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# Quo Vadis Regulation Of Drug Distribution On Non-Pharmaceutical Facilities

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#### **Abstract**

The distribution of drugs, especially over-the-counter drugs and restricted over-the-counter drugs, currently seems not to be properly controlled as there is a discrepancy between regulations and techniques in monitoring the distribution of them on non-pharmaceutical facilities. In response to this, the Government made changes by issuing Law Number 17 of 2023 about Health replacing Law Number 36 of 2009. This research aims to confirm that with the publication of Law Number 17 of 2023 about Health, there are regulations that explicitly regulate the procedures for implementing pharmaceutical practice. The results of this research show that although it is not perfect, the government has fulfilled its obligation to protect the public in terms of drug distribution.

**Keywords:** Drug, Pharmacists, Non-Pharmaceutical Facilities, Health Law.

# INTRODUCTION

#### **Background**

Indonesia is a State of Law. This is stated in the Explanation of the 1945 Constitution, formulated firmly in Article 1 paragraph (3) which states, "The State of Indonesia is a State of Law". In the concept of the rule of law, what must be used as a reference in running the state is law, not politics or economics. Therefore, the term that commonly used to refer to the principle of the rule of law is 'the rule of law, not of man'. What is called government is essentially the law as a system, not individuals who only act as 'puppets' of the scenario of the system that regulates it.<sup>1</sup>

The idea and concept of the rule of law is generally intended to prevent the state or government from taking arbitrary actions. Somehow, a government that is not controlled by strict and concrete legal instruments will be very vulnerable to various forms of deviation and abuse of power. Even in the modern era, it can be said that a country is very relevant and ideal if all its series of state activities are based on a clear and firm legal mechanism.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Asshiddiqie, J. Gagasan negara hukum Indonesia. In *Makalah Disampaikan dalam* Forum Dialog Perencanaan Pembangunan Hukum Nasional yang Diselenggarakan oleh Badan Pembinaan Hukum Nasional Kementerian Hukum dan Ham. (Nopember, 2011)

<sup>&</sup>lt;sup>2</sup> Simamora, J. Tafsir Makna Negara Hukum dalam Perspektif Undang-Undang Dasar Negara Republik Indonesia Tahun 1945. *Jurnal Dinamika Hukum*, Vol. 14 No. 3, (2014): 547-561.

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The term rule of law in Indonesian literature is a direct translation of Rechstaat. According to Julius Stahl, the concept of the rule of law, which he calls 'rechtsstaat', includes four important elements, namely: 1. Protection of human rights; 2. Division of power; 3. Government based on law; 4. State administrative court.<sup>3</sup> According to the 1945 Constitution of the Republic of Indonesia, Article 28H paragraph 1 states that "Everyone has the right to live in physical and spiritual prosperity, to live and to have a good and healthy living environment and the right to receive health services".<sup>4</sup>

The state established the Indonesian Food and Drug Authority (Indonesian FDA) through Presidential Decree of the Republic of Indonesia No. 103 of 2001 concerning Position, Duties, Functions, Authority, Organizational Structure and Work Procedures of Non-Departmental Government Institutions, which was last amended by Presidential Regulation of the Republic of Indonesia No. 4 of 2013 concerning Position, Duties, Functions, Authority, Organizational Structure and Work Procedures of Non-Ministerial Government Institutions. The position of the Indonesian FDA is clarified in the Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Indonesian FDA and strengthened by the Instruction of the President of the Republic of Indonesia Number 3 of 2017 concerning Increasing the Effectiveness of Food and Drug Control.

Indonesian FDA as a non-ministerial government agency that carries out government affairs in the field of food and drug supervision<sup>5</sup> has responsibility for monitoring pharmaceutical products both before they are distributed and monitoring the products during distribution.<sup>6</sup> In carrying out supervision of Food and Drugs, Indonesian FDA is spread in the form of Technical Units throughout Indonesia with a total of 76 Technical Units. Each technical units have technical duties and functions including, Enforcement; Inspection; Information and Communication; and Examination.<sup>7</sup>

In Law No. 17 of 2023 about Health, the nomenclature of Pharmaceutical Preparations is known, which includes drugs. Drugs plays a very important role in health services. Handling and prevention of various diseases cannot be separated from therapy with drugs or pharmacotherapy. When using drugs, they must always

<sup>&</sup>lt;sup>3</sup> Asshiddiqie, J.). Gagasan negara hukum Indonesia. In *Makalah Disampaikan dalam* Forum Dialog Perencanaan Pembangunan Hukum Nasional yang Diselenggarakan oleh Badan Pembinaan Hukum Nasional Kementerian Hukum dan Ham. (Nopember, 2014).

<sup>&</sup>lt;sup>4</sup> Indonesia, Undang-Undang Dasar Republik Indonesia Tahun 1945, Pasal 28H ayat (1)

<sup>&</sup>lt;sup>5</sup> Indonesia, Peraturan Presiden No.80 Tahun 2017 Tentang Badan Pengawas Obat dan Makanan, Pasal 1

<sup>&</sup>lt;sup>6</sup> *Ibid.*, Pasal 3 ayat (1)

<sup>&</sup>lt;sup>7</sup> Indonesia, Peraturan Badan Pengawas Obat Dan Makanan No.19 Tahun 2023 Tentang Organisasi Dan Tata Kerja Unit Pelaksana Teknis Pada Badan Pengawas Obat Dan Makanan

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be used correctly to provide optimal clinical benefits.<sup>8</sup> Drugs are then divided into three groups of drugs, namely over-the-counter drugs, limited over-the-counter drugs and hard drugs.

Over-the-counter drugs and limited over-the-counter drugs can be purchased by patients without a doctor's prescription and are believed to be relatively safe and can be used without the supervision of a health professional. This is in line with the increase in self-medication, which is directly proportional to the increase in drug use. Deep though self-medication is considered important so that people can help themselves, this activity must be carried out appropriately, safely and rationally.

In practice, self-medication can be a source of medication errors due to limited public knowledge of drugs and their use. 12 Responsible self-medication requires medicinal products that have proven safety, efficacy and quality, and requires selecting the right drug according to the indications of the patient's disease and condition.

Pharmaceutical workers have a very important role in providing assistance, advice and guidance to people who wish to carry out self-medication so that they can do so responsibly. Pharmacists must be able to emphasize to patients that the use of drugs, even those in the category that can be obtained without a doctor's prescription, can still cause danger and unwanted side effects if used improperly.<sup>13</sup>

Therefore, to prevent drug abuse, drug delivery can only be carried out by pharmaceutical workers at facilities that have permits in accordance with statutory regulations. Based on Article 320 paragraph (3) and paragraph (6), prescription medicines are delivered by pharmaceutical workers at pharmaceutical service facilities, while non-prescription medicines are obtained from pharmaceutical service facilities or other facilities in accordance with the provisions of statutory regulations. Based on Government Regulation number 51 of 2009 about Pharmaceutical Work, pharmaceutical service facilities are pharmacies, pharmacy installations, health centers, clinics, drug stores and joint practices. <sup>14</sup> Then it is expressly regulated in Article 145 of Law No. 17 of 2023 about Health that pharmaceutical practice must be carried out by pharmacists in accordance with the provisions of statutory regulations.

<sup>&</sup>lt;sup>8</sup> Badan Pengawas Obat dan Makanan "Pedoman Umum", Pusat Informasi Obat Nasional, 2015, https://pionas.pom.go.id/ioni/pedoman-umum

<sup>&</sup>lt;sup>9</sup> Indonesia. Kementerian Kesehatan. Peraturan Menteri Kesehatan No
919/Menkes/Per/X/1993 tentang Kriteria Obat yang Dapat Diserahkan Tanpa Resep

<sup>&</sup>lt;sup>10</sup> Asri Widodo Mukti dkk, Penggolongan Obat, (Padang: PT Global Eksekutif Teknologi, (2022), hlm.12

<sup>&</sup>lt;sup>11</sup> *Ibid.*, hlm. 22

<sup>&</sup>lt;sup>12</sup> Departemen Kesehatan RI "Pedoman Penggunaan Obat Bebas dan Bebas Terbatas", Direktorat Bina Farmasi Komunitas Dan Klinik Ditjen Bina Kefarmasian Dan Alat Kesehatan, (2007).hlm. 9

<sup>&</sup>lt;sup>13</sup> *Ibid.*, hlm.72

 $<sup>^{\</sup>rm 14}$  Indonesia. Peraturan Pemerintah Republik Indonesia No51tahun 2009 tentang Pekerjaan Kefarmasian

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A phenomenon that is explicitly occurring at the moment is that there are still many medicines distributed in non-pharmaceutical facilities such as retail facilities. Based on existing regulations on pharmaceutical preparations, in this case drugs can only be distributed by pharmaceutical workers as referred to in Article 199 paragraph (1) Letter d and paragraph (5) of Law No. 17 of 2023 concerning Health are "Health workers referred to as pharmaceutical workers are vocational pharmacists, pharmacists and specialist pharmacists". Based on the results of supervision carried out by the author as a food and drugs supervisor at the Food and Drug Authority in the Technical Unit in Rejang Lebong Regency, in the period 2019 to the first semester of 2023, widespread distribution of drugs was found in non-A more complex problem occurs in the distribution of drugs that occurs in minimarkets. Although in the explanation of Article 320 paragraph (6) of Law No. 17 of 2023 about Health, non-prescription drugd are obtained from pharmaceutical service facilities or other facilities in accordance with the provisions of the laws and regulations including Hypermarkets, Supermarkets and Minimarkets. However, the majority of minimarkets are spread across does not have pharmaceutical workers. They do have pharmaceutical staff in the distribution warehouse<sup>15</sup>, but not in their scattered outlets.

This phenomenon makes entrepreneurs of pharmaceutical service facilities such as pharmacies and drug stores feel unfair. This is because for pharmaceutical services, if they have a branch of their business, they must have different permits and pharmaceutical workers even though they are managed by the same procurement source. Based on regulations, minimarket outlets that do not have pharmaceutical workers in charge of the drugs are deemed to have violated Article 145 of Law No.17 of 2023 about Health and consider as crime according to Article 436 of Law No.17 of 2023 about Health.

Another deviation occurred in Pharmaceutical Wholesalers who carried out panel activities. This is when Pharmaceutical Wholesalers and the pharmaceutical industry appear to be distributing them to pharmaceutical service facilities even though the drugs never arrive and end up going to non-pharmaceutical facilities or even individuals. Pharmaceutical service facilities are only used as an administrative mask because the drugs are actually received by irresponsible individuals. Distributing drugs based on Good Drugs Distribution Methods, each Pharmaceutical Wholesaler can only distribute medicines to other wholesaler's, and pharmaceutical

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<sup>&</sup>lt;sup>15</sup> Ajeng Illastria Rosalina," Kajian Distribusi, Keamanan dan Pengembangan Kebijakan Obat Bebas dan Bebas Terbatas", Jurnal Penelitian dan Pengembangan Pelayanan Kesehatan, Vol. 5, No. 1, April 2021.

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

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service facilities include pharmacies, hospital pharmacy installations, health centers, clinics or drug stores.<sup>17</sup>

Because of these deviations, the distribution of medicines in non-pharmaceutical facilities has become uncontrolled. This deviation does not include medicines obtained online. Facility owners, most of whom do not have sufficient knowledge about drugs, tend to provide these medicines based on public demand, prioritizing purely economic factors.

In response to this problem, the Government has taken the right steps by tightening regulations on drug distribution by enacting Law Number 17 of 2023 about Health. The research that will be carried out by the author will focus on comparing the provisions for drug distribution before and after Law no. 17 about Health which relates to Indonesian FDA's duties in supervising drugs in non-pharmaceutical facilities. Based on the description above, the author is interested in conducting research with the title Quo Vadis Regulation of Drug Distribution in Non-Pharmaceutical Facilities, which raises the problem of formulating the comparison of drug distribution regulations before and after the existence of Law no. 17 About Health.

In order for this research to provide results that can be used for broad purposes and can be used as guidance in future drug control, this research was carried out using normative juridical research (normative legal research methods). The data sources used are statutory regulations, literature, and the results of the author's observations as a food and drugs supervisor at the Indonesian FDA in Rejang Lebong Regency.<sup>18</sup>

# RESULT AND DISCUSSION

# 1. The Weakness of Regulations Regarding Drug Distribution Before Law No. 17 of 2023 About Health

According to Selznick, regulation is continuous and focused control carried out by public institutions on service activities needed by the community. One is as a special device for command, where regulation involves a set of binding rules to be implemented by a body specifically assigned for this purpose. <sup>19</sup> In monitoring drug distribution, there are several types of regulations ranging from laws, regulations from the Minister of Health to regulations from the Food and Drug Authority.

<sup>&</sup>lt;sup>17</sup> Mustaqimah, "NARRATIVE REVIEW: IMPLEMENTASI DISTRIBUSI OBAT YANG BAIK DIPEDAGANG BESAR FARMASI", *Jurnal Surya Medika* (JSM), Vol. 6 No.2 (Februari, 2021): 119-124.

<sup>&</sup>lt;sup>18</sup> Soerjono Soekanto dan Sri Mahmudji, Penelitian Hukum Normatif, Suatu Tinjauan Singkat, (Jakarta: Raja Grafindo Persada, 2003), hlm. 13.

<sup>&</sup>lt;sup>19</sup> Robert Baldwin dkk, *Understanding Regulation (Theory, Strategy and Practice)* Second Edition, (New York: Oxford University Press Inc, 2012). hlm. 3.

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In essence, drug distribution is only safe through pharmaceutical service facilities. Where in fact there are regulations that technically explain how medicines can be distributed, namely through Government Regulation number 51 of 2009 about Pharmaceutical Work, which states that pharmaceutical service facilities are pharmacies, pharmacy installations (clinics and hospitals), health centers, clinics, drug stores and Joint Practice.<sup>20</sup>

Basically, Law No. 36 of 2009 about Health regulates that pharmaceutical practice can only be carried out by pharmaceutical technical workers who have the knowledge and authority.<sup>21</sup> This is then confirmed by the imposition of criminal sanctions as regulated in Article 198, where every person who does not have the expertise and authority to carry out pharmaceutical practice as intended in Article 108 is punished with a fine of up to Rp. 100,000,000.00 (one hundred million rupiah).<sup>22</sup>

However, the author feels that it is precisely this fine that makes business actors who violate the provisions of Article 108 not feel threatened. In a criminal sanction, suffering is an important element, as important as other criminal elements. Crime is basically a means to achieve certain goals, namely community protection and individual protection. Punishment is an absolute consequence that must exist as retribution to the person who committed the crime.<sup>23</sup>

Fines are often threatened as an alternative to imprisonment for almost all offenses (overtredingen) listed in Book III of the Criminal Code. For all minor crimes, a fine is punishable as an alternative to imprisonment. Likewise, the majority of crimes are not committed intentionally. The criminal fines regulations in the Criminal Code are determined in Article 10 in conjunction with Article 30 and Article 31.<sup>24</sup>

Analyzing Article 30 of the Criminal Code there is no time limit for payment of fines. If the fine is not paid due to inability or even unwillingness then the fine can be replaced with imprisonment which can be given for at least one day and a maximum of six months to eight months if there is weighting or repetition.<sup>25</sup>

This is considered not to have a sufficient deterrent effect. Because if a person is unable to pay a fine then the adage *Quinon potest solvere poenam in aere, luat in corpore* applies, that is, whoever is unable to pay, then he must pay with bodily

 $<sup>^{20}</sup>$  Indonesia, Peraturan Pemerintah No.51 Tahun 2009 tentang Pekerjaan Kefarmasian.

 $<sup>^{21}</sup>$  Indonesia. Undang-Undang Republik Indonesia No36tahun 2009 tentang Kesehatan, Pasal 108ayat 1

<sup>&</sup>lt;sup>22</sup> Indonesia. Undang-Undang Republik Indonesia No 36 tahun 2009 tentang Kesehatan, Pasal 198

<sup>&</sup>lt;sup>23</sup> Dr. Fitri Wahyuni, S.H.,M.H, *Dasar-Dasar Hukum Pidana di Indonesia*, Tanggerang Selatan. (PT Nusantara Persada Utama,Cet.1, 2017), hlm. 151.

<sup>&</sup>lt;sup>24</sup> *Ibid.*, hlm. 150.

 $<sup>^{\</sup>rm 25}$  Indonesia, Undang-Undang Republik Indonesia No.1 Tahun 1946 Tentang Kitab Undang-Undang Hukum Pidana (KUHP) Pasal 30

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suffering. This is very well understood by the people of Indonesia as is then reflected in the adage *Quaelibet poena corporalis*, *quanvis minima*, *majorest quaelibet poena pecuniaria* (no matter how light a corporal punishment is, it will be heavier than a fine).<sup>26</sup> Then, looking at article 31 of the Criminal Code, the convict can carry out a substitute prison sentence without waiting for the fine payment deadline and can free himself by paying the fine at a later date in proportion to the prison sentence.<sup>27</sup>

It can be seen from the threat of a fine in Article 198 of Law Number 36 of 2009 about Health which is Rp. 100,000,000 (One Hundred Million Rupiah) then even if the maximum sentence is imposed, the Defendant will only tend to serve 8 (eight) months in prison and if the Defendant, in this case, is a business actor with a fairly large turnover, then the fine will tend to be lighter than with impacts resulting from the distribution of drugs outside the supervision of Pharmaceutical Workers.

Apart from that, the technical implementation of investigations regarding Article 198 of Law Number 36 of 2009 about Health will also make it difficult for investigators because suspects cannot be detained as regulated by Article 21 paragraph (4) letter a of the Criminal Procedure Code which states that detention can only be imposed on a suspect or defendant who commits a criminal offense that carries a prison sentence of five years or more. If the suspect cannot be detained, there is a risk that the suspect will run away and/or will damage or destroy evidence.

#### 2. Changes After Law No. 17 of 2023 About Health

Apart from the many polemics that emerged from the birth of Law 17 of 2023 about Health, the author believes that this Law is a form of the Government's seriousness in dealing with problems in the health sector, especially drug control. Significant changes can be seen from the confirmation in the explanation regarding health workers in the pharmaceutical sector. Previously, Law No. 36 of 2009 about Health was only divided into Pharmacists and other Pharmaceutical Workers. In Article 199 paragraph (1) Letter d and paragraph (5) of Law 17 of 2023 about Health it is clarified into the Vocational Pharmacy, Pharmacist and Specialist Pharmacist.

This certainly confirms that only those who are Health Workers in the Pharmaceutical sector are those mentioned in the article. The impact given regarding supervision of drug distribution as regulated in Article 145 of Law 17 of 2023 about Health is to facilitate supervision and of course provide clarity regarding who is allowed to practice pharmacy.

<sup>&</sup>lt;sup>26</sup> Abdul Majid, dkk., *Kebijakan Formulasi Delik dalam Peraturan Daerah*, Malang: Universitas Brawijaya Press, 2021, hlm.50

 $<sup>^{\</sup>rm 27}$  Indonesia, Undang-Undang Republik Indonesia No.1 Tahun 1946 Tentang Kitab Undang-Undang Hukum Pidana (KUHP) Pasal 31

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Pharmaceutical practices as referred to in Article 145 include production, including quality control, procurement, storage, distribution, research and development of Pharmaceutical Preparations, as well as management and pharmaceutical services. Article 320 also regulates facilities that may distribute drugs. According to this article, prescription medicines may only be delivered by pharmacists at pharmaceutical service facilities in accordance with the provisions of statutory regulations and non-prescription medicines can be obtained from pharmaceutical service facilities or other facilities in accordance with the provisions of statutory regulations. Through these articles it is clear that only facilities that have a drug distribution permit and have pharmaceutical health workers are allowed to distribute drugs. <sup>29</sup>

Perubahan lainnya dapat dilihat pada bagian Penyidikan oleh Penyidik Pegawai Negeri Sipil (PPNS) dan ketentuan Pidana dalam Undang-Undang 17 Tahun 2023 tentang Kesehatan ini, pada bagian Penyidikan tepatnya Pasal 424, PPNS ditambah kewenangannya untuk melakukan penggeledahan. Kemudian pada ketentuan pidana Pasal 436 ayat (1) menjelaskan bahwa setiap orang yang melakukan praktik kefarmasian tanpa keahlian dan kewenangan sebagaimana diatur dalam Pasal 145 ayat (1) maka dipidana denda sebanyak Rp. 200.000.000 (dua ratus juta rupiah) dan pada ayat (2) dalam hal apabila sediaan farmasi yang dimaksudkan adalah Obat Keras maka diancam pidana penjara 5 (lima) tahun dan denda Rp. 500.000.000 (lima ratus juta rupiah).

Other changes can be seen in the section on Investigations by Civil Investigators and the criminal provisions in Law 17 of 2023 about Health, in the Investigation section, specifically Article 424, Civil Investigators has increased authority to carry out searches. Then, the criminal provisions of Article 436 paragraph (1) explain that every person who carries out pharmaceutical practice without the expertise and authority as regulated in Article 145 paragraph (1) will be subject to a fine of Rp. 200,000,000 (two hundred million rupiah) and in paragraph (2) in the event that the pharmaceutical preparation referred to is Hard Drugs then the threat of imprisonment is 5 (five) years and a fine of Rp. 500,000,000 (five hundred million rupiah).

This is in line with Sudarto's opinion which states that in dealing with a problem of determining the sanctions that can be imposed on perpetrators of criminal acts, they must pay attention to: National development goals; The act being prevented is detrimental to society; Costs and outcomes; and The capabilities of relevant law enforcement agencies.<sup>30</sup> Within changes in the regulation of criminal sanctions, which are more severe than Law no. 36 of 2009

<sup>&</sup>lt;sup>28</sup> Indonesia. Pasal 145 Undang-Undang Negara Republik Indonesia No 17 tahun 2023 tentang Kesehatan

<sup>&</sup>lt;sup>29</sup> *Ibid.*, Pasal 320

<sup>&</sup>lt;sup>30</sup> Dr. Septa Candra, S.H., M.H, Perumusan Ketentuan Pidana Dalam Hukum Pidana Administratif, (Jakarta: Kencana, 2021), hlm. 27

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indicates that the government considers that the act of distributing drugs without authority and expertise is a form of action that is undesirable to occur in Indonesia.

Still paying attention to Sudarto's opinion, the government understands that the Food and Drug Supervisory Agency must be given better weapons in carrying out its duties in monitoring drug distribution both preventively and repressively. The use of the criminal provisions in article 436 does not only target non-pharmaceutical facilities but also individuals without the need for an element of distribution so that the procurement of drugs itself fulfills the criminal elements.

#### 3. Models of Drug Distribution Regulations in Various Countries

Indonesian law is a law that refers to the law applied by the Netherlands which applies the Continental European legal system. The Continental European legal system is a legal system that emphasizes written law and legislation which is a very important source of law.<sup>31</sup>

In several European countries, especially countries with the Continental European legal system, there are restrictions regarding the sale of drugs. For example, in France medicines can only be purchased at pharmaceutical facilities. In this case, patients can carry out self-medication by choosing products sold at the pharmacy, but patients still have to consult with the pharmacist on duty.<sup>32</sup> Then in Austria it is even stricter where medicines including herbal and homeopathic medicines are registered as medicines because their use can only be sold in pharmaceutical facilities.<sup>33</sup> but it is a little more relaxed in Bulgaria where Limited Over-the-Counter Drugs and Over-the-Counter Drugs can be available in automatic machines operated by pharmaceutical facilities and owned by pharmaceutical facilities.<sup>34</sup>

Comparing Law no. 17 of 2023 about Health with existing regulations in various countries, actually the regulations that apply in Indonesia are already similar. Although there are no detailed regulations regarding the technical form of implementing drug sales outside pharmaceutical facilities.

#### **CONCLUSION**

Through Law Number 36 of 2009 about Health, the government has actually emphasized that those who have the right to practice pharmacy are pharmaceutical

<sup>&</sup>lt;sup>31</sup> Wagiman, dkk, *Pengantar Hukum Indonesia*, Padang: PT Global Eksekutif Teknologi, Cet. 1, 2022, hlm.46

<sup>&</sup>lt;sup>32</sup> <u>Patrycja Oleszkiewicz</u> et al. Access to Medicines via Non-Pharmacy Outlets in European Countries-A Review of Regulations and the Influence on the Self-Medication Phenomenon. Healthcare (Basel), 9(2): 123, 2021, doi: 10.3390/healthcare9020123

<sup>&</sup>lt;sup>33</sup> *Ibid.*,

<sup>&</sup>lt;sup>34</sup> *Ibid.*,

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workers. However, the law does not yet specify the limitations of Other Pharmaceutical Workers. This was then accommodated in Law Number 17 of 2023 about Health which replaced the previous Law, where the term used was health workers in the pharmaceutical sector which was divided into Pharmacy Vocational, Pharmacist and Specialist Pharmacist. Apart from confirming the authority to carry out pharmaceutical practice, the establishment of the classification of health workers in the pharmaceutical sector also increases the demand for these qualifications, which means increasing job opportunities in the pharmaceutical sector.

Through Article 320 paragraph (6) the government also explains that other facilities outside of pharmaceutical facilities can distribute medicines without a prescription, limited to facilities such as Hypermarkets, Supermarkets and Minimarkets. Even though there are pros and cons, this restriction is a clear reference for the Food and Drug Authority in carrying out supervision. However, it would be better regarding Article 320 paragraph (6) to immediately formulate implementing regulations so that there are no deviations in the application of this article.

Then, in Law Number 17 of 2023 about Health, the government also changed the criminal provisions related to pharmaceutical practice. The government increased the fines and added prison sentences, especially for pharmaceutical practices related to the sale of hard drugs. Still related to criminal provisions through Law Number 17 of 2023, the government is also increasing the capacity of Civil Investigators in the Health sector by increasing the authority to carry out searches.

This form of change is an appropriate step taken by the government regarding problems in the health sector, especially pharmaceutical practice, in this case the distribution of drugs. Although it deserves appreciation, for more effectiveness, the government should separate the scope of Food and Drug controls into a separate law through the Food and Drug Control Law, which has not been legalized for years. This was also followed by increasing the capacity of the Food and Drug Supervisory Agency to have its own detention center so that the authority to arrest and detain previously granted in the draft Law Number 17 of 2023 concerning Health could be implemented.

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Ajeng Illastria Rosalina," Kajian Distribusi, Keamanan dan Pengembangan Kebijakan Obat Bebas dan Bebas Terbatas", *Jurnal Penelitian dan* 

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