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JURIDICAL STUDY OF REPRESIVE LEGAL PROTECTION AGAINST THE CIRCULATION OF FAKE "PATENT" MEDICINE

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ABSTRACT; Consuming medication is an effort to maintain and maintain health. The high demand for medicines and low consumer knowledge create opportunities for business actors to produce fake medicines. The aim of this research is to determine the causes of the spread of fake patent medicines as well as the legal protection for consumers regulated in law along with BPOM's efforts to prevent the spread of fake patent medicines. The research method used in this research is empirical juridical, the research specifications used are analytical descriptive with data collection techniques through direct research in the field, namely open interviews and literature studies. Based on the research results obtained, the causes of the circulation of counterfeit patent medicines in influenced by business actors and consumer factors. Repressive legal protection for consumers is regulated in the Consumer Protection Law Article 8 Paragraph 1 Letter (a), Law Number 17 of 2023 concerning Health Article 138, Article 140 and Article 142. Apart from that, it is also regulated in the Regulation of the Medicine Supervisory Agency and Food Number 34 of 2018 concerning Guidelines for Implementing Good Medicine Manufacturing Methods. The prevention efforts carried out by BPOM are carried out in two forms, namely pre-market control in the form of standardization and product evaluation and post-market control in the form of Communication, Information and Education (KIE).

Keywords: Consumer; Fake Medicine; Legal protection

INTRODUCTION

As we all know, medicine users, both short and long term, want safe medicines to be available to improve their health. In Article 1 Number 11 of Law Number 17 of 2023 concerning Health, hereinafter referred to as the Health Law, it is stated that: "Health efforts are any activity and/or series of activities carried out in an integrated and sustainable manner to maintain and improve the level of public health in the form of preventing disease, improving health, treating disease, and restoring health by the government and/or society."

Continuing human benefit is one of the most important component elements, namely the availability of medicines as part of health services[1]. Nowadays, increasing public awareness and health knowledge has also driven public demand for health services, including an increase in the number of professional medicines[2]. Medicine is a health product that is useful in supporting consumer health.

Consumers require medical needs so that patients as consumers have the right to know and receive clear information regarding the medicines they consume, both in terms of medicine content, medicine benefits and the effectiveness of the medicine benefits.[3]. Medicine regulations in Indonesia are regulated in the Health Law. In Article 138 Paragraph (1) of the Health Law, it is stated that pharmaceutical preparations (medicines) and medical devices must be safe, useful/efficacious, high quality, affordable, meet the requirements for halal products and comply with the law.

Free trade tends to result in goods and services in circulation that do not necessarily guarantee the security, safety and health of consumers[4]. The high demand for medicines and low consumer knowledge provide opportunities for unscrupulous business people to produce fake medicines. Business actors use generic medicines that have expired and change their appearance in such a way that they become new patented medicines with high selling prices.

Seeing this, the government, through the Food and Medicine Monitoring Agency (BPOM), has made efforts to prevent the circulation of fake medicines. Supervision carried out by BPOM starts from the licensing stage for distributing medicines, the registration stage until the stage after the medicine is distributed through the supervision stage of medicine registration, consumer information, as well as the

[1] Marisca Evalina Gondokesumo and Nabbilah Amir, "The Role of Government Supervision and the Food and Medicine Supervisory Agency (BPOM) in the Circulation of Counterfeit Medicines in Indonesia (Viewed from Law Number 36 of 2009 and Regulations of the Head of the Medicine and Food Management Agency)," Legal Perspective , 2021, 91–107, https://doi.org/10.30649/ph.v21i2.16.

[2] Purwanto Hardjosaputra, Indonesian Medicine List, II (Jakarta: PT. Mulia Purna Jaya Published, 2008).

[3] Anisa Utami and Herwastoeti Herwastoeti, "LEGAL PROTECTION OF CONSUMERS FOR ILLEGAL ONLINE SALES OF MEDICINES" 1, no. 2 (2022): 93–116, https://doi.org/10.32503/klausula.v1i2.2727.

[4] Hijawati Hijawati, "Illegal Medicine Distribution in View of Consumer Protection Law," Solusi 18, no. 3 (2020): 394–406, https://doi.org/10.36546/ Solusi.v18i3.310.

examination and investigation stage. Supervision of every activity related to the world of health is important for the government to advance community welfare[5].

In a news page published by detik news in 2019, the Bareskim Police succeeded in uncovering a case of counterfeiting patent medicines produced in a factory located in Semarang City, Central Java[6]. The case of patent medicine counterfeiting in Semarang City was carried out by the Director of PT. Motif Jaya Karunia Invesindo (JKI) fakes hard medicines from generic medicines to patent medicines with the aim of getting higher profits.

Counterfeit medicinal products are carried out by repackaging from expired generic medicine raw materials. Next, the perpetrator dismantled all the standard ingredients and combined them and manipulated the expiration date and the patented medicine was packaged into a genuine medicine complete with a medicine box and a brochure on how to use the medicine so that it really looks genuine. Counterfeiting medicines falls into the category of fraudulent crimes (bedrog). or better known as the crime of fraud[7].

In a journal written by Annisa Sholiya Honesty, she said that the reason why Indonesia has not been successful in dealing with medicine counterfeiting is the efforts made by Indonesia in the international sphere and Indonesia is still experiencing several obstacles, such as not yet implementing all the recommendations of the Member State Mechanism, weak legal regulations and supervision regarding entry routes. fake medicines, lack of coordination between stakeholder sectors, the pharmaceutical industry in Indonesia which is not yet independent, and a lack of public awareness of the dangers of fake medicines[8].

Previous studies stated that efforts to empower consumers to prevent the circulation of counterfeit medicines have been implemented by BPOM Semarang, the Central Java Provincial Health Service, the Central Java Institute for Development and Consumer Protection (LP2K) as well as pharmaceutical staff found in various medicine stores in the Semarang area.[9]

Consumer protection against the use of counterfeit patent medicines is based on Article 1 paragraph (1) of Law Number 8 of 1999 concerning Consumer Protection, hereinafter referred to as the Consumer Protection Law, consumer protection is all efforts that guarantee legal certainty in the use of providing protection to consumer. It is hoped that the sentence that reads "every effort is guaranteed to have legal

[5] Leli Juwanti and Marta Tilov, "Legal Protection for Consumers for Selling Illegal Medicines Online," NIAGAWAN 7, no. 3 (2018): 163–70, https://doi.org/10.32503/klausula.v1i2.2727.

[6] Ahmad Bil Wahid, "197 Pharmacies Become Subscribers to Fake Patent Medicine Factory in Semarang," detik news, 2019, https://news.detik.com/berita/d-4634616/197-apotek-jadi-langganan-pabrik-obat- fake-patent-in-semarang.

[7] Yuliana Surya Galih, "THE STATE'S OBLIGATION TO PROTECT THE NATION'S CHILDREN," Galuh Justisi 5, no. 1 (2017): 374, https://doi.org/10.25157/jigj.v5i1.249.

[8] Annisa Sholiya Honesty, "Indonesia's Efforts to Handle Medicine Counterfeiting," Journal of International Relations 3 (2017): 1, https://doi.org/10.14710/jirud.v3i1.14598.

[9] TA Yulianingsih, Bambang Eko Turisno, and Aminah, "Consumer Empowerment in Preventing the Circulation of Counterfeit Medicines in the Community," Diponegoro Law Journal 5, no. 4 (2016): 1–11, https://doi.org/10.14710/dlj.2016.13762.

certainty" can become a bulwark to eliminate arbitrary actions carried out by naughty business actors just for personal gain, and guarantee legal certainty for consumers.

Article 4 Letter (a) of the Consumer Protection Law states that consumers have the right to comfort, security and safety in consuming goods. In this case of fake patent medicines, consumers do not obtain their rights to safety and security when consuming goods. Protection of consumers is seen in material terms and the consumer's health[10]. In fact, the existence of these regulations becomes a bulwark to eliminate arbitrary actions carried out by perpetrators who commit fraud just for personal gain.

PROBLEM

Based on the background explanation, the problem can be formulated as follows:

1. What causes patent medicine counterfeiting?
2. What are the legal protections and prevention efforts for consumers using counterfeit patent medicines?

RESEARCH METHODS

The methodological approach used in this research is an empirical juridical approach by analyzing problems by combining a number of legal materials (secondary data) with primary data obtained in the field[11]. The empirical aspect relates to the situation in the field regarding the circulation of fake patent medicines in Semarang City as well as legal protection efforts to prevent the circulation of fake medicines. Emphasis on the juridical aspect of the legal aspect, namely reviewing statutory regulations regarding legal protection against the use of counterfeit patent medicines, namely Law Number 8 of 1999 concerning Consumer Protection and Law Number 17 of 2023 concerning Health and several regulations.

Research specifications: This is analytical descriptive research, namely by collecting facts/data and explaining them thoroughly and researching according to the problem to be solved.[12]. This research uses primary data in the form of direct interviews at the BPOM Semarang office with the Head of the BPOM Action Division. The data obtained is then processed and analyzed using qualitative methods, namely research results analysis methods that produce data expressed by respondents in writing or verbally and also in real behavior, behavior that is researched and studied in its entirety.[13]

[10] Reda Mantovani, "Consumer Protection Against the Crime of Medicine Counterfeiting," Master of Law Journal 6, no. 2 (2023): 78, https://doi.org/10.36722/jmih.v6i2.2315.
[11] Soerjono Soekanto, Introduction to Legal Research (Jakarta: UI Press, 1986).
[12] M Iqbal Hasan, Basic Materials of Research Methodology & Its Applications (Jakarta: Ghalia Indonesia, 2002).
[13] Mukti Fajar Nur Dewata and Yulianto Achmad, Dualism of Normative & Empirical Legal Research (Yogyakarta: Student Library, 2010).

DISCUSSION

Causes of Patent Medicine Counterfeiting in Semarang City

Definition of Medicines

The understanding of medicines as stated in the Health Law Article 1 Number 15 explains that medicines are ingredients or guiding materials, including the biology of products used to influence or investigate physiological systems or pathological conditions. To be used in determining diagnosis, prevention, healing, recovery, improvement. health and as contraception for humans.

Patent medicines are part of Intellectual Property Rights which are then called IPR which in this framework are included in the category of Industrial Property Rights[14]. Patent medicines are medicines that still have their own patent rights and can only be produced by the patent holder manufacturer[15]. If the patent has expired, the patented medicine is then referred to as a generic medicine. Generic medicines are divided into 2, namely generic medicines with a logo and branded generic medicines[16].

Definition of Counterfeit Medicines

The definition of counterfeit medicines as stated in the Regulation of the Minister of Health of the Republic of Indonesia Number 1010/Menkes/PER/XI/2008 concerning Medicine Registration as amended by Regulation of the Minister of Health Number 1120/Menkes/Per/XII/2008, counterfeit medicines are "medicines produced by a person who is not entitled under the applicable laws and regulations or who produces medicines with imitation markings of the identity of other medicines which have received their own permission to circulate." The definition of counterfeit medicines conveyed by BPOM of the Republic of Indonesia is:

1) Produced by unauthorized parties.
2) The labeling intentionally imitates the original medicine.
3) Haphazard production stages.
4) The medicine dose is not weighed carefully so it is too little or too much, or may not contain the same medicine ingredients or contain ingredients that are dangerous to health.

Causes of Circulation of Counterfeit Medicines

[14] Lidya Shery Muis, "The Right to Accessibility of Patented Medicines for the Community," Widya Pranata Hukum: Journal of Legal Studies and Research 1, no. 1 (2019): 36–64, https://doi.org/10.37631/widyapranata.v1i1.259.

[15] Directorate of Pharmaceutical Services Development, Medicine Classification Pocket Book (Jakarta: Indonesian Ministry of Health, 2015).

[16] Khoiruzzad Zakaria, "Profile of the Use of Generic Medicines with Logos and Branded Generic Oral Anti-Diabetic Medicines in the Inpatient Installation of Dr. Regional General Hospital. Moewardi Surakarta" (Muhammadiyah University of Surakarta, 2010).

The circulation of counterfeit medicines can originate from the production process carried out by producers who are not authorized to produce medicines but deliberately produce counterfeit medicines, or distributors who deliberately produce counterfeit medicines, or from distributors who deliberately redistribute expired medicines by deleting the expiry text. and replace it with the extended expiration day, month, year.

The case of fake patent medicines originating from production is a factory making fake patent medicines by PT. JKI found in Puri Anjasmoro, Semarang City. Based on the description of BPOM's response. Generic medicines are considered more vulnerable to abuse due to lack of supervision during the production process. This distrust arises because generic medicines are not produced by the legitimate brand owner[17].

Violations are committed through the production of counterfeit medicines by repackaging generic medicines into branded medicines. The source of the medicines to be repackaged was obtained by the perpetrator from buying generic medicines and collecting expired medicines from a number of pharmacies in Jakarta and Semarang. Basically, managing, storing and distributing hard medicines and certain medicines must basically meet special criteria in accordance with applicable laws and regulations.[18]

Mrs. Dra. Zeta Rina Pujiastuti, M.Kes., Apt as the Medicine and Food Control Enforcement Division stated that medicines originating from the pharmaceutical industry, distributors, sub-distributors, and PBF (Pharmaceutical Wholesalers), should not be allowed to reach clinics and doctors directly. , orderlies, medicine stores, and consumers because they must first be registered to get a distribution permit number. However, what happened was that a number of medicines that did not have distribution permits were given to the pharmaceutical industry, distributors, sub-distributors and PBF. A number of parties issue a distribution permit so that it appears as if they had a distribution permit from the start, then a number of medicines are distributed to pharmacies.[19]. Based on the research results, it is known that a number of factors contribute to the circulation of counterfeit medicines:

1) Entrepreneur Factors

   Business actors or producers should have complied with existing standard regulations made by the government. However, in fact there are still parties who do this, one of which is the PT violation case. JKI. Provisions regarding material quality assurance are regulated in Government Regulation Number

[17] Honesty, "Indonesia's Efforts to Handle Medicine Counterfeiting."
[18] Dicky William, "Circulation of Counterfeit Medicines in View of Health Law and Information Law and Electronic Transactions," Bandung Conference Series: Law Studies 2, no. 1 (2022): 286–91, https://doi.org/10.29313/bcsls.v2i1.806.
[19] Zeta Rina Pujiastuti, Interview (24 January 2020).

72 of 1998 concerning Safeguarding of Pharmaceutical Preparations and Medical Devices. Article 2 states that every pharmaceutical preparation in the form of a medicine or material produced by a medicine must meet the quality, safety and benefit requirements stipulated in the pharmacopoeia book. determined by the Minister. Medicine production requires certain expertise in the pharmaceutical field related to the composition contained in the medicine, requiring authority granted by the government[20].

Medicine business actors carry out medicine counterfeiting due to cooperation between several parties which facilitates the distribution of fake medicines. The parties involved in the circulation of counterfeit medicines are hospital medicine distributors, producers of genuine and fake medicines, nurses, doctors, hospital cleaners and hospital directors.[21]. They operate in order to maximize profits with inadequate government supervision of medicine distribution.

The obligations stated in Article 7 of the Consumer Protection Law include having good faith in carrying out business activities and guaranteeing the quality of goods and/or services produced or traded according to the provisions on the quality of said goods and/or services. Failure to fulfill the obligations of business actors in production facilities results in the possibility that the products made do not meet existing quality and safety standards. In producing medicines, the standards that must be met are the cleanliness and quality of the equipment and production sites used to make fake medicines, which also do not necessarily comply with the requirements set out in Good Medicine Manufacturing Practices (CPOB).

The Consumer Protection Law regulates in Chapter IV Articles 8 to 17 regarding actions that are prohibited for business actors. In principle, the responsibility of producers is aimed at protecting consumers[22]. Article 8 paragraph (3) explains that business actors are prohibited from trading in defective, damaged, used or contaminated pharmaceutical preparations and food, with or without providing complete and correct information. As is the case at PT. JKI.

2) Consumer Factors

According to Dra. Zeta Rina Pujiastuti, M.Kes., Apt. The people of Semarang City still have the mindset that medicine can be bought anywhere, because

[20] Renti Alwina Tatangidatu, "Judicial Study of the Crime of Medicine Counterfeiting in Indonesia" (Sebelas Maret University Surakarta, 2010).
[21] Pujo Utomo, "Circulation of Counterfeit Medicines and Efforts to Protect Consumers," Journal of Legal Sciences, 2017.
[22] Yustrang Gowasa et al., "Consumer Protection Against the Distribution of Illegal Medicines," RECTUM JOURNAL: Juridical Review of Handling Crime 5, no. 1 (2023): 750, https://doi.org/10.46930/jurnalrectum.v5i1.2813.

the price is relatively cheaper than in pharmacies. We can just buy the medicine at a pharmacy or medicine store that has a pharmacist or medicine waiter[23]

Consumers are the weak party when compared to business actors or producers. This is because consumers are not involved in the production process carried out by producers or business actors. Therefore, there is a dire need for consumer protection so that consumers do not become disadvantaged parties, including the protection of medicine consumers from the distribution of counterfeit medicines in the community.[24]

Dra. Zeta Rina Pujiastuti, M.Kes., Apt also added that consumers as medicine users must be smart and independent in choosing and determining which medicines to buy and consume. In reality, the public, especially medicine consumers, still do not know what medicines are, where is the right place to buy them, what is the good condition of medicines, how to store medicines, how to make them and what effects medicines cause and the simplest thing is about medicine classification.[25]

Public knowledge is still insufficient to be able to choose and use products appropriately, correctly and safely[26]so that in this case consumers must be more careful in purchasing medicines and can prevent the circulation of fake medicines around them.

According to the Consumer Protection Law, the public still has several other consumer rights that medicine consumers need to know, namely that medicine consumers have the freedom to choose medicines, when purchasing medicines, the security, comfort and safety of the medicines they consume are protected, and have the right to receive compensation. as well as legal protection when violations occur.

Legal protection and prevention efforts against users of fake patent medicines

Legal protection against the use of counterfeit patent medicines

The aim of law is to provide legal protection to society, in fact legal protection is an essential element and is a consequence in a rule of law. This can be found in Article 28D Paragraph (1) of the 1945 Constitution of the Republic of Indonesia. Therefore, the State is obliged to guarantee a number of legal rights for those who inhabit its country. Legal protection is a form of recognition of the dignity of the country's residents as human beings.

[23] Pujiastuti, Interview.
[24] Yulianingsih, Turisno, and Aminah, "Consumer Empowerment in Preventing the Distribution of Counterfeit Medicines in the Community."
[25] Pujiastuti, Interview January 24 2020.
[26] Hijawati, "Illegal Medicine Distribution in View of Consumer Protection Law."

Actions taken by the Government and BPOM to protect consumers from the actions of naughty business actors, especially medicine sellers who do not answer honestly and responsibly, include existing laws:

a. Law Number 8 of 1999 concerning Consumer Protection

Law Number 8 of 1999 concerning Consumer Protection provides legal protection to every consumer who feels disadvantaged by business actors. In Article 1 Number 1, it is explained that consumer protection is any effort that guarantees legal certainty in its use to provide protection to consumers. This protection effort is provided to consumers so that the position of consumers themselves is equal to that of business actors.

Consumers have the right or guarantee for the goods or services they will use, protection for themselves from these goods or services, as well as legal certainty in the measures taken if losses occur due to these goods or services in the future.[27].

Consumers and business actors must have a balanced position, namely as subjects and not as objects of business activities carried out by business actors. Basically, the Consumer Protection Law is implemented as an effort to provide protection for consumer rights so that they are not harmed or to protect consumers from fraudulent acts carried out by business actors[28]. Article 8 Paragraph (1) of the Consumer Protection Law regulates actions that are prohibited for business actors, but the medicine regulations are not explicitly stated.

KThe provisions in the Consumer Protection Law Article 8 Paragraph 1 Letter (a) can be used as a basis for protection for consumers who buy fake patent medicines that contain dangerous ingredients. According to this article, business actors cannot trade goods that do not meet or are not in accordance with the required standards and provisions of statutory regulations. Basically, medicines that have been produced can only be circulated after previously passing the testing stages in terms of quality, facilities, safety and usefulness. If the medicine violates regulations such as being unsafe or dangerous, it can be declared that the medicine cannot be traded

b. Law Number 17 of 2023 concerning Health

The law on health provides legal protection to consumers against pharmaceutical preparations that do not comply with established quality standards. One of the efforts to maintain health as intended in Article 48

[27] Finulius Bu'ulolo, Karisman Jaya Ndruru, and Jaminuddin Marbun, "LEGAL PROTECTION OF CONSUMERS REGARDING THE SALE OF FOOD AND BEVERAGES IN EXPIRED PACKAGING" 4, no. 2 (2022): 611–27, https://doi.org/10.46930/jurnalrectum.v5i1.2592.

[28] Muhammad Ridho Al Hasymi Daulay, Utary Maharani Barus, and Rafiqi Rafiqi, "Jurisdicial Review of Legal Protection for Consumers Against Illegal Medicine Products (Case Study: BPOM Medan)," JUNCTO: Legal Scientific Journal 1, no. 2 (2019): 121–28, https://doi.org/10.31289/juncto.v1i2.206.

Paragraph 1 Letter (n) of the Health Law is through activities to safeguard and use pharmaceutical preparations and medical devices. This health care effort is not enough to be the government's answer. Regarding the safety and use of pharmaceutical preparations and medical devices, it is regulated in Article 138 of the Health Law.

Based on Article 138 of the Health Law, it can be interpreted that medicines distributed must be safe, useful/efficacious, high quality and affordable. And the distribution of medicines must meet quality standards as regulated in government regulations. So it is clear that medicines containing dangerous ingredients must not be distributed and consumed by the public.

Protection for consumers is also contained in Article 140 concerning the aim of safeguarding pharmaceutical preparations and medical devices which is implemented to protect the public from dangers resulting from use that does not meet quality and/or safety requirements and/or efficacy and benefits.

Article 142 Paragraph 1 also states that the supply of medicines in the form of medicines and the standards for medicine ingredients must meet the requirements of the Indonesian pharmacopoeia or other book standards. This means that medicines distributed or sold must comply with the medicine standard book issued by an official government body that explains medicine ingredients, chemicals, usual dosages and medicine properties.

c. Food and Medicine Supervisory Agency Regulation Number 34 of 2018 concerning Guidelines for Implementing Good Medicine Manufacturing Methods

Regulation of the Head of the Food and Medicine Supervisory Agency regarding the Implementation of Guidelines for Good Medicine Manufacturing Methods in Article 3 states that, the pharmaceutical industry or business entity that has a permit from the Minister of Health to carry out activities for manufacturing medicines or medicinal substances, in all aspects and series of medicine manufacturing activities and /or medicinal substances are required to apply the Guidelines for Good Medicine Manufacturing Methods aimed at ensuring that the quality of the medicines and/or medicinal substances produced is in accordance with the requirements and intended use.

Improving the quality of medicines, increasing the availability of cheap essential medicines, and strengthening the regulatory authority for medicines are very important tasks for developing countries to combat counterfeit medicines.[29].

Prevention efforts against the use of counterfeit patent medicines

[29] Desy Nuryunarsih, "Counterfeit Medicines in Socioeconomic Perspective," Public Health 11, no. 4 (2017): 153–62, https://doi.org/10.21109/kesmas.v11i4.1440.g555.

a. The role of the Food and Medicine Supervisory Agency in dealing with counterfeit patented medicines

Supervision carried out by the Food and Medicine Supervisory Agency includes two forms, namely: Pre-Market Supervision and Post-Market Supervision.

1) Pre Market Control

According to Dra. Zeta Rina Pujiastuti, M.Kes., Apt, Pre Market Control is supervision carried out before medicines and food are permitted to be produced or imported and distributed to the public, which must first be carried out to assess the safety, quality and benefits and label/information of the product. . The form of supervision is directly to the manufacturer, one of which is by providing a distribution permit and ensuring quality so that the medicine does not contain dangerous ingredients[30]

a) BPOM carries out standardization which is the function of preparing standards, regulations and policies related to medicine and food supervision.
b) Carry out an evaluation based on existing standards, namely evaluating the product before it gets a circulation permit number so that it can finally be produced and distributed to consumers. Evaluation is carried out centrally, intended for products that have a distribution permit valid nationally.

2) Post Market Control

Post Market Control is supervision carried out after the product has been circulated using the method of routinely searching for industrial/production facilities for medicinal and food preparations, with the aim of carrying out direct supervision of the production and distribution activities of medicines, in order to ensure that business actors are consistent in implementing the Concept of Good Medicine Manufacturing Practices (CPOB). Efforts should be made to provide BPOM education to increase the knowledge of pharmaceutical staff regarding counterfeit medicines.[31]

BPOM's role in protecting consumers who consume fake patent medicines is also carried out through Communication, Information and Education (KIE) in the form of education to the public, information about medicines, activities aimed at increasing knowledge, understanding and public concern for problems that invite the public to choose products. which is safe for consumption. Distribute leaflets, brochures and put up notice boards which

[30] Pujiastuti, Interview January 24 2020.

[31] Nisa Febrinasari, Arifin Santoso, and Ria Hasrawati, "The Relationship between Knowledge, Attitudes and the Behavior of Pharmaceutical Workers Regarding the Distribution of Counterfeit Medicines in Semarang City Pharmacies," JPSCR: Journal of Pharmaceutical Science and Clinical Research 7, no. 3 (2022): 347, https://doi.org/10.20961/jpscr.v7i3.58200.

are distributed in the community through seminars, CFDs, exhibitions, educational institutions.

The establishment of a Consumer Complaints Service Unit (UPLK) by BPOM is useful for receiving complaints or requests for information regarding medicine and food. These complaints or requests can be made by the public to be submitted to BPOM via short message, fax, letter and/or making direct visits to BPOM UPLK and UPLK Balai Besar/POM Halls throughout Indonesia.[32].

CONCLUSION

The reason for the circulation of counterfeit patent medicines in this research is the factor of business actors as medicine counterfeiters who want to obtain maximum profits by repackaging, namely making materials from expired generic medicine raw materials, dismantling all the raw materials, combining and manipulating the date. medicine expiration. Business actors repackage it into original medicine complete with medicine boxes and brochures on how to use it so that it looks genuine. Apart from these factors, there is a lack of consumer knowledge and ignorance regarding the characteristics of rogue business actors who produce fake medicines. Legal protection against the distribution of counterfeit patent medicines is regulated in the Health Law and Consumer Protection Law, and the Food and Medicine Supervisory Agency Regulations concerning Guidelines for Implementing Good Medicine Manufacturing Methods with the aim of ensuring the quality and medicinal materials produced are in accordance with the conditions and intended use. . The government, through BPOM, has made efforts to prevent the circulation of counterfeit medicines, namely monitoring business actors in the form of pre-market control and post-market control. For consumers, especially medicine users, to avoid losses, consumers are expected to be smart and wise in choosing and buying medicines to check the medicines they will buy. BPOM, as the party that monitors medicine distribution, also invites the public to work together in monitoring medicines sold in their area. If fake medicine is found, immediately report it to BPOM so that the action process can be carried out immediately. And to increase the effectiveness of medicine and food supervision (Waspom), institutional strengthening in the field of Waspom needs to be supported, namely with a Draft Law (RUU) on Medicine and Food Control so that BPOM has the authority to carry out investigations.

[32] Norma Sari, "Empowering Consumer Rights to Medicine Information," Legal Media Journal 21, no. 2 (2018): 293–308, https://doi.org/10.18196/jmh.v21i2.1194.

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