International Journal of Social Science Research and Review

http://ijssrr.com
editor@ijssrr.com
Volume 6, Issue 7
July, 2023
Pages: 531-542

Urgency of the Republic of Indonesia Law No. 36/2009 Concerning Health Against the Distribution of Fake Drugs in the Context of Supervision of Pharmacy Institutions

Haryoko Njoto

Doctor of Law Science, Faculty of Law, University of August 17, 1945, Surabaya, Indonesia

E-mail: haryoko.nyoto1502@gmail.com

http://dx.doi.org/10.47814/ijssrr.v6i7.1478

Abstract

According to WHO, Health is a human right. Meeting the needs of the right to health is the responsibility of the government in every country. In Indonesia, health is also grouped into human rights, which in its placement are stipulated in Article 28 H of the 1945 Constitution of the Republic of Indonesia, which is formulated: "Everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy environment and entitled to health services". The right to obtain health, especially in the distribution of medicines for every citizen, must be fulfilled, respected, and guaranteed to be protected by the state. The government as the embodiment of the state must describe health protection in the applicable legal regulations. The continuity of human benefit, one of the most important elements or components is the availability of drugs as part of health services. Medicine has an urgency that is useful for saving lives and the lives of many people. When viewed from the health aspect, medicine is a very important element because it is needed in most health efforts. Today there is increasing awareness and knowledge about health and encouraging people to demand more professional health services, including drug services. Drug safety criteria are regulated by the Drug and Food Control Agency in the Regulation of the Head of the Drug and Food Control Agency of the Republic of Indonesia Number Hk. 03.1.23.06.10.5166 of 2010 concerning the Inclusion of Information on the Origin of Certain Materials, Alcohol Content, and Expiration Limits on the Marking or Label of Drugs, Traditional Medicines, Food, and Food Supplements. Articles 6 and 7 stipulate that drugs, traditional medicines, food, and food supplements must include an expiration date on the marking or label. The expiration date must be stated clearly so that it is easy to see and read by including the month and year. On drug packaging like this, there is usually a warning marked with a small town based on a dark color or a white box with black borders with the following inscription a. P.No. 1: Watch out! Potent drug. Read the terms of use; b. P.No. 2: Watch out! Potent drug. For external use only; c. P.No. 3: Watch out! Potent drug. Not to be taken internally; d. P.No. 4: Watch out! Potent drug. Only to be burned; e. P.No. 5: Watch out! Potent drug. Hemorrhoid medicine, don't swallow it.

Keywords: *Counterfeit Drugs; Health; Surveillance*

Introduction

Health is the most important factor for everyone. Efforts to improve the quality of healthy life are the needs of everyone and must be supported by developments in the health sector as a whole, covering nutrition, pharmacy to medical services, and so on. The national health system states that health concerns certain situations and conditions with a state of uncertainty and injustice in society in providing a sense of security, a sense of health, and all forms of services that exist in society, such as medical services, as well as optimizing good drug and nutrition services for the public.

Public health services in the aspect of medicine are currently experiencing ups and downs, so it must give meaning when the mandate of the Preamble to the IV Alenia of the 1945 Constitution of the Republic of Indonesia states that "...to protect all and all of Indonesia's bloodshed...", in where in the context of world public health say that "*A state of complete physical, mental and social, well being and not merely the absence of disease or infirmity"*(Mathers, 2020). In the context of the World Health Organization as a world health organization, it also provides an understanding of health, namely as a state of physical, mental, and social well-being and not just the absence of disease or infirmity.

According to WHO (Rudnicka et al., 2020), Health is a human right. Meeting the needs of the right to health is the responsibility of the government in every country. In Indonesia, health is also grouped into human rights, which in its placement are stipulated in Article 28 H of the 1945 Constitution of the Republic of Indonesia, which is formulated: "Everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy environment and entitled to health services". The right to obtain health, especially in the distribution of medicines for every citizen, must be fulfilled, respected, and guaranteed to be protected by the state. The government as the embodiment of the state must describe health protection in the applicable legal regulations.

This responsibility is certainly inseparable from the importance of the health factor as an indicator of the level of community welfare, so it must receive top attention and priority in national development. One important component of health is the availability of adequate medicines, both in terms of quality and quantity, as part of public health services. Drugs are used to save a life, restore or maintain health (S. W. Wibowo et al., 2021). Healthy is a shared hope, but this does not always match reality. If in an unhealthy condition, there is no other choice but to take medication. Various types of drugs and treatments are not always curative, and often using drugs that are not appropriate wicausetse new diseases.

The continuity of human benefit, one of the most important elements or components is the availability of drugs as part of health services. Medicine has an urgency that is useful for saving lives and the lives of many people. When viewed from the health aspect, medicine is a very important element because it is needed in most health efforts. Today there is increasing awareness and knowledge about health and encouraging people to demand more professional health services, including drug services.

Drug status as an irreplaceable component in health services. Medicine is different from trading commodities in general, medicine also has a social function. Drugs are substances or combinations of materials, including biological products used to influence or investigate physiological systems or pathological conditions in the context of establishing a diagnosis, prevention, cure, recovery, health promotion, and contraception for humans. Drugs play a very important role in health services because the treatment and prevention of various diseases cannot be separated from drug therapy. As for the role of drugs in general, among others (Silaban, 2022):

a. As a determination of the diagnosis;
b. disease prevention;
c. cure disease;

d. Can restore health;
e. Changing the body's normal function for a specific purpose;
f. To improve health;
g. Reduce pain

Many drugs, including hard drugs, are traded freely by people or business entities without rights or violating the rules. Despite decades of progress, serious government efforts to enforce drug distribution regulations have yet to materialize. Rows of shops selling medicines and medical devices in the market show how easy it is to get medicines. This convenience opens up great opportunities for the distribution of counterfeit drugs, expired drugsandnd gs without a distribution permit to drugs that contain dangerous ingredients.

Various types of over-the-counter drugs are easy to obtain, although over-the-counter drugs must comply with the regulations, business entities that are allowed to sell are drugstores or pharmacies. Many stalls and minimarkets are free to sell even without permission from the Health Office. In pharmaceutical facilities, violations of drug sales regulations were also found. Medicines with a doctor's prescription, which should only be purchased at pharmacies, can be purchased freely at drugstores, online stores, and pharmacies even without a doctor's prescription. The information on the drug packaging states that it must be prescribed by a doctor. In addition, many doctor's clinics can provide medicine even though they do not have pharmaceutical facilities. This has prevented the consumption of prescription drugs during the implementation of National Health Insurance from increasing significantly. The high number of visits by members of the National Health Insurance to health facilities should increase sales of prescription drugs.

The pattern of sale and distribution of drugs that are haphazard and community actors who want to get medicine easily and recover quickly has led to the widespread distribution of drugs that violate the rules. Opening opportunities for the entry of counterfeit drugs, drugs with inappropriate active substances that threaten the lives of consumers. The process of making drugs has become an obligation to carry out scientific evidence both through animals and clinical trials or other evidence by the status of scientific development and Good Medicine Manufacturing Practices (GMP). GMP aims to guarantee that drugs are made consistently, meet the specified requirements, and are by their intended use.

Seeing the development of globalization, especially in the science sector, drug formulations can be changed for drugs that are distributed to look the same and can be sold at lower prices compared to the prices of drugs that already have distribution permits and also make markings that are similar to drugs medicines that are already in circulation, so that with a lot of knowledge that is not based on reliable references and has not been clinically tested and does not pay attention to the applicable laws and regulations. This will have a dangerous impact on the community, such as the circulation of counterfeit drugs among the community. As a result, people do not know whether the drug has efficacy and safety for consumption. It is also easy for the public to be tricked by counterfeit drug dealers with low prices and markings that look similar to drugs in circulation so people will be tempted by this.

Counterfeit drugs are very difficult to distinguish from the original, people are encouraged to be careful in taking drugs. It will be difficult to distinguish genuine drugs from counterfeit drugs. Distinguishing between counterfeit drugs requires special expertise so that distinguishing cannot be done with the naked eye, experts and sufficient knowledge and experience are needed to differentiate. Therefore, supervision is needed for the Government and the Food and Drug Supervisory Agency (hereinafter referred to as BPOM) to always supervise the circulation of counterfeit drugs circulating in the community as a form of prevention.

Drugs are strictly regulated, starting from production, distribution to distribution to consumers. Drugs are chemicals that have pharmacological reactions that can be beneficial or detrimental. The distribution of drugs is strictly regulated in every aspect to avoid opportunities for dangerous illegal drugs to enter. Various problems that arise in the field show the poor management of pharmacy in Indonesia.

BPOM supervision is limited to products and supervision in pharmaceutical facilities by the Ministry of Health through the Health Office. The Dinas Kesehatan does not have oversight resources. Violations committed pharmaceutically include not having a license, not having pharmacists, and improper drug storage. Some sell drugs without a distribution permit, do not destroy expired drugs, or sell hard drugs without a doctor's prescription. Weak oversight is an irony considering that Indonesia has many pharmaceutical regulations. With complete regulations, it remains only to implement them. Drug and food control is a program related to many sectors, both government and non-government. For this reason, it is necessary to establish good cooperation, communication, information, and education. Supervision by business actors should be carried out from upstream to downstream, starting from inspection of raw materials, production processes, and distribution until the product is consumed by the public. Business actors have a role in providing guarantees for medicinal and food products that meet the requirements (safe, efficacy/beneficial, and quality) through a production process that complies with the provisions. BPOM seeks to provide support to business actors to obtain convenience in their business by providing incentives, clearing houses, and regulatory assistance.

Legal protection guarantees can be carried out through government intervention in drug manufacturers, up to distribution to the public through statutory regulatory products. The importance of government intervention is inseparable from the government's duties as a regulator, which is obliged to control the behavior of its citizens to achieve the desired goal of realizing the welfare and happiness of the whole community. BPOM in this case as a state formation has an important role in drug and food control with the applicable statutory provisions, every drug and food before being distributed to be marketed must be tested for the feasibility of drugs before finally being declared fit for distribution to the wider community. BPOM's obligation to carry out due diligence is regulated in Article 98 paragraph (4) of the Health Law, which determines as follows: *The government is obliged to foster, regulate, control, and supervise the procurement, storage, promotion, and distribution as referred to in paragraph (3) which states as follows: Provisions regarding the procurement, storage, processing, promotion, distribution of pharmaceutical preparations and medical devices must meet quality standards for pharmaceutical services stipulated by Government Regulation.*

Based on Article 98 paragraph (2) of the Health Law, states as follows:

> *"Any person who does not have the expertise and authority is prohibited from procuring, storing, processing, promoting and distributing drugs and substances with medicinal properties".*

In connection with this article, if you deliberately distribute drugs that do not meet pharmaceutical standards, you will be given sanctions as Article 196 of the Health Law states:

> *"Anyone who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or benefits and quality as referred to in Article 98 paragraphs (2) and (3) shall be punished with imprisonment for a maximum 10 (ten) years and a maximum fine of Rp. 1,000,000,000.- (one billion rupiah)".*

Distribution of drugs in the community must be accompanied by supervision carried out by BPOM. This supervision aims to provide consumer protection. According to Presidential Regulation

Number 80 of 2017 concerning the Food and Drug Supervisory Agency (hereinafter referred to as Presidential Regulation Number 80 of 2017), Article 2 states:

(1) BPOM has the task of carrying out governmental tasks in the field of drug and food control by the provisions of laws and regulations;
(2) Drugs and food as referred to in paragraph (1) consist of drugs, medicinal ingredients, narcotics, psychotropics, precursors, addictive substances, traditional medicines, health supplements, cosmetics, and processed food.

BPOM's function is regulated in Article 3 of Presidential Decree Number 80 of 2017 which states:

1) In carrying out the task of drug and food control, BPOM carries out the following functions:
a) Formulation of national policies in the field of drug and food control;
b) Implementation of national policies in the field of drug and food control;
c) Formulation and stipulation of norms, standard procedures, and criteria in the field of supervision before circulation and supervision during circulation;
d) Implementation of supervision before circulation and supervision during circulation;
e) Coordinating the implementation of drug and food control with central and regional government agencies;
f) Provision of technical guidance and supervision in the field of drug and food control;
g) Implementation of action against violations of statutory provisions in the field of drug and food control;
h) Coordinating the implementation of tasks, coaching, and providing administrative support to all organizational elements within BPOM;
i) Management of state property/wealth which is the responsibility of BPOM;
j) Supervision of the implementation of tasks within the BPOM; and
k) Implementation of substantive support to all organizational elements within BPOM.

2) Control before distribution as referred to in paragraph (1) is control of drugs and food before distribution as a preventive measure to guarantee that drugs and food in distribution meet the stipulated standards and requirements for safety, efficacy/benefits, and product quality.
3) Supervision while in circulation as referred to in paragraph (1) is control of drugs and food during distribution to ensure drugs and food in circulation meet the stipulated standards and requirements for safety, efficacy/benefits, and product quality as well as law enforcement measures.

BPOM's authority is regulated in Article 4 of Presidential Decree Number 80 of 2017, which states that in carrying out drug and food control duties, BPOM has the authority to:

a. Issuing product distribution permits and certificates by standards and requirements for safety, efficacy/benefits, and quality as well as drug and food testing by statutory provisions;
b. Carry out intelligence and investigations in the field of drug and food control by statutory regulations; And
c. Administrative sanctions by the provisions of the legislation.

By looking at some of the explanations above, the researchers studied from the point of view of the urgency of RI Law NO. 36/2009 concerning health against the distribution of counterfeit drugs in the

context of oversight of pharmaceutical institutions contains several problems related to the protection of witnesses and victims of the distribution of counterfeit drugs, resulting in a moral hazard in anticipating the distribution of counterfeit drugs that are illegal for consumption by the public.

Research Method

The research used in this research process uses a type of normative legal research (Soekanto & Mamudji, 2015). By using library materials or secondary materials that have been collected. Legal research is also a process to determine legal rules, legal principles, and legal doctrines to answer the legal issues faced. Critical law school is a critique of legal theory that demands that the doctrinal approach was flawed, with abstract principles such as independence, freedom of contract, and property rights can contradict each other in many ways. They use sociological, anthropological, and ideological techniques in order law. They try to delineate the tension between normative ideas and social structures.

Result and Discussion

1. Critical Legal Studies on Drug Packaging Expired Date Labels as the Initial Expiration, as well as the Distribution Period and Appropriate Use of the Medicine

Expired drugs are one of the causes of resistance to the body. Taking drugs that have expired for a long time can cause immunity and organ damage. This is closely related to the production process. Storage and distribution and use of raw materials that are not suitable for consumption. The selection of good raw materials is one of the keys to avoiding things that are not desirable (Khairani et al., 2021).

No matter how sophisticated the production process is, it will not be able to cover up the poor quality of raw materials. Consumers should always remember the saying garbage in garbage out, which means bad raw materials will produce bad products too. One of the indicators that can be used to determine the quality of a drug is to observe the expiration time listed on the packaging label. Wherever possible, consumers should choose drug products that are far from their expiry date, especially products that are likely to be stored before use (Halawa & Rusmana, 2021).

Determining the expiration date can be done using certain methods. The determination of the expiration date is carried out to determine the shelf life of the product. Shelf life determination is based on factors that affect the shelf life of drug products. These factors are the natural state, the mechanism for the change and the possibility of chemical changes, atmospheric conditions, and the durability of the packaging during transit and before use against the entry and exit of water, ga,s, and odors.

In the world of trading, the expiry period has several terms. The terms that are often used are (Widiasih et al., 2018) :

a) Both were used before (best before). This sentence has the meaning that a food product should be consumed before the date stated because that date is the optimal limit for producers to guarantee the suitability of the product for consumption. The phrase "best used before" is generally stated on products that have a shelf-life life;
b) Use before (use by or expiry date). This sentence has the meaning that the medicinal product must be consumed maximally on the date stated. The date listed is the maximum limit the manufacturer can guarantee that the product has not been damaged and is still suitable for consumption. After that date, it is suspected that the quality of the product is no longer acceptable to consumers. The phrase "use before" is generally applied to products that are perishable and have a short shelf life;

c) Limit before withdrawal (pull date). This sentence has a meaning, limit before a withdrawal is another way of giving information about "use before". The sentence "limit before withdrawal" indicates the last date recommended for consumers to buy the product, so that they still have a period to consume it without the product starting to break down. After that date, a product will be withdrawn from retailers and shops because it is considered that its quality will soon decline and,f it is not withdrawn it will cause harm to consumers;
d) Date packed (pack date). This sentence has a meaning, the date packaged is information in the form of the date when the product was packaged, both packaging by manufacturers and retailers;
e) Store entry date (sell-by date). This sentence has a meaning, the store entry date is information in the form of the date when the product enters the storage warehouse in a store or other sales place.
f) Display date. This sentence has meaning, the display date is information in the form of the date when the product began to be displayed on shelves or displays in shops or other sales places.

The technique of adding expiration dates by using the sentences pack date, sell-by date, and display date, is generally applied to products whose shelf life is widely known by consumers. This technique forces consumers to be more active in knowing the product's shelf life to the point where it is safe for consumption. The technique of including the expiration date is generally carried out in developed countries because their level of understanding and concern for drug safety is very high. Developments in today's society are increasing attention to consumer protection issues. These techniques are still less popular in Indonesia. Security issues receive great attention in the Consumer Protection Act (Kesuma et al., 2022).

Drug safety criteria (Haritsa & Haskas, 2021) which is regulated by the Drug and Food Control Agency in the Regulation of the Head of the Drug and Food Control Agency of the Republic of Indonesia Number Hk. 03.1.23.06.10.5166 of 2010 concerning the Inclusion of Information on the Origin of Certain Materials, Alcohol Content, and Expiration Limits on the Marking or Label of Drugs, Traditional Medicines, Food, and Food Supplements. Articles 6 and 7 stipulate that drugs, traditional medicines, food, and food supplements must include an expiration date on the marking or label. The expiration date must be stated clearly so that it is easy to see and read by including the month and year.

Writing the expiry date for the product is carried out with the month and year, as long as it is not written in 4 (four) digit numbers (Julianti et al., 2020). Writing expiration is for the benefit of consumer protection. The existence of the community as consumers need to be protected from drugs that can harm and endanger health. Things to pay attention to in consuming medicinal products. Every time, if you want to buy medicine, the first step that a potential consumer must take is to look at the packaging and label. These packages come in a wide variety of shapes and materials, however, what is more important is the label on the package. It is from this label that consumers know many things about the drug product, which can guarantee safety in consuming the drug product.

This information must be considered carefully so that consumers do not buy wrongly. There is also information that may not be included on the packaging label. This information concerns things that confuse and confuse consumers. Information about a characteristic that is owned by similar drug products. One of the information on the label that is most popular and often considered is the expiration date of the product, the expiration date must be included on the product packaging.

Information about the identity of product origin and others can be stated in the barcode (bar code). Under the vertical lines that can be read using optical technology, generally, there are 13 (thirteen) numbers, the first 2 (two) numbers indicate the country of origin, the next 5 (five) numbers are the manufacturers and distributors, the next 5 (five) numbers are product identification itself and the last 1 (one) digit is the control number. With various information on drug product packaging labels, it is hoped

that consumers will not be mistaken and determine and obtain product quality. Drug registration is regulated in Minister of Health Regulation No. 1010/Menkes/Per/XI/2008 amended by Regulation of the Minister of Health No. 1120/Menkes/Per/XII/2008 concerning amendments to Regulation of the Minister of Health No. 1010/Menkes/Per/XI/2008 concerning drug registration.

Regarding permits for medicines, cosmetics, and food supplements, there is very little from the government. Permit for a cosmetic product, medicine, or food supplement. Distribution permits specifically for medicinal products including traditional medicines, cosmetics, and food supplements that are in circulation. BPOM is an institution in Indonesia that is tasked with overseeing and regulating the circulation of drugs, food, beverages, cosmetics, supplements, and herbal medicine in Indonesia. All kinds of medicines including traditional medicines, cosmetics, and food supplements must have a distribution permit from BPOM. Industrial business actors (local products) in the above product category in the inspection of industrial facilities will involve the Health Service in examining their industrial permits. For the registration of the distribution permit, it remains at BPOM or the one issuing the distribution permit is BPOM, not the Health Office (Polopadang et al., 2021).

Home Industry Actors (PIRT) are intended for small-scale home industry players such as food and beverages and home industry permits with the following product criteria: (Gustiawan et al., 2022) :

Provisions for PIRT according to BPOM that is produced cannot be in the form of (Sellia & Atmadja, 2019) :

1. Milk and its processed products;
2. Meat, fish, poultry, and their processed products that require processing and or frozen storage;
3. Low acid canned food (PH > 4.5);
4. Baby food;
5. Alcoholic beverages;
6. Bottled drinking water (AMDK);
7. Other food that must meet SNI requirements; or
8. Other food stipulated by BPOM.

The PIRT Health Service distribution permit is only valid for 5 (five) years and cannot be extended at the Health Service and must be renewed with the BPOM distribution permit, which of course must have production standards and a minimum individual business entity. PIRT is household health equipment, such as fruit washing soap, car, and others. PIRT is intended for local and imported products. ALKES is a medical device and must have a distribution license from the Health Office (Julianto et al., 2021). Herbal medicine, if it does not function as a treatment, is classified as a household business, but if its function is to treat and heal, it is categorized as a home industry. These products must have BPOM permits, as well as cosmetics and supplements must have distribution permits from BPOM, not the Health Service.

2. The Urgency of RI Law NO. 36/2009 Concerning Health Against Circulation of Counterfeit Drugs in the Context of Supervision

The pharmacy is one of the health service facilities in helping to achieve optimal health status for the community, besides that it is also a place of dedication and practice of pharmacists in carrying out pharmaceutical work. The function of the Pharmacy is to provide medicines needed by the community to achieve optimal health status. From this first function, a pharmacist must be present with a very social face, full of ethics and morals. In addition, the functions and duties of the Pharmacy are (A. Wibowo & Handoko, 2020):

a. Place of dedication of pharmacy personnel;
b. Pharmaceutical facilities that carry out compounding, shape changing, mixing, and delivery of drugs and medicinal substances;
c. This means distributing pharmaceutical supplies which must spread the medicines needed by the community widely and evenly.

Hard drugs that can be delivered without a doctor's prescription in their original packaging from the manufacturer or manufacturer are marked with a blue circle with a black outline and are given a warning.

Hard drugs are all drugs that include (Janik et al., 2017):

a. Have a dose or maximum dose (DM) listed on the list of hard drugs determined by the government;
b. Specially marked with a round red circle with a black border and the letter "K" touching the border;
c. All new drugs unless stated by the government (Ministry of Health. R.I.) are not dangerous;
d. All parental preparations/intravenous injections/infusions;
e. Psychotropics are:

Drugs that affect mental processes, stimulate, or calm, change people's thoughts, feelings, or behavior, for example, ecstasy, diazepam, barbital, or luminal;

a) Narcotics; Drugs needed in the field of medicine as well as science and technology (IPTEK) can cause dependence and addiction (addiction) which are very detrimental to society and individuals if used without restrictions and doctor's supervision. Examples: opium/opium, morphine, pethidine, methadone, codeine, and others;
b) Compulsory medicine for pharmacy; Pharmacy Compulsory Drugs (OWA) are drugs that can be delivered without a doctor's prescription by pharmacists at pharmacies;
c) Generic Drugs; Drug whose name is based on the active substance contained in the drug and uses a trademark;
d) Generic Drugs with Logo. Essential medicines that are listed on the list of essential medicines (DOEN) whose quality is guaranteed because they are produced by the requirements for good drug manufacturing (GMP) and are re-tested by the Food and Drug Examination Center of the Ministry of Health;
e) Patent Drugs. Patent drugs are drugs that use a certain brand or trade name. Examples: my coral, final, ketoconazole, captopril, cefadroxil, and others;
f) Herbal medicine. Ingredients that are plant ingredients, animal ingredients, mineral ingredients for herbal preparations (galemik), or mixtures of these ingredients which have been used for generations for medicinal purposes;
g) Phytomarkers. Are medicinal preparations and traditional medicines whose efficacy has been proven based on clinical trials and has been standardized on the raw materials used in finished products.

According to the Regulation of the Minister of Health Number 1332/Menkes/SK/X/2002, which states that a Pharmacy is a certain place, where pharmaceutical work is carried out and the distribution of pharmaceutical preparations and pharmaceutical supplies to the public. Government Regulation Number 51 of 2009 Article 1 paragraph (13), a pharmacy is a pharmaceutical service facility where pharmacists practice pharmacy (Nguyen et al., 2022).

On drug packaging like this, there is usually a warning marked with a small town based on a dark color or a white box with black borders with the following inscription (Sarkar, 2022):

a. P.No. 1: Watch out! Potent drug. Read the terms of use.
b. P.No. 2: Watch out! Potent drug. For external use only.
c. P.No. 3: Watch out! Potent drug. Not to be taken internally.
d. P.No. 4: Watch out! Potent drug. Only to be burned.
e. P.No. 5: Watch out! Potent drug. Hemorrhoid medicine, don't swallow it.

Within certain limits, mild illness is still justified for self-medication, which of course also includes over-the-counter and limited over-the-counter drugs that are easily obtained by the public. However, if the condition of the disease is getting serious, you should consult a doctor. It is advisable not to even conduct self-medication trials of drugs that should be obtained using a doctor's prescription. Psychotropic Drugs and Narcotics. These drugs are the same as the drugs we know can be addictive with all the known consequences. Therefore, these medicines, from manufacture to use, are strictly monitored by the government and may only be handed over by pharmacies on a doctor's prescription. Each month the Pharmacy is required to report its purchases and usage to the government.

The Directorate of Dangerous Products and Materials Supervision in carrying out its duties has the following functions (Dalle Mura et al., 2021):

a) Preparation of the formulation of technical policies, preparation of guidelines, standards, criteria, and procedures as well as the implementation of control, monitoring, provision of guidance, and guidance in the field of standardization of hazardous products and materials;
b) Preparation of the formulation of technical policies, preparation of guidelines, standards, criteria, and procedures as well as implementation of control, monitoring, provision of guidance and guidance in the field of safety of hazardous products and materials;
c) Preparation of materials for the formulation of technical policies, preparation of guidelines, standards, criteria, and procedures as well as implementation of control, monitoring, provision of guidance, and guidance in the field of counseling on hazardous products and materials;
d) Preparation of plans and programs for control of hazardous products and materials;
e) Coordination of functional activities for the implementation of technical policies in the field of control of hazardous products and materials;
f) Evaluation and preparation of reports on the supervision of hazardous products and materials;
g) Implementation of other tasks by the policies stipulated by the Deputy for Food Safety and Hazardous Material Supervision.

The development and opening of the national market and supported by advances in communication and information technology have resulted in a major influence on the life of the nation which is marked by the creation of extensive relations between countries in terms of business practices, especially in the health sector so that goods and/or services engaged in health and the needs in the health sector are offered in a very varied manner where this is also experienced by the Indonesian nation. It is undeniable that this will lead to intense competition among business people which will lead to dishonest or fraudulent business practices because their orientation is more on how to get the maximum possible profit with the minimum possible capital. Seeing this, protection for consumers is very necessary and needed to create a healthy trade order and not ignore consumer rights. The insistence on the need and interest of law and regulation that can protect the rights and interests of consumers is implemented by Act No.8/1999 concerning Consumer Protection (hereinafter referred to as the consumer protection law) (Khasanah et al., 2021).

Conclusion

Oversight of drug distribution has been carried out by BPOM, but there are still many problems related to drug distribution, both expired drugs, drugs that do not meet the requirements, and drugs that are not hygienic. The existing problems cannot be resolved completely legally, many obstacles occur and the sanctions given are only administrative in nature, not prison sanctions. This causes business actors to commit violations and the sanctions given are relatively light. These business actors are very influential in drug distribution in society. Ethics and business cannot be separated. Actually business practices that do not harm other people, all parties must be invited, especially business people as well as the government to build a more dignified business civilization. Ethical and moral business can certainly guarantee the comfort and welfare of mankind.

References

Dalle Mura, M., Pistolesi, F., Dini, G., & Lazzerini, B. (2021). End-of-life product disassembly with priority-based extraction of dangerous parts. *Journal of Intelligent Manufacturing*, *32*(3). https://doi.org/10.1007/s10845-020-01592-z.

Gustiawan, W. D., Satriyono, G., & Satriyono, G. (2022). Pelatihan Membuat Akun Toko di Tokopedia pada Pelaku Industri Rumah Tangga (IRT) di Desa Rejomulyo Kota Kediri. *Bubungan Tinggi: Jurnal Pengabdian Masyarakat*, *4*(2). https://doi.org/10.20527/btjpm.v4i2.5429.

Halawa, M., & Rusmana, W. E. (2021). Evaluasi Pengelolaan Obat Rusak atau Kadaluwarsa terhadap Sediaan Farmasi di Salah Satu Rumah Sakit Umum Swasta Kota Bandung. *Jurnal Education and Development*, *9*(4).

Haritsa, A. isti, & Haskas, Y. (2021). EVALUASI PELAKSANAAN KESELAMATAN PASIEN (PASIEN SAFETY) DI RUMAH SAKIT UMUM DAERAH LABUANG BAJI MAKASSAR. *JIMPK : Jurnal Ilmiah Mahasiswa & Penelitian Keperawatan*, *1*(1). https://doi.org/10.35892/jimpk.v1i1.495.

Janik, P., Kosticova, M., Pecenak, J., & Turcek, M. (2017). Categorization of psychoactive substances into “hard drugs” and “soft drugs”: a critical review of terminology used in current scientific literature. In *American Journal of Drug and Alcohol Abuse* (Vol. 43, Issue 6). https://doi.org/10.1080/00952990.2017.1335736.

Julianti, A. I., Amalia, L., & Hartini, S. (2020). Identifikasi Kejadian Reaksi Obat Merugikan pada Pasien Geriatri yang Menderita Hipertensi di Salah Satu Rumah Sakit di Bandung. *Majalah Farmasetika.*, *4*. https://doi.org/10.24198/mfarmasetika.v4i0.25879.

Julianto, R., Lestari, M., & Parwati, N. W. (2021). Aplikasi Pengenalan Alat Kesehatan Berbasis Android. *Jurnal Informatika Upgris*, *6*(2). https://doi.org/10.26877/jiu.v6i2.6686.

Kesuma, C., Handayani, V. R., & Damayanti, O. (2022). Sistem Informasi Inventory Alat Kesehatan Menggunakan Metode Fefo. *Joournal Speed-Sentra Penelitian Engineering Dan Edukasi*, *4*(1).

Khairani, R. N., Latifah, E., & Nila Septianingrum, N. M. A. (2021). Evaluasi Obat Kadaluwarsa, Obat Rusak dan Stok Mati di Puskesmas Wilayah Magelang. *JURNAL FARMASI DAN ILMU KEFARMASIAN INDONESIA*, *8*(1). https://doi.org/10.20473/jfiki.v8i12021.91-97.

Khasanah, N. U., Safira, M. E., Agung, W. K. S., Chotib, M., Lahuri, S. Bin, & Nimasari, E. P. (2021). Regulation of halal and healthy products for small-scaled businesses as consumer protection. *Open Access Macedonian Journal of Medical Sciences*, *9*(E). https://doi.org/10.3889/oamjms.2021.6643.

Mathers, C. D. (2020). History of the global burden of disease assessment at the World Health Organization. *Archives of Public Health*, *78*(1). https://doi.org/10.1186/s13690-020-00458-3.

Nguyen, A., Lamouri, S., Pellerin, R., Tamayo, S., & Lekens, B. (2022). Data analytics in pharmaceutical supply chains: state of the art, opportunities, and challenges. *International Journal of Production Research*, *60*(22). https://doi.org/10.1080/00207543.2021.1950937.

Polopadang, Y., Mongi, J., Maarisit, W., & Karauwan, F. (2021). Pola Peresepan Penggunaan Obat Antihipertensi Di UPTD Puskesmas Airmadidi. *Biofarmasetikal Tropis*, *4*(1). https://doi.org/10.55724/j.biofar.trop.v4i1.315.

Rudnicka, E., Napierała, P., Podfigurna, A., Męczekalski, B., Smolarczyk, R., & Grymowicz, M. (2020). The World Health Organization's (WHO) approach to healthy aging. *Maturitas*, *139*. https://doi.org/10.1016/j.maturitas.2020.05.018.

Sarkar, S. (2022). Pharmaceutical serialization: Impact on drug packaging. *International Journal of Advance Research in Computer Science and Management Studies*, *10*(3). https://doi.org/10.32628/CSEIT228390.

Sellia, N. M., & Atmadja, I. B. P. (2019). KAJIAN TENTANG IZIN PADA INDUSTRI RUMAH TANGGA PANGAN. *Kertha Semaya : Journal Ilmu Hukum*, *7*(8). https://doi.org/10.24843/km.2019.v07.i08.p01.

Silaban, C. (2022). Pengetahuan, Perilaku, dan Kesadaran Para Dokter dalam Penggunaan Obat yang Rasional. *Jurnal Ilmiah Indonesia*, *7*(7).

Wibowo, A., & Handoko, A. R. (2020). Segmentasi Pelanggan Ritel Produk Farmasi Obat Menggunakan Metode Data Mining Klasterisasi Dengan Analisis Recency Frequency Monetary (RFM) Termodifikasi. *Jurnal Teknologi Informasi Dan Ilmu Komputer*, *7*(3). https://doi.org/10.25126/jtiik.2020702925.

Wibowo, S. W., Suryawati, C., & Sugiarto, J. (2021). Analisis Pengendalian Persediaan Obat-Obatan Instalasi Farmasi RSUD Tugurejo Semarang Selama Pandemi COVID-19. *Jurnal Manajemen Kesehatan Indonesia*, *9*(3). https://doi.org/10.14710/jmki.9.3.2021.215-224.

Widiasih, E. S., Zahrulfa, A., Rustamaji, R., & Suryawati, S. (2018). Analisis dasar hukum, kebijakan dan peraturan penghapusan obat rusak dan kadaluwarsa di Dinas Kesehatan Kota Yogyakarta. *Jurnal Kebijakan Kesehatan Indonesia : JKKI*, *7*(1).

Copyrights

Copyright for this article is retained by the author(s), with first publication rights granted to the journal.

This is an open-access article distributed under the terms and conditions of the Creative Commons Attribution license (http://creativecommons.org/licenses/by/4.0/).