Implementation of the Indonesian Food and Drug Authority Agency's (BPOM) Health Service Policy on the Sale of Non-Prescribed Prescription Drugs at Pharmacies in Makassar

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ABSTRACT

The delivery of prescription drugs without using any prescription in Indonesian pharmacies is still frequent, such as the delivery of amlodipine (97.7%) and allopurinol (92.0%) without a doctor's prescription (Rokhman, 2017). The studies of Siahaan (2017) and Djawaria (2018) also show a similar trend, highlighting low compliance with BPOM policies. This indicates that the implementation of BPOM policies related to prescription drugs has not been optimal, increasing the risk of irrational drug use and shows public disapproval of the drug and food control system. Improvements in the implementation of BPOM policies are needed to reduce the risk of using hard drugs without a prescription. This research uses qualitative research methods with a descriptive approach. The data was analyzed using content analysts. Interviews were conducted with 5 informants in several agencies, including 2 Key Informants and 3 Ordinary Informants. Effective communication occurs between BPOM, health offices, and pharmacies through offline and online programs. Although resources in pharmacies are considered sufficient, challenges arise from the inadequacy of transportation facilities. Compliance with SOPs, especially related to the prescriptions supervision of prescription drug, is a problem. Improving SOP compliance, coordination, and public education are considered important to improve the effectiveness of BPOM policy implementation in Makassar City pharmacies. The implementation of BPOM policy related to the sale of prescription drugs without any doctor's prescription in pharmacies in Makassar City has been going well, supported by diverse communication and the availability of adequate resources. However, there are still practical obstacles such as transportation problems, lack of public education, budget constraints, lack of formal procedures in some pharmacies, and lack of interaction with relevant agencies.

Keywords: BPOM, Hard Drugs, Health Service, Policy, Supervisory Agency's.

INTRODUCTION

Law of the Republic of Indonesia No.8 of 1999 ¹ states that consumer protection is all efforts that ensure legal certainty to provide protection to consumers. Consumer Protection in the Health Sector, is something that is needed for consumers in obtaining drug products circulating in the community, where circulating drug products have been supervised by the Food and Drug Supervisory Agency (BPOM) which is able to be responsible for drug and food control, so that traders who are required to be able to distribute the drug must register the drug with BPOM.

The government established BPOM through Presidential Decree No. 166 Year 2000 which is tasked with carrying out government duties in the field of drug and food control. However, there are still traders who commit misappropriation in selling prohibited goods, especially drugs 2. In order to carry out these duties and functions, the head of BPOM issued Regulation of the Food and Drug Supervisory Agency Number 12 of 2018 concerning the Organization and Work Procedures of Technical Implementation Units within BPOM. This regulation aims to monitor the distribution of prescription drugs by determining the UPT BPOM classification in accordance with Article 5 paragraph 1, namely: a. Center for Drug and Food Control (Balai Besar POM), b. Food and Drug Monitoring Center (Balai POM), and c. Food and Drug Supervisory Locations (POM Workshops) ⁹.

A drug is a product whose distribution is strictly regulated by the rules. Drug classification in Indonesia is determined based on the Regulation of the Minister of Health of of Indonesia No. 44 949/Menkes/Per/VI/2000 which consists of overthe-counter drugs, limited over-the-counter drugs, mandatory pharmaceuticals, prescription drugs or medicines on list G (gevaarlijk), namely drugs with strong properties, must be obtained with a doctor's prescription, based on the Decree of the Minister of Health of Indonesia Number 02396/A/SK/VIII/1986 marking prescription Drugs with a red round circle and black outline and letters K that touches the edge line ¹⁷

In Indonesia, prescription drugs in pharmacies can only be given based on a doctor's prescription and delivered by a pharmacist. However, in practice in the field there are still many cases where prescription medicines are delivered without complying with the provisions, some are even done online or, worst of all, they are not distributed by pharmacies but by drug retailers without pharmaceutical expertise ^{23, 24, 29, 32}. In fact, there is widespread use of prescription drugs without a doctor's prescription, in this case large pharmaceutical companies (PBF), pharmacies and drug stores are suspected of providing many



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prescription drug services without a doctor's prescription ²². Factors that influence the sale of medicines without a doctor's prescription from the Pharmacy side include Economic Factors, Demand Factors, Juridical Factors, and Technological Development Factors. Purchasing factors on the consumer side are Economic Factors, Medical Factors, Educational Factors, Cultural Factors and Juridical Factors ^{25, 27, 28, 30}.

This is in line with what was stated by ³ in the results of his study that out of 138 pharmacies 97.7% (132 pharmacies) gave *amlodipine* without a prescription and 92.0% (127 pharmacies) gave *allopurinol* without a prescription. The majority of pharmacists (>85%) have the perception that prescription drugs for chronic diseases (*glibenclamide*, *metformin*, *amlodipine*, *captopril*, *allopurinol* and *simvastatin*) are drugs that can be delivered without a prescription for the main reason that patients are used to using them. The research shows that pharmacists have not fully implemented the applicable regulations. The pharmacist's responsibility for selling Cytotec prescription drugs without a doctor's prescription explains the criminal and administrative responsibilities that can be imposed on the pharmacist as a sanction for the actions carried out and contains the legal consequences of selling prescription drugs not according to procedures ²⁶.

Apart from that, research results from Putra et al (2014) also found that there are still many prescription drugs circulating in Pekanbaru City and this is detrimental to consumers ¹⁶. Research in Banda Aceh City also shows that there are still consumers who buy prescription drugs without a doctor's prescription at pharmacies. The reason consumers buy those drugs without a doctor's prescription at pharmacies is the low level of public knowledge, especially regarding drug classes, so they don't know the drug classes and the conditions for buying the said drugs. The next reason is to get these drugs easily and quickly and the costs incurred are smaller/ little ²⁰.

Selling prescription drugs without a doctor's prescription is illegal. This illegal activity is subject to a criminal violation of Article 197 in conjunction with Article 106 Paragraph (1) of Republic of Indonesia Law Number 36 of 2009 concerning Health and Law Number 8 of 1999 concerning consumer protection. Pharmacies that sell prescription drugs must follow existing regulations. They also have to report the sale of those drugs to the government, namely the Health Service. Selling prescription drugs without a doctor's prescription may result in administrative sanctions, written warnings, and temporary suspension until the SIA is revoked. The government formed BPOM to monitor illegal prescription drugs so that people are safer and more comfortable using the drugs they need 11,13,18.

Based on the problems and field facts that have been mentioned, it can be observed that the implementation of policies from BPOM has not been carried out optimally. The large circulation of prescription drugs without a doctor's prescription in the community caused by existing factors proves that the drug and food supervision system by BPOM is not fully well received by the public both from consumers and health facilities themselves. This results in an increased risk of irrational use of these drugs and can lead to bigger problems in the future.

In the Regulation of the Head of BPOM RI No. 24 of 2017, it is explained that G list of prescription drugs (*gevaarlijk*) are drugs included in the list of dangerous drugs that have the efficacy of treating, strengthening, gooding, disinfecting and others of the human body, which can only be submitted by pharmacists and their submission must be based on a doctor's prescription. A special sign of a G list of the drugs is a red round circle with a black border with the letter K touching the border, and the marker must include the sentence "Must be prescribed by a doctor".

Supervision is carried out related between one part of the supply chain and other parts ranging from the pharmaceutical industry, pharmaceutical wholesalers, pharmaceutical service facilities to drugs obtained by consumers. The effects that can occur when taking drugs without a doctor's prescription according to [4] are: (a) side effects; (b) idiosyncrasies; (c) allergies; (d) photosensitization; (e) the effect of toxy; and (f) teratogenic effects.

In response to the problems described above, researchers are interested in conducting further research related to the implementation of BPOM policy on the sale of hard drugs without a doctor's prescription.

METHODS

Participants

The informants in this study were 5 (five) people consisting of 2 key informants and 3 supporting informants. The key informants are DFM Associate Expert of the Food and Drug Authority Agency (BBPOM) of Makassar city and Kasifarmasi of the Makassar city Health Office. Supporting informants are resource persons who work as pharmacists and have a pharmacy business located in the city of Makassar.

Data Collection

The data collection techniques carried out in the field are:

In-depth interview: researchers conducted in-depth face-to-face interviews with informants regarding Implementation of the Food And Drug Supervisory Agency's (Bpom) Health Service Policy On The Sale Of Hard Drugs Without A Doctor's Prescription At Pharmacies In Makassar.

Data Analysis

Researchers used qualitative data analysis with content analysis methods. The data analysis technique used is through data reduction, data presentation and conclusion drawing by researchers repeatedly listening to audio recordings and transcribing them. For document review, you will review the available documents and match them to the interview results.

RESULTS

Audio recordings for 1 hour, 40 minutes, and 25 seconds were collected from the interviews. This was transcribed into a 52-page document consisting of 12,753 words.

Here are the characteristics of research informants (Table 1).

Exposure of Data from Research Subject Interviews related to BPOM Policy on Communication Aspects

Based on data from interviews by key informant 01 and key informant 02, policies related to the supervision and sale of prescription drugs without any doctor's prescription have been communicated to pharmacies and drug stores in Makassar through socialization programs that are carried out regularly every year with the help of various parties such as IAI, IDI, PAFI, and the Makassar city health office.

"... Usually we involve professional organizations, be it IAI, IDI, PAFI, to the health office..." (IK1, Makassar City Food and Drug Supervisory Agency)

As for delivering information to the public, the Health Office also supervises and assists pharmacies or drug stores to educate customers who want to consult / buy drugs.

"... Within a year, we have a target for pharmacy supervision and coaching. So it is the main task of the Pharmacy to supervise and guide pharmacies as well as drug stores..." (IK2, Makassar City Health Office).

Delivery of information to the public is not only verbally through pharmacists, but also through electronic and non-electronic media such as posters, leaflets, to through social media of health agencies.

Table 1. Table of Informant Characteristics.

Informer (Code)	Age	JK	Position	Agency	Ket.
Drs. Hamka Hsan, Apt, M.Kes (IK1)	56 yrs	L	DFM Experts Associate	ВВРОМ	Informant Key 01
Nurlaela (IK2)	52 yrs	P	Cassipharmacy	Service Health	Informant Key 02
Andi Hardani, AM (IP1)	27 yrs	P	Head Pharmacy	Pharmacy Jeddah	Informant Supporter 01
Imran Yusuf (IP2)	27 yrs	L	Head Pharmacy	Infarma Medika Pharmacy	Informant Supporter 02
Karlina Amir Tahir (IP3)	36 yrs	P	Head Pharmacy	Pharmacy Ash-Shura Farma	Informant Supporter 03

"... We have a lot of socialization programs. One of them is infocomm programs such as disseminating Communication, Information, and Education (KIE) or disseminating information carried out through social media, electronic media, print media, etc..." (IK, Makassar City Food and Drug Supervisory Agency).

Socialization programs related to applicable policies are routinely carried out every year either by BPOM or from the Makassar city health office so that the delivery of information to pharmacies and drug stores can be received evenly throughout the city of Makassar. However, based on the results of interviews by supporting informant 03 that pharmacists are still not aware of these socialization programs so that pharmacists do not get direct assistance related to applicable policies in terms of selling prescription drugs without any doctor's prescription.

"... None. To my knowledge, there have been no activities such as socialization related to the sale of hard drugs without a doctor's prescription, in this case communication between pharmacies and BPOM. So far we only refer to the regulations set by the government..." (IP3, Pharmacist Apotek Asy Syura Farma)

Data Exposure of Research Subject Interviews related to BPOM Policy on Resource Aspects

Based on data from interviews by informants, although in terms of transportation facilities still need to be improved because according to key informant 02 from the health office that with the unavailability of field transportation, the health office needs to use private transportation to carry out duties to jump into pharmacies in the city of Makassar.

"... I don't think so. We have proposed regarding the provision of official transportation for the benefit of duty but until now there has been no approval. This caused us to have to use private vehicles..." (IK2, Makassar City Health Office)

As for the budget given, both BPOM and the Makassar city health office feel that it is very sufficient.

"... It is more than enough (Budget availability). As for the budgeting system based on data on facilities, sampling, to official costs..." (IK1, Food and Drug Administration)

In line with key informants, according to supporting informants, the availability of resources in pharmacies is very sufficient in carrying out prescription drug sales services in accordance with applicable BPOM policies and directions from the Makassar city education office.

"...Pharmacies are very sufficient in providing health services, especially in providing human resources related to BPOM policies..." (IP2, Pharmacist Apotek Infarma Medika)

The factor of technological progress is also very easy to control prescription drug products traded to the community and rejuvenate to analyze the level of public satisfaction in terms of services provided by pharmacies.

"... Pharmacies can measure the quality of service from the arrival rate of patients who repeatedly come to make purchases and also through social media related to monitoring drugs or drug availability at pharmacies..." (IP2, Pharmacist Apotek Infarma Medika)

Exposure of Data from Research Subject Interviews related to BPOM Policy on Disposition Aspects

Based on data from key informant interviews that with a permit letter from PTSP and recommendations from the health office, BPOM can implement a well-planned program. The main task of BPOM is to supervise pharmacies and drug stores in the city of Makassar, especially in this case is the sale of hard drugs without a doctor's prescription.

"... Regarding the permission given by the PTSP and the authority of the Health Office in the form of providing recommendations in accordance with the Minister of Health listed to the PTSP to issue a permit..." (IK2, Makassar City Health Office)

However, the main obstacle of every supporting informant is how to educate the public regarding the prohibition of using hard drugs without a doctor's prescription because of the risk that is quite dangerous. However, it is part of the responsibility of every pharmacist to protect the rights and obligations of patients who in this case are the general public.

- "... Pharmacies must be able to educate patients regarding the use of hard drugs..." (IP2, Pharmacist Apotek Infarma Medika)
- "... Very much. For example, in terms of educating customers regarding the use of antibiotic drugs that are not in accordance with the doctor's recommendations..." (IP3, Pharmacist Asy Syura Farma)

Exposure of Data from Research Subject Interviews related to BPOM Policy on Bureaucratic Aspects

Based on data from interviews by key informant 01 and key informant 02 that the implementation of tasks is carried out jointly both from existing health organizations and from related agencies. However, there are still many who consider that the implementation of supervision of these drugs in circulation is the main task of BPOM so that the implementation of the work program cannot run optimally. Apart from the mindset that has been embedded in related agencies, this is also because the budget given is still somewhat insufficient for related agencies so that they cannot actively participate in carrying out tasks in accordance with applicable policies.

"... I don't think it's maximized. One of the reasons may be that drug supervision is considered the main task of BPOM and the budget given is very little to the relevant agencies..." (IK1, Agency Food and Drug Controller)

On the other hand, according to supporting informant 01 and supporting informant 02, internal briefings in pharmacies related to policy implementation by BPOM are submitted directly by pharmacists and reporting results related to the sale of the aformentioned drugs are actively reported through SIPNAP every month.

"... Reporting on the use of hard drugs is carried out monthly through SIPNAP for narcotic and psychotropic preparations and for other hard drugs..." (IP1, Jeddah Pharmacy Pharmacist)

DISCUSSION

Analysis of BPOM Policy Implementation on the Sales of prescription Drugs Without a Doctor's Prescription at Pharmacies in Makassar City based on Communication Aspects

The Ministry of Health has provided drug information through the publication of the Guidelines for the Use of Over-the-counter Drugs and Limited Over-the-counter Drugs as a reference for the public in self-medication. In the book, pharmacists are expected to provide appropriate information so that the public avoids *drug abuse* and *drug misuse* ¹.

a. BPOM Communication Effectiveness

BPOM is active in communicating policies through offline and online programs. The participation of related parties such as LAI, IDI, PAFI, and the Makassar city health office in the socialization activities carried out can be a focus to determine the effectiveness of information communicated to pharmacies, drug stores, and other facilities.

b. The Role of Makassar City Health Office

The health office has an important role to know the extent to which the regulations that have been implemented are effective in preventing the sale of prescription drugs without any doctor's prescription in pharmacies. One form of communication is by conducting socialization programs to pharmacies and drug stores and conducting guidance related to applicable policies.

c. Positive Impact of Socialization Program

BPOM or from the health office also provides education and appeals to pharmacists regarding the sale and abuse of those drugs without a doctor's prescription in the hope that pharmacists can educate patients or the public regarding the impact that can be caused.

d. Communication and Education to the Community

The use of various media such as print media or online media makes the dissemination of information can run effectively in achieving public awareness of the policy of selling and using prescription drugs without any doctor's prescription.

e. Pharmacists' Efforts in Community Education

Pharmacists act as a communication bridge for the public regarding applicable rules and policies that have been regulated in the regulation of the minister of health. However, results from informants show that not all pharmacies get information uniformly. This indicates that the provision of training and communication guidance for each pharmacy needs to be improved in terms of equitable distribution of information related to applicable BPOM policies.

Analysis of BPOM Policy Implementation on Sales of Hard Drugs Without a Doctor's Prescription at Pharmacies in Makassar City based on Resource Aspects

As an agency authorized to supervise drugs and food, BPOM has very limited resources in supervising the circulation of drugs and food online. BPOM institutions are not available in every district/city, human resources that oversee online circulation are limited and limited authority in cracking down on alleged violations ². The results of this research are in line with the findings of Septianingsih et al who found that the main obstacles in government supervision of the sale of hard drugs without a doctor's prescription in Lebak Regency were the minimal number of personnel, lack of funds and limited facilities for carrying out supervision ¹¹. As well as other research in Banda Aceh in 2022 which found that there was still a very lack of human resources at BBPOM in Banda Aceh with a fairly large working area ¹⁴.

a. Resource Availability

Monitoring is carried out using a risk analysis approach, and budgeting of funds is based on data on facilities, sampling, and official costs. The facilities available are also up to standard. The results of this study stated that overall, the availability of resources in pharmacies was very sufficient.

b. Coordination with the Health Office

The Makassar City Health Office, especially the Pharmacy department, coordinates directly with pharmacies without the involvement of other parties.

c. Service and Management of prescription Drugs

The availability of adequate resources, the services provided by pharmacies run well. Management of the availability of those drugs is carried out regularly, and pharmacies only provide drugs that are classified as safe to be traded to the public, improving the quality of service.

d. Service Quality Monitoring Strategy

Pharmacies use strategies to measure service quality by looking at the quantity of repeated purchases by the public related to the aforementioned drugs and monitoring social media.

e. Constraints and Challenges

Inadequacy of special transport facilities

f. Efforts to Improve Service Quality

Pharmacies only provide drugs that are classified as safe. This step can be considered as a proactive effort to ensure the safety and security of drug use by the public.

Analysis of BPOM Policy Implementation on the Sales of Prescription Drugs Without a Doctor's Prescription at Pharmacies in Makassar City based on Disposition Aspects

Article 24 letter c of the Pharmaceutical Government Regulation stipulates that pharmacists can provide prescription drugs, narcotics, psychotropic drugs only on prescription. Thus, the purchase of those drugs without a doctor's prescription is a fight prohibited by law. However, there are some prescription drugs that are allowed to be given without a doctor's prescription, these drugs are regulated in Permenkes 919 of 1993 which regulates Mandatory Pharmacy Drugs (OWA)

a. Compliance with SOPs

Identified problems related to compliance with SOPs, especially related to the supervision of these drug prescriptions that are not recorded in the pharmacy database.

b. The Role of the Health Office and Operational Constraints

The role of the health office in providing permits, supervisory recommendations, and socialization related to BPOM policies. However, operational constraints such as limited transportation facilities become obstacles in carrying out supervisory duties. Moreover, there are still many people who lack knowledge regarding BPOM and purchasing the drugs without a doctor's prescription ¹⁴. However, BPOM plays a major and important role in this problem because it is the main task and function of BPOM employees themselves ¹⁹.

c. Support and Motivation in Policy Implementation

The BPOM policy is considered not to be a problem and provides support and motivation to other pharmacy employees to comply with the policy. They are also active in providing direction and conducting socialization to the community.

d. The Role of Education and Communication with the Community

The importance of maintaining compliance with SOPs, improving coordination with relevant agencies, and continuously educating the public will be crucial points in an effort to improve the effectiveness of BPOM policy implementation related to the sale of hard drugs without a prescription in Makassar City pharmacies.

Analysis of BPOM Policy Implementation on the Sales of Prescription Drugs Without a Doctor's Prescription at Pharmacies in Makassar City based on Bureaucratic Aspects

Supervision of the circulation of prescription drugs in its implementation did not go well because there were several policies from each agency that overlapped with the policies of other agencies, so that BPOM found it difficult to carry out its supervisory duties. These results are in line with the findings of Khalid et al who explain that the factor influencing the supervision of these drugs in North Aceh Regency is the lack of coordination between institutions regarding the control of the aforementioned drugs ¹⁴.

To avoid overlap, it is necessary to arrange the laws and regulations made by the POM Agency with laws and regulations issued by the Ministry of Health and other Ministries. In addition, an inventory or mapping of overlapping laws and regulations will also be carried out, as well as structuring procedures for their preparation and formation and documentation ⁴. Supervision is needed by optimizing the three-pillar drug and food control system (government, producers and society) to prevent the circulation of prescription drugs ¹⁰. As found by Suriangka who found that BPOM Makassar protects the public from drug and food products that endanger health, outlined in a full spectrum monitoring system starting from pre-market to post-market control accompanied by law enforcement efforts and community empowerment. empowerment) ³¹. Apart from that, good collaboration and coordination is needed between BPOM and the National Police in tackling the crime of distributing those drugs in society ¹⁵.

Based on the results of the analysis of legal materials, it can be stated that the sale of the drugs without a doctor's prescription is a violation of the law and consumers who are harmed, in accordance with Article 45 of the Consumer Protection Law Number 8 of 1999, can sue for compensation either through the court or outside the court, namely through the Consumer Dispute Resolution Agency. This is a form of repressive legal protection, while preventive legal protection can

be through IEC (Information Communication and Education) and outreach to the community ²¹. The legal liability that can be imposed on pharmacies is liability based on fault, so that pharmacies must provide compensation to consumers (buyers) if it is proven that their mistakes have caused losses to buyers through misuse of antibiotic drugs which can cause overdoses, resistance, even death ²⁴.

a. Supervision and Implementation of SOPs by BPOM

Supervision in pharmacies in Makassar City is considered not optimal. The main obstacle faced is budget limitations in related agencies, including BPOM.

b. Coordination and Support of Related Agencies

The Health Office coordinates with various relevant agencies, such as BPOM, Satpol PP, and IAI. Nevertheless, supporters from various parties and technological developments help smooth implementation of tasks, especially in field socialization

c. The Role of the Health Office and Regulatory Guidelines

The Health Office actively participates in the coordination and implementation of tasks, with support from various parties.

d. Authority of Pharmacists and Use of SIPNAP

The use of SIPNAP in reporting prescription drug sales activities every month is one of the efforts of pharmacies in complying with regulations. Active communication with the health department is also a positive step.

e. Authority of Pharmacy Owners and Lack of Formal Process

Pharmacy owners give full authority to the person in charge of the pharmacy, but there is a lack of formal procedures for managing and selling hard drugs.

LIMITATIONS

During interviews with informants sometimes there is a repetition of questions so that informants better understand what the researcher asks, besides that researchers cannot limit informants' answers to remain in context or topic.

CONCLUSION

- The implementation of BPOM's policy on the sale of prescription drugs without any doctor's prescription at pharmacies in Makassar City involves various communication efforts. While there has been a positive impact on some pharmacies, there are also limited information in some places. Therefore, further efforts are needed to improve the effectiveness of communication and policy understanding in all pharmacies in Makassar City.
- 2. BPOM's policy on the sale of prescription drugs without a doctor's prescription in pharmacies in the city of Makassar has been implemented quite well. The availability of adequate resources, good coordination between the health department and pharmacies, as well as evaluation and control strategies implemented by pharmacies, all contribute to the effective implementation of this policy. However, some obstacles such as lack of transportation facilities need to be overcome to improve operational efficiency.
- 3. The implementation of BPOM's policy on the sale of those drugs without a doctor's prescription in pharmacies in Makassar City has received support from related parties. However, there are still some practical barriers, especially related to transportation and public education. Therefore, further efforts are needed to improve the effectiveness of supervision and education to ensure policies can be implemented optimally.

4. Although the BPOM policy has been implemented, there are still several obstacles such as budget constraints, lack of formal procedures in some pharmacies, and lack of interaction with related agencies. Therefore, further efforts are needed to improve the effectiveness of the implementation of this policy through improved coordination, adequate budget allocation, and increased interaction between pharmacies and related agencies.

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CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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