000 (equal to revenues)

Profitability Analysis

Profitability analysis refers to the systematic evaluation of the rate at which profit is made. Industry profitability analysis may focus on the total company performance, product, market, customer type, individual customer, or regional profitability.

Using customer type level, Table 22.7 gives an example of a product profitability analysis that focuses on different medical specialties.

Furthermore, using a per customer basis, Table 22.8 gives an example of a key account profitability analysis.

When determining company profitability, two commonly used tools are the income statement (see Table 22.9) and the profit and loss statement (see Table 22.10).

Contribution Analysis

Contribution analysis is defined as the systematic study of a product's or total company's contribution to the company's financial chest, that is, the difference of sales revenues

Table 22.7: Revenue by Physician Specialty Compared to Costs Assigned to Each

	GPs	OB/GYN	ENT	GI	ER
Revenue					
Costs					
Profit or loss					
Costs/Revenue					
Profit / Revenue					

Table 22.8: Key Account Profitability Analysis (per Customer)

		Competitive Position				
		Strong			Weak	
Account Potential	Account	Calls	Sales	Account	Calls	Sales
	A			B		
High	E			F		
	I			J		
	Total:					
	Average:					
	Account	**Calls**	**Sales**	**Account**	**Calls**	**Sales**
Low	C			D		
	G			H		
	K			L		
	Total:					
	Average:					

minus costs. Contribution can be expressed as fixed (sales revenues minus fixed costs), variable (sales revenues minus variable costs), or total (sales revenues minus total costs). Where the relationships that exist between the different parameters are:

Total variable margin or contribution = Sales revenue – Total variable costs

Table 22.9: An Example of a Pharmaceutical Product's Income Statement (U.S. Dollars)

	December 31, 2000		
Sales revenues (500,000 units at $10 each):			5,000,000
Less:	Cost of Goods Sold (COGS):		
	Raw materials		30,000
	Operational fixed costs		125,000
	Direct labor		540,000
	Direct clerical		185,000
	Social benefits		150,000
Operational Expenses (OPEX):			1,030,000
Operating or Gross Margin (GM):			3,970,000
Less:	Sales expenses		
	Product development	1,000,000	
	Import taxes	10,000	
	Distribution	20,000	
	Advertising	160,000	
	Promotion	98,000	
	Sales Force	220,000	
	Marketing	140,000	
	Marketing research	50,000	
	Disease management	80,000	
	Customer service	25,000	
	Postmarketing clinical trials (Phase IV)	75,000	
	Product samples	45,000	
G&A		128,000	
Total Expenses:		2,051,000	
Operating Profit:			1,919,000

Table 22.10: Profit and Loss Analysis Statement

	Year 1	Year 2	Year 3	Year 4	Year 5
Sales Revenue					
COGS					
Gross Margin					
Development Costs					
Marketing Costs					
Allocated Overhead					
Gross Contribution					
Supplementary Contribution					
Net Contribution					
Discounted Contribution					
Cumulative Discounted Cash Flow					

Unit variable margin or contribution = Unit selling price – Unit variable costs

Net profit margin = Sales revenue – Variable costs – Fixed costs

Variable margin rate or contribution margin = (Sales revenue – Total variable costs)/Sales revenue

Break-even Units = Fixed costs/Variable margin per unit

Table 22.11: A Pharmaceutical Product's Contribution Margin Statement (U.S. Dollars)

Sales revenue (500,000 units at $10.00 each):		5,000,000
Variable costs:		
Operations overhead	750,000	
Import taxes	23,000	
Distribution	150,000	
Sales force	75,000	
Disease management	25,000	
Total variable costs:		1,023,000
Contribution margin (79.5 %):		3,977,000
Fixed costs:		
Raw materials	47,000	
Direct labor	1,380,000	
Operations administrative	356,000	
Social benefits	510,000	
Product development	213,000	
Advertising	189,000	
Promotion	67,000	
Sales force	432,000	
Marketing	139,000	
Marketing research	90,000	
Disease management	110,000	
Customer service	47,000	
Postmarketing clinical trials (Phase IV)	39,000	
Product samples	50,000	
G&A	70,000	
Total fixed costs:		3,739,000
Operating profit:		238,000

Break-even Values = Fixed costs/Variable margin rate

Table 22.11 gives an example of a product's variable contribution (or contribution margin) statement.

Variance Analysis

Variance analysis is defined as examination of the deviation of actual results from a standard. For example, *spending variance* is the difference between actual spending and budgeted spending. *Volume variance* is equal to Planned Price × (Actual Volume – Planned Volume). *Total variance* is equal to (Actual Volume × Actual Price) – (Planned Volume × Planned Price). Variance analysis is an important analytical tool that is important to every organization seeking ways to monitor and control its costs. Table 22.12 provides an example of a product's variance analysis.

Customer Satisfaction Analysis

Customer satisfaction analysis is the systematic analysis of customer satisfaction levels from all aspects of a product's offering, such as the product characteristics and benefits, informational and educational content, other product-related services, customer service, and so on. This analysis involves the evaluation of actual satisfaction versus customer expectations *(gap analysis),* and can be performed using a variety of methods.

Direct methods of customer satisfaction analysis include perception mapping or quality of life measurements, which have been described in previous chapters. Furthermore, a variety of indirect methods offer pharmaceutical marketers an insight into their product's perceived value. Some of the most common indirect methods are described next.

Customer Lifetime Value (CLV)

A customer's lifetime value refers to the NPV of all past and estimated future profits; that is, total revenue minus the costs to capture the customer (personal selling, advertising, and so on) and the costs to retain him or her (customer service, sponsorships, and so on).

Table 22.12: Product Variance Analysis Example (U.S. Dollars)

Parameter	Planned	Actual	Variance
Revenues			
Sales	15,000,000	23,000,000	8,000,000
Price per unit	3.20	2.95	(0.25)
Revenues	4,687,500	7,796,610	3,109,110
Total market size	60,000,000	80,000,000	20,000,000
Market share	25%	28.75%	3.75%
Costs			
Variable cost per unit	0.50	0.50	—
Contribution			
Per unit	2.70	2.45	(0.25)
Total	40,500,000	56,350,000	15,850,000

$$\text{CLV} = \text{NPV of past/future profits} =$$
$$= \text{NPV of (Net Revenue} - \text{Acquisition Costs} - \text{Retention Costs)}$$

CLV comparisons among customers yield the following categories: most valued customers, valued customers, emerging or high potential customers, basic customers, and the rest of the market.

Other methods of analysis include the following:

Customer share of wallet: the percentage of own product purchases of all customer purchases.

Customer retention rate (RR): RR = Repeat customers/Total customers

Customer duration: the time period during which a given customer continued to purchase our products.

Customer acquisition rate (AR): AR = Purchasing customers/Aware customers

Customer gain rate (GR): GR = New customers/Existing customers

Customer acquisition/Defection matrix: a useful tool comparing the number of customer acquisitions or defections between competitor products (can be done easily with hospital accounts). (Table 22.13 shows an acquisition/defection matrix of hospital clinics switching between different cephalosporin brands.)

Competitor benchmarking: the benchmarking of customer satisfaction levels with our company's products versus competitor products allows useful strategic considerations.

Net marketing contribution (NMC): NMC = Unit Volume × (Revenue per customer – Variable cost per customer) – Marketing expenses. This customer profitability analysis tool gives indirect insight into customer satisfaction.

Finally, plotting the estimated customer satisfaction levels versus their perceived importance for each product attribute or product helps visualize the opportunities for product improvement (see Figure 22.4).

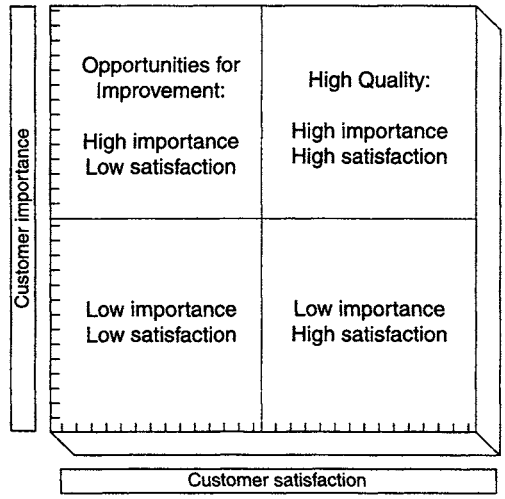
Performance Ratios

Several financial ratios have been used for evaluating a company's performance. The most important of these are ROI and ROAM.

Table 22.13: A Hospital Account Acquisition/Defection Matrix

	Cephalosporin A	Cephalosporin B	Cephalosporin C	Cephalosporin D
Cephalosporin A		3	4	2
Cephalosporin B	2		2	4
Cephalosporin C	5	4		5
Cephalosporin D	3	1	1	

Figure 22.4. Customer satisfaction versus customer importance matrix



Return on Investment (ROI)

$$\text{ROI} = \frac{\text{Net Profit}}{\text{Capital Employed}} \times 100 = \frac{\text{Net Profit}}{\text{Sales Revenue}} \times \frac{\text{Sales Revenue}}{\text{Capital Employed}} \times 100$$

where Net Profit/Sales Revenue = Profit Rate; Sales Revenue/Capital Employed = Capital Turnover.

Return on Assets Managed (ROAM)

$$\text{ROAM} = \text{Contribution as a percentage of sales} \times \text{Asset turnover}$$

where contribution as a percentage of sales = Net contribution/Sales; Asset turnover = Sales/Assets.

FURTHER READING

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Appendix A

Glossary

Advertising is a nonpersonal, paid communication about an organization, product, or idea by an identified sponsor.

Agent is an intermediary who brings sellers and buyers together for a commission.

Attitude is an acquired, long-term disposition to consistently respond in a given manner to various aspects of the world.

Brand is a name, term, sign, symbol, or design, or a combination, intended to identify goods or services of one seller and to differentiate them from those of the competition (Kotler, 1980).

Broker is an agent that does not have a continuous distribution relationship with the seller.

Crisis management is public relations under adverse circumstances.

Decision support system is a system that involves processes, methodologies, and technologies in order to assist in decision making (i.e., resolving a problem or choosing alternative routes).

Development is the activities following the preliminary NCE selection, including the detailed characterization, purification, formulation, toxicity, pharmacokinetic, and pharmacodynamic evaluation of the test entity.

Disease is a judgment of one's state of health by a medical professional.

Disease management is a population-based, systematic approach that identifies persons at risk; it then intervenes, measures the outcomes, and provides continuous quality improvement.

Distribution channel is a group of independent firms composed of manufacturers, wholesalers, and retailers designed to deliver the right set of products to the customers at the right place and time.

Drug is any chemical agent that can alter processes of living.

Fixed costs are costs that stay the same as volume increases; however, if volume surpasses a given point (break-even), they change inversely on a per unit basis.

Forecasting is the prediction of future events used for planning purposes (e.g., the sales amount expected to be achieved within a set time under certain conditions).

Health care is any helpful activity intended to maintain or improve health.

Health is a complete state of physical, mental and social well being (WHO).

Illness is a person's own perception of how he or she feels.

Market is all potential customers sharing a particular need or want.

Marketing is the process of planning and executing the conception, pricing, promotion, and distribution of ideas, goods, and services to create exchanges that satisfy individual and organizational goals (AMA, 1985).

Marketing management is the analysis, planning, implementation, and control of programs designed to bring about desired exchanges with target markets for the purpose of achieving organizational objectives (Kotler, 1980).

Marketing research specifies the information required to define marketing opportunities and problems; generate, refine, and evaluate marketing actions; monitor market performance; improve understanding of marketing as a process; as well as design the method for collecting information, manage and implement the data collection process, analyze the results, and communicate the findings and their implications (AMA, 1987).

Marketing strategy is a plan identifying what basic goals and objectives will be pursued and how they will be achieved within the specified time.

Micromarketing is the process of creating and offering customized products combined with customized communications to each submarket's customers.

Mission is a set of directions to achieve a company's vision.

Patent for an invention is a grant of a property right by the government to the inventor (or his or her heirs or assigns), acting through the Patent and Trademark Office.

Positioning is choosing the therapeutic segments in which we wish to place a product to compete.

Price is the value attached to a product or service.

Product is anything that can be offered to a market for attention, acquisition, use, or consumption that might satisfy a want or need (Kotler, 1991).

Profiling is the selection of positive promotional statements, as well as negative statements, that are used in support of the chosen targeting and position strategies.

Public relations is an attempt to create a climate of mutual understanding between an organization, the organization's stakeholders, and the community as a whole, as well as the evaluation of public attitudes and the execution of plans to gain public understanding and acceptance.

Research is the science and technology applied to the discovery of NCEs.

Retail pharmacist is one who buys pharmaceutical products from the wholesaler and sells to the public.

Sales management is the planning, implementing, and control of personal selling designed to achieve the sales and objectives of a firm.

Sales promotion is the short-term offer of incentives to stimulate customer purchasing.

Segmentation is the process of analyzing and breaking down the whole market into specific submarkets, each with their own characteristics and needs.

Spending Variance is the difference between actual spending and budgeted spending.

Stakeholder is any person or group of persons with which a company has, or wants to develop, a relationship.

Strategy is a statement describing the general course the company will follow to achieve its objectives.

Supply chain is a network of facilities and distribution options that procures materials, transforms these materials into intermediate and finished products, and distributes these finished products to customers.

Targeting is choosing the specific individuals or market segments to win over.

Total variance is equal to (Actual Volume × Actual Price) – (Planned Volume × Planned Price).

Variable costs are costs that do not change per unit when volume increases, but change as a direct result of the volume increase.

Variance analysis is examination of the deviation of actual results from a standard.

Vision is the desired state of the organization in the future.

Volume variance is equal to Planned Price × (Actual Volume – Planned Volume).

Wholesaler is an intermediary who buys pharmaceutical products from the manufacturer and sells to retail pharmacists.

Appendix B

Core Concepts on the Web

PART 1

The Pharmaceutical Market

1. The Healthcare Environment

www.doh.gov.uk	UK Department of Health
www.hcfa.gov	Health Care Financing Administration (HCFA)
www.hhs.gov	U.S. Department of Health and Human Services (HHS)
www.hsj.co.uk	Health Service Journal
www.mamcp.com	National Association of Managed Care Physicians
www.managedhealthcare.com	Managed Healthcare Magazine
www.bira.org.uk	British Institute of Regulatory Affairs (BIRA)
www.eudra.org/en_home.htm	European Medicines Evaluation Agency (EMEA)

www.fda.gov	U.S. Food and Drug Administration (FDA)
www.ifpma.org/ich1.html	International Conference on Harmonization (ICH)
www.mhw.go.jp/english	Japan Ministry of Health and Welfare (MHW)
www.regulatory.com	The Regulatory Forum
www.who.int	World Health Organization (WHO)

2. The Pharmaceutical Industry Environment

www.abpi.org.uk	The Association of the British Pharmaceutical Industry (ABPI)
www.apma.com.au	Australian Pharmaceutical Manufacturers Association, Inc.
www.bio.org	Biotechnology Industry Association
www.bms.com	Bristol-Myers Squibb Company
www.fdcreports.com	F-D-C Reports Journal
www.ifpma.org	International Federation of Pharmaceutical Manufacturers Associations
www.merck.com	Merck & Co., Inc.
www.novartis.com	Novartis
www.pharmexec.com	Pharmaceutical Executive Journal
www.phrma.org	Pharmaceutical Research and Manufacturers of America (PhRMA)
www.pjbpubs.com/scrip	SCRIP World Pharmaceutical News Journal
www.pmac-acim.org	Pharmaceutical Manufacturers Association of Canada (PMAC)
www.roche.com	F. Hoffman-La Roche Ltd.
www.schering-plough.com	Schering-Plough Corporation
www.serono.com	The Serono International Group
pubs.acs.org/journals/jpmsae	Journal of Pharmaceutical Sciences
www.aafp.org	American Academy of Family Physicians (AAFP)
www.ama-assn.org	American Medical Association (AMA)
www.aphanet.org	American Pharmaceutical Association (APhA)
www.drugtopics.com	Drug Topics Magazine
www.nursingworld.org	American Nurses Association (ANA)

3. The Pharmaceutical Marketing Environment

www.ama.org	American Marketing Association (AMA)
www.ams-web.org	Academy of Marketing Science (AMS)
www.hbs.harvard.edu/marketing	Harvard University Marketing Department
www.eiasm.be/emac/emachp.html	European Marketing Academy
www.diahome.org	Drug Information Association (DIA)
www.cim.co.uk	Chartered Institute of Marketing (CIM)
www.smei.org	Sales & Marketing Executives–International
www.salesandmarketing.com	Sales & Marketing Management magazine
www.bus.utexas.edu/~marketing/	University of Texas at Austin Marketing Department

www.rx.olemiss.edu/depts/rips/pmmrp	The University of Mississippi Center for Pharmaceutical Marketing and Management
www.sju.edu/www/PHARMACEUTICAL_MARKETING	St. Joseph's University Pharmaceutical Marketing MBA Program
www.liu.edu/cwis/pharmacy	Arnold & Marie Schwartz College of Pharmacy and Health Sciences
www.umkc.edu/umkc/catalog/htmlc/pharm/c641.html	University of Missouri–Kansas City Pharmaceutical Marketing Course

PART 2

Marketing Strategy

4. What Is Marketing Strategy ?

www.markstrat.com	Markstrat Strategic Marketing Simulation Software
www.phor.com/site/med.html	PhOR Medical Marketing Strategies
www.fastcompany.com	Fast Company Journal
www.hbsp.harvard.ed/products/hbr	Harvard Business Review Journal
web.mit.edu/smr-online	Sloan Management Review Journal
www.strategy-business.com	Strategy & Business Magazine
www.strategymag.com	Strategy—The Canadian Marketing Report
www.capsim.com	Capstone Business Simulation Software
www.corporatehealthgroup.com	Corporate Health Group
Migmar.com/issm.html	International Society for Strategic Marketing
www.slfnet.org	Strategic Leadership Forum

5. Marketing Research

www.ims-int.com	Intercontinental Medical Statistics (IMS) International
www.ephmra.org	European Pharmaceutical Marketing Research Association (EPhMRA)
www.ephmra.org/6_002.html	EPhMRA Anatomical Classification Guidelines Index
www.pbirg.com	Pharmaceutical Business Intelligence and Research Group (PBIRG)
www.esomar.nl	European Society for Opinion and Marketing Research (ESOMAR)
www.mra-net.org	Marketing Research Association (MRA)
www.mmrx.com	Medical Marketing Research, Inc.
www.scottlevin.com	Scott-Levin Online
www.usadata.com	USADATA Demographic Information Site
www.odci.gov/cia/publications/factbook/index.html	CIA World Factbook
www.drugintelligence.com	Drug Intelligence

6. Market Segmentation

www.census.gov	U.S. Census Bureau
www.demographics.com	American Demographics Magazine
www.nielsen.com	A.C. Nielsen Global Market Research
www.micromass.com	MicroMass Communications, Inc.
www.dvc.com	Dugan Valva Contess
demographics.caci.com	CACI demographic data

7. Situational Analysis

www.scip.org	Society of Competitive Intelligence Professionals (SCIP)
www.fuld.com	Fuld & Company, Inc.
www.straffordpub.com/products/jht	Stafford Jenks Healthcare Business Report Top 100
www.aurorawdc.com	Aurora WDC
www.competitiveanalysis.com	Competitive Benchmarking Associates
www.sla.org	Special Libraries Association
www.competitiveanalysis.com	Competitive Benchmarking Associates
drugnet.com/gateway/home.htm	IDdb Investigational Drugs Database
www.loyola.edu/dept/politics/intel.html	Loyola University Homepage on Strategic Intelligence

8. Positioning, Targeting, Profiling

www.pdma.org	Product Development & Management Association (PDMA)
www.brandinst.com	Brand Institute Inc.
www.dudnykhealth.com	Dudnyk Healthcare Group
www.brandpackaging.com	BrandPackaging Journal
www.brandweek.com	BrandWeek Online Journal

9. New Product Development

news.drugdiscoveryonline.com	Drug Discovery Online
www.tufts.edu/med/research/csdd	Tufts Center for the Study of Drug Development
www.pjbpubs.co.uk/pharma/index.html	Pharmaprojects R&D database
sp-research.com	Schering-Plough Research Institute
speak.icmb.utexas.edu.ellington/main.html	University of Texas at Austin Ellington Lab
www.pharmaquality.com	Pharmaceutical Formulation & Quality Magazine
www.barnettinternational.com	Barnett International
www.farmaci.uu.se/ulla	European University Consortium for Pharmaceutical Research
www.searlehealthnet.com/pipeline.html	Searle HealthNet Pharmaceutical Pipeline Game

www.qpri.gu.edu.au	Queensland Pharmaceutical Research Institute
www.pharsight.com/prod_ptd_kadd.htm	Pharmsight Knowledge-Accelerated Drug Development
www.dml.georgetown.edu/depts/pharmacoloy/cdds	Georgetown University Center for Drug Development Science

10. Product Life Cycle and Portfolio Management

www.uspto.gov	U.S. Patent and Trademark Office
www.westpharma.com	WEST Pharmaceutical Services
www.medadnews.com/Magazines/R_D_Directions	R&D Directions Journal

11. Competitive Strategies

www.ndmainfo.org	Consumer Healthcare Products Association (CHPA)
www.gpia.org	Generic Pharmaceutical Industry Association (GPIA)
www.egagenerics.com	European Generic Medicines Association (EGA)
www.egagenerics.com/internat.htm	International Generic Pharmaceutical Alliance (IGPA)
www.ethwaite.com	E.W. Thwaite Associates, Inc. Generic Pharma Consulting

PART 3

Distribution Strategy

12. Overview of Pharmaceutical Distribution

www.amerisource.com	AmeriSource Corporation
www.apothecarian.com	The Apothecarian Society
www.bergenbrunswig.com	Bergen Brunswig Corporation
www.cwda.com	Canadian Wholesale Drug Association (CWDA)
www.hida.org	Health Industry Distributors Association (HIDA)
www.ifpw.com	International Federation of Pharmaceutical Wholesalers (IFPW)
www.ifpw.org	International Federation of Pharmaceutical Wholesalers (IFPW)
www.nacds.org	National Association of Chain Drug Stores (NACDS)
www.ncpanet.org	National Community Pharmacists Association (NCPA)
www.nwda.org	U.S. National Wholesale Druggists' Association (NWDA)
www.syntaxis.net/logistics	Logistics Quarterly Magazine

13. Distribution Strategy

www.bindley.com	Bindley Western Drug Company
www.cardinal-health.com	Cardinal Health, Inc.
www.csc.com/industries/healthcare/	Computer Sciences Corporation
www.pharmacyinternational.com	Pharmacy International Internet Pharmacy
www.qad.com	Qad

PART 4

Pricing Strategy

14. Pricing Concepts

www.Pharmac.govt.nz	New Zealand Pharmaceutical Management Agency Ltd.
www.healtheconomics.com	Health Economics site
www.ipe.ab.ca	The Institute of Pharmaco-Economics
www.ispor.org	International Society for Pharmacoeconomics and Outcomes Research
www.ph.ucla.edu/hs/research.html	Pharmaceutical Economics and Policy Research Program at UCLA
www.pmprb-cepmb.gc.ca	Patented Medicine Prices Review Board (Canada)
www.pricing-advisor.com	Professional Pricing Society and The Pricing Advisor
www.unc.edu/depts/ppes	Pharmaceutical Policy & Evaluative Sciences at UNC
www.usc.edu/go/pharmaecon	Department of Pharmaceutical Economics and Policy at USC
www.utexas.edu/pharmacy/research/institutes/pharmacoeconomics	The Center for Pharmacoecon Studies, University of Texas Austin College of Pharmacy

15. Pricing Strategy

www.spgboston.com	Strategic Pricing Group, Inc.

PART 5

Communication Strategy

16. Integrated Communications

www.acxiom.com	Acxiom Corporation
www.adelphi-group.com	Adelphi Group Limited
www.bbkweb.com	BBK Communications
www.commonhealth.com	CommonHealth
www.corbett.com	Corbett HealthConnect
www.creativehealthcare.com	Creative Healthcare Solutions (CHS)
www.ghgroup.com	Grey Healthcare Group

www.hastingshc.com	Hastings Healthcare Group
www.hdsinc.com	McKesson Healthcare Delivery Systems (HDS)
www.qdcommunications.com	QD Communications
www.snyderhcs.com	Snyder Communications
www.strategichealthcare.com	Health Care Communications

17. Personal Selling

www.salesmarketing.com	Sales & Marketing Management Magazine
www.ashfield-uk.com	Ashfiled Healthcare Sales Recruitment & Placement Agency
www.cmrinstitute.org	The Certified Medical Representatives Institute, Inc.
www.drte.com	Dendrite International, Inc.
www.mce.be	Management Centre Europe
www.medec.com/pr	Pharmaceutical Representative Magazine
www.nspst.com	National Society of Pharmaceutical Sales Trainers (NSPST)
www.pharmasales.net	Pharmaceutical Sales Professionals Network
www.ppponline.com	Pharmaceutical Promotional Products
www.prometrics.com	Prometrics Consulting, Inc.
www.salesandmarketing.com	Sales & Marketing Management Magazine
www.sellingpower.com	Selling Power Magazine
www.zsassociates.com	ZS Associates

18. Advertising

www.commercepack.com/AAAA	American Association of Advertising Agencies (AAAA)
www.aaf.org	American Advertising Federation (AAF)
www.adage.com	Advertising Age Journal
www.adweek.com	Adweek Online Journal
www.adtalk.com	Advertising resources site
www.pravachol.com	Pravachol product page, Bristol-Myers Squibb Company
www.premarin.com	Premarin product page, Wyeth-Ayerst Laboratories
www.prozac.com	Prozac product page, Eli Lilly and Company
www.evista.com	Evista product page, Eli Lilly and Company
www.zyrtec.com	Zyrtec product page, Pfizer Inc.
www.4meridia.com	Meridia product page, Knoll Pharmaceutical Company
www.zomig.com	Zomig product page, Zeneca Pharmaceuticals

19. Public Relations (PR) and Sales Promotion

www.hcpra.org	Health Care Public Relations Association of Canada

www.national.ca	National Public Relations Inc.
meniscus.com	Meniscus Ltd. Health Care Communications

20. The Internet

www.docguide.com	Doctor's Guide to the Internet
www.drugstore.com	Drugstore cyber pharmacy
www.nielsen-netratings.com	Nielsen/NetRatings, Inc.
www.oncolink.com	University of Pennsylvania Cancer Center's Oncolink
www.pareras.com	Dr. Pareras' page on medical applications of the Internet
www.pharminfo.com	Pharmaceutical Information Network
www.planetrx.com	PlanetRx cyber pharmacy
www.rxlist.com	Rx List Internet Drug Index
www2.hcia.com	Health Care Information Association (HCIA)

PART 6

Forecasting, Planning, and Evaluating

21. Forecasting and Planning

www-marketing.wharton.upenn.edu/forecast	University of Pennsylvania Wharton School Principles of Forecasting Project
www.marketingplan.co.uk	The Marketing Plan Centre (UK)
www.businessplans.org	Business Resources Software, Inc.

22. Evaluating Marketing Performance

www.thesequoiagroup.com	The Sequoia Group

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