

## Correlation of the Obligation to Implement a Patent by a Registered Patent Owner with the Drug Production Independence Policy in Indonesia



Dian Utari<sup>1</sup>, Kholis Roisah<sup>2</sup>

<sup>1,2</sup> Diponegoro University Jl. Imam Bardjo, S.H. No 1-3 Pleburan, Semarang City, Indonesia

**ABSTRACT:** Article 20 of Law Number 13 of 2016 concerning Patents, as amended by Article 107 of Law Number 11 of 2022 concerning Job Creation, regulates the provisions regarding the obligation to implement patents in Indonesia. This amendment removes labor supply, investment retention, and technology transfer restrictions and adds provisions for importing or licensing patented products or processes. Changes in regulation regarding the obligation to implement patents have changed the rules governing patent enforcement, making it challenging to achieve self-reliance in domestic drug production. This study uses a doctrinal approach by analyzing secondary data on regulations for implementing registered patents in Indonesia, which are linked to the policy of self-sufficiency in domestic drug production. Based on the results of the study, Article 20 of the Patent Law has been amended so that Patent Holders are not burdened with the obligation to support technology transfer, maintain investment or provide employment; Article 107 of the Job Creation Law has changed the way patents are implemented by Patent Holders registered in Indonesia. Changes to these points need to be reviewed because they are considered to be contrary to the Government Policy on the Independence of the Ministry of Health's Drug Production Number 21 of 2020 The Strategic Plan of the Ministry of Health for 2020–2024, which was previously in line with Article 20 of the Patent Law.

**KEYWORDS:** Policy, Obligation, Patent, Independence, Medicine

### I. INTRODUCTION

The most basic human need is health. It is often said that health is everything and everything is worthless without health.<sup>1</sup> In order to protect and carry out the idea of health as a Human Right (HAM), the 1945 Constitution of the Republic of Indonesia requires that the population be given access to various health services.<sup>2</sup>

According to Article 28 H paragraph 1 of the 1945 Constitution of the Republic of Indonesia, everyone has the right to live in a peaceful and healthy environment and must comply with health law. This article regulates the right to health. The government specifically issued the Health Law, often known as Law Number 36 of 2009, concerning Health. The law states that everyone can lead a fulfilling life on a social and economic level if they have suitable physical, mental, emotional, and social health.

Everyone has the right to obtain health services from health institutions to achieve the highest degree of health, as stated in Article 4 of the 1945 Constitution. In addition, Article 5 of the 1945 Constitution explains more deeply the right to obtain health services, defined as having access to treatment, safe, quality, and inexpensive.

A decent degree of health is one of the fundamental rights of every person, according to the 1946 Constitution of the World Health Organization (WHO). One of the fundamental rights of every human being is the right to health care, regardless of race, religion, political viewpoint, economic background, or social standing. It can be said that everyone has the fundamental right to health, which every nation must respect regardless of their religion, political, economic, or social circumstances.<sup>3</sup>

One of the most essential components of health products related to implementing health programs for the general public is medicine. Drugs must be available, with items and quantities to meet the needs of the whole community. The government has made several policies, such as the national policy Regulation of the Minister of Health Number 189 of 2006 and the creation of a roadmap for the development of raw materials for the pharmaceutical industry (BBO) and raw materials for traditional medicines (BBOT) through Decree of the Minister of Health of the Republic of Indonesia Numbers 87 and 88 of 2013. Subsequently issued Presidential Instruction No. 6 of 2016 concerning the Growth Rate of the Pharmaceutical and Medical Devices Industry Action

<sup>1</sup> Indra Perwira, *Health as a Human Right, in Bagir Manan, et.al., Dimensions of Human Rights Law*, PSKN FH UNPAD, Bandung, 2009., p. 138

<sup>2</sup> Hafid Abbas et al., *Handbook of Human Rights for Doctors and Patients in Preventing Medical Malpractice*, Human Rights Research and Development Agency, Ministry of Law and Human Rights of the Republic of Indonesia, 2008., p. 1

<sup>3</sup> Firdaus, *Fulfillment of the Right to Health for Persons with Schizophrenia in the Special Region of Yogyakarta (Rights Fulfillment on Health of People With Schizophrenia In Special Region of Yogyakarta)*, Scientific Journal of Legal Policy Vol 10, 2016, p. 6.

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Plan for the Development of the Pharmaceutical and Medical Devices Industry, that national investment in the pharmaceutical industry supports the mission of Assured Access, Self-sufficiency in Drug Production and Health Service Facilities.<sup>4</sup>

Drugs, as the most essential component in the world of health, consist of 2 types: patent and generic drugs. A patented drug grants its owner the right to use it exclusively for an uninterrupted period or permits the use of the drug by others.<sup>5</sup> With this exclusive right, the patent holder is obliged to innovate in the country of origin of the patent, as well as in other countries where the invention has been registered as a patent.

Pharmaceutical product patent registration functions to ensure that the manufacturer will be compensated for all research and development costs required during the validity period of the patent.<sup>6</sup> Producers or persons in charge of patents are obliged to manufacture, distribute, make use of patent contents economically, and warn other parties that they are not allowed to manufacture these drugs due to the existence of exclusive rights to patented drugs.<sup>7</sup>

Indonesia is one of the countries that has implemented the obligation to implement patents (Local Working Requirements) in its Patent Law. It is done to facilitate the advancement and transfer of technology, expand industrial capacity, manage the economy, and other related purposes. However, currently, the criteria for utilizing technology transfer, investment, and job creation should be included by the LWR regulations in Article 20 of Law No. 13 of 2016 concerning Patents, later amended to become Article 107 of Law No. 11 of 2020 concerning Job Creation. Article 107 of the Job Creation Law explains what is categorized as LWR, including importing or obtaining a license for a product and process. Provisions for the implementation of patents in Article 20 of Law no. 13 of 2016, which was amended contrary to Article 27 of the TRIPS Agreement, which states that patents must be available and patent rights must be respected regardless of the location of the owner, the technology sector, or whether the product is imported or produced locally.<sup>8</sup>

Amendments to the Regulation on the Obligation to Implement Patents (LWR), which imports of patented drugs can replace, can complicate the development of self-sufficiency in domestic drug production which is feared will make it difficult for the public to obtain patented drugs and can increase the cost of patented drugs. Therefore, the author is interested in discussing the regulation of the obligation to implement patents in Indonesia and its correlation with the drug production independence policy.

The study on the regulation of patent implementation obligations in Indonesia and its relation to the policy of self-sufficiency in drug production in this article differs from previous discussions or studies conducted in this field. Rahayu et al.'s article focuses on the need for governments to uphold human and civil rights to health care as a component of their responsibilities and the impact changes in implementing patent provisions or LWRs have on government policy obligations in health-related laws.<sup>9</sup> Article by Yustisiana Susila Atmaja et al. regarding the legal protection of drug patents intended for government use, the department studies and analyzes the enforcement of drug patents by the government and the legal protection of drug patents for government patents.<sup>10</sup> Gabriela Madeline Hutaaruk et al. discuss the position of Patents by the Government on COVID-19 from the perspective of Indonesian law and discussion of the standards that must be met for Government Patents to protect public health and their exclusive property rights.<sup>11</sup> This article focuses more on discussing the regulation of the obligation to implement patents by registered patent owners in Indonesia and the correlation of the obligations to implement patents by registered patent owners with the policy of self-sufficiency in drug production.

## II. FORMULATION OF THE PROBLEM

In the above context, this paper will focus on the following:

1. What is the regulation of the obligation to implement patents by registered patent owners in Indonesia?
2. What is the correlation between a registered trademark owner's obligation to implement a patent and the Drug Production Independence Policy?

## III. RESEARCH PURPOSES

This article aims to:

1. Know and describe the arrangement of obligations to implement patents by registered patent owners in Indonesia.

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<sup>4</sup> Rahayu, Kholis Roisah, Diastama Anggita Ramadhan, Leony Sondang Suryani, *The Influence of Regulations on the Obligation to Implement Patents Against the Policy of State Obligations in Fulfilling Accessibility Rights to Patented Drugs*, Scientific Journal of Legal Policy, Volume 16 No 1, 2022, p. 32.

<sup>5</sup> Gaetan de Rassenfoss & Kyle Higham, *Decentralizing the Patent System*, Government Information Quarterly journal, 2020, p. 4.

<sup>6</sup> Edward James Sinaga, *Implications of Registered Foreign Patents for Inventions in the Field of Technology According to Law Number 14 of 2001 Concerning Patents*, Scientific Journal of Legal Policy Vol 7, 2013, p. 14.

<sup>7</sup> Selvi Sinaga, *Patent Threats to Public Health and Safeguard Trips*, Intellectual Property Rights Articles, 2015, p. 6.

<sup>8</sup> *Academic text of the Draft Law on Job Creation* P. 23.

<sup>9</sup> Rahayu, Kholis Roisah, Diastama Anggita Ramadhan, Leony Sondang Suryani, *Op.Cit.*, p. 19.

<sup>10</sup> Yustisiana Susila Atmaja, Budi Santoso, Irawati, *Legal Protection of Pharmaceutical Patents for Governmental Use of Patents*, Journal of Legal Issues, Volume 50 No.2, April 2021, p. 196-208.

<sup>11</sup> Gabriela Madeline Hutaaruk, Ahmad M Ramli, Tasya Safiranita Ramli, *Implementation of Patents by the Government for Covid-19 Vaccines and Drugs in the Pandemic Period Based on Indonesian Law and Trips-WTO*, Journal of Sosio Humanities Science, Volume 6 No 1, 2021, p. 538-550.

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2. Describe and analyze the correlation of registered brand owners' obligation to implement patents with the Drug Production Independence Policy.

### IV. RESEARCH METHODS

This paper uses the normative legal research method because the focus of the study departs from changes in a legal regulation/statutory regulation. The data used is secondary data consisting of primary legal sources, such as applicable laws and regulations related to the obligation to implement patents and the policy of self-reliance in drug production. In contrast, secondary legal material consists of principles of patent law, especially those related to the obligation to implement patents and the concept of independence policy: drug production and similar studies from various reference books and journals.<sup>12</sup>

### V. DISCUSSION

#### 1. Arrangements for the Obligation to Implement Patents by Registered Patent Owners in Indonesia

According to Article 28C paragraph (1) of the 1945 Constitution, Indonesia has recognized the need for technology as a human right. "Everyone has the right to develop himself through meeting his basic needs, the right to education, the right to knowledge and technology for advancing human welfare." The existence of Article 28C paragraph (1) of the 1945 Constitution is believed to have a strong connection with patent regulation.

Patents are generated by analyzing human intellectual capacity using technology and science. According to Mahendra, Patents is the result of using technology and science to enhance human knowledge.<sup>13</sup> Patents are an essential form of intellectual property in protecting innovation in technology. In addition, patents also demonstrate the existence of a modern industry that focuses on advanced technology and high-quality standards. For the technology and goods developed, patent holders can be granted rights by the government, either for their use or transfer to other parties. Furthermore, patents also serve as a sign of a contemporary industry focusing on cutting-edge technology and high-quality standards. The government may grant exclusive rights to patent holders to use new technologies and productions created, both for its purposes and for transferring such rights to other parties.<sup>14</sup>

Through Law Number 13 of 2016 concerning Patents, the Government of Indonesia has established specific limitations to protect patent rights. By Article 20 of the Patent Law, patent holders are required to produce in Indonesia. According to this clause, every person who has requested and been granted patent protection from Indonesia at home and abroad is obliged to manufacture or process in Indonesia. They must also absorb investment, create jobs, or help transfer technology.<sup>15</sup>

Law No. 13 of 2016 has been discussed, especially in Article 20, among international investors and the business world. In 2016, when the Patent Bill was being discussed at the Indonesian Parliament Building, Article 20 was rejected by the US Chamber of Commerce. According to the United States Chamber of Commerce, this article will cause many problems for international businesses with patents in Indonesia.<sup>16</sup> As a member of the WTO, Indonesia complies with international agreements regulating trade between countries, such as the TRIPS agreement. It is related to Article 20 of Law No. 13 of 2016 concerning Patents and Subsequent Agreements. A nation's national priorities are not accurately reflected by these international agreements.<sup>17</sup>

According to Teuku May Rudy, national priorities are tasks that must be completed related to the needs of a country.<sup>18</sup> In the context of national leadership, specific goals must become part of the nation's agenda in the hope of achieving positive development.<sup>19</sup> A country needs to use internal cooperation to modernize its country and achieve national goals. It also applies to the Intellectual Property Rights (IPR) sector because IPR issues have an essential role in international trade, especially international trade in goods. IPR is a crucial indicator in measuring a country's economic growth.

The creation of public welfare is the goal of Article 20 of Law Number 13 of 2016 concerning Patents. Investors are required to set up a business, transfer technology, and cultivate a work environment to register patents. However, Article 107 of the Job Creation Law has replaced and revoked the responsibility imposed on patent holders for the manufacture or processing as referred to in Article 20 of Law Number 13 of 2016 concerning Patents.

<sup>12</sup> Johnny Ibrahim Jonaedi Efendi, *Normative and Empirical Legal Research Methods*, Jakarta: Prenada Media, 2018, p. 35.

<sup>13</sup> Mahendra, *Patent Law Legal Protection for Inventors and Means of Encouraging Invention*, Jakarta: Sinar Harapan Library, 1991, p. 2.

<sup>14</sup> Saidin, *Legal Aspects of Intellectual Property Rights*, Jakarta: Raja Grafindo, 2015, as quoted indirectly by Fahnizar Dandy Hedyanto et al., *Obstacles to Regulatory Obligations of Patent Holders by Foreign Investors in Indonesia*, *Journal of Notary* 14, No. 1, May 2021, p. 617.

<sup>15</sup> Muh Ali Masnun et al., *Problems Setting Obligations of Patent Holders to Make Products or Use Processes in Indonesia*, *Journal of Law Ius Quia Iustum* 2, No. 2, May 2019, p. 328.

<sup>16</sup> Klik Legal.com, *American Chamber of Commerce Objection Story Against Article 20 of Law Number 13 of 2016 concerning Patents*, 20 December 2021, <https://kliklegal.com/kisah-keberatan-kamar-dagang-amerika-against-article-20-uu-patent/>.

<sup>17</sup> Tri Setiady, *Harmonization of the TRIPS Agreement Principles in Intellectual Property Rights with the National Interest*, *Journal of Fiat Justicia* 8, No. 4, October 2014, p. 604.

<sup>18</sup> Muhammad Syahril, *The Role of the Intermediate Directorate General of Customs and Excise Smuggling of Cross-Country Methamphetamine at Cross-Border Posts in Entikong District, Sanggau Regency, West Kalimantan Province*, *Journal of International Relations, Diponegoro University* 4, No. 3, August 2018, p. 493.

<sup>19</sup> Maria Dhiu et al., *Indonesian Government Policy Analyst on Moratorium on Indonesian Migrant Workers to the Middle East in 2015*, *Journal of Global Insight* 6, No. 2, April 2021, p. 3.

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Article 20 of Law Number 13 of 2016 concerning Patents as a principle of "local working patent requirements." According to Prof. Agus Sardjono, the principle of local working is a payment made by the state to patent holders in return for using their innovation in the patenting country.<sup>20</sup> The local working principle has been applied by America since 1989 until now. Indonesia has also adhered to the local working principle since the first Patent Law was enacted until Law Number 13 of 2016. Applying the local working principle to Law Number 13 of 2016 concerning Patents stipulates sanctions for patent revocation if the holder's obligations are not carried out. By applying the local working principle, countries that follow this principle can ask patent holders (proper recipients) to manufacture their products within the jurisdiction of the patenting country.

The implementation of patents by registered patent holders in Indonesia, which had previously been regulated in Article 20 of Law Number 13 of 2016, has changed after the passage of the Job Creation Law. In addition, modifications to the patent rules on the Job Creation Law could cause new problems. For example, patent holders are now only required to implement their patents in Indonesia without being subject to obligations to support technology transfer, absorb investment, or create jobs. Under these conditions, Indonesia may face difficulties because investors need to provide significant benefits. Furthermore, Article 20 of Law Number 13 of 2016 is considered to directly impact patent holders, such as having to extend the processing time. The explanation regarding "the obligation of a patent holder in producing or processing in Indonesia" in Article 20 of Law Number 13 of 2016 concerning Patents is insufficient. Further explanation regarding time limits, scope, and types of patents similar to those in Indonesia, whether made or processed, is needed to create legal certainty.

Decree of the Minister of Health No. 1120/Menkes/PER/XII/2008 concerning Amendments to the Decree of the Minister of Health No. 1010/Menkes/PER/XI/2008 regarding drug registration is not in line with changes to Article 20 of Law No. 13 of 2016 concerning Patents. Meanwhile, the Minister of Industry No. 16 Decree concerning the Procedures for Calculation of Domestic Ingredients in Health Products 2020 (Ministry of Industry Regulation No. 16 of 2020) stipulates that all medicines in Indonesia must be produced domestically for pharmaceutical products. Based on existing understanding, the government wants to issue Minister of Industry Regulation Number 16 of 2020 to encourage independence and boost the competitiveness of the local pharmaceutical sector. Indonesia wants to be independent in the pharmaceutical sector, especially in manufacturing pharmaceutical raw materials. Therefore, regulations governing the sector's local content level are applied. The purpose of this regulation is to motivate and encourage workers in the industry to establish a national raw material industry.<sup>21</sup>

In a short time, large pharmaceutical companies are estimated to create space for a monopoly on drug patents through amendments to Article 20 of Law No. 13 of 2016 concerning Patents. According to some observers, this could make it difficult for Indonesians to obtain medicine. This problem arises because pharmaceutical companies with patents in certain countries can enjoy monopoly rights for a certain period. The Patent Holder has full access to information about the product, including product origin, price, and supplier, and determines the country where the product is marketed.

### 2. Correlation of Obligation to Implement a Patent by Registered Brand Owners with Drug Production Independence Policy

The government's drug production independence policy is regulated in the Ministry of Health's Strategic Plan for 2020-2024 in Permenkes No. 21 of 2020, where the goal of ensuring drug availability, drug production independence, and quality is the main thing in national development. The strategic objectives of the mission are:

- a. Realization of Increasing the Availability of Equity and Affordability of Medicines and Vaccines;
- b. Realization of Independence in Pharmaceutical Preparations and Medical Devices;
- c. Guaranteed Safety, Quality Benefits of Medical Devices;
- d. Increase independence and use of domestic pharmaceutical products and medical devices.<sup>22</sup>

In order to realize the national industry as a support and driving force for the national economy, a draft Government Regulation (RPP) has also been prepared. In particular, a solid industrial structure, competitive, based on innovation and technology, synchronization of upstream industry support, and support for developing medicinal raw materials are all considered. It is all part of the effort to realize drug production independence. Herbal preparations, spices, cephalosporins, amlodipine, pharmaceutical grade glucose (for infusion), amoxicillin, glimepiride/metformin, paracetamol, biologics, and vaccines are some of the priority ingredients used in the manufacture of drugs.<sup>23</sup>

Domestic production has fulfilled 70% of the national drug needs in the pharmaceutical sector. However, the pharmaceutical sector must still import up to 95% of its raw materials. These drug components contribute 25-30% of the total cost of drug production, so interventions on these components can harm drug prices. Through coordination and cooperation by the Ministry of

<sup>20</sup> Agung Prakoso, *Impact of Eliminating Article 20 of Law Number 13 of 2016 concerning Patents on Access to Drugs*. <https://igj.or.id/article-monitoring-diskusi-dampak-penghapusan-pasal-20-uu-paten-pada-access-obat/>.

<sup>21</sup> Rina Anggraeni, *Key to the Independence of the Pharmaceutical Industry, Calculation of Domestic Content Amended*, 2021, <https://ekbis.sindonews.com/read/91784/34/key-independence-industry-pharmaceutical-calculation-in-country-content-modified-1594019220>.

<sup>22</sup> Rahayu, Kholis Roisah, Diastama Anggita Ramadhan, Leony Sondang Suryani, *Op.Cit.* p. 32.

<sup>23</sup> Indonesian Ministry of Industry, *National Industrial Development Master Plan 2015 - 2035*. Jakarta: Indonesian Ministry of Industry; 2015.



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Health, 50 types of drugs were developed and produced in Indonesia in 2019. Among these drugs, there is one type of biotechnology drug, one type of vaccine, 36 types of natural cosmetics, and 12 types of cosmetics-related health products.<sup>24</sup>

Fifty-three cosmetics, including 1 biotechnology product, 1 type of vaccination, 39 natural goods, and 12 chemical drugs, were introduced in Indonesia in 2019. 34 different categories of raw materials, consisting of 6 types of biopharmaceuticals, 3 types of vaccines, 13 types of components natural ingredients, and 12 types of chemicals (APIs), are expected to be developed between 2020 and 2021. In addition, 47 different types of raw materials are expected to be developed between 2022 and 2025, including 4 biopharmaceuticals, 10 types of vaccines, 17 types of natural ingredients, and 16 types of chemicals (API).<sup>25</sup>

Indonesia's dependence on imports of raw materials for the pharmaceutical industry is one of the limiting factors for independent drug production. Since Indonesia imports more than 90% of the raw materials used to make medicines, these countries include India, China, the United States, and Europe. Products made by the pharmaceutical industry currently contain more than 92.1% of chemicals. The market share of the downstream sector, which consists of product manufacturing companies, is only around 4%. Due to the country's low level of drug production, the result is a strong demand for imported drugs. 95% of the raw materials used to manufacture drugs in Indonesia are imported raw materials. Raw materials are imported from China (60%), India (30%), and the European Union (10%).<sup>26</sup>

The government issued several policies, including Presidential Instruction Number 6 of 2016 concerning Tariffs for the Development of the Pharmaceutical and Health Industry and Permenkes Number 17 of 2017 concerning Action Plans for the Development of the Pharmaceutical and Health Sector. The government also formed 14 companies between other countries' pharmaceutical and health industries, including the United Arab Emirates, Hong Kong, Korea, India, Israel, and other countries. The joint partnership between the food and pharmaceutical sectors is expected to produce state-of-the-art cosmetics and healthcare products that will benefit the pharmaceutical sector as a whole.<sup>27</sup>

Article 20 of Law No. 13 of 2016 concerning Patents is regulated regarding the obligation to implement patents in Indonesia:

- 1) The patent owner must produce the goods or use the process in Indonesia.
- 2) Producing goods or using processes in Indonesia by paragraph (1) must support technology transfer, create jobs, and support technology transfer.

Article 107 of Law Number 11 of 2020 Concerning Job Creation which replaces Article 20 of Law Number 13 of 2016, changes the requirements for technology transfer, investment absorption, and job creation. In addition, steps that fall under the LWR category have been introduced, such as the import or application for a patent license for a product or process.

Before the changes to the LWR policy in Article 20 of the Patent Law No. 13 of 2016, particularly in drug patents, this policy is generally in line with the drug production independence policy. Implementation of requirements to enforce pharmaceutical patents will support independent domestic pharmaceutical production, more affordable patented drugs (availability and lower prices), higher quality and more effective drugs, and development of the pharmaceutical industry (transfer of innovative drug technology).<sup>28</sup>

## VI. CONCLUSION

Article 20 of Law Number 13 of 2016 concerning Patents, amended by Article 107 of Law Number 11 of 2020 concerning Job Creation, regulates the obligation to implement patents. Due to this change, registered patent holders in Indonesia are no longer required to facilitate technology transfer, absorb investment, or create jobs. Amendments to Article 20 of Law Number 13 of 2016 concerning Patents are expected to exacerbate the situation of drug access and the independence of the pharmaceutical sector in Indonesia.

Regulations governing drug production independence can be found in Permenkes No. 21 of 2020, linked to the 2020–2024 Strategic Plan of the Ministry of Health. Previously, the government's policy regarding independent drug production was in line with Article 20 of Law Number 13 of 2016 concerning Patents. Patent implementation will be mandatory for patent owners registered in Indonesia to support the expansion of the pharmaceutical industry, investment, and independence of domestic drug production. However, the implementation of patent implementation obligations can be replaced by imports in Article 107 of the Job Creation Law; this is undoubtedly contrary to the policy of self-sufficiency in domestic drug production. Therefore changes to the regulations on the obligation to implement patents contained in the Job Creation Law need to be reviewed.

<sup>24</sup> Ministry of Health, *Action Plan Book for Pharmaceutical Production and Distribution Activities*, Directorate General of Pharmaceuticals and Medical Devices, Jakarta: Ministry of Health, 2020, p.12.

<sup>25</sup> Ministry of Health of the Republic of Indonesia, *Pharmaceuticals and Medical Devices Profile*, 2019.

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<sup>27</sup> Rahayu, Kholis Roisah, Diastama Anggita Ramadhan, Leony Sondang Suryani, *Op.Cit.* p. 33.

<sup>28</sup> *Ibid.*, 36.

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