Protection of Drug Raw Materials Through Price Standardization as a Business Rule in Supporting Competitive Local Drug Production

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Abstract. One of the contents of the Economic Policy Package Volume VI concerns the importation of drugs and raw materials. Because the price of drugs is very high because the raw materials come from abroad. Almost 95% of medicinal raw materials are still imported, which makes the price of drugs expensive. It is necessary to have the independence of the domestic pharmaceutical industry to reduce drug prices and dependence on imported drug raw materials. This is not impossible because the pharmaceutical industry was included in Indonesia's priority industry in 2015–2035. Efforts are needed to reduce imports of medicinal raw materials (BBO) to support drug independence in Indonesia. Using domestic medicinal raw materials will likely adjust the quality of circulating drugs to applicable standards. They have BPOM (Food and Drug Supervisory Agency) in Indonesia, which can regulate drug quality standards and their production. Because drugs produced locally must be guaranteed quality and safety, which cannot be equated with other commodities. Currently, the number of pharmaceutical industries in Indonesia is more than 200, consisting of 4 (four) BUMN (Biofarma, Indofarma, Kimia Farma, and Phapros), 24 multinational companies, and 190 national private companies. However, the current domestic industry is more inclined to move on to industrial formulations or manufacture finished drugs. Meanwhile, medicinal raw materials are still imported with a percentage of 95%, and most of the raw materials are imported from China, Europe, and India. Furthermore, solutions and efforts that the Government can take are sought to facilitate and protect domestic production from competitiveness. The long-term goal to be achieved is to reduce dependence on imported medicinal raw materials to improve the domestic economy and the standard of living of many people. The results of this study are expected to find the right form of regulation in protecting medicinal raw materials that are useful in increasing competitiveness and the domestic economy. The benefits of this research are expected to be able to contribute to the Indonesian Government and business actors to improve the domestic economy. This study uses a normative juridical method supported by empirical juridical, as well as a study using a qualitative juridical approach to Economic Law, Company Law, and Health Law.

Keywords: Price Benchmark for Raw Materials for Drugs · Business Rules · Domestic Economic Competitiveness

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1 Introduction

One of the contents of the economic policy package volume VI in November 2015 was regarding the reduction of import permits for drugs and their raw materials. The reason is, drug prices are very expensive because the majority of raw materials are imported from abroad (Wartakota, Tribun News, January 22, 2016). The Ministry of Health has encouraged the independence of the domestic pharmaceutical industry to reduce drug prices and reduce dependence on imported drug raw materials, this is not impossible because the pharmaceutical industry is included in Indonesia's priority industry from 2015–2035. For this reason, efforts need to be made to reduce dependence on imports of medicinal raw materials (BBO) to support the achievement of drug independence in Indonesia. By using domestic medicinal raw materials, the quality of circulating drugs will be adjusted according to applicable standards.

The Food and Drug Supervisory Agency (BPOM) usually regulates drug quality standards and their production. This is because drugs that are produced locally must be guaranteed safety quality and efficacy which cannot be equated with other commodities. Currently, the number of pharmaceutical industries in Indonesia is more than 200 companies, consisting of 4 state-owned enterprises (Biofarma, Indofarma, Kimia Farma and Phapros), 24 multinational companies, and 190 national private companies. However, the domestic pharmaceutical industry is currently more inclined to engage in the formulation industry or the manufacture of finished drugs. While medicinal raw materials are still imported with a percentage of 95%, the majority of raw materials are imported from China (60%), Europe (25%) and India (10%). Moreover, the majority of these pharmaceuticals are generic, which are commonly used for the needs of the Health Social Security Administering Body (BPJS).

There are several problems that make the local pharmaceutical industry less significant. The first is the existence of environmental protection regulations carried out by the Chinese government, thereby suppressing the production of medicinal raw materials. Second, the soaring exchange rate of the yuan against the United States Dollar, thus affecting the price of medicinal raw materials. For the record, the Chinese government applies environmental protection to the chemical industry with strict standards. As a result, manufacturers who were deemed unfit for operation were forced to close. This condition also causes the supply of raw materials for medicines to decrease. In fact, most of Indonesia's pharmaceutical raw materials are imported from China. (Kotan.Co.Id, Pharmaceutical industry depressed by raw material prices, 3 November 2017).

The Indonesian government is now working to improve access to health care for all Indonesians. The pharmaceutical and pharmaceutical components business is one of the core industries that will play a vital role as the main driver of the economy in the future, according to the National Industrial Development Master Plan (RIPIN) 2015–2035.

Through research on the business regulations of medicinal raw materials in Indonesia, things that are needed to make the pharmaceutical industry are able to produce quality drugs, by looking at the potential and opportunities in the pharmaceutical world. Based on the above background, the problems can be formulated as follows: (1) how to protect the production of local raw materials, (2) how the government establishes a business regulation mechanism in determining prices, such as drug prices, (3) how to facilitate

the government's interest who want cheap drug prices, so that sometimes it does not facilitate the interests of the pharmaceutical industry.

The specific objectives of this research activity are oriented towards the protection of local raw materials. The long-term goal to be achieved in this research is the existence of a business rule mechanism in determining drug prices.

The urgency (priority) of this research activity can provide recommendations to the Government and the pharmaceutical industry players related to the development of local medicinal raw materials, so that it is expected to be able to facilitate the interests of the government who want drug prices to be cheap and facilitate the pharmaceutical industry related to investment, especially in terms of return on investment. Investment (ROI).

The target of this research is the establishment of a protection mechanism for local medicinal raw material products accompanied by a pricing mechanism in regulating the competition in the pharmaceutical industry and the interests of the government, so as to increase competitiveness and improve the domestic economy.

The history of the pharmaceutical industry in Indonesia begins with the establishment of the first pharmaceutical factory in the East Indies in 1817, namely NV. Chemicalien Rathkamp & Co and NV. Pharmaceutische Handel Vereneging J. Van Gorkom & Co. in 1865, with the Quinine factory in Bandung being the first modern pharmaceutical industry in Indonesia in 1896. Further developments, in 1957–1959 after the war of independence after the Dutch-owned pharmaceutical companies, namely Bovasta Bandoengsche Kinine Fabriek which produced quinine pills and Ondememing Iodine which produces Iodine was nationalized by the Government of Indonesia which is currently developing into PT. Kimia Farma (Persero). Meanwhile, the manufacturer of ointments and gauze, Centrale Burgerlijke Ziekeninrichring, which was established in 1918, became Perum Indofarma, which is currently PT. Indofarma (Persero). However, the issue of the Foreign Investment Law (PMA) in 1967 and the Domestic Investment Law (PMDN) in 1968, which have promoted the growth of the Indonesian pharmaceutical industry to date, has been a key development for the development of the Indonesian pharmaceutical industry.

Today, Indonesia's pharmaceutical business is one of the fastest expanding industries in the world, with the largest pharmaceutical industry in the ASEAN area. According to data from the Food and Drug Supervisory Agency (BPOM), the Indonesian pharmaceutical business grew at a pace of 14.10% per year, which was greater than the national growth rate of 5–6% per year. However, as measured by worldwide sales turnover (all over the world), the Indonesian pharmaceutical market accounts for little more than 0.44% of the global pharmaceutical market.

2 Method

This is a descriptive analytical study that describes the existing conditions in the development of medicinal raw materials. One of the impediments is the legal content, which is the primary focus of the study. This study employs a normative juridical approach that is supported by empirical juridical evidence. The following steps can be defined in the research flow: (1) Library research collects secondary data in the form of primary legal documents, such as binding legal materials, statutory rules, secondary legal materials, and tertiary legal materials. In addition, (2) Field Research. Field research is conducted

to collect primary data, which will be utilized to supplement the analysis of library research results. The following level is data processing and analysis in a qualitative legal way.

3 Result and Discussion

3.1 Development of the Pharmaceutical Industry in Indonesia

Indonesia has the largest pharmaceutical market in ASEAN. Given that Indonesia has the lowest medication consumption per capita among ASEAN nations, the future of Indonesian pharmaceuticals is expected to be rather high. The low drug use per capita in Indonesia is attributed not just to poor purchasing power, but also to a distinct pattern of drug consumption in Indonesia than in other ASEAN nations. In Malaysia, the drug usage pattern is largely focused on patent medications. Patent medications are significantly more costly than branded generic pharmaceuticals.

With a rising per capita income and a health insurance system in Indonesia, the value of medication distribution in Indonesia will be significant in the future. This circumstance will almost probably have a favorable impact on the future expansion of the Indonesian pharmaceutical sector. According to this, the overall sales of the Indonesian pharmaceutical business continue to rise year after year. In comparison to other ASEAN countries, Indonesia's domestic pharmaceutical industry has a much larger market share than PMA/MNC (Multi National Company). (Drug Pharmacy, Pharmacy and Doctor's Ethics, https://akfarjember0910.wordpress.com/farmasi-dan-etika-dokter/).

Indonesia's medicine exports have increased year after year, despite the fact that the value is very small (about 5% of total pharmaceutical sector sales in Indonesia). With the implementation of ASEAN pharmaceutical rules harmonization by 2010 at the latest, an ASEAN single market in the pharmaceutical sector will be formed, with no more tariff and non-tariff obstacles in ASEAN pharmaceutical trade. This indicates that there is a chance for the pharmaceutical sector to grow exports in the ASEAN market, but the Indonesian domestic market will be threatened as ASEAN pharmaceutical items enter Indonesia more freely. In addition to a fragmented market, the national pharmaceutical business faces the following challenges:

1. Absence of raw material industry. This results in 95% of raw materials being imported (the price of domestically produced raw materials is not cheaper than imports). Import dependence has not been matched by efforts to develop local raw materials. Apart from requiring high investment costs, the carrying capacity of the equipment is also still inadequate.
2. Idle production capacity of the national pharmaceutical industry reaches 50% because there is no appropriate solution to overcome it, including alternatives through toll manufacturing and the concept of production house.
3. The application of international rules for standardization of the pharmaceutical industry, especially regarding C-GMP, registration and the lack of good coordination between the government (BPOM) and the pharmaceutical industry.

4. The condition of the national pharmaceutical industry is uneven. On the one hand, there are a small number of pharmaceutical industries that are ready to face the free market, both in terms of hardware, software and brainware (HR), on the other hand, there are still many industries that have not met the demands of international requirements.

Facing the upcoming harmonization of the ASEAN market, BPOM as the regulator of the national pharmaceutical industry has implemented various strategies to improve the capabilities of the national pharmaceutical industry, including:

1. Implementation of C-GMP to increase compliance with global pharmaceutical requirements and standards.
2. Encourage the national pharmaceutical industry to be more efficient and focus on the implementation of drug production, including the selection of production facilities that are feasible to develop.
3. Implementation of the latest GMP (c-GMP) according to international standards.

3.2 Economic Law

The legal requirements of the business community evolve in tandem with the advancement of trade. Soekardono, R. (1993: 3). Economics has a responsibility to provide rational steps in improving people's living standards, so that economic activities not only meet individual and short-term human needs, but also generate a surplus for the welfare of many people, particularly in the development of the pharmaceutical industry. According to the notion of "law as a tool of social engineering" (Mochtar Kusumaatmadja 2016:5), the law is a tool for community rejuvenation that must be capable of carrying out social engineering. As a result, the law must always carry out modifications to aid progress. The law is the entire norm that is declared or deemed a binding regulation for some or all members of the community by the state authorities or community authorities who have the capacity to make law, with the goal of differentiating an order sought by the ruler. Purwosutjipto, 1999:1).

Alvin Toffler in his theory has divided the waves of economic civilization, namely starting from the wave of the agricultural/agrarian economy, the wave of the industrial economy, the wave of the information economy, and the wave of the creative economy that is oriented towards creative ideas. (Ririn Noviyanti, 2017:77–99). In the era of creativity-based economy, there is also a shift in the economic model from the owning economy model to the sharing economy which is identical to business ownership by business actors themselves (both individuals, business entities, and legal materials), where capital ownership, production processes, investment and all business related matters shall be borne by the business actor himself. (Mayana, Fauza, Mayana, 2022:5).

Several hurdles remain in the growth of the Drug Raw Materials Sector (BBO), notwithstanding Presidential Instruction No. 6 of 2016 addressing the acceleration of the development of the pharmaceutical industry and medical devices. Until far, only three or four businesses have produced modest volumes of chemical-based BBO. Low Production Capacity makes it difficult for industry players to achieve competitive prices with imported BBO. It should be noted that in international trade law, human legal

subjects (naturlife persoon) and legal entities (recht persoon) have developed dimensions according to legal experts and based on international trade law in general can be classified into humans, companies, international organizations (international trade), and country. (Dijan Widijowato, 2020:15).

According to Law Number 17 of 2007 about the National Long-Term Development Plan (RPJP-N) of 2005–2025, health development is oriented at raising knowledge, willingness, and ability to live healthy for everyone in order to attain the maximum level of public health. Materialized. Health development is focused on humanity, empowerment and independence, fairness and equity, as well as prioritizing and benefitting vulnerable groups such as mothers, babies, children, the elderly, and disadvantaged families. Greater health efforts, health people resources, medications, and health supplies, as well as increased oversight and community empowerment, are used to carry out health development.

The direction of the health sector's long-term growth in 2005–2025, as stated in the Long-Term Development Plan for the Health Sector (RPJP-K) and confirmed in the Minister of Health's Decree Number 375/MENKES/SK/V/2009, indicates that the objective of health development is towards Indonesia. Healthy 2025 is an increase in awareness, willingness, and ability to live a healthy life for all so that the highest level of public health can be realized, through the creation of an Indonesian society, nation, and state characterized by its population living with behavior and in a healthy environment, having the ability to access quality health services in a fair and equitable manner, and having the highest degree of health throughout the territory. The health development strategies that will be pursued until 2025 in order to achieve health development goals and targets are as follows: (1) Health-oriented National Development,(2) Development of Health Efforts and Financing, (3) Development and Empowerment of Health Human Resources, and (4) Prevention of Health Emergencies.

For the period of 2014 - 2019, more specifically related to the scope of the pharmaceutical and medical devices sector, several achievement targets were stated, including:

1. The national pharmaceutical industry is not only able to meet the needs of domestic drugs, but is starting to be able to compete to export drugs to foreign countries;
2. Domestic production of raw materials for pharmaceutical preparations has developed in support of drug production, so that drug prices can be truly affordable by the public;
3. Guarantee the availability of pharmaceutical preparations and medical devices that are safe for consumption to be used equitably and are able to meet the demands for the quality of the implementation of health efforts, and are affordable by the general public;
4. The safety and quality of pharmaceutical preparations and medical devices can be guaranteed by strong supervision of pharmaceutical preparations, medical devices and food as well as PKRT;
5. Increasing the type of national medical device production.

3.3 Law of Business Competition

Since the establishment of AFTA (ASEAN Free Trade Area) and APEC (Asia Pacific Economic Corporation) in 1967 in the Asian region, since the beginning the Indonesian government has been serious about preparing everything to be involved in the regional and international trade environment, especially in the availability of legal instruments. or the laws governing it. The world trade system which is increasingly referring to liberalism, where the market share is economically determined by the superiority of the commodity is of particular concern. A free and fair world market (free trade and fair trade) triggers tariff and policy issues related to protection. These two things need to be removed because world trade is free and fair.

The national economic system based on the principles of economic democracy, monopolistic practices and business competition must be regulated in such a way so that it does not become a means of monopolistic practices that lead to unfair business competition. The crystallization of economic democracy based on Pancasila and the 1945 Constitution is in the form of maintaining a balance between the interests of business actors and the public interest, with the aim of:

1. Safeguard the public interest and improve economic efficiency and protect consumers.
2. Fostering a conducive business climate through the creation of fair business competition, and ensuring the certainty of equal business opportunities for everyone.
3. Prevent monopolistic practices and or unfair business competition caused by business actors.
4. Creating effectiveness and efficiency in business activities in order to improve people's welfare. (Munir Fuadi, 1999:2)

The simplest way to maintain a healthy and up-to-date trading climate is to require business actors to compete fairly in running their business and by continuing to be guided by the applicable laws.

As well as procuring sources of medicinal raw materials, there is a need for regulations that focus on regulating medicinal raw materials in Indonesia in order to build healthy Indonesian economic competition. So far, 95% of medicinal raw materials circulating in the Indonesian pharmaceutical industry are still sourced from abroad such as China, India and Europe, even though it is not impossible that Indonesia can produce raw materials of the same quality as raw materials originating from abroad, given the natural wealth. Indonesia is abundant and the technology owned by Indonesia continues to compete with developed countries.

The import of medicinal raw materials has practically hampered the development of the drug raw material industry in the country. This is because the three countries of origin for the raw materials of the drug have advantages that Indonesia does not yet have, for example, the Chinese government provides convenience for its domestic industry by providing sufficient land to build factories, the government also facilitates licensing arrangements for business establishment, the Chinese government also helps manage waste generated from a production plant. This is of course a very meaningful support for local Chinese entrepreneurs.

Another example is the advantages possessed by the Indian state. Similar to China, the Indian government provides sufficient land for factories for production. The Indian government has also simplified the business licensing process for factories that produce a product. Similar to the Chinese government, the Indian government also helps treat waste from factories. The Indian government also uses Trade Related Aspects of Intellectual Property Rights/TRIPs as a medium for conducting well-organized research and development. These things are a plus point for India to become an influential producer of medicinal raw materials in the world, because these facilities greatly support production figures. Apart from these things, the price of labor is also a point that determines the price of medicinal raw materials. In China and India the price of labor is suppressed in such a way that it can cut production costs.

Apart from supporting factors that are regional in nature, there are also important supporting factors that are global in nature, which causes the price of medicinal raw materials to become expensive. The existence of trade agreements related to Intellectual Property Rights also hinders competition in the drug industry. In the agreement, patents are applied to drug products from the pharmaceutical industry so that pharmaceutical companies holding patent rights can monopolize drug distribution. Currently, drug patents in many countries last for 20 (twenty) years from the date of filing and granting the patent. Although the distribution of drugs is essentially a supporter of human health, in fact, the granting of long-term patents is not for the sake of humanity and the improvement of human health globally, but rather for profit and commercialization.

Limited agreements between countries in the world such as the Pacific Four, which later developed into the Trans-Pacific Partnership (TPP), are also a determining factor in the distribution and sale of raw materials for medicines. The purpose of forming the Pacific Four is to make a trade agreement larger than the Pacific region as a form of implementation of trade liberalization among the member countries of the Pacific Four. The initiating countries of the Pacific Four, better known as P4 are Singapore, Chile, New Zealand and Brunei Darussalam. In the following years, many countries were attracted and joined the Pacific Four, so the Pacific Four was renamed the Trans-Pacific Strategic Economic Partnership as a form of a new agreement. The purpose of this change is to expand the reach of membership. Broadly speaking, this agreement provides an overview of the background, instruments, concepts and objectives of trade liberalization. This includes trading in medicinal raw materials and the drugs themselves. It is also feared that TPP will expand the monopoly protection of the pharmaceutical industry so that it will further narrow people's access to medicines. If there is an extension of the patent granting period, then public access to medicines at affordable prices will be increasingly narrow and limited. The extension of the patent granting period will result in generic drug manufacturers being increasingly difficult to compete.

Generic drug manufacturers have the same interests as premium drug manufacturers in the need for drug raw materials. With the difficult situation of obtaining various medicinal raw materials, then of course it will become a threat to the survival of the industry.

More serious attention is needed to find a solution to this problem. Even though Indonesia already has Law Number 5 of 1999 concerning the Prohibition of Monopolistic Practices and Unfair Business Competition, this regulation will still be difficult to touch

on multinational and global issues. In addition to global constraints, there are also local constraints, where only certain importers can import raw materials for certain medicines. This of course can lead to scarcity of medicinal raw materials and soaring production prices. The limited distribution of medicinal raw materials has led to the emergence of unfair business competition, because the distribution of drugs is only held by some parties on a limited basis.

Article 1 letter f of Law Number 5 of 1999 concerning the Prohibition of Monopolistic Practices and Unfair Business Competition reads, "Unfair business competition is competition between business actors in carrying out production and or marketing activities of goods and or services carried out dishonestly or against law or hinder business competition". In that article it is stated that a business activity will violate the rules if its business activity can hinder fair and good business competition.

Limited availability of medicinal raw materials and high prices due to long-term patents hinder the production of generic drugs. One solution that can be taken is to create a domestic drug raw material industry.

Indonesia has a large area of land and materials that can be used as raw materials for medicine. The government can help the success of the emergence of the drug raw material industry in Indonesia by providing support as is done by the government of other drug raw material producing countries. No less important support is that the government can make regulations that limit the import of medicinal raw materials, which will inevitably 'force' domestic manufacturers of medicinal raw materials to increase their production.

4 Conclusion

There must be restrictions related to the import of raw materials for drugs in Indonesia. Referring to the economic policy package VI, November 5, 2015 refers to the fast (paperless) licensing process for the import of medicinal raw materials, more to the technical simplification of the import process for drug and food raw materials. However, this step will not protect local entrepreneurs who will later invest in establishing a medicinal raw material factory, because the restrictions and support for reducing the import of medicinal raw materials are only in the form of a systematic rule that can really be applied in reducing imports of raw materials the drug raw.

Laws

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KUH Dagang.

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