



Volume 38 No 2, May 2023  
DOI: 10.20473/ydk.v38i2.43007

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Yuridika (ISSN: 0215-840X | e-ISSN: 2528-3103)

FAKULTAS HUKUM UNIVERSITAS AIRLANGGA

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Article history: Submitted 30 January 2023; Accepted 4 April 2023; Available Online 1 May 2023.

## State Responsibility for Access and Availability of Patented Drugs for Public Health

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### Abstract

Article 28H and Article 34 of the 1945 Constitution of the Republic of Indonesia stipulate that fulfilling the health rights of Indonesian citizens is the responsibility of the state. Human rights require that individuals have access to the availability of medicines in society. The high price of medicines, especially patent medicines, results in limited access and availability of essential medicines. This study uses normative legal research methods, with a statutory approach, and a conceptual approach. The purpose of this study is to examine and analyze the state's goals in fulfilling the right to health as a human right by the state as well as access and availability of patented drugs to fulfill the right to health. In addition to ensuring the availability of complete medicines in sufficient quantity, quality, affordable and easily accessible to the public, the government is also responsible for protecting the rights of inventors as long as the drugs are still under patent protection. To balance these two rights, the government plays the role of provider, regulator, entrepreneur and umpire.

**Keywords:** State Responsibility; Access and Availability of Drugs; Patent; Health Rights.

### Introduction

The Unitary State of the Republic of Indonesia was established with the aim of realizing general welfare and social justice for all Indonesian people. This is stated in the fourth paragraph of the Preamble to the 1945 Constitution of the Republic of Indonesia, namely: (1) to protect the entire Indonesian nation and all of Indonesia's bloodshed; (2) promoting public welfare; (3) educate the life of the nation; and (4) participate in carrying out world order based on freedom, eternal peace, and social justice. This national goal is imbued with the basis of the state, namely the precepts in Pancasila. Especially the fifth and second precepts, namely social justice for all Indonesian people, and just and civilized humanity. The fifth

precept of Pancasila reflects that Indonesia is a welfare state that aspires to realize general welfare. Pancasila already contains guarantees of human rights, especially to be treated in a fair and civilized manner. The second amendment to the 1945 Constitution contains a more complete arrangement of human rights than before.

Before the amendment, content material on human rights was contained in Article 27, Article 28, Article 29 Paragraph (2), Article 30 Paragraph (1), Article 31 Paragraph (1), and Article 34. The Assembly of People's Representatives included 10 new articles namely Article 28A, Article 28B, Article 28C, Article 28D, Article 28E, Article 28F, Article 28G, Article 28H, Article 28I, and Article 28J.<sup>1</sup> The results of the addition of these articles are not only complete, but also detail human rights aspects. Thus, since the change occurred, the articles of the 1945 Constitution of the Republic of Indonesia which regulate human rights have become more complete and detailed. These provisions cover the civil and political fields, as well as the economic, social and cultural fields.<sup>2</sup>

One of the new types of human rights included in the 1945 Constitution of the Republic of Indonesia is the right to health as stated in Article 28H Paragraph (1) which reads "Everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to get a good and healthy environment. and have the right to obtain health services." The 1945 Constitution of the Republic of Indonesia also explains about health insurance which is regulated in Article 28H Paragraph (3) which states that "Everyone has the right to social security which allows for his full development as a dignified human being". This is the basis for why the right to health is a human right.

The right to health is also regulated in Article 34 after the third amendment, especially in Paragraph (3) which reads "The state is responsible for providing proper health service facilities and public service facilities." Based on the provisions

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<sup>1</sup> Secretariat General of the MPR, 'Prison Guide to the 1945 Constitution of the Republic of Indonesia' (2020) <[https://mpr.go.id/socialisasi/panduan-pe Masyarakat](https://mpr.go.id/socialisasi/panduan-pe%20Masyarakat)> accessed December 6, 2022.[112].

<sup>2</sup> Miriam Budiardjo, *Fundamentals of Political Science* (Gramedia Pustaka Utama 2008).[248].

of Article 28H and Article 34 of the 1945 Constitution of the Republic of Indonesia, it is clear that the fulfillment of the right to health for every Indonesian citizen in the form of obtaining health facilities and public service facilities must be provided by the state.

Health is the main factor that must be maintained for the continuity of life in the world, health is very beneficial for everyone, activities that include situational factors can be achieved properly if in the process health can be maintained.<sup>3</sup> Medicine is a very important element in the health sector. Medication is needed in almost every process of treatment, healing and recovery. Patent drugs are not the only drugs that can be consumed by the public, and not all drugs are available in generic forms, so that people consume patented forms. To find new drugs, pharmaceutical companies that own patents pay Research and Development (R&D) costs, but rarely do companies publish R&D investment values for the manufacture of new drugs. On the other hand, the monopoly rights owned by these companies can control the availability and price of drugs. A patented drug guarantees that the R&D costs incurred by the manufacturer will be covered for the duration of the patent protection period.<sup>4</sup>

The high price of patented drugs has an impact on purchasing power and the level of public health. The community must set aside their income for medical expenses. Components of drug costs in Indonesia can reach 45% (forty five percent) of the total health costs. This is according to a study conducted by the World Health Organization (WHO) on several residents of developing countries, including Indonesia. The notion that there is a debilitating effect of buying drugs.<sup>5</sup>

The high price of drugs in Indonesia has led to many cases of counterfeit drugs, fake drug factories, and cases of expired drugs circulating in the market, both in big cities and small towns. Distribution of drugs through online media

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<sup>3</sup> Soekidjo Notoatmodjo, *Health Behavior Science* (Rineka Cipta 2010).

<sup>4</sup> V. Selvie Sinaga, "Patent Threats to Public Health and Safeguards TRIPs", *Articles on Intellectual Property Rights*, Atma Jaya Catholic University, May-August 2015.

<sup>5</sup> Kompas, "Expensive Drugs Have Impoverished Effects", <https://lifestyle.kompas.com/read/2011/10/28/13174413/Oba.Mahal.Punya.Efek.Memiskinkan>, accessed on 8 March 2018.

is also vulnerable to counterfeiting because online media offers a wider market, lower prices, faster, and the possibility of buying anonymously. For hard drugs, narcotic class drugs or psychotropic groups that should use a doctor's prescription, in online media the buyer does not need to show a doctor's prescription. The lack of information about drug content and addresses of drug sellers can endanger health and cause victims.<sup>6</sup>

Fulfillment of access and availability of medicines is the responsibility of the state, especially the internal government ensure the availability of patent medicines that are complete, sufficient in quantity, of good quality, affordable and easily accessible to the public. Implementation of government responsibilities is not only important but will also become a benchmark in improving people's lives as a manifestation of human rights. The main basis for the protection of human rights related to government obligations is the principle of democracy, which means that the government is actually entrusted with the power to protect the rights of citizens.

This type of research is normative legal research.<sup>7</sup> The problem approach used in this study is the statutory approach and the conceptual approach. The statutory approach is the approach taken by examining the statutory regulations concerned with the legal issues being discussed.<sup>8</sup>

The conceptual approach is an approach to the concept of law put forward by experts contained in various literatures. The legal materials used in legal research used to examine legal issues in this research consist of primary legal materials, secondary legal materials, and non-legal materials. From the materials obtained, the authors conducted an analysis of existing legal materials, then a conclusion was drawn which was the answer to the legal issues raised.

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<sup>6</sup> Ariyulinda, 'The Urgency of Establishing Drug Sales Regulations Through Online Media' (2018) 15 Journal of Indonesian Legislation 37 <<https://e-jurnal.peraturan.go.id/index.php/jli/article/view/10>>.

<sup>7</sup> Peter Mahmud Marzuki, *Introduction to Law* (Kencana 2008).[47].

<sup>8</sup> *ibid.*

### **Fulfillment of the Right to Health as a Human Right by the State**

Fulfillment of human rights, including the right to health, is the responsibility of the state, especially the government, as emphasized in Article 28 I Paragraph (4) which reads “Protecting, promoting, upholding and fulfilling human rights is the responsibility of the state. the state, especially the government.” The government is responsible for fulfilling the right to health as part of human rights. Implementation of government responsibilities is not only important but will also become a benchmark in improving people’s lives as a manifestation of human rights. The main basis that the protection of human rights is the obligation of the government is the democratic principle that the government is actually given the power to protect the rights of citizens.

To strengthen the view that the constitution is the most important part of a country, Bryce explained the political motives in drafting the constitution as quoted by Joeniarto, namely as follows:<sup>9</sup>

- a. The desire to guarantee the rights of the people and to control the behavior of the authorities;
- b. The desire to describe the existing system of government in a clear formulation in order to prevent possible arbitrariness on the part of future rulers;
- c. The desire of the creators of a new political life to guarantee or secure the enactment of a method of government in a form that is permanent and understandable to citizens;
- d. The will and desire to ensure the effective cooperation of several countries that initially stand alone.

CF Strong said that the substance of the constitution cannot be separated from the principles of constitutionalism itself. The constitution must contain at least the following contents:<sup>10</sup>

- a. Restrictions on state power;
- b. Guarantee of human rights; and

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<sup>9</sup> Joeniarto, *Overview of Sources of Constitutional Law in Indonesia* (FH UGM 1964).[36]. in Majda El Muhtaj, *Human Rights in the Indonesian Constitution From the 1945 Constitution to the Amendments to the 1945 Constitution in 2002* (Kencana 2015).[33].

<sup>10</sup> CF Strong, *Modern Political Constitutions An Introduction to the Comparative Study of Their History and Existing Forms* (Sidgwick & Jackson Limited 1960).[10]. in Majda El Muhtaj (n 5).[35].

c. arrangements regarding the exercise of state power.

Based on CF Strong's views regarding the principle of constitutionalism, one of them discusses guaranteeing human rights, in this case inseparable from health insurance. The right to health is a human right. This is in line with Article 9 of Law no. 39 of 1999 concerning Human Rights which states that:

1. Everyone has the right to live, maintain life, and improve their standard of living;
2. Everyone has the right to live in peace, security, peace, happiness, physical and spiritual prosperity;
3. Everyone has the right to a good and healthy environment.

Then the right to health is regulated in Law no. 36 of 2009 concerning Health. Article 4 confirms that "everyone has the right to health". Article 5 stipulates that:

- (1) Everyone has the same right to gain access to resources in the health sector;
- (2) Everyone has the right to obtain safe, quality and affordable health services;
- (3) Everyone has the right to independently and responsibly determine the health services needed for himself.

The government's obligation in the health sector is emphasized in Article 7 that "the government is tasked with organizing health efforts that are equitable and accessible to the community". Article 9 states that "the government is responsible for improving public health status".

UU no. 36/2009 not only regulates the right to health but also regulates the Government's obligation to fulfill the availability of medicines. Article 36 stipulates that "The government guarantees the availability, equity, and affordability of health supplies, especially essential medicines. Guaranteeing the availability of drugs in an emergency, the Government can make special policies for the procurement and use of drugs and substances with medicinal properties. Article 40 Paragraph (1) "The government compiles a list and types of drugs which basically must be available for the benefit of the public". Article 40 Paragraph (4) "in an emergency, the Government may adopt a special policy for the procurement and utilization of health supplies". Finally, Article 153 stipulates that "The government guarantees the availability of safe, quality, effective, affordable, and equitable immunization

materials for the community in efforts to control infectious diseases through immunization”.

According to Friedmann, the function of the state in a mixed economic system is as: (a) provider; (b) regulators; (c) entrepreneur; and (d) Umpire.<sup>11</sup> The state as a provider means that the state is responsible for providing social services and guaranteeing a minimum standard of living for all its people. For example, providing health services that can be accessed by the community. The function of the state as a regulator means that the state uses various levels of control, especially the power to regulate investment in industrial development, the type and volume of export-import and control of industrial licensing. For example, making regulations related to access to medicines and fulfilling the right to health.<sup>12</sup>

Meanwhile, the function of the state as an entrepreneur means that the state is engaged in certain economic fields through semi-autonomous government departments or BUMN. For example BUMN in the pharmaceutical sector such as Biofarma, Kimia Farma and Indofarma. The state's most difficult function is that of the state as an umpire, meaning that the state is a legislative, administrative, and judicial power that must set standards of fairness among various sectors of the economy, some of which are state enterprises.<sup>13</sup> Legislative power, namely making laws and regulations, administrative, namely setting policies, and judicial, namely that the state is a state of law. This is the most difficult function of the state because the state has to be the arbiter and be impartial when conflicts arise between the state and the private sector. So the difference in the function and role of the state is not only a matter of economic efficiency and political balance, but also a matter of justice.<sup>14</sup>

Based on rules and principles, health insurance will not be achieved without the main foundation in protecting human rights. Efforts to fulfill the right to health

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<sup>11</sup> Friedmann, *Government Public Company* (1967). [4-8] in Rahmi Jened, *Theory and Legal Policy of Direct Investment* (Kencana Kharisma Putra Utama 2016).[73].

<sup>12</sup> Rahmi Jened, *Resume the State and the Rule of Law in a Mixed Economy by Friedmann* (Airlangga University 2002).[11-16].

<sup>13</sup> Jened (n 11).

<sup>14</sup> *ibid.*

can be carried out in various ways, including prevention and treatment. Prevention measures include creating adequate conditions for good health, ensuring food and employment, good housing and a healthy environment. While healing efforts are carried out by providing optimal health services. Optimal health services include aspects of health social security, adequate health facilities, qualified medical personnel, and affordable service financing for the community.

In the context of guaranteeing human rights, the constitution gives its own importance to the creation of a legal state paradigm that prioritizes guarantees of human rights. The guarantee of human rights emphasizes the stance that the state is responsible for upholding the rule of law, in this case the constitutional guarantee of human rights can mean that the state is responsible for administering the state of a state.<sup>15</sup>

The importance of health as a human right and as a condition for fulfilling other rights has been recognized internationally. Where specifically in Article 25 of the Universal Declaration of Human Rights (UDHR) it is stated that “Every person has the right to a standard of living adequate for the health and welfare of himself and his family, including the right to food, clothing, housing and health services, social services needed, as well as the right to security in the event of unemployment, illness, disability, neglect by a spouse, old age, or other circumstances that result in a decrease in the standard of living that occurs outside of himself. control”.

The Universal Declaration of Human Rights adopted by the United Nations General Assembly in 1948 is the clearest scheme for regulating what the international community views as real human rights, which all human beings on this earth have, because they are human.<sup>16</sup> The Universal Declaration of Human Rights is the core source of human rights law. Declarations are statements of principle based on moral motivation, but not legal motivation. These two agreements are designed to make the principles of the Universal Declaration of Human Rights a legal obligation of the countries that have ratified the declaration. These two agreements are called the

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<sup>15</sup> Majda El Muhtaj (n 5).[85].

<sup>16</sup> Allan McChesney, *Advancing And Defending Economic, Social, And Cultural Rights* (Insist Press 2003).[6].



International Covenant on Civil and Political Rights (ICCPR), and the International Covenant on Economic, Social and Cultural Rights (ICESCR) .<sup>17</sup>

There are characteristic differences between civil rights and political rights with economic rights, social rights, and cultural rights. The characteristics of civil rights and political rights are: immediately realized, the state is passive , can be tried / judged , does not depend on resources, non-ideological, individual rights and is absolute and must be implemented immediately.<sup>18</sup> While the characteristics of economic rights, social rights, cultural rights, among others, are achieved gradually/progressive realization, the state active, unjustifiable , resource dependent, ideological, collective rights, and progressive/relative in nature.<sup>19</sup> Civil rights and political rights are classified as absolute and immediate rights, while economic, social and cultural rights<sup>20</sup> classified as a programmed right, which must be realized in stages, and therefore is not a legal matter.

The right to health is in the form of “gradual realization” as stipulated in Article 2 Paragraph (1) of the ICESCR, indicating that states can realize this aspect in stages. However, some elements are not subject to the gradual realization that must be realized soon, and create the notion of the right to public health. The right to health has economic, social and cultural aspects. This right is economic and social in nature because this right seeks to prevent individuals from suffering social and economic injustice as far as possible with regard to their health. This right is cultural because it seeks to ensure that the health services provided are adequately adapted to one’s cultural background.

States parties to the ICCPR and ICESCR recognize the right of everyone to a high standard of mental and physical health. International human rights law

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<sup>17</sup> *ibid.*

<sup>18</sup> *ibid.*

<sup>19</sup> *ibid.*

<sup>20</sup> Absjorn Eide, Catarina Krause and Allan Rosas, *Economic, Social, and Cultural Rights*. Translation by Rini Adriati, *Economic, Social and Cultural Rights* (Raoul Wallenberg Institute of Human Rights and Humanitarian Law). [10] in EW Vierdag, *The Legal Nature of The Rights Granted by the International Covenant on Economic, Social, and Cultural Rights*, Volume 9 (Dutch Yearbook of International Law 1978).[103].

establishes two rules relating to health:

- a. Public health protection that legally limits human rights;
- b. Individual health rights and the government's obligation to provide them.

In determining state obligations in relation to the human right to health, priority is given to public health regulation, as described in Article 12 of the ICESCR. This article was later strengthened in various international civil and political rights instruments. The implementation of public health regulations often conflicts with the rights and health of individuals, as well as matters relating to the protection of personal life, integrity and freedom which conflict with and/or with laws that become the authority of the community which aim to protect public health. Laws adopted to prevent the spread of epidemic diseases often limit their freedom of movement and deprive them of their freedom.<sup>21</sup>

The existence of international recognition of the right to health does not mean that society must be healthy because neither the government nor the individuals themselves can guarantee certain health conditions. Health conditions are often determined by an individual's heredity and environment, and to some extent by health disorders. Health interventions have been shown to be less capable of improving human health, when compared to broad development activities.<sup>22</sup>

International human rights law refers to the highest attainable level of health as the target for guaranteeing the right to health. The main objective of health law is to reduce and/or prevent the occurrence of health problems, as well as developing the potential of individuals and communities to overcome them. Both of these objectives become a reference in the formation of international law. The development of human rights standards in the health sector is influenced by everything that is included in the health sector. The definition of health used today is very broad, which shows why it is difficult for us to develop equal protection of the right to international health in the world.<sup>23</sup>

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<sup>21</sup> ELSAM Team, *Rights, Economy, Social, Culture* (ELSAM 2001).[263]

<sup>22</sup> *ibid.*

<sup>23</sup> *ibid.*[266].

The achievement of the highest possible standard of health is defined in the constitution of the World Health Organization (WHO) as the organization's most important goal, and is one of the basic rights of every human being. Health is defined as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.<sup>24</sup> This should be a serious concern for the government to achieve the target of fulfilling health quality for the right to health.

The scope of human rights to health is defined as every human being has the right to an environment that has minimal risk to health, and has the right to get access to health services that can prevent or reduce suffering, cure disease, and help maintain health. and promotes a state of good health throughout an individual's life.<sup>25</sup> Jonathan Montgomery explains the content of the right to health in a way that is not too ambitious, namely through three standards, namely:<sup>26</sup>

- a. enforceable individual rights (aimed at protecting minimum standards);
- b. the right to aspiration (directly referring to the national health development policy); and
- c. legal obligations protect conditions that allow citizens to choose a state of maximum health.

Human rights require individuals to have recognized access to the fulfillment of the right to health, and as a consequence, the government is obliged to provide this. The implication of this difference can be understood that access to health measures depends on the ability of individuals to adapt to government policies in managing public health budgets and marketing social services. If this practice hinders access to health for people who cannot afford to pay, it is considered contrary to human rights, then a guarantee of inability to pay is needed so as not to reduce access to health.<sup>27</sup>

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<sup>24</sup> *ibid.*[268].

<sup>25</sup> WHO, *Woman's Health: Across Age and Frontier* (1992) <<https://apps.who.int/iris/handle/10665/37677>> accessed 6 December 2022.

<sup>26</sup> J. Montgomery, *The Welfare of Citizens* (A. Coote ed., Development of Social Rights 1992).[89].

<sup>27</sup> ELSAM Team (n 17).[275].

Health as a human right has generated confusion and some controversy. Different terms are used to talk about health as a human right, such as the right to health,<sup>28</sup> the right to health care,<sup>29</sup> the right to health protection, in a broad sense with the term right to health.<sup>30</sup> The UN Human Rights Committee defined the obligation of states to protect human life, concluding that states are obliged to take action to eliminate epidemic disease (plague) and malnutrition.<sup>31</sup>

Fulfilling the right to health is the responsibility of the state in its function to protect all people and improve general welfare, availability and access to medicines must be guaranteed, regardless of the level of economic capacity, bearing in mind that meeting the need for medicines is an obligation. one of the protection of human rights.<sup>32</sup> The state guarantees the optimal implementation of health services for every citizen regardless of individual social status. Health services that must be provided by the state include ensuring the availability of complete medicines in sufficient quantities, guaranteed quality, good quality, affordable and easily accessible to people who need them.<sup>33</sup>

The elements that make up the right to health can be divided into two categories:

- a. contains elements related to health services;
- b. includes elements related to a number of basic health requirements in the form of clean drinking water, adequate nutrition, health information, environmental health and the workplace.<sup>34</sup>

The main content of the right to health consists of a set of elements that must be guaranteed by the state in any circumstances, regardless of available resources.

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<sup>28</sup> KE Mahoney and P. Mahoney, *Human Rights in the Twenty-First Century* (1993). Within the ELSAM Team (n 21).[183].

<sup>29</sup> R. Roemer, 'Right to Health Care Benefits and Gaps' (1993) Volume 78 of the American Journal of Public Health.[241-247].

<sup>30</sup> A. Eide et al. (ed), *Economic, Social, and Cultural Rights: A Textbook* (1995).[125-143].

<sup>31</sup> ELSAM Team (n 17).[275].

<sup>32</sup> Mikael Rostila, *Social Capital an Health Inequality in European Welfare State* (Palgrave Macmillan 2013).[10] in Aktieva Tri Tjitrawati, 'The Just Drug Distribution In The Perspective of Welfare State' (2013) 25, No. 3 Law Platforms.[10].

<sup>33</sup> *ibid.*

<sup>34</sup> Toebe BCA, *The Right to Health as a Human Right in International Law* (1999).[245].

The fulfillment of the right to health is the responsibility of the state which must be guided by the following principles:<sup>35</sup>

- a) Availability of health services: the country should have a sufficient number of health services for the population as a whole.
- b) Health services that are affordable and easily accessible financially, geographically and culturally.
- c) Quality of health services: the health services provided must conform to standards, which include requirements for the services to be suitable for a particular context.
- d) Equality of access to available health services.<sup>36</sup>

The state has an obligation to respect, protect and fulfill the human rights of its citizens. Remembering the obligation to respect is essentially an obligation not to act. The obligation to protect and fulfill is an obligation to protect individuals against certain acts by third parties, or to provide or facilitate certain services. This typology has been successfully applied to various economic, social and cultural rights and clarifies the normative content of these rights.<sup>37</sup> The obligation of the state to respect, protect and fulfill human rights, Toebes in his book proposes as follows:<sup>38</sup>

Duty to respect:

- a) Respect equal access to available health services and not eliminate individual and group access to available services;
- b) Do not take actions that interfere with human health, such as activities that cause environmental pollution.

Obligation to protect:

- a) Take legal and other measures to ensure that people have access (equivalent to health services if provided by a third party);
- b) measures to protect humans from violations in the health sector by third parties.

Obligation to fulfill:

- a) to adopt a national health policy and provide an adequate share of available health funds;

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<sup>35</sup> ELSAM Team (n 17).[191].

<sup>36</sup> BCA (n 30).[287-342].

<sup>37</sup> *ibid.*[193].

<sup>38</sup> *ibid.*[194].

- b) create conditions so that people have adequate and adequate access to health services, health services and clean water.

To fulfill the obligation to fulfill human rights, the state must guarantee that the rights of citizens are respected, protected and fulfilled. This task requires ensuring that there are no unfair differences or barriers in the private sector or public services. The government is responsible for optimally regulating and protecting the right to public health. The government's responsibility in fulfilling the right to health is realized in the form of providing proper health facilities and facilities that are easily accessible to the public.

### **Access to Patented Drugs to Fulfill the Right to Health**

The relationship between drug patents and human rights to health has become a major concern at the international level.<sup>39</sup> International attention to this problem has largely focused on the high cost of patented drugs for epidemic and pandemic diseases.<sup>40</sup> Protection of drugs with patents has an impact on the high price of drugs so that the prices of patented drugs are not affordable by the poor in Indonesia. This condition can hamper people's access to medicines because not all residents have health insurance. In addition, patent medicines are not medicines that are covered by Social Security Administrator. Trade Related Aspects of Intellectual Property Rights (TRIPs agreement) also hinders competition in the drug industry because drug patent owners hold monopoly rights over a drug. The issue of access to medicines in cases of HIV/AIDS and Covid-19 continues to be of international concern. Especially for Covid-19, which until now has not found a cure. Drugs used for post-Covid-19 therapy are limited and expensive. The increase in the number of Covid-19 cases was followed by an increase in the need for medicines to treat

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<sup>39</sup> WTO, 'Declaration on TRIPs Agreement and Public Health, Ministerial Conference' (*Fourth Session*, 2001) <[https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm#:~:text=1.,tuberculosis%2C malaria and other epidemics](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm#:~:text=1.,tuberculosis%2C malaria and other epidemics) > accessed 25 June 2020.

<sup>40</sup> UNICEF, 'Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS' (*WHO*, 2020) <<https://apps.who.int/iris/handle/10665/67323> > accessed 25 June 2020.

Covid-19. The government continues to make efforts to maintain the availability of drugs, especially Covid-19 therapeutic drugs, so that there is no shortage of supply.

From a legal perspective, there are two reasons for limited access to drugs, namely: *first*, human rights law through the agreement on Economic, Social, and Cultural Rights, has made significant changes to the codification of human rights for health.<sup>41</sup> *Second*, regarding access to medicines related to whether the drug must be patented.<sup>42</sup> The scope of patents in the health sector that has been regulated in TRIPs, broadens the scope of patents related to basic health needs and the development of health itself. The relationship between the two fields is becoming increasingly clear and direct, requiring further consideration of the relationship between the right to health and drug patents.

In the pharmaceutical sector, private industry in the health sector is urgently needed so that industry representatives stated that the pharmaceutical industry spends more on R&D than other industries, although the development of new drugs is an expensive process, it is easier to imitate existing drugs.<sup>43</sup> Thus the patent system allows companies to charge higher prices than production and distribution prices which are expected to absorb drug development costs. After patent protection expires, competition between generic versions can result in the cheapest drug prices.<sup>44</sup> Despite the pharmaceutical industry's demand for patent protection, a number of countries limit drug patents to the public for policy reasons. Though drug patents have become a growing norm in the pharmaceutical field and have resulted in patents for new drugs.<sup>45</sup> Patent protection for drugs and drug development for

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<sup>41</sup> ICESCR, 'International Covenant on Economic, Social and Cultural Rights' (16 December 1996) <[http://www.nwci.ie/download/ppt/icescr\\_presentation\\_fidelma\\_joyce.ppt](http://www.nwci.ie/download/ppt/icescr_presentation_fidelma_joyce.ppt)> accessed 25 June 2020.

<sup>42</sup> Lidya Shery Muis, 'The Right to Accessibility of Patented Drugs for the Community' (2019) 1 Widya Pranata Hukum : Journal of Legal Studies and Research 36 <<http://ejournal.widyamataram.ac.id/index.php/pranata/article/view/259>>.

<sup>43</sup> Jr. Harvey E. Bale, 'The Conflict Between Parallel Trade and Access to Products and Innovation: The Case of the Pharmaceuticals' [1998] Journal of International Economic Law I.[637].

<sup>44</sup> John H. Barton, 'Different Prices of Patented Products' (2001) No. WG4:2 Series of Working Papers of the Commission on Macroeconomics and Health.

<sup>45</sup> Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Center 2000).

certain diseases in developing countries is a matter of debate because patents do not necessarily trigger more drug development linked to the poor.<sup>46</sup> The issue of patent protection in the health sector creates a conflict of interest between the pharmaceutical industry's goal to return its investment returns and the government's interest in limiting health care costs.<sup>47</sup>

Accessibility generally refers to the idea that health policy should encourage the availability of affordable medicines for all those who need them.<sup>48</sup> However, providing incentives for the development of new drugs limits access due to relatively higher drug prices. This has implications for the poor's lack of access to medicines. Limited economic capacity means that not everyone in developing countries has health insurance and often pays for their own medicines.<sup>49</sup> Price is a major issue of access and patents are not the only factor affecting access as even cheap generic drugs may be out of reach for people below the poverty line, in this situation access can only be ensured through public subsidies and price controls.

Each country has its own drug distribution system determined by the government. This is based on the public health paradigm adopted by the state and the government's perspective on medicine. *First*, is the drug purely considered as an economic product; *secondly*, drugs are considered as part of the administration of the health system by the state; or a combination of the two concepts. The third concept is usually adopted by developing countries such as Indonesia as a solution to meet the needs of people who are usually placed in various welfare stratifications. This system differentiates pure drugs which are considered as economic products that are sold according to market mechanisms, but the government also provides drugs

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<sup>46</sup> Intellectual Property Commission, *Integrating I Intellectual Property Rights and Development Policy* (CIPR 2002).

<sup>47</sup> John H. Barton, 'Intellectual Property Rights and Innovation' in Nicholas Imparato (ed), *Capital for Our Time: Challenges to the Economy, Law and Management of Intellectual Capital* (Hoover Institution Press 1999).

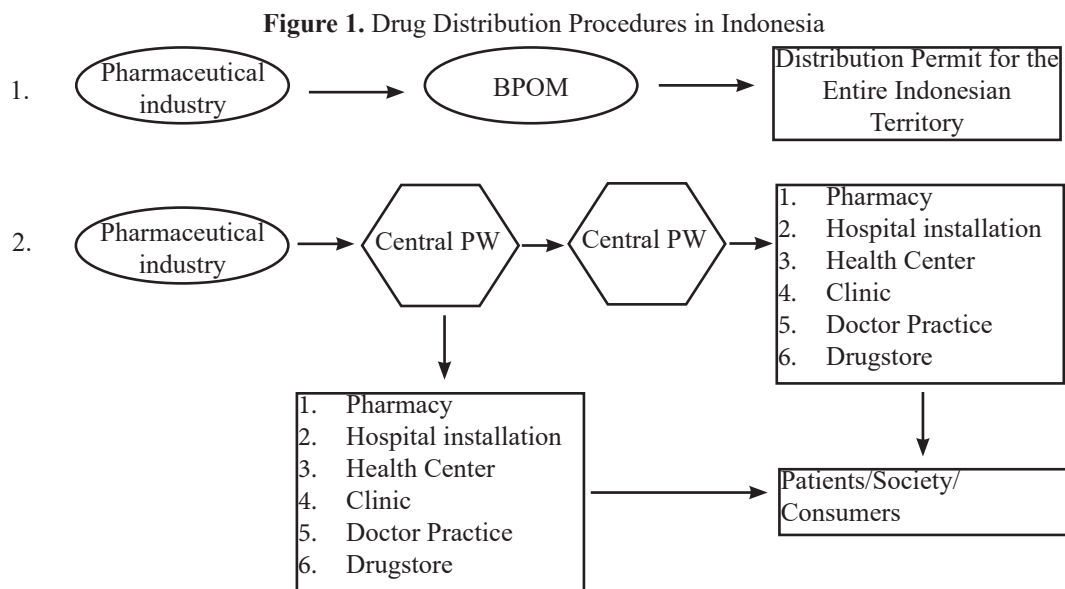
<sup>48</sup> Velasquez and Pascale Boulet Germany, 'Globalization and Access to Drugs: Implications of the WTO/TRIPs Agreement', *Globalization and Access to Drugs- Perspectives on the WTO/TRIPs Agreement 2*, vol doc.WHO/DAP/98.9 (WHO 1998) <<http://apps.who.int/iris/handle/10665/63905>> accessed 26 June 2020.

<sup>49</sup> *ibid.*



in the administration of the health system by the state which are easily accessible to the public at low prices.<sup>50</sup>

Drug distribution channels in Indonesia are determined by the government.<sup>51</sup> The drug distribution channel starts from the pharmaceutical industry which is then distributed to Pharmaceutical Wholesalers (PW) and then PW will distribute or distribute the drug to PW branches, pharmacies, hospital pharmacy installations, medical centers and pharmacy warehouses. Drug distribution channels can be understood through the following figure:



Models Description:<sup>52</sup>

1. The pharmaceutical industry is required to register drugs submitted to the Head of the Food and Drug Monitoring Agency/BPOM to obtain drug distribution permits throughout Indonesia, this is regulated in Minister of Health regulations No.1010/Menkes/Per/XI/2008 concerning Drug Registration.<sup>53</sup>
2. After obtaining registration approval, the drugs are distributed through Pharmaceutical Wholesalers which are separate from PW. PW is in charge of

<sup>50</sup> *ibid.*

<sup>51</sup> Muis (n 42).

<sup>52</sup> *ibid.*

<sup>53</sup> The Pharmaceutical Industry is a business entity that has a license from the Minister of Health to carry out activities to manufacture drugs or medicinal ingredients.

distributing drugs to pharmacies, hospital pharmacy installations, health centers, clinics, drugstores, and practicing doctors.<sup>54</sup>

The uneven distribution of medicines results in limited access to medicines. One of the distribution constraints is that for several types of drugs, PW as a place for storage, procurement and distribution of drugs must provide a refrigerated drug storage warehouse to maintain drug quality and provide pharmacists to be in charge of drug distribution. Limited facilities like this limit PW's ability to distribute drugs to remote and inaccessible areas, making access difficult and prices high.<sup>55</sup> Lack of awareness to take steps to reduce this level of disparity leads to errors in drug distribution policies. Drug distribution in Indonesia must be placed in the perspective of public welfare and not only seen as an economic activity because every component in the drug distribution system starts from the pharmaceutical industry to consumers so that their interests are protected.<sup>56</sup>

Drug distribution procedures have been regulated by the Government in BPOM Regulation No. 9 of 2019 concerning Technical Guidelines for Good Medicine Distribution (GMD), and changes to regulation No. 6 of 2020. The GMD method is a method for distributing/supplying drugs and/or medicinal ingredients that aims to guarantee quality along the distribution/distribution channels in accordance with the needs and intended use. Activities related to drug distribution include procurement, storage and distribution including the return of drugs and/or medicinal substances in the distribution chain from producers to consumers. Implementation of GMD aims to maintain and ensure the quality of drugs received by patients is the same as the quality of drugs issued by the pharmaceutical industry.

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<sup>54</sup> Drug Wholesalers are companies in the form of legal entities that have permits to procure, store, distribute drugs and/or medicinal substances in large quantities in accordance with statutory provisions. PW can establish branches in each province with permission from the Director General of the Ministry of Health who is responsible for pharmaceuticals and medical devices. The PW license is valid for 5 years. The Minister of Health regarding PW has undergone two changes, namely Number 1148/Menkes/per/VI/2018, amended by Permenkes No. 34 of 2014 and last changed to Permenkes No. 30 of 2017.

<sup>55</sup> Aktieva Tri Tjitrawati (n 28).[10].

<sup>56</sup> *ibid.*

Drug procurement policies are a tool to help governments buy quality medicines at the lowest possible prices. Procurement of drugs by the government has been regulated in Minister of Health Regulation Number 5 of 2019 concerning Planning and Procurement of Electronic Catalog-Based Medicines which aims to increase effectiveness, efficiency and transparency in the process of planning and procuring drugs. An effective procurement strategy must accurately estimate a country's drug needs and select the most appropriate strategy based on resources and time.

In the process of drug procurement, problems often occur, namely when there are many types of drugs procured, so that more drug providers are needed, which results in ordering inputs not being able to coincide, so delays and even failure of orders often occur. Then the drug provider turns out to be at the same distributor level so that an adequate drug procurement method is needed.<sup>57</sup>

There are four general ways in which drugs can be procured by the government, namely:<sup>58</sup>

- a. open tender, involving many bidders who meet the drug procurement requirements;
- b. limited auction, which involves certain participants who have a good history and is held behind closed doors;
- c. competitive negotiation, namely negotiation with competition to get the best price and quality offer; and
- d. direct procurement, namely making purchases directly to distributors without a tender process.<sup>59</sup>

The procurement method chosen by the government should strive to achieve the following objectives:<sup>60</sup>

- a. to obtain the most cost-effective drug in the right quantity;
- b. to select reliable suppliers for high quality products;
- c. to ensure timely delivery of essential medicines; and
- d. to achieve the lowest possible total cost.

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<sup>57</sup> Ulum Rokhmat Rokhmawan, Agus Yudha Hernoko and M. Khoirul Huda, 'Legal Analysis of Electronic Drug Procurement (E-Purchasing)' (2017) Vol 9 No.1, Medica Majapahit.

<sup>58</sup> WHO, 'A Practical Guide to Procurement of Pharmaceuticals for Countries with Small Procurement Agencies' (WHO) <<https://apps.who.int/iris/handle/10665/206932>> accessed 12 September 2020.

<sup>59</sup> Quick and et al, *Managing Drug Supply, Management Sciences for Health* (7th Printing, Massachusetts 2012).

<sup>60</sup> WHO, 'Operational Principles for Good Pharmaceutical Supply' (WHO) <<https://www.who.int/3by5/en/who-edm-par-99-5.pdf>> accessed 12 September 2020.

This method is used so that access to medicines to fulfill the right to health can be carried out properly. The state in its function must fulfill the availability and access of drugs regardless of individual social status and regardless of the level of economic ability of its people.<sup>61</sup> Health services must guarantee the availability of complete medicines in sufficient quantities, guaranteed quality, quality, affordable, and easily accessible to people who need them.<sup>62</sup>

The government is not only responsible for the availability of cheap, affordable drugs and equitable access, but is also responsible for the quality of drugs circulating in the community. The government agency that has the function of controlling the quality of drugs circulating in the community is BPOM. The BPOM functions to supervise and evaluate the safety, efficacy, quality, and marking/labeling of drug products prior to distribution (*pre-market evaluation*) and routinely supervises production and distribution facilities, as well as products circulating in Indonesian territory (*post market control*). This is confirmed in Article 3 of Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency.

Prior to granting a distribution permit, drugs must be registered in advance with the aim of evaluating the efficacy and quality of drugs in accordance with Good Manufacturing Practices (GMP). This must be considered by drug manufacturers to avoid the emergence of dangerous side effects from the consumption of these drugs. For example, kidney failure in children caused by the use of ethylene glycol in syrup drugs, especially paracetamol syrup for children, which exceeds the safe threshold.<sup>63</sup> Until October 2022 there were 269 children suffering from kidney failure and 157 of them had died.<sup>64</sup> BPOM has given administrative sanctions in the

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<sup>61</sup> Mikael Rostila (n 28). In Aktieva Tri Tjitrawati (n 32).

<sup>62</sup> *ibid.*

<sup>63</sup> Adi Wikanto, 'List of 69 Syrup Drugs Prohibited by BPOM 6 November 2022, There is Paracetamol, OBH' ( *Nasional Kontan News* , 6 November 2020) <<https://nasional.kontan.co.id/news/terbaru-registr-69-obat-syrup-prohibited-bpom-6-november-2022-ada-paracetamol-obh>> accessed 13 November 2022.

<sup>64</sup> Muhammad Isa Bustomi, 'Acute kidney failure in South Jakarta has increased drastically', 12 children will be infected in the near future' ( *Megapolitan Kompas* ) <<https://megapolitan.kompas.com/read/2022/10/28/15015431/gagal-kidney-acute-in-jaksel-increased-dramatically-12-infected-in-children>> accessed 13 November 2022.

form of revocation of GMP certificates for non-betalactam oral liquid preparations and distribution permits for syrup drugs produced by drug companies, namely PT Yarindo Farmatama, PT Universal Pharmaceutical Industries, and PT Afi Pertanian.<sup>65</sup> Learning from this case, the government is expected to be more aware of the consistency of drug quality standards during the registration process with the quality of drugs already on the market. Do not let the medicinal raw materials used cause casualties.

### **Conclusion**

State responsibility for access and availability of patented drugs for public health regulated in Article 28H and Article 34 of the 1945 Constitution of the Republic of Indonesia , namely the fulfillment of the right to health for every Indonesian citizen in the form of obtaining health facilities and public service facilities must be provided by the state. The state must respect, protect and the right to health as a human right. This includes an environment that poses minimal risk to health, and the right to have access to health services, cure disease, and help maintain and improve health conditions. Therefore the state must be able to fulfill its function as a provider, regulator, entrepreneur and referee . With the fulfillment of state functions, it is hoped that the state will be able to guarantee the availability of complete medicines in sufficient quantities, guaranteed quality, quality, affordable and easily accessible to people who need them regardless of individual social status. One of the reasons for the high price of patented drugs is due to the absence of regulations governing the price of patented drugs. So far, the price of patented drugs is determined by pharmaceutical companies that have patent rights. The government is expected to establish regulations regarding the Highest Retail Price (HRP) for patented drugs, so that the government can control the prices of patented drugs circulating in the community. Regulations on drugs and the highest retail prices for patented drugs are expected to make it easier for the public to meet their demand for

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<sup>65</sup> Adi Wikanto (n 64).

patented drugs at affordable prices. Drug companies in Indonesia are expected to be able to carry out research and development to find new drugs, so that Indonesia does not need to depend on patent flexibility for access to the medicines it needs. Director General of Intellectual Property Rights is expected to assist and simplify the process of drug patent registration.

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