

# LEGAL SHIELD TO THE PUBLIC AGAINST ABUSE OF CHEMICAL MEDICINAL RAW MATERIALS IN USUAL MEDICINE CONTAINING CHEMICAL MEDICINAL RAW MATERIALS

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## Abstract

*In Indonesia, usual medical systems have been practiced through hereditary traditions supported by cultural factors, customs, habits, and the social conditions of people. Almost everyone thinks that usual medicines are used as alternative medicines that are effective because they are made of ordinary ingredients without dangerous medicinal chemicals (BKO). The aim of this research was to determine legal shields and to know the oversight provided by the government regarding the circulation of usual medicines containing chemical raw materials. This study uses a standard legal procedure. Usual medicines containing chemical raw materials do not even have a distribution permit number for sale to the public. The form of legal shield given to the public as consumers of usual medicines containing chemical raw materials is a form of Defensive legal shield and repressive shield. Law No. 8 of 1999 on consumer shield also regulates the right to indemnity administered by consumers as individuals affected by the consumption of usual medicines containing hazardous chemicals. As a form of supervision, the government established the Food and Drug Supervisory Agency (POM) based on Part 23 of Presidential Decree No. 103 of 2001. Another form of oversight given by the government regarding the circulation of usual medicines made from chemical raw materials is the 2012 Health Rules on registration of usual medicines, which are controlled in Law No. 36 Year 2009 on Health, which also regulates restrictions for offenders in the manufacture, distribution/trade of usual medicines without permission to distribute them.*

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## 1. INTRODUCTION

Indonesia is a country with abundant ordinary resources, which has around 30,000 species of plants and 9,600 species of plants that can be used for medicinal plants. Usual medicine systems have been practiced in Indonesia through hereditary traditions supported by cultural factors, customs, habits and social conditions of the people. Usual medicine is defined as components or ingredients in the form of plants, animal ingredients, mineral ingredients, serian (galenic) preparations or combinations of these materials that have been used for treatment based on generational experience, applicable in accordance with current social norms.

Usual medicines are usually made from fruits, leaves, seeds, flowers, bark and plant roots as well as some animal products such as honey, royal jelly, milk and free-range chicken eggs, so that Indonesian people use usual medicines until now (back to nature). Usual medicine has played a very important role since ancient times and has been used in the world of health, including in Indonesia, because this medicine is used to maintain health, prevent disease and treat people, because it is considered very efficacious and effective without side effects or only a few side

effects. compared to modern medicine. Currently modern health services in Indonesia have developed, but the number of people who use usual medicine systems tends to remain high. Based on data from the 2019 National Basic Health Survey, it is stated that 40% -59% of Indonesia's population uses herbal medicines.

The practice of usual medicine has been controlled in Law no. 36 of 2009 regarding Wellbeing. In this law, there are 3 types of usual medicinal practices, including:

1. Usual and Complementary Medicine practiced by medical doctors in conventional healthcare settings.
2. Usual and Complementary Medicine practiced by practitioners with formal education.
3. Usual and Complementary Medicine practiced by people deemed capable of providing usual medicine such as usual healers in the informal health system.

Based on BPOM data, by 2022 there will be more than 11,000 herbal medicine products, 77 standardized herbal medicinal products that have obtained distribution permit numbers from the BPOM.<sup>1</sup> Almost all people view that usual medicines are used as alternative medicines that are efficacious because they are made with ordinary ingredients without containing dangerous Chemical Drugs (BKO). Not in harmony with the reality in society, because there are quite a lot of usual medicinal products whose composition contains a mixture of chemical raw materials so that they can endanger society as consumers.<sup>2</sup> Usual medicines that contain chemical raw materials also do not have a distribution permit number so they can be traded to the public. Regarding distribution permits for usual medicinal products, it has actually been regulated in laws and regulations.

BPOM Head Regulation Number: Hong Kong.00.05.41.1384 of 2005 regarding the principles and events for registering of common tablets, standard herbal pills and phytoplasmas, it states that the use of common drugs is prohibited; a) isolated or artificial elements with medicinal properties; b) drugs or psychotropics; c) Preserved animals or plants. Accurate and safe common drugs must use ingredients derived from nature from both plants and animals used for treatment, so common drugs containing medicinal chemicals (BKO) have violated several rules regarding the distribution of manufactures, manufactures, or formations. Common drugs containing chemical raw materials can have a negative effect on the body of the person taking them if they are freely disseminated and sold.

Not a few circulations of usual medicines containing hazardous chemical raw materials in the community, but due to the lack of knowledge and information obtained by the community related to usual medicines containing hazardous chemical raw materials, causes them to consume them unknowingly. In addition, the high price of modern medicines, uneven health infrastructure and the many side effects of modern medicines are motivating factors for people to use usual medicines, both products that have or have not obtained distribution permits, because people cannot distinguish between drugs. usual medicine that is safe for consumption with usual medicines that contain harmful chemical raw materials.

Based on the results of sampling and testing carried out during the 2021 period, the POM found as many as 64 items of usual medicinal products containing dangerous Medicinal Chemicals (BKO).<sup>3</sup> Usual medicines that are deliberately mixed with medicinal chemicals (BKO) by entrepreneurs or manufacturers certainly have their own side effects or dangers. Usual medicines containing dangerous chemical ingredients can cause stomach irritation and kidney damage if consumed continuously. Since the level of public alertness and information is still very low, which

<sup>1</sup> BPOM, "Badan POM Optimalkan Pemberantasan Obat Tradisional Mengandung BKO melalui Penguatan Sinergi Stakeholder", diakses pada laman <https://www.pom.go.id/new/view/more/pers/645/Badan-POM-Optimalkan-Pemberantasan-Obat-Tradisional-Mengandung-BKO--melalui-Penguatan-Sinergi-Stakeholder.html>

<sup>2</sup> Putri, R. E., Mohammad Z., Mokhamad K H "TINJAUAN HUKUM OBAT TRADISIONAL BERBAHAN KIMIA OBAT", *Jurnal Hukum Magnum Opus Volume 4 Nomor 1 Februari 2021*. Page 2

<sup>3</sup> Suara.com. "Waduh! BPOM Temukan Lebih dari 1.000 Produk Obat Tradisional Mengandung Bahan Kimia". Diakses pada laman <https://www.suara.com/health/2022/04/05/195208/waduh-bpom-temukan-lebih-dari-1000-produk-obat-tradisional-mengandung-bahan-kimia?page=1>

can be clearly seen by the proliferation of usual medicinal products circulating in the market, it is necessary to protect the public so that they can avoid the widespread distribution of usual medicines containing chemical raw materials, and there is a need for supervision provided by related parties, especially the government in overcoming the circulation of usual medicines containing chemical raw materials.

Based on the description of the background that has been put forward by the author, there are several main issues that can be expressed as follows, How is the Legal Shield Against the Use of Chemical Raw Materials in Usual Medicine Based on Positive Law? and How is the Control Provided by the Government Against Drug Distribution Usual Containing Chemical Raw Materials?

## 2. METHOD

Legal research is a scientific activity that is capable of studying a particular legal phenomenon based on systematics, methodology, and specific thinking. The type of research used is an ideal legal approach. This type of prescriptive legal study is conducted with a focus on the study of the application of principles or rules to optimistic law. The prescriptive legal study is a process that links applicable laws and regulations to the practice of implementing positive laws regarding issues. This method of research is a statutory method that focuses on the rule of law as its basis. The purpose of this research is to deliver a detailed, systematic, and complete description of issues related to the legal shield against the use of chemical drug raw materials in general medicine, as well as the regulations and oversight provided by the government. Sources of research are books, journals, articles, and laws and regulations.

## 3. DISCUSSION

### 1. Legal Shield Against the Use of Chemical Drug Raw Materials in Usual Medicine Based on Positive Law

In implementing the state's series of powers and authorities, a legal system is needed to function as a government boundary in determining legal policies to provide justice, legal certainty and legal shield to the community. With legal shield, legal subjects obtain immunity related to the shield of their rights as human beings so that certain parties do not act arbitrarily.<sup>4</sup> If it is related to consumers, consumer legal shield is defined as the fulfillment of the rights owned by consumers caused by something that causes these rights to be not fulfilled.

The most important thing in the life of a country is the aspect of health for the public, because the level of wellbeing is a picture of a country's success and prosperity. Human rights include public health, this is regulated in the provisions of Article 28 H number 1 of the 1945 Constitution of the Republic of Indonesia which states: "Everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to get a good and healthy environment. and have the right to obtain health services".

Usual medicine as a form of alternative healing efforts. Provisions regarding business licenses for the usual medicine industry and registration of usual medicines are not only formed for the legality of usual medicines, but are also needed to prevent the circulation of usual medicines containing medicinal chemicals so that they do not encounter the necessities for security, usability and superiority. In the modern health system, usual medicine is getting more and more attention from various parties, because usual medicine is a promising alternative medicine. Some people choose usual medicines as an alternative method of healing,<sup>5</sup> because it is very efficacious and the price is relatively affordable compared to modern medicine. The dominance of the back to nature lifestyle and the fear of the side effects of modern medicines has resulted in the use of usual medicines continuing to increase as evidenced by the increasing number of herbal and

<sup>4</sup> Sudewi N, I N P Budiarta, N M P Ujianti Perlindungan Hukum Badan Pengawas Obat Dan Makanan (BPOM) Terhadap Peredaran Produk Jamu Yang Mengandung Bahan Kimia Obat Berbahaya, Jurnal Analogi Hukum, 2 (2) (2020), 246–251

<sup>5</sup> Akbar Kurnia Wahyudi, *Obat Tradisional dan Prospek Pengembangannya Untuk Penyembuhan*, (Jakarta : Media Utama Persada Pustaka), 2002, hlm.6



pharmaceutical industries producing usual medicines using medicinal chemicals to reduce production costs. This causes several problems that arise from consuming these usual medicines, including: the worsening of the illness and various other problems that harm consumers as users of usual medicines.

The form of legal shield given to the public as consumers of usual medicines containing chemical raw materials is in the form of defensive legal shield and repressive shield.<sup>6</sup>

- a. Defensive legal shield, in this case, is prevention by law enforcement officials, BPOM and the Health Office regarding the circulation of usual medicines in the community, and can also provide outreach regarding the consumption and products of usual medicines. Defensive actions can also be carried out by law enforcement officials assisted by BPOM and the health service to raid roadside drugstores or pharmacies and conduct outreach to the public. As a follow-up to these Defensive actions, if illegal usual medicines are found being sold, BPOM first examines the substances contained in these medicines and at the same time sees whether there is a distribution permit or not. The results of research on drug content are reported to the Health Service to provide validity regarding the hazardous substances contained. That every manufacturer or seller of usual medicines must have a certificate issued by the Health Service, namely a Registration Certificate. Coordination between the Police and BPOM and the Health Office resulted in warning letters to producers or sellers which were issued 3 times by BPOM. If BPOM has given reprimands 3 times and producers or sellers continue to distribute usual medicines containing medicinal chemicals, then the Health Service will revoke the license on the recommendation of BPOM. Another Defensive action is counseling about the negative impact on the body due to frequent short- or long-term consumption of usual medicines containing harmful chemicals. Counseling also functions to invite the public to actively participate in eradicating the practice of manufacturing and distributing usual medicines containing medicinal chemicals through reporting to law enforcement officials and BPOM.
- b. Repressive legal shield, in this case BPOM or related institutions offer a warning effect to business actors/creators of usual medicines containing medicinal chemicals, in the form of strict sanctions, both administrative sanctions, from revocation of production permits to business licenses from usual drug producers; fines for losses suffered by the public as consumers; criminal sanctions if it is proven that there are harmful chemical substances in the usual medicinal products which are distributed which endanger the public.

The legal shield can be seen through a regulation of Law No. 8 of 19 on the consumer slope. The Customer Shield Act states to the philosophy of national development that includes legal growth that can provide the shield to the public as consumers to build a complete Indonesian culture founded on Pancasila and the 1945 constitution. The implementation of this Act aims to provide protection to the public as consumers so that consumer rights can be met. As consumers, the community can also get legal guarantees for common medicinal products in order to reduce the fraudulent activities of ordinary drug dealers containing dangerous chemicals.

In law No. 8 of 1999 on consumer shield, it also regulates the right to indemnity that can be administered by consumers as a community affected by the consumption of common drugs containing dangerous chemicals. Based on Law 8 of Act No. 19 relating to consumer protection, it is regulated that the business actors/manufacturers of common drugs containing hazardous chemicals have violated the provisions of Section 19 of this Act, namely:

- a) Entrepreneurs violate consumers' right to comfort, safety, protection in taking drugs. The drugs sold contain medicinal chemicals (BKO), which can imperil the health and protection of customers by consuming the drug.
- b) Business actors violate the right to accurate, clear and truthful information regarding the status of the product. That business actor did not provide accurate, clear, and honest data about the content of the drug.

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<sup>6</sup> *Ibid.*



c) Business actors do not have good faith in performing their business operations, and do not guarantee the quality of common drugs traded based on quality standards provisions. Products sold are not allowed to be supplied from BPOM, so these products do not meet the quality standards set in Indonesia.

d) Activities carried out by business persons such as trading of common drugs that do not comply with the required standards and statutory provisions, these common drugs are also not in accordance with the terms and functionalities and are not consistent with the quality of the composition and processing process without permission to distribute from BPOM.

Traders/producers must fulfill their responsibility to the community as consumers of common drugs containing medicinal chemicals if consumer rights are violated or damaged. For example, in relation to the problem of common drugs containing medicinal chemicals so that they do not have a BPOM label, accountability must comply with several principles, one of which is the principle of absolute duty. The principle of absolute liability in consumer shield law is a relatively new legal tool for fighting for consumer rights. Forms of obligation of business actors in the distribution of common drugs containing chemicals, namely: business actors/producers/sellers are accountable for compensation or loss, pollution and/or damage as consumers as a result of consuming common drugs containing medicinal chemicals produced or traded. Compensation may be as reimbursement or medical care and/or compensation, in accordance with the applicable legal and regulatory provisions. Compensating the community for the consumption of drugs with conventional chemical raw materials to the community as a consumer does not eliminate the possibility of criminal charges based on additional evidence of error and purpose.

## **2. Supervision Provided by the Government on the Circulation of Usual Medicines Containing Chemical Raw Materials**

Even though times are getting more modern, there are still many people who are comfortable with the original traditions of the nation's culture. Not only in terms of lifestyle but also in terms of medicines needed for the body. Even now, there are still many usual medicines circulating in usual markets, such as herbs and other types of herbs or health supplements. Usual medicines are still loved by many people because of their properties which are considered efficacious in terms of body health. Ordinary ingredients, usual manufacturing methods while maintaining their ingredients, and prices that are affordable and easy to find anywhere, are the main points because people choose to continue consuming usual medicines.

However, now many usual medicines containing chemicals are circulating in the community. In response to this, law enforcement against usual medicines containing chemicals cannot be said to be effective, so that it does not create a sense of deterrence for business actors who commit such fraud. The government, as the organizer of community life, regulates the appropriateness of drug consumption. The government established the Drug and Food Control Agency (POM) based on the Twenty-third Section of Presidential Decree Number 103 of 2001. This institution has the task of carrying out activities in the fields of Toxicology Research, Food Safety and Therapeutic Products through the function of Formulation of Drug and Food Research Programs and Plans.<sup>7</sup>

Based on the results of sampling and testing conducted during the period July 2020 to September 2021, the BPOM found many items of usual medicinal products, health supplements or cosmetic products containing hazardous ingredients. One of them, the BPOM found as many as 64 items of usual medicinal products and as many as 202 usual medicines and health supplements containing Medicinal Chemicals (BKO) which were studied contained Ephedrine, Pseudoephedrine, Sildenafil Citrate and its derivatives, Allopurinol, Prednisone, Paracetamol, Acetosal, Sodium Diclofenac, Furosemide, Sibutramin HCl, Cyproheptadine HCl, and Tramadol which can cause

<sup>7</sup> Pusat Riset Kajian Obat dan Makanan, 2021, "Sejarah" <https://riset.pom.go.id/profile/sejarah>, diakses pada 29 Juli 2022 Pukul 10.39 WIB



health problems.<sup>8</sup> Thus, usual medicines containing hazardous materials can be said to be unfit for consumption and circulation in the community.

Arrangements regarding prohibited ingredients in usual medicines are regulated in Article 7 of Regulation of the Minister of Health Number 007 of 2012 concerning Registration of Usual Medicines, where ingredients that are prohibited as ingredients for making usual medicines are:

- a. Ethyl alcohol is more than 1%, except in the form of tincture which is used by dilution;
- b. Medicinal chemicals which are the result of isolation or synthetic medicinal properties;
- c. Narcotics or psychotropics; and/or
- d. Other materials based on health considerations and/or based on research that are harmful to health.

According to Article 3 paragraph (1) of the Decree of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia (BPOM) Number: HK.00.05.3.1950 concerning the Criteria and Procedures for Drug Registration explains that drugs that have a distribution permit must meet the following criteria:

- a. Convincing efficacy or efficacy and adequate safety are proven through preclinical trials and clinical trials or other evidence in accordance with the status of the development of the science concerned;
- b. Quality that meets the requirements as assessed from the production process according to Good Drug Manufacturing Practices (GMP), specifications and testing methods for all materials used and finished products with valid evidence;
- c. The marking contains complete and objective information that can guarantee the correct, rational and safe use of the drug.

Clearer provisions regarding the criteria for distribution permits for usual medicines are regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 007 of 2012 concerning Registration of Usual Medicines, which in Article 6 paragraph (1) explains that usual medicines can be granted a distribution permit if they meet the following criteria:

- a. Using materials that meet safety and quality requirements;
- b. Made by applying CPOBT
- c. Meet the requirements of the Indonesian Herbal Pharmacopoeia or other recognized requirements;
- d. Efficacious proven empirically, hereditary, and/or scientifically; And
- e. The marking contains objective, complete and not misleading information.

Based on the foregoing, a person or group of people who distribute usual medicines or other medical devices without a distribution permit from the BPOM can be subject to sanctions. The public as consumers of usual medicines who are not aware of the presence of harmful ingredients in the usual medicines they consume, has become a ripe case among drug dealers who do not comply with permits.<sup>9</sup>

Sanctions for business actors who still produce drugs with prohibited ingredients in accordance with Article 7 of the Ministry of Health Regulation Number 007 of 2012 concerning Registration of Usual Medicines, as well as for actors who distribute and/or trade usual medicines without meeting the criteria and/or having a distribution permit can be subject to sanctions administrative in the form of cancellation of the distribution permit<sup>10</sup>, In addition, business actors

<sup>8</sup> Badan POM, 13 Oktober 2021, "Siaran Pers Public Warning Obat Tradisional, Suplemen Kesehatan, dan Kosmetika Mengandung Bahan Kimia Obat/Bahan Dilarang Tahun 2021", <https://www.pom.go.id/new/view/more/pers/625/SIARAN-PERS--Public-Warning-Obat-Tradisional--Suplemen-Kesehatan--dan-Kosmetika-Mengandung-Bahan-Kimia-Obat-Bahan-Dilarang-Tahun-2021.html> Diakses Pada 29 Juli 2022 pukul 10.59 WIB

<sup>9</sup> Anastasia Isabelle Regina Bolendea, "Perlindungan Terhadap Peredaran Obat Tradisional Berbahan Kimia Obat Menurut Undang – Undang Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen", Lex Privatum, Vol. VII No.2, (Februari, 2019), hal : 45

<sup>10</sup> Ketentuan Pasal 23 ayat (1) Peraturan Kementerian Kesehatan Nomor 007 Tahun 2012 tentang Registrasi Obat Tradisional

can also be given other administrative sanctions in the form of orders to withdraw from circulation and/or destroy usual medicines that do not meet the standards and/or requirements.<sup>11</sup>

In addition, business actors who produce or distribute and/or trade usual medicines made from chemicals and do not have a distribution permit, may be subject to criminal sanctions, which in this case are regulated in Law Number 8 of 1999 concerning Consumer Shield, wherein in Law No. the law elaborates on matters that are prohibited by business actors in producing or trading their goods and/or services, one of which is contained in point (a) which states that there is no conformity with predetermined standards.<sup>12</sup> Furthermore, it is also emphasized in Article 8 paragraph (2) of the Consumer Shield Law which says that, it is banned for business performers to occupation scratched, defective or used and soiled medical strategies and food, with or without providing whole and right information.

Sanctions for commercial agents who, on the basis of Law 1999, No. 8 on Consumer Protection, are producing and distributing and/or marketing conventional medicines containing chemical-based components and who do not have a distribution authorization, are controlled in Article 62 paragraph (1) which states that business performers who disrupt the provisions mentioned to in Article 8, Article 9, Article 10, Article 13 paragraph (2), Article 15, Article 17 paragraph (1) letter a, letter b, letter e, paragraph (2), and Article 18 shall be chastised with custody for a maximum of 5 years or a fine of up to Rp. 2,000,000,000.00 (two billion rupiahs). In addition, in Article 63 of Law Number 8 of 1999 concerning Consumer Shield, it is explained that, against illegal authorizations as mentioned to in Article 62, additional penalties can be imposed in the form of:

- a. Repossession of certain goods;
- b. Statement of the judge's decision;
- c. Recompence payment;
- d. Orders to stop certain activities that cause customer losses;
- e. Responsibility to withdraw goods from circulation; And
- f. Cancellation of business license.

In clarifying rules regarding distribution permits for usual medicines, the Government also stipulates them in Article 106 paragraph (1) of Law Number 36 of 2009 concerning Health, which states that pharmaceutical preparations and medical devices can only be distributed after obtaining a distribution permit. Where pharmaceutical preparations are the meaning of usual medicine, so that pharmaceutical preparations consist of drugs, medicinal ingredients, usual medicines and cosmetics. Also, in Law Number 36 of 2009 concerning Health, it is also explained regarding sanctions for actors who produce and/or distribute illegal usual medicines, explained in Article 197 that: Everybody who intentionally produces or allocates medicinal arrangements and/or medical devices that are not owning a distribution license as mentioned to in Article 106 paragraph (1) shall be subject to custody for a maximum of 15 (fifteen) years and a maximum fine of Rp. 1,500,000,000.00 (one billion five hundred million rupiah).

#### 4. CONCLUSION

Based on the discussion of the two problem formulations described above, the following conclusions are drawn:

- a) Positive legal shield against the circulation of usual medicines containing chemicals, reflecting on Article 28 H of the 1945 Constitution of the Republic of Indonesia which states that everyone has the right to live in prosperity both physically and spiritually, the Government as the organizer of life, establishes the Drug Monitoring Agency and Food and Drug Administration (BPOM) as well as the Health Office as a form of Defensive legal shield, as well as giving authority to BPOM and the Health Service to impose sanctions on business actors/producers of

<sup>11</sup> Ketentuan Pasal 23 ayat (2) Peraturan Kementerian Kesehatan Nomor 007 Tahun 2012 tentang Registrasi Obat Tradisional

<sup>12</sup> Ketentuan Pasal 8 ayat (1) Undang – Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen

usual medicines containing chemicals, either in the form of administrative sanctions, fines or criminal sanctions. In addition, sanctions for perpetrators/producers who produce, distribute and/or trade usual medicines by not fulfilling or violating the provisions on the distribution of usual medicines, are clarified in Law Number 8 of 1999 concerning Consumer Shield which regulates the right to compensation for perpetrators. businesses and/or producers of usual medicines which are marketed without fulfilling the criteria for distribution of usual medicines in the market.

- b) Supervision by the Government of usual medicines containing chemical raw materials in the form of ratification of Law Number 8 of 1999 concerning Consumer Shield which regulates prohibitions for business actors in producing or trading usual medicines containing hazardous chemicals; criminal sanctions for business actors/producers who produce, distribute, and trade usual medicines containing chemical-based ingredients; as well as regulations regarding distribution permits. Supervision by the Government on the circulation of usual medicines made from chemicals is also contained in Presidential Decree Number 103 of 2001 which contains the duties, functions and authorities of BPOM, where one of BPOM's powers is to conduct sampling tests on several usual medicines, so that the ingredients can be found. dangerous, so it is on this basis that the Decree of the Head of the Food and Drug Supervisory Agency of the Republic of Indonesia (BPOM) Number: HK.00.05.3.1950 was formed which regulates the Criteria and Procedures for Drug Registration. Furthermore, Regulation of the Minister of Health of the Republic of Indonesia Number 007 of 2012 concerning Registration of Usual Medicines which is guided by Law Number 36 concerning Health, in Article 7 regulates the criteria for granting distribution licenses to usual medicines, as well as administrative sanctions for business actors/producers who produce , distribute, and trade usual medicines in the community without a valid permit from the relevant institution. Criminal sanctions for business actors/manufacturers who violate the provisions on the production, distribution and trade of usual medicines regulated in Article 197 of Law Number 36 of 2009 concerning Health.

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