

Volume 5 No. 2, Maret 2022

# Pharmaceutical and Medical Devices Industry Regulation in Indonesia: Human Rights Perspective

# Giannina Meracellene Lesmana, Matthew Darrell Tenando, Vienda Mustika Dewi

s120121175@student.ubaya.ac.id Universitas Surabaya

#### How to cite:

Giannina Meracellene Lesmana, Matthew Darrell Tenando dan Vienda Mustika Dewi 'Pharmaceutical and Medical Devices Industry Regulation in Indonesia: Human Rights Perspective' (2022) Vol. 5 No. 2 Jurist-Diction

#### Histori artikel:

Submit 20 Januari 2022; Diterima 18 Februari 2022; Diterbitkan 31 Maret 2022.

#### DOI:

10.20473/jd.v5i2.34892

p-ISSN: 2721-8392 e-ISSN: 2655-8297



#### Abstract

A deficiency in supply of medicines and medical devices, especially in remote areas, has become a national problem since the mid-2000s until now. This problem is certainly made worse by the presence of *COVID-19. The main causes of this supply shortages are, among others,* economic factors, ineffective regulations that result in problems related to business and supply chains. Indonesia, a country where 90% of raw materials for medicines are imported from abroad, of course is deeply affected by the export ban of countries that supply raw materials. Do not forget that Indonesia's geographical condition is so vast that it creates huge obstacles for the distribution of drugs and medical devices, and it is understandable if the private sector does not want to open hospitals, pharmacies or clinics in remote areas due to economic factors. As a result, human health, something which should be a human right feels like a luxury during this pandemic. Therefore several policies have been implemented, ranging from increasing production capacity, enacting regulations regarding limits on the number of drugs that can be prescribed to patients or purchased by the public to prevent hoarding, simplifying the industrial licensing process to increasing hospital beds. Keywords: Medical Devices; Medicine; COVID-19.

#### Abstrak

Kurangnya pasokan obat dan alat kesehatan khususnya di daerah terpencil telah menjadi masalah nasional sejak pertengahan tahun 2000-an hingga saat ini. Masalah ini tentunya diperburuk oleh adanya COVID-19. Penyebab utama kekurangan pasokan ini diantara lain karena faktor ekonomi, regulasi yang kurang efektif yang mengakibatkan masalah terkait bisnis dan juga rantai pasok. Indonesia sebuah negara dimana 90% bahan baku obat obatan didatangkan dari luar negeri tentu sangat terpengaruh oleh larangan ekspor negara negara pemasok bahan baku. Tidak lupa kondisi geografis Indonesia yang begitu luas menghasilkan kendala yang begitu besar untuk distribusi obat dan alat medis, dan dapat dipahami jika pihak swasta tidak ingin membuka rumah sakit, apotek ataupun klinik di daerah terpencil karena faktor ekonomis. Lantas kesehatan yang seharusnya adalah Hak Asasi Manusia terasa seperti kemewahan di pandemi ini. Oleh sebab itu beberapa kebijakan yang dilakukan yaitu mulai dari meningkatkan kapasitas produksi, memberlakukan peraturan mengenai batasan jumlah obat yang dapat diresepkan untuk pasien atau dibeli oleh masyarakat untuk mencegah penimbunan, simplifikasi proses perizinan industri hingga memperbanyak tempat tidur rumah sakit.

Kata Kunci: Alat kesehatan; Farmasi; COVID-19.

Copyright © 2022 Giannina Meracellene Lesmana, Matthew Darrell Tenando, Vienda Mustika Dewi

#### Introduction

The crisis of essential drugs and medical devices is a serious problem faced by Indonesia in recent times, this can be seen from the scarcity of supplemental medicines and/or can be suspected as Covid-19 drugs. The scarcity resulted in panic buying of drugs in pharmacies. Meanwhile, access to medicine is a human right that must be protected and guaranteed by the government.

In the end, the crisis made counterfeit vitamins and supplements more spread like wildfire in the community even worse than it did in pre-pandemic. This crisis is driven by the increasing demand for medicines, vitamins, and supplements due to the COVID-19 pandemic. This also had a positive impact on the pharmaceutical sector, which increased in the third quarter of 2020 by 14%. Unfortunately, this also opens the door for certain parties to trade counterfeit drugs, vitamins, and supplements.

In addition, the government's efforts to carry out vaccinations continue to be intensified to overcome the current pandemic problem, to form herd immunity, but the government's efforts are also under threat from the crisis of the disposable syringe used to inject the vaccine. Which is widespread and affects most Indonesians will certainly greatly increase the usage of syringes. Therefore, this paper will discuss how to regulate the supply chain of essential drugs, especially during the pandemic, and the government's efforts to ensure that every community has access to these essential drugs.

### Access to Essential Drugs as a Human Right

Health is very essential for the survival of every human being. However, as we know at this time, health seems more like a privilege that is very difficult to obtain, giving rise to various problems, one of which and the most common is the problem of equity, but this problem also arises because it is based on several underlying factors including geographical factors, quantity and quality of domestic production, and besides that, Indonesia also has a large population spread throughout Indonesia. Moreover, due to the lack of clarity of regulations to regulate the quality

<sup>&</sup>lt;sup>1</sup> Undang-Undang Dasar Negara Republik Indonesia, 'Undang-Undang Republik Nomor 36 Tentang Kesehatan' (2009).

of health services in Indonesia. (insert article on human rights for health).

The Ministry of internal affairs of the Republic of Indonesia (Kemendagri RI) stated that the total population of Indonesia in 2021 was 272,229,372 people. This number can be classified as large and considering that the geographical condition of the State of Indonesia is vast and is an archipelagic country that participates in influencing issues related to the difficulty of health equity that is currently happening in Indonesia.<sup>2</sup> As we know Health is a very essential thing and Health is a human right that must be obtained by every individual, As stated in the Universal Declaration of Human Rights / UDHR in article 25 which explains that everyone has the right to a standard of living adequate for health, the welfare of himself and his family, then what about in Indonesia? Basically, in Indonesia, it also provides health insurance for every citizen as stated in the 1945 Constitution article 28 H paragraph 1 which reads as "Everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy living environment and have the right to receive health services. health." This means here that every Indonesian citizen has the right to live in physical and spiritual prosperity, to have a place to live, and to get good health services without exception.<sup>3</sup>

However, in its current application, as we know that not all Indonesian citizens have the opportunity to get proper health services, speaking of health equity, of course, we also must not forget the fundamental thing to make this equal distribution successful, namely all the need for adequate pharmaceuticals and medical equipment. for everyone to get, but here if we refer to the needs, we also have to see what about the pharmaceutical and medical device industry in Indonesia, whether the production is sufficient for the people of Indonesia and can be evenly distributed to remote areas, let alone us. It is also necessary to remember

<sup>&</sup>lt;sup>2</sup> Dukcapil Kemendagri, 'Distribusi Penduduk Indonesia Per Juni 2021: Jabar Terbanyak, Kaltara Paling Sedikit' [2021] Dukcapil.Kemendagri.Go.Id 10 <a href="https://dukcapil.kemendagri.go.id/berita/baca/809/distribusi-penduduk-indonesia-per-juni-2021-jabar-terbanyak-kaltara-paling-sedikit">https://dukcapil.kemendagri.go.id/berita/baca/809/distribusi-penduduk-indonesia-per-juni-2021-jabar-terbanyak-kaltara-paling-sedikit</a>.

<sup>&</sup>lt;sup>3</sup> Undang-Undang Dasar Negara Republik Indonesia, 'Undang-Undang Dasar Negara Republik Indonesia 1945' (1945).

<sup>&</sup>lt;sup>4</sup> Menteri Kesehatan, 'Permenkes NOMOR 1191/MENKES/PER/VIII/2010' (2010).

524

that during the COVID-19 pandemic, as there is currently a significant increase in health needs, so to regulate the availability and distribution of health so that all Indonesian people can feel it, the government takes steps to issue regulations that function, to regulate the performance of the pharmaceutical industry and medical devices and to ensure that the availability of medical devices is sufficient and that health can be enjoyed by every citizen of Indonesia.

## Regulation of the Supply Chain of Medical Devices and Pharmaceutical Products

It is undeniable that the business potential in the pharmaceutical and medical device industry is huge, it was reported in 2013 that the market value of Indonesian medical devices reached US\$ 672.8 million and with a growth of around 12% per year, it is estimated that in 2018 the value will reach US\$ 1,221, 9 million (BMI, 2016). However, one of the obstacles to the development of the local pharmaceutical and medical device industry is the cost, both capital, and operational costs, one way to solve this problem is by lean manufacturing to reduce operational costs and increase efficiency.5

As we know earlier that the amount of production/quantity of production of pharmaceutical materials and medical devices is a very fundamental thing in the luck of health equity in a country, because with a sufficient amount of production, the greater the possibility for the whole community to have the opportunity to However before I go into a more specific discussion, I will explore the condition of the pharmaceutical and medical equipment industry which is included in the nonoil and gas industry in Indonesia, the opportunity for the pharmaceutical industry in Indonesia is currently considered to have a great opportunity to develop, which is marked by an increase in The number of pharmaceutical industries is quite significant, citing data from the Ministry of Health in the last 5 years (2015-2019), the number of domestic pharmaceutical industries has increased by 132 industries, which from the number of industries which was originally 198 in 2015 increased

<sup>&</sup>lt;sup>5</sup> Kementrian Perindustrian, 'Membangun Kemandirian Industri Farmasi Nasional' (2021) Buku Analisis Pembangunan Industri 1.[9-10].

to 230 in 2015. 2019, as well as In the pharmaceutical raw material industry sector, there has also been an increase which initially only amounted to 8 industries in 2016 which developed into 14 industries in 2019, of all the industries above divided into 3 types of companies, namely, BUMN (State-Owned Enterprises), domestic private sector and multinational corporations. National Company (MNC), which we can see Most are domestic private companies. Besides that, with a dense population in Indonesia which reaches 270 million people and is the most densely populated country in Southeast Asia, and being the fourth-most densely populated country in the world, Indonesia can be said to have a very large pharmaceutical market size. largest pharmaceutical market share in ASEAN, holding 27.8% of the total market share in ASEAN, reaching 5.93 billion in 2014.6 Meanwhile, if looked at globally, the Indonesian pharmaceutical market is ranked 26th in the world ranking, this value can be considered quite good even though it is still far below developed countries such as the United States, Japan, China, etc.<sup>7</sup>

While in Indonesia itself, it is local pharmaceutical companies that dominate 73% of the national pharmaceutical market share, this is certainly very proud because Indonesia is the only country in the ASEAN Region where local companies dominate the market share, when compared to neighboring countries such as, Singapore, Malaysia, and Thailand whose market share has been largely controlled by foreign companies/multi-national companies.<sup>8</sup>

It should be remembered that the need for medicines is a major need with a high level of urgency because the need for medicinal products will also increase along with the increase in population, besides that of course it will also ignore the ups and downs of the economy in a country. In addition, I will also look at the trend of Total market share in the Indonesian pharmaceutical sector which continues to increase from 65.9 trillion in 2016 which skyrocketed to 88.36 trillion in 2019, this also shows that the demand for and consumption of drugs is increasing. This is also due to increasing public awareness about

<sup>&</sup>lt;sup>6</sup> *ibid*.[3].

<sup>&</sup>lt;sup>7</sup> Perindustrian (n 5).[4].

<sup>&</sup>lt;sup>8</sup> *ibid*.[8].

the importance of health and medicines, besides that, it is also driven by the increasing income of people in the middle class which also increases, which also contributes to the increasing demand for medicines. This increase is also expected to continue to skyrocket in the next few years also because it is influenced by the implementation of the National Health Insurance – the Healthy Indonesia card or commonly referred to as JKN-KIS, this program will also continue to be improved by the government to help equitable distribution of health to all Indonesian people. Of course, the number of participants will continue to grow over the years, with the number of participants increasing, the demand for drugs will automatically increase to meet their needs. In addition, with the increase in per capita income and the Health insurance system in Indonesia which is getting better and better, the value of drug circulation will also be large, this will certainly bring a positive correlation to the growth of the pharmaceutical industry in Indonesia in the future, in 2017 Indonesia's pharmaceutical industry is in the top 20 in the world and this ranking has great potential to increase to 19th in 2020.

The Covid-19 pandemic has opened the world's eyes to the inefficiency of the existing world supply chain. This is very dangerous because it involves the supply chain of basic needs such as pharmaceutical products, namely drugs, and also medical device products such as masks, syringes, and others. As a result, during this pandemic where the crisis of medical equipment and pharmaceutical products is very prone to occur, a country will prioritize the interests of its people and limit exports to ensure that the needs of its people are met. The main factor in this problem is that the existing supply chain is too dependent on developing countries with a high population like China. This is because the regulations made by the Chinese government provide subsidies for companies that want to build production centers there, one of which is the production of medicinal raw materials. It also has regulations that stipulate that foreign companies wishing to invest in production centers there must transfer their

<sup>&</sup>lt;sup>9</sup> ibid.

<sup>&</sup>lt;sup>10</sup> *ibid* [5]

<sup>&</sup>lt;sup>11</sup> Timothy Meyer, 'Trade Law and Supply Chain Regulation in a Post-COVID World' (2020) SSRN Electronic Journal.[1].

<sup>&</sup>lt;sup>12</sup> *ibid*.

technology to Chinese companies. In addition, there are trade agreements that are theoretically made to diversify supply chains but in practice only strengthen supply chain dependence centered on one or a few countries.

Furthermore, because of this issue, the American government, which was then led by President Obama, used FTAs or free trade agreements to diversify the existing supply chain. So the FTA contains a group of countries such as countries in the European Union that have entered into an agreement in which trade between countries agreeing is not subject to tariffs, while countries that are not members of the agreement, such as China, are subject to tariffs. But unfortunately, this agreement is not effective because of the provisions in the agreement itself which have many loopholes, for example, provisions regarding the nationality of a product. A product that is 50% or more manufactured outside the free trade area and the remainder is manufactured in the free trade area is still eligible to enjoy the benefits of a free trade agreement. Another way to diversify supply chains is to provide incentives or subsidies to producers of medical devices and medicines who want to build production centers in the country. However, a strategy like this is carried out by many countries will lead to competition which in the end opens up opportunities to create a competition between countries to provide high incentives for manufacturers of medical devices and pharmaceutical products to attract investors to invest there and in the end a resource-rich country can monopolize the supply chain as it is now.<sup>13</sup>

The supervision of imported goods entering the country is still inadequate. The lack of responsibility of importers and negligence of officers in drug and BBO control has led to a large number of illegal imports being smuggled in through this fragile supply chain. These illegal products often use the guise of including information on a product that does not correspond to reality.<sup>14</sup>

Based on the Decree of the Minister of Health of the Republic of Indonesia

<sup>&</sup>lt;sup>13</sup> *ibid*.

<sup>&</sup>lt;sup>14</sup> Dewi Hendrawati Enel Reza Hafidzan, Ery Agus Priyono, 'Diponegoro Law Journal' (2015) 6 Serambi Hukumfile:///Users/gia/Desktop/Policy Brief \_ Addressing Distance Learning Barriers in Indonesia Amid the Covid-19 Pandemic.pdf 1 <a href="https://www.academia.edu/34113996/EKSISTEN-SI\_HUKUM\_KONTRAK\_INNOMINAT\_DALAM\_RANAH\_BISNIS\_DI\_INDONESIA">https://www.academia.edu/34113996/EKSISTEN-SI\_HUKUM\_KONTRAK\_INNOMINAT\_DALAM\_RANAH\_BISNIS\_DI\_INDONESIA</a>.

Number 1010/MENKES/PER/XI/2008, importers need to obtain a SKI or Import Certificate so that the importer can provide accountability for the products that are circulated. Registration for this letter can be done online through the BPOM website. After that, BPOM standardized it concerning Good Manufacturing Practice or GMP and also with Good Manufacturing Practices of GMP. An imported product itself requires a Circulation Permit Number to be legally circulated in Indonesia. Then if the importer already has a distribution permit from the head of BPOM, the distribution permit is valid for 5 years. In this way, the responsibility of the importer is guaranteed regarding the imported products. This responsibility can be carried out in administrative or criminal terms. This responsibility is regulated in Article 19 of Law Number 8 of 1999 concerning consumer protection where business actors are also obliged to be responsible to consumers by providing compensation for damage to pollution and losses of consumers due to consuming traded goods or services. The word "responsible" here in the sense of providing compensation in the form of money or financing health care due to illness suffered due to consuming the product, and providing compensation to consumers or their heirs such as the consumer has died. 15

When considering the many cases of imported drugs that are detrimental to the public, the implementation of a drug and food control system carried out by BPOM is a comprehensive process and includes pre-market and post-market supervision which consists of the function of setting standards, regulations, and policies related to supervision. Drug and Food product assessment before obtaining the NIE and then finally being produced and circulated. Then after being circulated to see the consistency of quality, safety, and product information, it is carried out by taking samples of drugs and food products in circulation to find out whether the drugs meet the safety, benefits, and quality requirements and law enforcement is based on evidence of test results, examinations and also preliminary investigations and investigations.<sup>16</sup>

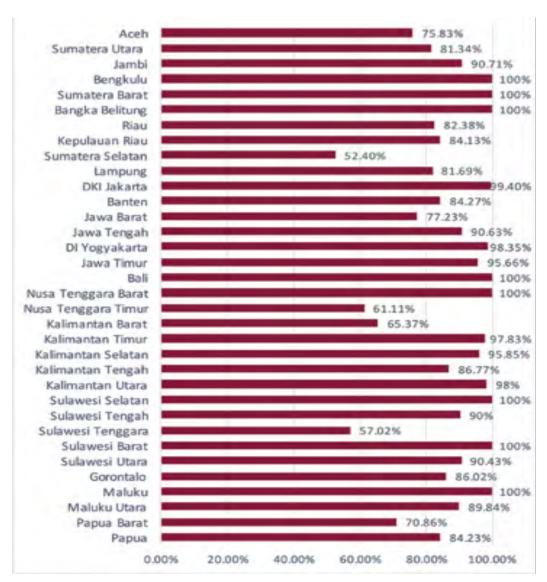
This section will be more specific about how the non-raw drug supply chain and the regulations that govern this, before going into a more specific section, I will

<sup>&</sup>lt;sup>15</sup> *ibid*.

<sup>&</sup>lt;sup>16</sup> *ibid*.

analyze the fundamentals in this matter, which is none other than the availability of the object of the problem itself. , drugs, the availability of drugs in the country is now considered to be in the red line, which can also be said to be worrying, from the data table quoted from the Directorate General of Pharmacy and Health of the Republic of Indonesia which shows the availability of drugs in every health center spread across various provinces in Indonesia as of 2017 which if the average percentage of availability is still below 90%, the following table is presente:





The average number can be considered quite good, but unfortunately, this figure is not balanced with the stabilization of the availability of each drug which has an impact on the lack of availability of some drugs in several health facilities in Indonesia. 2016, several drug items have a significant imbalance, can be seen that the availability of ORS salt can reach 95.32% in 1080 health centers out of 1133 health centers reporting, while there is also a very significant difference in the low availability of 5mg injection diazepam /ml with a figure of 53.22% which is only found in 603 health centers out of 1,133 health centers that reported it, of course, it is clear in these conditions that the even distribution of drugs to all health facilities has not achieved a good balance.<sup>17</sup>

In this case, the Government is also trying to provide affordable medicines using the E-catalog system, but in practice, the government's efforts are considered to be still not successful, refers to research conducted by Hendrawan et al in 2018 which showed that there are still some hospitals that still have problems related to emptying of drugs and lead times that are too long, on the other hand, the supply chain is also influenced by suppliers who are in default / can be called by not carrying out obligations in a contract the government goods/service procurement policy agency (LKPP) can apply sanctions for default drug providers which have been regulated in Presidential Regulation No. 54 of 2010 concerning government procurement of goods/services, but if the winner of the tender process is a single winner with a low priority price, then there will be a disincentive for LKPP in applying these sanctions., Therefore, even though the Perka LKPP has been issued, in its application the sanctions are only empty and in the field, therefore this will of course also have a very bad impact on the level of compliance of drug providers, this has been proven and seen in the poor compliance of providers. medicines at the provincial and district and city levels. This problem has prompted health facilities to look for substitute medicines at prices equivalent to e-catalogs, hence the total cost of procuring medicines has also increased.<sup>18</sup>

<sup>&</sup>lt;sup>17</sup> NF Azzahra, 'Addressing Distance Learning Barriers in Indonesia Amid the Covid-19 Pandemic' (2020) Policy Brief.[1].

<sup>&</sup>lt;sup>18</sup> *ibid*.

In addition to supporting the speed of drug distribution, the head of BPOM has also issued regulation number HK.03.1.34.11.12.7524 of 2012 regarding technical guidelines for proper and correct drug distribution procedures, but it is unfortunate according to a study conducted by the KPK in 2017, Not all pharmaceutical wholesalers (PBF) have a certificate of good drug distribution method (CDOB), with the figure that only about 304 PBFs have this certificate, while only 15% of registered centers and branches are certified.<sup>19</sup>

On the other hand, the government also stipulates to suppliers that there is only one supplier who has the opportunity to win a tender for one type of drug in the e-catalog in each province, but this is also feared to cause new problems, where when the tender winner does not fulfill the number of drugs that have been ordered. agreed, but this has also received a solution by allowing the existence of multi-suppliers and multi-year as an example of international practice, since 2018 the category in the multi-winner has been given an expansion of application to other types of drugs, which is a development of the previous regulation which can only reach for cytotoxic drugs.

The government is also trying to initiate a policy called the One gate policy, which is a system created by the government to regulate the distribution and availability of drugs through one door, one door here can be described as managing public drugs and health supplies or pharmaceutical installations. philosophically and in its meaning, it can be said that the government's policy is considered extraordinary, but if we look deeper, it turns out that the policy has many weak points, and in its implementationnnnn, this policy has not been able to reach widely and evenly in all provinces in Indonesia. Indonesia, this can be proven from research conducted by the Research and Development Agency for Health as a Health Research and Development Agency which examined 11 provinces and the results turned out that there were only 4 provinces that we're able to implement it, including West Java, East Java, NTB, and South Kalimantan. and coupled with several cities/

<sup>&</sup>lt;sup>19</sup> *ibid*.

regencies located in Papua and North Maluku, of course, this is also influenced by several problems that affect them, including the length of the bureaucratic process which hurts the realization of the health service process, especially in the field of health services. unitization, as well as the facilities and infrastructure that support the policy, have also not been fulfilled properly, the pharmacy warehouse used as storage is still very limited which has an impact on the poor effectiveness of the storage process and standardization of governance, as well as limitations on the human resources available also contribute to important points in the course of the policy, especially in the section that specifically handles the procurement process, which will affect the slowness of the procurement process.

Medical devices (lakes) are the most crucial component in health services other than medicines. However, the problem that occurs in Indonesia today is that most of the needs for medical devices in Indonesia still depend on imports. The General Chairperson of the Association of Indonesian Medical Device Manufacturers (Aspaki) stated that Indonesia relies on imported medical devices, especially imports from the United States, this is due to one of which is the domestic medical device industry which is still very small in number. Currently, the number of domestic companies that produce medical devices is only 332 companies. This can lead to a lack of supply of medicines and medical devices, especially in remote areas, The legal basis governing the licensing of medical devices include:

- 1. Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen;
- 2. Undang-Undang Nomor 11 Tahun 2008 tentang Informasi dan Transaksi Elektronik:
- 3. Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan;
- 4. Peraturan Pemerintah Nomor 72 Tahun 1998 tentang Pengamanan Sediaan Farmasi dan Alat Kesehatan;
- 5. Peraturan Pemerintah Nomor 64 Tahun 2019 Tentang Jenis dan Tarif Atas Jenis Penerimaan Negara Bukan Pajak yang Berlaku Pada Kementerian Kesehatan.

In addition, the Indonesian government, based on PERMENKO No. 6/2017 concerning the Establishment of a Goods Classification System and Imposition of Import Duty Tariffs on Imported Goods, imposes 5-30% import tax depending

on the type of medical device imported for importers of medical devices.<sup>20</sup> The Indonesian government also prohibits the entry of medical devices that have been used before or medical devices made using materials from old or used medical devices. In contrast to developed countries such as Germany, for example, which allows the import of medical devices that have been used before or medical devices made using materials from old or used medical devices to enter their country.

In addition to this, in discussing equalization efforts, The role of the government is considered very important in regulating the distribution of equity, especially those that focus on the formation of regulations to regulate the pharmaceutical and medical device industry and of course this regulation must also be adjusted and looked at from several aspects, including thinking about all human rights owned by the people in the right to health. But whether the regulation of the pharmaceutical and medical device industry in Indonesia is good in regulating the quantity of production to meet the needs of all people in Indonesia,

According to the World Health Organization (WHO), health is a state of complete mental, physical and social well-being and not merely the absence of disease or infirmity and disability. So, this health includes all aspects of human life, namely its physical and spiritual nature. However, according to Article 1 of the Law concerning health, it is stated that health is a condition of physical, mental, and social well-being and not just a state of illness or weakness. So, health covers all aspects of human life, both physical and spiritual.

Indonesia's general health condition can be influenced by several factors, namely environmental factors and health services. Meanwhile, health services also consist of several components, namely the availability and quality of health service facilities, medicines and health supplies, and health workers. Basic health service facilities, namely health centers that are strengthened by supporting health centers and mobile health centers, but the distribution and affordability of health services are also still obstacles.

<sup>&</sup>lt;sup>20</sup> Pepsi Maryarini, 'Indonesia - Country Commercial Guide Healthcare (Medical Devices & Equipment)'[1].

In Undang-Undang Pasal 1 ayat 3 states that health supplies are all materials and equipment needed to carry out health efforts. With these efforts to organize health, everyone can avoid disease. Where this is inversely proportional to reality, especially in remote areas. The government pays little attention to the supply of medicines and medical devices in remote areas, this has become a national problem since the mid-2000s until now. Of course, this problem is exacerbated by the presence of COVID-19 in Indonesia. According to the Minister of Health (Menkes) stating that there was a spike/increase in the need for medicines, the spike/increase could reach around 12 times, that this problem could arise due to economic factors, ineffective regulations that could lead to problems related to business and supply chain. Therefore, the role of the government in regulating medicines and medical devices, especially in remote areas, is to increase the capacity to produce medicines and medical devices.<sup>21</sup>

Enacting regulations regarding limits on the number of drugs that can be prescribed to patients or purchased by the public to prevent hoarding Efforts that have been made by the government in addition to increasing the production capacity of medicines and medical devices, of course, must also be accompanied by the enactment of regulations regarding the number of limits on drugs that can be consumed. prescribed for patients or to be purchased by the public to prevent hoarding, because at the time of the COVID-19 pandemic that occurred in Indonesia at this time people tended to panic buying. Panic buying is the action of people in buying an item in very large quantities because people are afraid or worried that they will not get the item so that it can make the price of goods soar / expensive.<sup>22</sup>

## Conclusion

It can be concluded that Indonesia has a fairly good legal basis to regulate the pharmaceutical and medical device industry, but unfortunately, the biggest problem

<sup>&</sup>lt;sup>21</sup> Kesehatan (n 4).

<sup>&</sup>lt;sup>22</sup> Dasrun Aprilia, Cindy Sovhie; Hidayat, 'Perilaku Panic Buying Dan Berita Hoaks Covid-19 Panic Di Kota Bandung' (2021) 10 Jurnal Communio: Jurnal Ilmu Komunikasi.[36]. <a href="https://ojs.unikom.ac.id/index.php/jipsi/article/view/3943">https://ojs.unikom.ac.id/index.php/jipsi/article/view/3943</a>.

is in law enforcement in the pharmaceutical industry, especially in the provision of sanctions for counterfeit drug dealers, which are still not severe enough to cause a deterrent effect. Meanwhile, Indonesia is still too dependent on other countries such as China and the United States in the supply of medical devices as well as in the supply of medicinal raw materials. In addition, the government's efforts so far have been on a promising path, but there is still a long way to go for the distribution of medicines and medical devices.

# **Bibliography**

#### Books

Perindustrian K, 'Membangun Kemandirian Industri Farmasi Nasional' (2021) Buku Analisis Pembangunan Industri.

#### Journal

- Aprilia, Cindy Sovhie; Hidayat D, 'Perilaku Panic Buying Dan Berita Hoaks Covid-19 Panic Di Kota Bandung' (2021) 10 Jurnal Communio : Jurnal Ilmu Komunikasi.
- Azzahra NF, 'Addressing Distance Learning Barriers in Indonesia Amid the Covid-19 Pandemic' (2020) 2020 Policy Brief.
- Dukcapil Kemendagri, 'Distribusi Penduduk Indonesia Per Juni 2021: Jabar Terbanyak, Kaltara Paling Sedikit' (2021) Dukcapil.Kemendagri.Go.Id.
- Enel Reza Hafidzan, Ery Agus Priyono DH, 'Diponegoro Law Journal' (2015) 6 Serambi Hukumfile:///Users/gia/Desktop/Policy Brief \_ Addressing Distance Learning Barriers in Indonesia Amid the Covid-19 Pandemic.pdf.
- Kesehatan M, 'Permenkes NOMOR 1191/MENKES/PER/VIII/2010' (2010) 15 Africa Education Review.
- Maryarini P, 'Indonesia Country Commercial Guide Healthcare (Medical Devices & Equipment).
- Meyer T, 'Trade Law and Supply Chain Regulation in a Post-COVID World' [2020] SSRN Electronic Journal.

# Regulation

Undang-Undang Dasar Negara Republik Indonesia, 'Undang-Undang Dasar Negara Republik Indonesia 1945' (1945).

—, 'Undang-Undang Republik Nomor 36 Tentang Kesehatan' (2009).