

## CRIMINAL LAW POLICY OF ILLEGAL PHARMACEUTICAL PREPARATIONS IN THE HEALTH OMNIBUS LAW

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### Abstract

The purpose of the omnibus law is to simplify the legislation amidst the overlapping legal conditions in Indonesia. The purpose of this article is to explain how the criminal law policy of the Omnibus Law applies to the circulation of illegal pharmaceutical preparations in Indonesia, seen from the position of the criminal article regarding the circulation of pharmaceutical preparations in Law Number 17 of 2023 concerning Health. Where Law Number 17 of 2023 concerning Health has revoked the old Health Law, namely Law Number 36 of 2009 concerning Health. This raises doubts for law enforcement officers in law enforcement efforts, whether they can still use the omnibus law of the Job Creation Law which has changed the article related to Illegal Pharmaceutical Preparations in the old Health Law. Based on the results of research on applicable laws and theories related to the formation of the omnibus law, the author argues in the conclusion that the criminal law policy of pharmaceutical preparations in the Health omnibus law aims to simplify the licensing regulations for pharmaceutical preparations into one Law, namely the Job Creation Law. Laws using the omnibuslaw method can only be repealed by the same law so that the articles in the old Health Law which have been amended in the job creation law are still declared valid and can be used by law enforcement officials in enforcing the law against the distribution of illegal pharmaceutical preparations.

**Keywords:** *Criminal law policy, Health, illegal pharmaceutical supplies, job creation, omnibus law*

### INTRODUCTION

The laws and regulations in Indonesia are very numerous. A fundamental and large-scale simplification and restructuring of the laws and regulations is needed. Professor Jimly Asshidiqqie stated that the quantity and quality of the products of laws and regulations in Indonesia are already very complex, and are obese and trapped in a condition commonly called super regulation or hyperregulation. Omnibuslaw or so-called universal law is a solution in organizing the system of laws and regulations in Indonesia so that they run harmoniously and integrated so that there is no overlap between one law and another. (Asshiddiqie, 2020)

Simplifying laws and regulations amidst overlapping legal conditions in Indonesia is one of the government's top priorities. Through the Omnibus Law, the government is trying to simplify various regulations. In the context of the Theory of Legislation, the formation of the Omnibus Law is an opportunity to harmonize laws and regulations in Indonesia. The Job Creation Bill (Omnibus Law) was drafted with the consideration of supporting work copyright where it is necessary to adjust various aspects of regulations where changes to sectoral laws are partly considered ineffective and inefficient, so that a legal breakthrough is needed through the formation of laws using the Omnibus Law method which can resolve various problems in several laws into one law comprehensively. (Rodiyah et al. 2021)

Law number 36 of 2009 concerning Health, regulates the licensing article related to the distribution of pharmaceutical preparations. Where every pharmaceutical preparation circulating in Indonesia is required to have a distribution permit. The obligation to have a distribution permit, followed by a criminal article as a threat to producers or distributors who distribute pharmaceutical preparations without a distribution permit/illegally. With the formation of a Law that adheres to the Omnibus law which aims to simplify the licensing process, the article regulating the Distribution Permit for Pharmaceutical Preparations in Law number 36 of 2009 concerning Health was also changed by the Job Creation Law by changing the phrase "distribution permit" to "business permit". In

accordance with the initial purpose of the formation of the omnibus law, namely to simplify the many regulations in Indonesia into one Law, namely the Job Creation Law. The Health Law is also included in the Omnibus law.

Law enforcement officers in enforcing the law against producers and distributors of illegal pharmaceutical preparations, use Article 197 of Law Number 36 of 2009 concerning Health which has been amended in Article 60 number 10 paragraph 11 Part Four CHAPTER III Health, Drugs and Food Government Regulation in Lieu of Law No. 2 of 2022 concerning Job Creation, attachment to Law no. 6 of 2023 concerning Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law.

On August 8, 2023, the President of the Republic of Indonesia signed Law Number 17 of 2023 concerning Health which was ratified in the DPR Plenary Meeting on July 11, 2023. This Health Law has become a hot issue, one of which is related to the absence of articles regulating the licensing of Pharmaceutical Preparations, both administratively and criminally. Meanwhile, Law Number 17 of 2023 concerning Health clearly states that it revokes the old Law, namely Law Number 36 of 2009 concerning Health.

Prevention of criminal acts in the Health sector requires supervision from the authorities on activities suspected of committing crimes in the Health sector, and law enforcement efforts carried out by investigators from both the National Police and certain Civil Servant Investigators who carry out affairs in the health sector need to increase cooperation in order to reduce and provide a deterrent effect on perpetrators of crime. (Ririhena 2016)

Existing regulations have not been regulated harmoniously, resulting in weak supervision and law enforcement of drug and food distribution. Supervision carried out by the Food and Drug Supervisory Agency and the Police is still not optimal with the large number of drug and food distributions, so that the involvement of a clear, firm and comprehensive legal basis is needed. (Kurniasanti et al. 2020)

The perpetrators of the crime of distributing illegal pharmaceutical preparations are usually driven by the reason of wanting to get rich quickly by getting high profits but at a low cost, the public's ignorance of illegal and dangerous drugs including laws and regulations is exploited by the perpetrators to gain maximum profit. Economic factors, social factors and the environment also influence the large number of illegal pharmaceutical preparations in Indonesia. This is the responsibility of the entire community, the police, the Food and Drug Supervisory Agency, together with other government institutions that have the authority. (Polamolo et al. 2023)

The absence of an Article regulating the obligations or criminal sanctions against producers or distributors of pharmaceutical preparations in Law Number 17 of 2023 concerning Health, raises doubts for Law Enforcement Officers whether they can still use the Job Creation Law which has amended Article 197 of the old Health Law, even though on the one hand the new Health Law has revoked the old Health Law. This doubt causes a legal vacuum in law enforcement efforts against producers or distributors of pharmaceutical preparations who do not have a business license.

Based on the explanation of the problem above, the focus of this article is how the Omnibus Law regulates the circulation of illegal pharmaceutical preparations in Indonesia. reviewed from the position of the criminal article on the distribution of illegal Pharmaceutical Preparations in Law no. 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law after the issuance of Law number 17 of 2023 concerning Health. With this writing, it is hoped that it can be a legal basis for Law Enforcement Officers in enforcing the law against producers and distributors of illegal pharmaceutical preparations in the territory of Indonesia.

## **RESEARCH METHODS**

This research is a normative legal research. To achieve this goal, this study uses a statutory and conceptual approach. Secondary data collection methods come from primary legal materials (eg, laws and regulations), secondary legal materials (eg, scientific papers) and tertiary legal materials (eg, articles on the internet).

## **DISCUSSION**

### **Omnibuslaw Criminal Law Politics**

Legal Politics according to Professor Mahfud MD is an official line (policy) on laws that will be enforced either by making new laws or by replacing old laws, in order to achieve state goals. Legal politics is a choice of laws that will be enforced as well as a choice of laws that will be revoked or not enforced, all of which are intended to achieve the state goals stated in the opening of the 1945 Constitution. (MD, Mahfud. 2017)

The definition of criminal law policy can also be put forward based on the definition of criminal policy. Criminal policy is a rational effort to combat crime. Criminal law policy is manifested in the form of Penal (criminal law) and Non-penal (without criminal law). Thus, as part of criminal policy, criminal law policy can be

interpreted as "a rational effort to combat crime by using criminal law". In this regard, according to Sudarto, criminal law policy or politics is identical to the definition of "crime management policy with criminal law"..(Arief, BN (nd))

In general, it can be stated that criminal law policy is: an effort to overcome crime through rational criminal law enforcement, namely fulfilling a sense of justice and utility. It is said to be rational considering that criminal law enforcement goes through several stages including the formulation stage, application stage and execution stage and these stages are interrelated with each other. At the formulation stage, placing oneself is the most important considering that at this stage criminal law policy is formulated to be operationalized at the next stage. In order for the quality of criminal law to be reliable in overcoming the development of crime in society, the formulation of legal principles and norms in the formulation stage must be carried out with various approaches, not only a normative legal approach but also a sociological approach.(Maroni. 2016)

### **Law of the Republic of Indonesia No. 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law as a form of Omnibus Law.**

In the academic manuscript for the formation of the Job Creation Law, the basis for the formation of the Job Creation Law (RUU Ciptaker) is explained, namely:

1. Physiological basis, namely efforts to improve the welfare of society in a fair and prosperous manner by providing decent work and life through efforts to increase investment
2. Sociological Basis, namely the condition of society with a high number of job seekers but not balanced with adequate job vacancies, as well as a complicated and time-consuming licensing process. Thus inhibiting investment in order to increase the number of job vacancies.
3. Legal basis, namely the many regulations that overlap and lock each other and incur high costs.

The formation of Job Creation Law has a long history. In November 2020, President Jokowi signed Law Number 11 of 2020 concerning Job Creation after the completion of its discussion in the DPR. However, based on social studies, the concept of law enforcement and the lack of acceptance of the Job Creation Law by some people show that Law Number 11 of 2020 concerning Job Creation has little social acceptance. Negative public views, communication processes with minimal procedures and the large number of documents are considered detrimental to social justice as one of the criteria for the effectiveness of law enforcement in society. (Nurhayati et al. 2021)

The formation of the Job Creation Law is also not in accordance with the fulfillment of the philosophical basis because the basic foundations of Indonesian society as referred to in the Pancasila principle are not fulfilled, namely social justice for all Indonesian people. The Job Creation Law is also considered morally flawed because it does not involve sufficient community participation and seems to only prioritize government interests. (Ikhwan Bintarto et al 2021.)

In dealing with these problems, the best strategy is to establish a legal basis for the creation of an omnibus law, determine the legislative objectives of the omnibus law, involve the community to obtain aspirations, involve local governments, accelerate the formation of the omnibus law and openness (Hartono et al. 2021) In 2021, Law Number 11 of 2020 concerning Job Creation was challenged at the Constitutional Court (MK) and declared conditionally unconstitutional. In response to the Constitutional Court's decision, President Jokowi issued Government Regulation in Lieu of Law no. 2 of 2022 concerning Job Creation in December 2022, and was passed into law after discussions in the DPR in early 2023 by issuing Law Number 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law. The enactment of Law Number 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law was again challenged in the Constitutional Court and was declared based on all legal considerations stating that the process of forming Law Number 6 of 2023 formally did not conflict with the 1945 Constitution.(Syaharani 2023).

Based on the physiological, sociological and legal basis of the formation of the Job Creation Law, the main objective is to realize a prosperous, just and prosperous Indonesian society based on Pancasila and the 1945 Constitution of the Republic of Indonesia, the State needs to make various efforts to fulfill the rights of citizens to work and a decent living for humanity through job creation. Namely by cutting laws and regulations relating to business licensing in order to facilitate investment in Indonesia which results in an increase in job vacancies. Law Number 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law is an Omnibuslaw product that unites all articles on business licensing including administrative and criminal sanctions. One of them is in the Health sector, namely the Drug and Food subsector.

All articles related to pharmaceutical preparations must have business licensing contained in Health Law Number 36 of 2009 concerning Health are made into one in the Job Creation Law. To facilitate its implementation.

### **Law of the Republic of Indonesia Number 17 of 2023 concerning Health**

Pharmaceutical preparations as referred to in the general provisions of Law no. 17 of 2023 concerning Health include Drugs, Drug Ingredients, Natural Drug Ingredients, including Natural Drug Ingredients, cosmetics, health supplements, and quasi-drugs. Pharmaceutical preparations must meet the requirements for safety, efficacy/benefit, and quality in order to fulfill the purpose of creating the pharmaceutical preparation itself. If it does not comply with the requirements for safety, efficacy/benefit and quality, the pharmaceutical preparation can have dangerous side effects for the community.

Illegal drugs (do not have a business license) are threatened with criminal penalties for producers and those who distribute them, this is regulated in Article 197 of Health Law Number 36 of 2009 concerning Health which has been revised in Article 197 of Law Number 36 of 2009 concerning Health which has been amended in Article 60 number 10 paragraph 11 Part Four CHAPTER III Health, Drugs and Food Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation attachment to Law no. 6 of 2023 concerning Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law. With the threat of a maximum prison sentence of 15 (fifteen) years and a maximum fine of Rp. 1,500,000,000.00 (one billion five hundred million rupiah).

In the Academic Manuscript of the Draft Law Number 17 of 2023 concerning Health. There is a discussion regarding the obligation for pharmaceutical preparations circulating in Indonesia to have a distribution permit or business license. In addition, there is also a discussion regarding criminal provisions for anyone who produces and/or distributes pharmaceutical preparations that do not have a business license (Academic Manuscript of the Health Bill). However, it turns out that in Law Number 17 of 2023 concerning Health which was ratified by the President of the Republic of Indonesia, the provisions governing business licensing for pharmaceutical preparations are not included. This is caused by because the article has been regulated in Law Number 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law.

In accordance with the purpose of the formation of the omnibus law, namely to simplify laws and regulations, the rules that have been regulated in the Job Creation Law in the form of an omnibus law do not need to be regulated again in other laws. This aims to prevent the re-emergence of many separate laws and cause complexity in legislation. Although Law Number 17 of 2023 has been ratified, the existence of this Law has the potential to be sued as a formal or material test lawsuit at the Constitutional Court for several reasons, namely the existence of conflicts between users of laws in the network shows that the principle of openness as one of the formal requirements in the formation of legislation is not met. Several related to other discourses also show that the process of forming the new Health Law is contrary to Law Number 12 of 2011 concerning the Formation of Legislation. (Kurniawati 2024)

### **Law of the Republic of Indonesia Number 13 of 2022 concerning the Second Amendment to Law Number 12 of 2011 concerning the Formation of Legislation.**

In order to achieve systematic, organized and sustainable regulation in the making of laws, it is necessary to organize and improve the procedures for making laws and regulations starting from the planning, drafting, discussion, ratification or determination stages to the publication of laws and regulations. Formal legal policy in the formation of laws is carried out by the legislative institution, namely the DPR together with the executive institution, namely the Government. Material legal policy is needed with the aim of achieving general welfare. In its formation, the Job Creation Law must have a legal basis that specifically regulates the omnibus law system where its implementation must be supervised by all elements. Namely by making changes to the regulations of Law Number 12 of 2011 concerning the Formation of Legislation. (Dwi Kartika. 2020)

Legislation that adopts the Omnibuslaw system requires the creation of regulations for drafting laws as a basis for its formation. Law of the Republic of Indonesia Number 13 of 2022 concerning the Second Amendment to Law Number 12 of 2011 concerning the Formation of Legislation is an improvement on Law Number 12 of 2011 concerning the Formation of Legislation. One of them is to include rules regarding the basis for the formation of legislation using the omnibuslaw method.

The legal policy of the Republic of Indonesia Law Number 13 of 2022 concerning the Second Amendment to Law Number 12 of 2011 concerning the Formation of Legislation is to provide a legal umbrella for the formation of a Law with an omnibus law system, namely the Job Creation Law. Despite opposition from

various parties, the legislators did not make changes to the Job Creation Law in substance or in the process of its formation. So that the political will of the legislators clearly revised Law Number 12 of 2011 to provide a legal umbrella for the formation of the Job Creation Law as an omnibus law. (Ummah. 2022)

Law of the Republic of Indonesia Number 13 of 2022 concerning the Second Amendment to Law Number 12 of 2011 concerning the Formation of Legislation has inserted Article 97A between Article 97 and Article 98 of Law Number 12 of 2011 concerning the Formation of Legislation. Where in Article 97A it is stated that the material content regulated in the Legislation that uses the omnibus method can only be changed and/or revoked by changing and/or revoking the Legislation.

In the explanation of Article 97A, a real example of the implementation of the article is given, namely with an example that reads, Article 6 of Law Number 26 of 2007 concerning Spatial Planning has been amended by Law Number 11 of 2020 concerning Job Creation. The article can only be changed and/or revoked by making changes and/or revocation of Law Number 11 of 2020 concerning Job Creation. If viewed from the text of Article 97A of the Republic of Indonesia Law Number 13 of 2022 concerning the Second Amendment to Law Number 12 of 2011 concerning the Formation of Legislation along with examples of its explanation. Then the article in the old Health Law, namely Law Number 36 of 2009 concerning Health which was amended in the Republic of Indonesia Law no. 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into a Law becomes a norm in itself in the omnibuslaw system, so that the articles that have been amended can only be revoked and declared invalid by amending or revoking it with the omnibuslaw law, namely the Job Creation Law. The issuance of the new Health Law, namely Law Number 17 of 2023 concerning Health, cannot revoke or change the articles that have been amended in the Job Creation Omnibuslaw.

## **CONCLUSION**

The criminal law policy in the pharmaceutical omnibus law system in general aims to facilitate licensing and provide protection to the public from the use of illegal pharmaceutical preparations that have dangerous risks to health. The purpose of using pharmaceutical preparations (Drugs, Cosmetics, Natural Medicines) is to improve health, both to prevent, improve health and cure diseases. The circulation of illegal pharmaceutical preparations is not registered with the authorized agency, which means there is no evaluation process for the active ingredient content. If the illegal pharmaceutical preparation contains hazardous materials, it can cause dangerous side effects for the public. while specifically, the purpose of criminal law for pharmaceutical preparations is to provide sanctions or deterrent effects to perpetrators who commit crimes for personal gain.

Enactment of the Lawnumber 6 of 2023 concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law is a Law that adheres to the omnibus law, aiming to simplify the very large number of laws and regulations into one Law so that it is expected to be able to create large employment opportunities in Indonesia. One of the sectors regulated in the Job Creation Law is in the Health sector, the Drug and Food subsector related to business licensing, including criminal sanctions. So that the position of the criminal articles regulated in Article 197 of Law Number 36 of 2009 concerning Health which has been amended in Article 60 number 10 paragraph 11 Part Four CHAPTER III Health, Drugs and Food Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation attachment to Law no. 6 of 2023 concerning Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 concerning Job Creation into Law is still valid.

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