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THE EFFECT OF THE ARRANGEMENT TO IMPLEMENT LOCAL WORKING OF PATENTS ON THE POLICY OF STATE'S RESPONSIBILITY IN FULFILLING PUBLIC ACCESSIBILITY RIGHTS TO PATENT MEDICINE

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ABSTRACT

The amendment of Article 20 of Law Number 13 of 2016 concerning Patents through Article 107 of Law Number 11 of 2020 concerning Job Creation raises concern. The public shows concern that their accessibility rights to get medicines in order to fulfill the right to health will be restricted. There is a conflict of interest between Government of Indonesia's obligation to fulfill its citizen's right to access medicine and its commitment to international agreements. This study used a doctrinal approach by analyzing secondary data. Specifically, it analyzed various policies related to the provision of medicines by government as part of it s obligations to fulfill the right to health of its citizens. The results of this study conclude that the state's obligation to fulfill the accessibility of patent medicine is carried out through several policies. These policies include the policy on the development of the pharmaceutical industry for medicine raw materials and innovative medicine. There is also the policies on ensuring the safety and efficacy of medicine through medicine registration. The government also fulfills the accessibility of patent medicine through the policies for medicine availability in urgent circumstances with the implementation of patent held by the government (governmental use). In addition, there is also the policy of independence in the use of domestically produced medicine. The policy on the obligation to apply local patent that can be replaced by importing does not really affect the availability of patent medicine. It is because the technological capabilities of the pharmaceutical industry are still limited to the ability to formulate medicine. Indonesian pharmaceutical industry does not yet have the ability for the development of innovative medicine. Furthermore, the government issues various policies and regulations to facilitate the acceptance of qualified generic medicine. It is done to meet the needs of the community, as well as to fulfill the right to health for the community as part of the state's obligations. Indonesia as a country rich in bio-diversity needs mandatory policies for national pharmaceutical companies to develop raw materials for biopharmaceutical medicine.
Keywords: policy; right to health; patent medicine

INTRODUCTION

Background

The right to health is part of human rights. Health problems do not stand alone but are closely related to other factors in human life. Political, economic, legal, educational, social and cultural aspects greatly affect the quality of individual and community health in a country.[1]

1 Marlies Hesselman, *Socio-Economic Human Rights in Essential Public Services Provision*

The international commitment to guarantee the right to health is contained in Article 25 paragraph (1) of the Universal Declaration of Human Rights (UDHR). Meanwhile, the affirmation of the state's obligation to take appropriate steps to fulfill the right to health is contained in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). It states that: *The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the State Parties to the present Covenant to achieve the full realization of this right…'*.

To achieve the highest standard of health is a real effort to meet a decent standard of living for humans.[2] In Indonesian context, the right to health is recognized as a constitutional right as regulated in Article 28 H paragraph (1) of the 1945 Constitution of the Republic of Indonesia. It states that: *Every person is entitled to live prosperous physically and spiritually, to have a place to reside, and to acquire a good and healthy living environment as well as be entitled to obtain healthcare*. Specifically, the right to health is regulated in Law Number 36 Year 2009 concerning Health (hereinafter referred to as the Health Law). Article 1 point 1 of Health Law provides an understanding that what is meant by health is *a healthy state, both physically, mentally, spiritually and socially that allows everyone to live socially and economically productive*. Meanwhile, the definition of the right to health can be found in the Elucidation of Article 4 of Health Law. It states that: *The right to health referred to in this article is the right to obtain health services from the health service facilities in order to realize the highest quality of health*. Furthermore, Article 5 of the Health Law further explains in detail that the right of access to health includes the same right in obtaining access to resources in the health sector (paragraph 1). These rights include the right to safe, qualified and affordable health services (paragraph 2).

The right to health accessibility is a part of the basic rights that belongs to every individual as a human being. It is contained in the Preamble of the World Health Organization (WHO) Constitution 1946 which states: *The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. without distinction of race, religion, political belief, economic or social conditions*. Thus, it can be said that the right to health accessibility is one of the fundamental rights owned by every individual that must be respected and fulfilled by the state regardless of ethnicity, religion, political background, economy or social conditions.[3]

One of the main factors in the health system is the availability of good quality and affordable medicine, both in terms of price and in terms of the number of medicine circulating in the community. There are two types of medicine, namely generic medicine and patent medicine. The existence of a patent status on medicine gives exclusive rights for the patent owners. These rights include the ability for the patent owners to produce their own invention for a certain period of time or give approval to another party to produce their invention.[4] With this exclusive right, the patent owner has

(Oxfordshire: Routledge, 2017) Page 48.

2 Sholahuddin Al-Fatih & Felinda Istighfararisna Aulia, "Tanggung Jawab Negara Dalam Kasus Covid-19 Sebagai Perwujudan Perlindungan Ham," *JURNAL HAM* Vol. 12 No (2021) Page 349-366.

3 Firdaus, "Pemenuhan Hak Atas Kesehatan Bagi Penyandang Skizofrenia Di Daerah Istimewa Yogyakarta (Rights Fulfillment on Health of People With Schizophrenia In Special Region of Yogyakarta)," *Jurnal Ilmiah Kebijakan Hukum* Vol 10, No (2016) Page 87-103.

4 Ga´etan de Rassenfoss & Kyle Higham, "Decentralising the Patent System," *Government Information Quarterly journal* (2020), www.elsevier.com/locate/govinf https://doi.org/10.1016/j.giq.2020.101559 Page 56.

the obligation to produce their invention in the country where the patent rights originate and or in other countries where the invention is registered as patent.[5]

The patent registration of medicine aims to ensure that the research and development costs required by the manufacturer can be covered during the period of patent protection (minimum twenty years)[6]. With the existence of exclusive rights arising from patent status, the producer or patent owners of the medicine have the right to produce, distribute, exploit economically and prohibit third parties who are not authorized to produce their medicine during the period of patent protection.[7]

The existence of patents as a part of Intellectual Property Rights has the minimum standards as regulated by the World Trade Organization (WTO) for its member countries in The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).[8] Indonesia is one of the WTO member countries. Therefore, it has become a logical consequence for Indonesia to balance the national legal provisions with WTO provisions, including TRIPs.[9]

Another factor causing the importance of this adjustment is as a logical consequence of Indonesia's involvement in international trade in which TRIPs itself requires the elimination of the trade discrimination through national laws and regulations.[10] Undoubtedly, this has an impact on the availability of patent medicine and the high price of patent medicine circulating in developing countries.[11] To overcome this, developing countries encourage the implementation of Local Working Requirements (LWR) so that further dissemination and development of technology, technology transfer, job creation, industrial capacity increase, offset of payments balance and economic independence can be realized.[12] Consequently, if this obligation is not carried out, the patent which is owned can be deleted or a mandatory license is implemented.[13]

Indonesia is one of the countries that regulates LWR policies in its Patent Law in Law Number 6 of 1989, Law Number 13 of 1997, and Law Number 14 of 2001 to Law Number 13 of 2016 concerning Patents (Patent Law). Article 20 of Law Number 13 of 2016 concerning Patents states that: (1) Patent holders are required to manufacture products or apply the process in Indonesia; and (2) The making of product or applying the process as referred to in paragraph (1)

5 Marketa Trimble, "Patent Working Requirements: Historical and Comparative Perspectives," *UC Irvine Law Review* Vol. 6 (2016): Hlm. 484.

6 Edward James Sinaga, "Implikasi Paten Asing Yang Telah Terdaftar Atas Invensi Di Bidang Teknologi Menurut UU Nomor 14 Tahun 2001 Tentang Paten," *Jurnal Ilmiah Kebijakan Hukum* Vol 7, No (2013) Page 25.

7 Selvi Sinaga,"*Ancaman Paten Terhadap Kesehatan Publik Dan Safeguard Trips*, *Artikel Hak Kekayaan Intelektual"*,https://m.atmajaya.ac.id/web/KontenUnit.aspx?gid=artikel-hki&ou=hki&cid=ancaman-paten-terhadap-kesehatan-publik-dan-safeguards-trips, accessed 20 November 2022.

8 Paul A. David, "Intellectual Property Institutions and the Panda's Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History, in (Mitchel B. Wallerstein et Al. Eds.,).C," in *Global Dimensions of Intellectual Property Rights in Science and Technology* (Washington DC: National Academies Press, 1993), Page 158.

9 Ahmad Jazuli, "Settlement of Application for Patent Registration in Public Service Improvement," *Jurnal Ilmiah Kebijakan Hukum* Vol 12, No (2018) Page 243-257.

10 Jamilus, "Analysis Of The FunctionAnd Benefits Of WTO For Developing Countries (Especially Indonesia)," *Jurnal Ilmiah Kebijakan Hukum* Vol 11, No (2017) Page 209.

11 Martin J. Adelman, *Case and Material on Patent Law, Second Edition* (St.Paul: West Group, 2003) Page 79.

12 M Halewood, "Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law," *Osgoode Hall Law Journal* Vol. 35 (1997) Page 249.

13 Paul Champt and Amir Attarant, "Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.- Brazil Patent Dispute," *The Yale Journal of International Law* Vol. 27 (2002): Page 370.

must support technology transfer, investment absorption and/or job creation. Unfortunately, the LWR arrangement in Article 20 of the 2016 Patent Law was later amended by Article 107 of Law Number 11 of 2020 concerning Job Creation (UU Cipta Kerja). This amendment eliminates the requirements for technology transfer, investment absorption and job creation. This article actually adds provisions that are categorized as LWR, namely importing or carrying out product or process patents. The changes in the regulation state that the obligation to implement patents (LWR) can be replaced by importing patent of pharmaceutical product. Consequently, it can eliminate the opportunity to develop patent pharmaceutical medicine that is domestically produced. The assumption is when a patent medicine is produced domestically, the medicine is cheaper. In addition, it allows the transfer of technology to manufacture patent medicine. The cheaper paten medicine can open wider access for the public to get the patent medicine which all this time considered more efficacious than the generic one. In addition, the high cost of patent medicine can cause problems related to the obligation of the state in the field of human rights to respect, fulfill and protect the human rights of every citizen. This includes the right to health, in particular, to ensure the availability of cheap and affordable patent medicine that is accessible to the general public.

The discussion in this article is different from the previous discussions or studies on the obligation to implement patents and health access rights. Lidya Seri Muis' articles[14] discussed the accessibility of patent medicine for the public. It highlighted the legal ratio of the right to the accessibility of patent medicine for the public and the comparison of the right to access medicine for the community in international agreements and patent regulations in Indonesia. It also reviewed and evaluated the issue of regulating the patent holders' obligation to manufacture products or apply the process in Indonesia.

Ali Masnun and Dina Roszana's article[15] entitled *The Issue of Regulating the Patent Holders' Obligation to Manufacture Products or Apply the Process In Indonesia* discussed reviewed and evaluated the issue of regulating the patent holders' obligation to manufacture products or apply the process in Indonesia. An article written by Yustisiana Susila Atmaja et al,[16] concerning *Legal Protection of Pharmaceutical Patent for Governmental Use of Patent*, reviewed and analyzed the implementation of patent for pharmaceutical product by the government. In addition, this article also analyzed the legal protection of the patent holders of pharmaceutical product on the implementation of patent held by the government. This article focuses more on discussing the policy of state obligations in fulfilling health access rights as part of human rights. Furthermore, this article analyzes the implications of the regulatory changes regarding implementing patent or LWR on the state's obligation policy in fulfilling health access rights to patent medicines.

Research Questions

This article will explore more about:

1. How is the policy of fulfilling the right to health in Indonesia as part of the state's obligations implemented?
2. How do the regulatory changes on the obligation to implement patents (LWR) affect the policy of state responsibility

14 Lidya Seri Muis, "Hak Aksesbilitas Obat Paten bagi Masyarakat," *Pranata Hukum* Vol.2, No.1, Februari 2019: 39.

15 Muh Ali Masnun dan Dina Roszana, "Persoalan Pengaturan Kewajiban Pemegang Paten untuk Membuat Produk atau Menggunakan Proses di Indonesia", *Jurnal Hukum IUS QUIA IUSTUM*, NO. 2 VOL. 26 MEI 2019: 326 - 348

16 Yustisiana Susila Atmaja, Budi Santoso, Irawati, "Perlindungan Hukum Terhadap Paten Farmasi Atas Pelaksanaan Paten Oleh Pemerintah (Govermental Use)", *Masalah-Masalah Hukum*, Jilid 50 No.2, April 2021: 196-208

in fulfilling public accessibility rights to patent medicine?

Objectives

This article aims to:

1. Describe and analyze policies to fulfill the right to health in Indonesia as part of the state's obligations.
2. Describe and analyze the effect of regulatory changes on the obligation to implement patents (LWR) on the policy of state responsibility in fulfilling public accessibility rights to patent medicine

Research methods

This study used doctrinal approach by conducting literature study on secondary data consisting of primary legal materials and secondary legal materials. The primary legal material was in the form of laws and regulations (Law Number 36 of 2009 concerning Health and its derivative regulations and Law Number 13 of 2016 concerning Patent and their derivative regulations). Meanwhile, the secondary legal material was in the form of concepts, principles of human rights law related to the right to Health. Patent Law is mainly related to the obligation to implement patent and similar studies from various reference books and scientific journals.

This paper conducted a qualitative analysis which is based on the principles, doctrines of human rights, and patent protection. Furthermore, it also used the utilitarian theory or the expediency theory towards primary legal materials which are in a form of all policies and laws and regulations related to the protection of human rights, especially the fulfillment of the right to medicine accessibility as a sub-system of the rights to gain proper health for Indonesian as a result of the amendment to Article 20 of Law Number 13 of 2016 concerning Patent.

DISCUSSION

Policy on the Right to Health as a Human Right.

According to Article 1 of the Health Law, health means a healthy state, physically, mentally, spiritually and socially that allows everyone to socially and economically live productive lives. The right to health is part of the basic rights that every individual owns as human being. It is because the right to health is one of the essential rights besides the right to life. Healthy humans can do any activities that allow them to easily access other human rights. Then, building health is supported by various related factors, including social, cultural, economic, which are dynamic and complex.[17]

Fulfilling the basic needs of the community for health is the main role of the state as a logical consequence of the recognition of health as a form of human rights.[18] In the context of human rights, the right to health is included in the second and third generations of human rights. This is related to 2 (two) points of view, namely individual health or public health. If the right to health is related to individual health, then this right is classified along with economic, social and cultural rights. Meanwhile, if the right to health is interpreted as public health, then it will be categorized as the right to development.[19]

The right to health is part of human rights that must be protected and fulfilled by the state as regulated in Article 25 of the Universal Declaration of Human Rights (UDHR) which states:

17 Rifatul Hidayat, "Hak Atas Derajat Pelayanan Kesehatan Yang Optimal," *Syariah Jurnal Hukum Dan Pemikiran* Volume 16 (2016). hlm. 128.

18 Mikho Ardinata, "Tanggung Jawab Negara Terhadap Jaminan Kesehatan Dalam Perspektif Hak Asasi Manusia," *JURNAL HAM* Vol. 11 No (2020) Page 323.

19 Muladi, *Sumbang Saran Perubahan UUD 1945* (Jakarta: The Habibie Center, 2004) Page 83.

*Everyone has the right to a standard of living which is adequate for the health and the well-being of himself and his family, including the right to food, clothing, housing and health services, necessary social services, as well as the right to security when unemployed, sick, disabled, abandoned by spouse, old age, or other conditions that result in a decline in the standard of living that occur beyond their contro*l.

The assurance for this right is also listed in the Opening of the World Health Organization (WHO) Constitution 1946 which reads:*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions.*[20] This means that the right to health as one of the fundamental rights owned by every individual must be respected and fulfilled by the state regardless of ethnicity, religion, political background, economy or social conditions.[21]

Furthermore, Article 12 paragraph (1) of the International Covenant on Economic, Social and Cultural Rights states that *Everyone has the right to enjoy the highest attainable standard of physical and mental health". Health is one of the basic human needs*. Since the right to health is so important, it is often said that health is not everything, but without health everything is meaningless.[22]

The provision of the right to health as a fundamental human right was later highlighted in the General Comment of the Committee on Economic, Social and Cultural Rights. It states that *Health is a fundamental human right indispensable for the exercise of other human rights.*[23] Based on the General Comment, health is placed as a fundamental and invaluable human right for the basis of other human rights implementation.

The right to health is respected and implemented by the state as one of the fundamental rights. The state has the obligation and responsibility to provide protection for the right to health owned by all citizens. This is in accordance with the WHO mandate that *government has a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures.* It means that the state, in this case the government has the responsibility for the health of its citizens.[24]

The state's obligation to fulfill the right to health was also agreed in The International Conference on Primary Health Care in 1978, regarding the Declaration of Alma-Ata that states [25]

> *The Conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the*

20 Virginia A. Leary, "The Right to Health in International Human Right Law, Health and Human Right," The President and Fellows of Harvard College Vol 1 No.1 (1994), hlm. 32.

21 Kerry O'Halloran, *Human Rights, Religion and International Law* (Oxfordshire: Routledge, 2019) Page 154.

22 Indra Perwira, "Memahami Kesehatan Sebagai Hak Asasi Manusia" (Jakarta, 2001), https://referensi. elsam.or.id/wp-content/uploads/2014/12/Kesehatan_Sebagai_Hak_Asasi_Manusia.pdf, diakses pada 5 Oktober 2021.

23 CESCR General Comment No 14*: The Right To The Highest Attainable Standard Of Health,* (Commitee on Social and Cultural Rights, 2000), hlm 1.

24 The tenth of Preamble Constitution of the World Health Organization (WHO) 1946, ***https://www.globalhealthrights.org/instrument/constitution-of-the-world-health-organization-who/***, diakses pada 5 Oktober 2021.

25 The First Declaration Alma-Ata 1978 ***https://www.who.int/publications/almaata_declaration_en.pdf***, diakses pada 5 Oktober 2021.

action of many other social and economic sectors in addition to the health sector.

The conference reaffirmed the right to health is part of human rights. The fulfillment of the right is the responsibility of the state in which the implementation must be supported by various sectors. WHO is a world authority that directs, coordinates and supports cross-border efforts in achieving commitments to improve the quality of the world community and emphasizes all stakeholders to ensure healthy lives and promote well-being for all ages through The Thirteenth General Program of Work (GPW) 2019-2023. WHO's missions include promoting health, keeping the world safe, and serving the vulnerable.[26]

The 2018 WHO *Global Conference on Primary Health Care* produced *the Astana Declaration* in which the governments of countries have agreed to raise government and community commitments to: [27]

a. Prioritize, promote and protect people's health and well-being through strong health systems; high-quality, safe, comprehensive, integrated, accessible, available and affordable healthcare services for all. The services are provided with respect and dignity by well-trained, skilled, motivated and committed healthcare professionals;
b. Provide a conducive environment for health that enables individuals and communities to be empowered and involved in maintaining and improving their health and well-being;
c. Work with partners and stakeholders to provide effective support for national health policies, strategies, and planning.

Given that the right to health is a basic right that must be respected and fulfilled by the state, this right has the same position as other fundamental rights.[28] This is in accordance with what was stated by Paul Hunt:

> *…Although the right to health is a fundamental human right that has the same international legal status as freedom of religion or the right to a fair trial, it is not as widely recognized as these and other civil and political rights…*[29]

In Indonesia, the recognition of the right to health as a human right is a consequence of Indonesia's position as a state of law[30] It is constitutionally stated in Article 28 H paragraph (1) of the 1945 Constitution: *Every person is entitled to live prosperous physically and spiritually, to have a place to reside, and to acquire a good and healthy living environment as well as be entitled to obtain healthcare*. Article 28 I paragraph (4) regulates

26 The Thirteenth General Programme of Work, 2019–2023, ***https://apps.who.int/iris/bitstream/handle/ 10665/324775/WHO-PRP-18.1-eng.pdf***, diakses 20 September 2021.

27 *Global Conference on Primary Health Care From Alma-Ata towards universal health coverage and the Sustainable Development Goals Astana, Kazakhstan, 25 and 26 October 2018. Invision : Governments and societies that prioritize, promote and protect people's health and well-being, at both population and individual levels, through strong health systems; Primary health care and health services that are high quality, safe, comprehensive, integrated, accessible, available and affordable for everyone and everywhere, provided with compassion, respect and dignity by health professionals who are well-trained, skilled, motivated and committed; Enabling and health-conducive environments in which individuals and communities are empowered and engaged in maintaining and enhancing their health and well-being; Partners and stakeholders aligned in providing effective support to national health policies, strategies and plans. https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.p*df

28 Rico Mardiansyah, "Dinamika Politik Hukum Dalam Pemenuhan Hak Kesehatan Di Indonesia," Jurnal Veritas et Justicia Vol. 4, No (2018): 229.

29 Paul Hunt, "The UN Special Rapporteur on The Right to Health: Key Objectives, Themes, and Intervention," The President and Fellows of Harvard College Health and Human Rights Journal Vol. 7, No (2003): 1-27.

30 Taufik H. Simatupang, "Hak Asasi Manusia Dan Perlindungan Kekayaan Intelektual Dalam Perspektif Negara Hukum," *JURNAL HAM* Vol. 12 No (2021): 114.

the responsibility of the state. Specifically, the government has the responsibility in protecting, promoting, upholding and fulfilling human rights. The right to health is a constitutional right. Thus, the state and the government are obliged to fulfill the health rights of their citizens through real and concrete efforts.[31]

In addition, the right to health is closely related to the right to live which is a natural human right.[32] This constitutional right is further regulated in Article 9 of Law Number 39 of 1999 concerning Human Rights which states that: …*Everyone has the right to live, maintain life and improve their standard of living. Everyone has the right to live in peace, security, peace, happiness, prosperity, physically and mentally. Everyone has the right to a good and healthy living environment…*

The national and international commitment towards the right to health as a human right without a doubt has to be reflected into existing laws and regulations.[33] Numerous perceptive regarding the right to health are further regulated by defining health in the Act of Law Number 36 of 2009 regarding Health It explains that health is a healthy state of being, not only physically but also mentally, socially, and spiritually that allows the individual to live socially and economically. Therefore, this definition is legitimated by what is mandated by Article 2 of the Act of Law which stated: *Everyone has the right to access safe, excellent and affordable health services*. In this case, the right to health must be recognized broadly, not only the healthy condition that is felt by each individual and group of people, but also several other stakeholders who have their shares in supporting this healthy condition.[34] One of responsibility for stakeholders to create healthy conditions is by guaranteeing the availability of access to proper medicine for the community.

In the context of human rights, the state has responsibilities to respect, to fulfill and to protect the human rights of its citizens.[35] The state is responsible to implement human rights norms over health that must comply with these following requirements:[36]

a. **Availability** of health services for all citizens;

b. **Accessibility** that all health facilities, goods and services must be accessible to everyone without discrimination in state jurisdiction. Accessibility has four dimensions, such as : not discriminatory, physically affordable, economically affordable and accessible for searching, accepting and or distributing information and ideas in relation to health problems;

c. **Acceptance** that all health facilities, goods and services must be in accordance with medical ethics and in accordance with culture, for example respecting the culture of individuals, local wisdom, minorities, groups and communities, gender sensitivity and life cycle requirements. It is also designed to respect the confidentiality of health status and improve health status for those in need;

d. **Quality** which requires medical personnel to be medically capable, scientifically proven medicine and hospital equipment, safe and drinkable drinking water, and adequate sanitation.

31 Fheriyal Sri Isriwati, "Tanggung Jawab Negara Dalam Pemenuhan Hak Kesehatan Masyarakt Berdasarkan Undang Undang Dasar NRI 1945," *Jurnal Ilmu Hukum Legal Opinion* Vol. 3 (2015): 4.

32 Carolus Boromeus Kusmaryanto, "Hak Asasi Manusiaatau Hak Manusiawi?," *JURNAL HAM* Vol. 12 No (2021): 521-532.

33 Harison Citrawan, "Analisis Dampak Hak Asasi Manusia Atas Regulasi: Sebuah Tinjauan Metodologi," *Jurnal HAM* Vol. 8 No. (2017): 13-24.

34 Rifatul Hidayat, Op.Cit.,

35 Rahayu, *Hukum Hak Asasi Manusia,* (Semarang: Badan Penerbit Universitas Diponegoro Semarang, 2015), hlm. 59.

36 Dedi Afandi, "Hak Atas Kesehatan Dalam Perpektif HAM," *Jurnal Ilmu Kedokteran* Vol. 2 No. (2008) Page 13.

The right to health as human rights is explicitly reflected in Article 4 of the Act of Health which regulates that "everyone has the right to health". It is an *inherent right for humans since our.*[37] The explanation of Article 4 states that *The right to health meant on this article is the right to obtain health services from health service facilities in order to accomplish the highest quality of health.* Furthermore, these rights to health are further explained in the Act of Health as follow:

a. Everyone has the same rights to obtain resources access in the health sector (Article 5 paragraph (1);
b. Everyone has the right to obtain safe, excellent, and affordable health services (Article 5 paragraph (2);
c. Everyone has the right to responsibly determine the health services needed for themselves independently (Article 5 paragraph (3);
d. Everyone has the right to a healthy environment for achieving a health standard (Article 6);
e. Everyone has the right to obtain information and education about health which is balance and responsible (Article 7).
f. Everyone has the right to gain information about his/her health data including actions and treatments that have been or will be received from health workers (Article 8).

This Act of Health also arrange several obligations, that everyone is obliged to:

a. Participate, preserve and improve the public health to the highest standard (Article 9).
b. Respect other people's rights in the attempt to obtain a healthy environment, whether physical, biological, or social (Article 10).
c. Maintain a healthy lifestyle in order to create, preserve, and develop the highest health degree (Article 11).
d. Maintain and improve the health standard for others who are their responsibility (Article 12).
e. Participate in the social health insurance program according to the clause of the legislation.

In order to implement its obligations to respect, protect and fulfill the rights to health of its citizens, the Act of Health needs to regulate the state's responsibility to:

a. Plan, regulate, organize, develop, and supervise the implementation of health efforts (public services) (Article 14);
b. Provide environment, structure, health facilities both physically and socially (Article 15);
c. Provide resources in the health sector (Article 16);
d. Provide access for information, education, and health service facilities (Article 17);
e. Empower and encourage the community to actively participating in various forms of health efforts (Article 18);
f. Provide excellent, safe, efficient and affordable in all forms of health services (Article 19); and
g. Implement public health insurance (Article 20).

The state's responsibility towards the fulfillment of the right to health could be interpreted as legal, political, economic, and social responsibilities.[38]

First, as legal responsibilities, the state has a legal responsibility as the most important party in granting the right to health in accordance with constitutional orders. The

37 Muhamad Beni Kurniawan, "Politik Hukum Pemerintah Dalam Penanganan Pandemi Covid-19," *JURNAL HAM* Volume 12, (2021) Page 37-55.

38 Hernadi Affandi, "Implementasi Hak Atas Kesehatan Menurut Undang-Undang Dasar 1945: Antara Pengaturan Dan Realisasi Tanggung Jawab Negara," Jurnal Hukum Positum Vol. 4, No (2019), hlm. 36-56.

state must not disregard or ignore granting the right to health for any reason. In this case, the state can be legally prosecuted for intentionally disregarding the fulfillment of right to health. Legal responsibilities can be based on penal law, civil law, state administrative law, constitutional law, or international law.

Second, as political responsibility, the state has a political responsibility to take all policies in granting the right to health through existing political mechanisms or channels. The state as an organization with authority and politics must take political steps which support and strengthen policies in granting the right to health based on the political interest of its national law. In this context, political responsibility will show the seriousness of the state in granting the right to health in accordance with the objectives of the state in the Constitution.

Third, as economic responsibilities, the state also has the responsibility to prepare and grant all facilities and infrastructure for health services in the context of granting the right to health. The state must provide sufficient budget to build and maintain health facilities in the State Revenue and Expenditure Budget (APBN) and Regional Revenue and Expenditure Budget (APBD). The state must ensure the fulfillment of the right to health with its own capabilities as the main factor, while the support from others is only a complimentary factor.

Fourth, as social responsibilities, which means that the state in this case has the responsibility to make continuous effort in granting the right to health as an effort to accomplish and improve general welfare. The state must act as the most responsible party if other stakeholders are unable or not involved in fulfilling the right to health. The state has to constantly make an effort to fulfill the right to health as a manner of state social responsibility in accomplishing and improving general welfare.

Fifth, the moral responsibilities of the state, which means that the state has a moral responsibility for continuous effort to grant the right of health if others responsibilities have not been fully accomplished. The state also have to continue make an effort to educate and indoctrinate public awareness about the importance of right to health as part of human rights that must be protected by every person or society. The state has to make a continuous effort to grant the right to health even though the state is in its worst situation or condition such as in a state of war, natural disaster, riots, and so on.

Related to the definition of the state's responsibility in fulfilling the right to health, there are at least 3 (three) configurations as follow:[39]

a. Legal protection. The legal protection is done through regulation or law-making arrangement over the principles of fulfilling the rights to health, including the stipulation standards of the health services, process, mechanism, institutions and assurance for the community to easy access of health service based on these standards.
b. Several policies over the fulfillment to the right of health, such as funding, procurement of medicine, physicians, nurses, health education, drugs surveillance, and many more, as well as the policies in developing health service facilities organized by the communities.
c. The availability of "due process of law" infrastructure for the people whose rights are violated or neglected by the state or the third party.

39 Indra Perwiran, *Op.Cit*, hlm. 180

The Effect of Policy Arrangement Changes in Implementing Local Working Requirements (LWR) of Patents on the Policies of the State's Responsibilities in Fulfilling Community Accessibility Rights to Patent Medicine

1. The Amendment of Article 20 of the Act of Law Number 13 about Patent

The amendment of Article 20 of the Act of Patent number 13 in 2016 with Article 107 of the Act of Law Number 11 in 2020 about the Act of Job Creation (The Job Creation Act) eliminates technology transfer requirements, investment assimilation, and employment provisions as well as enhancing provisions categorized as LWR by importing or licensing products or process patents. The legal politics of the Amendment of Article 20 of the Act of Patent which an adjustment of the regulation of the TRIPs Agreement (Article 27 paragraph 1) is seen as legal politics' discrimination element reflected from the reasons made by the government in the Amendment of Article 20 of the Act of Patent as written in the Manuscript of the Amendment of The Act of Patent of 2016.[40]

This amendment raised pros and cons. On the other hand, Article 20 of the Act of Patent of 2016 is considered contradictory with the discrimination principals written in Article 27 (1) of the TRIPs Agreement. This claim and objection is stated by the representatives from Uni-European countries, Switzerland, and The United States of America. However, according to the legal experts in HKI, LWR concept is the balance of the rights and obligations of the patents' holder. This is something that needs to be contemplated and to be searched for its depth value. Granting the monopoly of patent rights without the counterbalance of transfer of technology and local working will cause abuse of patent impact in the form of patent blocking. This patent blocking can be in the form of patent registration that is done only to prevent others not to sell the products which technology is protected by law.[41]

The reason that article 20 is contradictory with Article 27(1) of TRIPs which considered discriminatory is actually groundless. Article 27 of TRIPs clearly cannot be read by its own. It needs to be read systematically as the unity of ideas with other Articles. *First*, TRIPs highly respects the rule of law of its participating countries. *Second*, TRIPs respects the national interests of its participating countries. Third, TRIPs still requires the monopoly rights to bring good social impacts by preventing abuse of intellectual property rights conducted by the patent holders in the form of blocking patent and failure to work which is adapted from Article 5A Paris Convention.

In addition, these reasons are considered unjustified because basically: (i) the contradictions of LWR arrangement based on Article 5A Paris Convention and Article II of Trips Agreement based on reference sources and based on text interpretation and the goal context of Trips (in accordance with the good intention principals in Wina Convention in 1969 about Legal Agreement) mostly are not contradictory; (ii) Historically, there are not any verdicts from Dispute Settlement Body which expressed the contradictions between LWR and Article 27 Paragraph 1 of Trips; and (iii) The arrangement of LWR has the same goals and principles with TRIPs written in Article 7 and 8 which is the harmony between the rights and obligations of the patent rights holder; to promote and contribute to innovation, technology transfer, to social and

40 Kementerian Hukum Dan HAM, Badan Pembinaan Hukum Nasional, 2019, *Naskah Akademik Perubahan Undang Undang Paten Nomor 13 Tahun 2016*, hlm. 90.

41 Oka Saidin, "Paten, Alih Teknologi Dan Local Working," Catatan Diskusi Akhir Pekan APHKI, 2021, https://fnn.co.id/2021/08/29/paten-alih-teknologi-dan-local-working-catatan-diskusi-akhir-pekan-aphki/, diakses pada 2 Oktober 2021 pukul 15.05.

economic welfare, to protect public health and interest, and to prevent intellectual property rights abuse.

2. The Policy of the State's Responsibility in Fulfilling Public Accessibility Rights to Patent Medicine

The Government Policy about increasing access to medicine is implemented through several levels of policy, namely the Act of Law and the Minister of Health Decree that arrange some regulations related to medicine. Based on Article 36 of the Act of Health number 36 in 2009, government guarantees the availability, equity, and affordability of health supplies, especially essential medicines.

The national drug policy states that the development in the field of medicine aims to ensure the availability and affordability of safe, efficacious and good quality medicines for the community with the types and quantities according to their needs. The national drug policy aims to increase equity and affordability of medicine continuously in order to achieve a high public health standard. It also aims for the affordability and rational use of medicine. In addition, the national drug policy has purpose that by selecting appropriate medicine through prioritizing the supply of essential medicine can increase the accessibility and rationality of the use of medicine. All medicine circulating in public should have safe, efficacy, and good quality assurance in order to provide health advantages. Public must be protected from medicine misuse and abuse.

The policy to ensure medicine availability must be done on policies at the upstream (sufficient medicine production) and downstream level (availability of medicine in the market). For the upstream policy, the first step to be done is by arranging National Drug Policy based on the Decree of the Ministry of Health number 189 in 2006. It is done by mapping the industrial development of Medicine Raw Material (also known as BBO), and Traditional Medicine Raw Material (also known as BBOT) through the Decree of The Minister of Health of the Republic of Indonesia number 87 and 88 in 2013. In addition to the first step, there are also the issuance of policy that needs to be accommodated, namely the Instructions of the President of the Republic of Indonesia number 6 in 2016 about the Acceleration of the Development of the Pharmaceutical and Medical Devices Industry, and lastly an Action Plan for the Development of the Pharmaceutical and Medical Devices Industry through the Regulation of the Ministry of Health of the Republic of Indonesia number 17 in 2017. The Action Plan for the Development of the Pharmaceutical and Medical Devices Industry is done step by step in 4 (four) pillars of the primary focus on the development of raw materials availability for pharmaceutical industry in the field of Natural and Chemical raw materials (API, Bio-pharmaceutical and Vaccine).

The policy of the availability of medicine production is also written in the Regulation of the Minister of Health number 21 in 2020 about the Strategic Plan of the Ministry of Health 2020-2024. It states that national development in the pharmaceutical availability field emphasizes on the mission of Guaranteed Access, Independence and Quality of Pharmaceutical Preparations and Medical Devices for Efforts to Realize Healthy, Productive, Independent and Righteous. This strategic mission has several aims, which are: (i) The realization of Increased Equitable Availability and Affordability of Medicines and Vaccines; (ii) The Realization of Independence, Preparation of Pharmaceuticals and Medical Devices; and (iii) Guaranteed Safety, Quality Benefits of Medical Devices; and (iv) Increase independence and use of domestic pharmaceutical products and medical devices.

In the field of pharmaceutical production, almost 70% of the national needs of medicine

can be fulfilled from domestic production. However, 95% of the raw materials used by the pharmaceutical industry can only be obtained through imports. Medicine raw material components contribute to 25-30% of total medicine production costs. Thus, some interventions in medicine raw material component will affect the cost of the medicine itself. Nevertheless, through coordination and cooperation between the stakeholders until 2019, there are 50 (fifty) raw materials consisted of 1 (one) type of biotechnology, 1 (one) type of vaccine, 36 (thirty-six of natural raw material types, and 12 (twelve) chemical raw material types that can be developed and produced domestically.[42]

Nonetheless, pharmaceutical companies are still concentrating in the downstream level by producing chemical finished product as much as 92.1 percent. Meanwhile for upstream level which involves companies that produce medicinal raw materials, the production in this level is still under 4 percent. Consequently, the need for medicinal raw materials is highly dependent on imports due to limited domestic production. Indonesia has reached 95 percent in terms of importing medicine raw material. The largest imports of medicine raw materials come from China (60 percent), followed by India (30 percent) and European countries (10 percent).

The level of public consumption of medicine is increasing, from Rp65.9 trillion in 2016 to Rp88.36 trillion in 2019. In addition, 73% of the national pharmaceutical market share is dominated by domestic pharmaceutical companies.[43] As the population increases, the awareness of the Indonesian people regarding health and the needs for medicine has increased. Furthermore, the increase of income for the middle-class has increased their effort in purchasing medicines and health supplements. The level of consumption of pharmaceutical products is also expected to keep increasing. In the next few years, with the implementation of the National Health Insurance - Health Indonesia Card (JKN-KIS) until September 2021, the number of JKN-KIS participants has reached 226.3 million participants or about 83.5% of the total population of 270 million people.[44] This program continues to be improved to reach the wider community. It is targeted to provide health insurance for all citizens of Indonesia. Thus, the number of JKN-KIS participants will increase every year, which has an influence on the growth of the pharmaceutical (medicine) industry.

Through the Presidential Instruction Number 6 of 2016 concerning the Acceleration of the Development of Pharmaceutical and Medical Devices Industry and its follow up by The Decree of the Ministry of Health Number 17 of 2017 concerning the Action Plan for the Development of Pharmaceutical and Medical Devices Industry, 14 pharmaceutical industries have been established in the form of joint venture with the pharmaceutical industry from other countries such as the United Arab Emirates, Hong Kong, Korea, India, Germany and many more. These pharmaceutical joint venture industries have produced innovative products needed in health services and medicine raw materials productions, which are expected to make pharmaceutical industry independence.

42 Kementerian Kesehatan, *Buku Rencana Aksi Kegiatan Direktorat Produksi dan Distribusi Kefarmasian Direktorat Jenderal Kefarmasian dan Alat Kesehatan*, (Jakarta: Kementerian Kesehatan, 2020) hlm.12.

43 Kementerian Kesehatan, 2020, Renstra Kementerian Kesehatan RI 2020-2024, https://farmalkes.kemkes.go.id/2021/03/rencana-strategis-kementerian-kesehatan-tahun-2020-2024/, diakses 2 September 2021

44 Badan Penyelenggara Jaminan Sosial, 2021, BPJS Kesehatan Berbagi Pengalaman dengan India Capai UHC, https://bpjs-kesehatan.go.id/bpjs/post/read/2021/2050/BPJS-Kesehatan-Berbagi-Pengalaman-dengan-India-Capai-UHC, diakses 25 September 2021

Until 2019, 53 raw materials have been developed, one type of biotechnology product, one type of vaccine product, 39 types of natural product, and 12 types of raw materials for chemical medicine products. In 2020-2021, there was a plan to develop 34 raw materials consisting of six types of biopharmaceuticals, three types of vaccine, 13 types of natural, and 12 types of chemicals (API). In 2022-2025 there is a plan to develop 47 raw materials consisting of 4 types of biopharmaceuticals, 10 types of vaccines, 17 types of natural, and 16 types of chemicals (API).[45]

The policy of medicine availability in an emergency when dealing with urgent situations. One of them is limited pharmaceutical products as an effort to cure an outbreak of a disease that can cause a public health emergency and require intensive treatment. The example of this situation is the case of the availability of Antiviral and Antiretroviral Medicine which are difficult to obtain by Hepatitis B sufferers and HIV/AIDS in Indonesia in the past few years. The government issued a policy for implementing patents done by the government (governmental use) with the stipulation of Presidential Decree Number 83 of 2004 concerning the Implementation of Patent by the Government on Antiretroviral Medicine which was amended by Presidential Decree Number 6 of 2007 concerning Amendments to Presidential Decree Number 83 of 2004 concerning Implementation of Patent by the Government on Antiretroviral Medicine and Presidential Regulation Number 76 of 2012 concerning the Implementation of Patent by the Government on Anti-viral and Antiretroviral Medicine.

45 Kementerian Kesehatan Republik Indonesia, Profil Kefarmasian dan Alat Kesehatan Tahun 2019.

The government has reissued a policy in order to fill the urgent and emergency needs of medicines and especially vaccines in the situation of Covid-19 pandemic through Presidential Regulation Number 77 of 2020 concerning Procedures for Implementing Patent by the Government. Government also used policies in the context of the availability of medicine to deal with the Covid-19 pandemic through Presidential Regulation Number 101 of 2021 concerning the Implementation of Patents by the Government on the Favipiravir Medicine;

Regarding the policy to ensure safety, efficacy and quality in order to provide health benefits, the Government issued a policy through Article 4 of the Minister of Health Number 1010 of 2008 concerning Medicine Registration and Article 4 of the Regulation of the BPOM Number 24 of 2017 concerning Criteria and Procedures for Medicine Registration, which was updated with the Regulation of the BPOM. Number 13 of 2021, then medicine circulating in Indonesia have been registered with National Agency of Drug and Food Control (BPOM) by the following requirements. :

a. Convincing efficacy and adequate safety, proven through non-clinical trials and clinical trials or other evidence in accordance with the status of scientific developments. Clinical trials are conducted to protect the public from the use of medicine that do not meet safety, efficacy/benefit and quality requirements. In certain conditions, the accuracy of the safety and efficacy/benefit aspects of medicine must be scientifically proven through clinical trials. In the clinical trial procedure to determine the equivalence between generic medicine and their innovators, there are provisions regarding the obligation to conduct equivalence tests (in vivo and/or in vitro tests). It must be done with the Good Clinical Trial Method (CUKB), which is a

standard for the design, implementation, achievement, monitoring, auditing, recording, analysing, and reporting of clinical trials that provide assurance of the data and the results reported are accurate and reliable, and the rights, integrity, and confidentiality of Clinical Trial Subjects are protected. This standard is based on the principles of the Helsinki Declaration on Ethical Principles of Medical Research Involving Human Subjects (regulation of the Head of BPOM No. 21 of 2015).

b. Guaranteed quality means that the medicine meets the requirements with the established standards. The production process must comply with Good Manufacturing Practices (GMP) and be proofed by valid evidence. GMP is a method of manufacturing medicine that aims to ensure the quality of medicine produced with the requirements and intended use and covers all aspects of production and quality control. This manufacture includes all activities from the receipt of materials, the production process, repackaging, labelling, re-labelling; quality control, passing status, storage and distribution of medicine and related controls. CPOB must refer to the Guidebook for Good Manufacturing Practices of Drug regulated in the Minister of Health Regulation Number 1799 of 2010 about the Pharmaceutical Industry Jo with the Regulation of the Head of BPOM No. HK.03.1.33.12.12.8195 of 2012 concerning the Implementation of Guidelines for Good Manufacturing Practices of Medicine;

c. Product information and labels are complete, objective and contains non-misleading information that can guarantee the use of medicine properly, rationally and safely;

d. Specifically for new psychotropics, they must have advantages compared to medicines that have been approved circulating in Indonesia.

In the last 5 (five) years (2016-2021), medicines registered with BPOM were around 21,128. There is an increase in the types of medicine registered. If in 2016 there were 1,973 types of medicine registered, then by October 2021 there were 2,128 types of medicine registered. Meanwhile, for medicine registration based on production status and marketing purposes, out of 17,595 medicines registered, there were 16,729 (95.08%) medicines produced for local market, 768 (4.36%) medicines produced for export needs and 98 (0.56%) medicines produced from imported half-finished products.

Based on the Regulation of the Minister of Health Number 1010 of 2008, the registration of patent medicine products or efficacious medicine that still protected by patent (proven by a valid patent certificate) is carried out by domestic pharmaceutical industry agents as patent holders, or other domestic pharmaceutical industry agents appointed by the patent holder. Registration of medicines that are still under patent protection in Indonesia can be submitted by domestic pharmaceutical industry agents before the 5-year expiration date of the patent (article 21 of BPOM Regulation Number 24 of 2017). Circulation rights can only be done after the patent protection period is over.

According to the Regulation of BPOM Number 24 of 2017 (updated by Regulation of BPOM No. 13 of 2021) regarding the Criteria and Procedure for Medicine Registration, patent medicines are categorized as new medicine. It is considered as medicine with new active substances, new dosage forms, new strengths or new combinations which have never been approved in Indonesia. New medicine registration can be classified into new medicine with new active substance, new combination, new dosage form, new strength, new route of administration. The evaluation process for new medicine, including biological products, is carried out thoroughly on the

aspects of efficacy, safety, quality, product information and marking.

In 2019 as an effort to support the development of investment in the medicine sector and the acceleration of public services in the medicine registration, the BPOM issued Regulation of the Head of BPOM Number 15 of 2019 which is an amendment to the Regulation of the Head of BPOM No. 24 of 2017 concerning Medicine Registration Criteria and Procedures. This regulation simplifies the new medicine registration process: (1) The Reliance Mechanism for New Registration and New Medicine Variations which are originally evaluated for 300 working days with reference to three countries are changed to 120 working days with reference to one country; (2) The first registration of new medicine by the Pharmaceutical Industry investing in Indonesia changes from 300 working days to 100 working days; and (3) The elimination of Approvable Letter (AL) for several registration categories.

This simplification has resulted in an increase of new applications, as seen in the number of new applications being approved to obtain a Circular Permit Number (NIE). This trend can be seen in the following table:

Table 1. Trend in New Medicine Registration 2017-2020

Number	Year	Application	Cancel	Rejected	NIE
1.	2017	406	23	31	92
2.	2018	371	28	19	98
3.	2019	98	9	22	119
4.	2020	113	6	2	120

Source: BPOM Annual Report, Directorate of Medicine Registration 2020

Meanwhile, the generic medicine registration trend can be seen in the table below:

Table 2. A Generic Medicine Registration Trend in 2017-2019

No.	Year	Application	Cancel	Rejected	NIE
1.	2017	1793	9	54	760
2.	2018	2017	10	15	882
3.	2019	1061	198	45	1158

Source: BPOM Annual Report, Directorate of Medicine Registration 2020

Compared to the registration of new medicine, the registration number of branded generic medicine and medicines with names according to the Modified International Non-proprietary Names set by the World Health Organization (WHO) is much higher. Branded generic medicine are medicine with trade names containing active substances with the same composition, strength, dosage form, route of administration, indications and posology as the approved originator medicine. The comparison shows that in the last 4 years 429: 3560 or 1: 12 or the number of new medicines (patents) registered, or circulating in the market is 12% of all medicines in the market. It means that the availability of innovative/patent medicine available on the market and accessible to the public is 12% of the total number of medicines in the market.

Table 3. The Registration Comparison of New (Patent) and Generic Medicine in 2017-2020

Number	Year	New Drug	Generic Drug
1.	2017	92	760
2.	2018	98	882
3.	2019	119	1158
4.	2020	120	2796

Source: Results of Processed Research

The condition of medicine accessibility is determined by the availability of medicine for health services, especially for government health service facilities. This effort is carried out through the policy of the Minister of Health Regulation Number 54 of 2018 concerning

Formulation and Implementation of the National Formulary in the Implementation of the Health Insurance Program. These efforts include strengthening medicine selection through FORNAS or the National Formulary. The availability of medicine by public health services continues to increase from year to year. This can be seen from the percentage of essential medicine availability in Puskesmas (Public Health Centre) as shown in the following table:

Table 4. The Availability of Essential Medicines in the Community Health Centre in 2015-2019

Number	Year	Percentage
1.	2015	79,38 %
2.	2016	81,57 %
3.	2017	89,30 %
4.	2018	92,47 %
5.	2019	94,22 %

Source: BPOM Annual Report, Directorate of Drug Registration 2020

Before the changes were made, especially in the pharmaceutical patents, government policies related to LWR in Article 20 of the Patent Law were generally supported or parallel with policies on the availability, safety, affordability and independence of domestic medicine. These policies were from the National Drug Policy in 2006, development of the medicine raw material industry, medicine registration, urgency need for medicine, accelerating the development of the pharmaceutical industry, to policies on Strategic Plans related to availability, affordability, safety and independence, development and use of domestic medicine in 2020-2024.

The obligation to implement pharmaceutical patents actually supports the policy on the availability of medicinal raw materials, more affordable medicines (availability and cheaper prices) and more qualified and efficacious medicines. Furthermore, it supports the development of the pharmaceutical industry (transfer of innovative drug technology) and also the investment and independence of the use of domestically produced medicine.

Amendment to Article 20 of the Patent Law by substituting importation to bring down the obligation to implement domestic patents (LWR) is the same as mitigating or marginalizing the main mission of the accessibility policy on the availability, affordability of medicine and independence in using domestically produced medicine. In addition, importation can hinder the development of medicinal raw materials and the independence of using domestically produced medicine.

However, the government's policy of providing access and promotion of generic medicine rather than providing access to innovative/patent medicine in Indonesia is because the price of innovative/patent medicine is much more expensive than generic one. The reason is also because the domestic generic medicine industry is growing compared to patent/innovative medicines that are still limited. On the other hand, the government has policy to limit/restrict the imported medicinal products, including patent/innovative medicine (that is still under patent protection) which are mostly produced by foreign pharmaceutical companies by requiring the registration of imported medicine to go through the domestic pharmaceutical industry. This policy is taken in order to protect the domestic pharmaceutical industry, which partly produces the generic medicine to serve the needs of the public's access rights to cheap and affordable medicines.

The technological capability of the pharmaceutical industry in Indonesia is still largely limited to medicine formulations. One of which is this industry is still developing the final product by relying on its superiority or

equivalence in bioavailability/bioequivalent (BA/BE) to comparator products. As an implication in the future, Indonesian national pharmaceutical company has not been able to compete in the patent/innovative medicine market segment. Moreover, the Indonesian pharmaceutical industry has not been able to achieve the discovery of new medicines because there are still many obstacles, especially from the investment aspect. It costs US$350–800 million to find a new medicine (new chemical entity /NCE) and sell it in the market. The amount of Litbang (research and development) costs relate to the following three matters: (1) Technology; (2) New active ingredients are more complex; (3) The stricter regulatory requirements of preclinical trials and clinical trials. In addition, the national pharmaceutical industry is more interested in the market needs for pharmaceutical products that are generally needed by the community, that is the production and marketing of the off-patent medicine or known as a generic medicine.

These generic medicines are cheaper and available from domestic production (75% of the medicine requirement). According to the government, the generic drug and branded generic drug contain active substances with the same composition, strength, dosage form, route of administration, indications, and doses as patent medicine or originator medicines that have been approved in Indonesia. Before being produced, generic medicine and branded generic medicine are required to go through an equivalence test with the innovator/originator medicine. By doing this, the similarity of medicine quality can be determined based on the effect, absorption function, and medicine safety. Bioequivalence is a mandatory requirement that must be met by generic medicine. It is done to declare that the generic medicine is equivalent to innovator/patent medicine.[46]

This condition causes the limited availability of innovative/patent medicine in the market as well as medicine available in the National Formulary of drugs – National Formulary (FORNAS). 92% of them are generic drugs. It means that the fulfillment of the National Health Insurance program is dominated by generic medicine rather than innovative/patent medicine. It raises concerns related to the effectiveness of treatment outcomes as things that need to be taken into the fulfillment of the rights to public health.

Meanwhile, innovative medicines are assumed to improve people's lives and health. A study conducted by Lichtenberg[47] found that innovation in the pharmaceutical sector has played a major role in increasing the life expectancy and health of Americans. In addition, Lichtenberg conducted research with Australia as the object and found that innovation in the pharmaceutical field reduced the mortality rate under 75 years of age by 60% during 1998-2011.

This government policy's choice considers the availability of medicine is better to fill the medicine access for the major public. In other words, the policy choice aims to maximize the utility and the benefit of the availability and affordability of generic medicine and to limit the patent medicine. This policy is according to the principle of utility or expediency in the results of right action, when a person chooses to maximize utility or happiness. *Utilitarian believes that the right action is the one that has the best results for the most individuals, and this belief*

46 Berdasarkan informasi dari I Gusti Ngurah Bagus Kusuma Dewa, S.Si, Apt, MPPM, Kepala Pusat Pengembangan Sumber Daya Manusia Pengawas Obat dan Makanan Badan Pengawas Obat dan Makanan 9 Nopember 2021

47 Lichtenberg F. R. (2017). The impact of public and private research support on premature cancer mortality and hospitalization in the U.S., 1999-2013 (NBER Working Paper No. 23241). Retrieved from http://www.nber.org/papers/w23241

is commonly known as achieving the "the greatest happiness for the greatest number.[48]

In the perspective of state obligations according to human rights, all policies issued by the government to facilitate the issuance of permits for these innovative medicines, including generic medicine, are part of efforts to fulfill human rights in the health sector. The state's obligation to fulfill is the state's obligation to take all steps, both legislative, administrative and practical steps to ensure the widest possible implementation of human rights.[49] Fulfillment of the rights to health through the accessibility of quality medicine for the entire community, including for underprivileged groups through the National Health Insurance program, has been pursued in such a way by providing good quality of generic medicine. It means that the state's obligation to fulfill the right to health as mandated in Article 28 H paragraph (1), Article 28 I paragraph (4) of the Constitution of Indonesia Article 9 and Article 71 of Law Number 39 of 1999 concerning Human Rights, and Law Number 36 of 1999 2009 on Health has been attempted to be implemented.

CLOSING

Conclusion

a. The policy change regarding LWR for pharmaceutical patents, which was originally regulated in Article 20 of the 2016 Patent Law to Article 107 of Law Number 11/2020 on Job Creation, actually do not have much effect on the fulfillment of the right to health in Indonesia, especially the availability of patent medicines. The articles that regulate LWR so far have only been dormant articles. There has never been a regulation to implement the arrangements contained in the articles. However, the availability of patent medicine is regulated through a policy on developing the pharmaceutical industry, medicine registration and a policy of independence in the use of domestically produced medicine. The policies for guaranteeing the fulfillment of the right of health are based on various regulations such as the 1945 Constitution of the Republic of Indonesia (Article 28 H), Law Number 39 of 1999 concerning Human Rights (article 9) and Law Number 36 of 2009 concerning Health.

b. The policy of Indonesian government regarding its obligation to fulfill the availability of medicine as part of the fulfillment of the health and human rights are to procure generic medicine which efficacy is considered as the same as patent medicine. It is because before the generic medicine is circulated, it is required to conduct an equivalence test with the innovator medicine.

Suggestion

Several policies to encourage the independence of pharmaceutical productions have been quite successful in ensuring the availability of medicine. However, there are still obstacles related to the availability of medicine raw materials. 90% of raw materials are still dependent on imports. As a rich country in bio-diversity and supported by a culture of people that like to consume herbal medicine, Indonesia has the potential to develop medicine raw materials that leads to biopharmaceuticals. Therefore, it is necessary to have mandatory policies for pharmaceutical companies (especially State Owned Enterprises/BUMN) to develop innovations through research in order to produce medicine raw materials with local ingredients.

48 Mill, J. S..*Utilitarianism (From a 1879 edition).* London: The Floating Press,2009 dalam Arief Budiono, Teori Utilitarianisme dan Perlindungan Hukum Lahan Pertanian dari Alih Fungsi, *Jurnal Jurisprudence*, Vol. 9, No. 1, 2019, pp.102-116

49 Rahayu, *Op.Cit.,*hlm. 59.

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