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The Omnibus Law Concept and Changes in Substantive Provisions in Law Number 17 of 2023 on Health

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Abstract

The omnibus law concept refers to an approach that consolidates numerous regulations into a single regulatory framework. In 2023, the government applied this concept to Law Number 17 of 2023 on Health, with the objective of reforming health services to improve the health status of the Indonesian population and to address current and future health issues. However, various problems occurred during the drafting process, which affected the substance contained in the Health Law. The purpose of this study is to analyze the omnibus law concept and its influence on the Health Law. The research method employed is normative juridical, using a statutory approach by examining the Health Law and Government Regulation Number 28 of 2024 concerning the implementing regulations of the Health Law, as well as a conceptual approach. The results of this study indicate that the drafting process of the Health Law was conducted within a short period and did not adequately observe the principle of public participation, limiting public access to information regarding the substance of the law. This condition generated polemics within society and influenced substantive changes, including concerns from professional organizations that the Health Law removes their authority to supervise medical and health personnel, the expansion of authority in the supervision of the distribution of drugs and medical devices by BPOM, and the emergence of legal protection for pharmacists not only when performing their duties in pharmacies but also in extraordinary circumstances. The novelty of this research lies not only in examining the legislative process but also in analyzing substantive changes within the Health Law. Accordingly, this study provides a new perspective for future empirical research to examine the implementation of the Health Law.

1. Introduction

Article 1 paragraph (3) of the 1945 Constitution stipulates that Indonesia is a state governed by law, meaning that law constitutes the highest element of the state. Therefore, all actions of both the government and citizens must comply with the applicable law. In the concept of a state governed by law, the existence of legislation is one form of legal norm that serves as a guideline for national and state life. Laws are enacted through mutual agreement and bind all elements of society and state institutions in order to establish order, justice, and legal certainty.[1] In its implementation in the health sector, the government has established health regulations that have undergone several changes. This is reflected in Law Number 23 of 1992 concerning Health, which was the first health law and was no longer in accordance with developments, demands, and legal needs in society. Therefore, it needed to be revoked and replaced by Law Number 39 of 2009 concerning Health, which served as the first amendment to the previous law. However, along with the development and increasing health needs over nearly sixteen years, the legislative body, namely the House of Representatives of the Republic of Indonesia (DPR), together with the executive, namely the President, drafted the Health Bill, hereinafter referred to as the Health Bill.

The Health Bill constitutes one of the important stages in the process of establishing health regulations. The presence of this bill is expected to serve as a legal instrument capable of providing solutions to various health problems faced by society. In addition, the Health Bill is also intended to strengthen the legal system related to health services, protection, and the fulfillment of the public's right to health.[2] However, the Health Bill faced opposition from members of the public in the health sector, as it was considered a regulation that had been drafted in haste. In 2023, after dynamics of rejection in the planning and formulation process, the House of Representatives carried out health regulatory reform by enacting Law Number 17 of 2023 concerning Health, hereinafter referred to as the Health Law.

This latest Health Law should have been formulated as an effort to reform the health system in order to address various problems in the health sector, such as health services that remain curative-oriented, the availability and distribution of health resources, preparedness for health crises, self-sufficiency in pharmaceuticals and medical devices, financing aspects, and the utilization of health technology.[3] To

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[1] Hikmah Istiqamah et al., "Konsep Negara Hukum Rechtsstaat Dan Rule of Law," *Al-Muqaranah* 3, no. 1 (2024): 9–18.

[2] Heryna Oktaviana Kurniawati, "Analisis Jejaring Wacana Rancangan Undang-Undang Kesehatan Tahun 2023 Dan Potensi Judicial Review Ke Mahkamah Konstitusi," *UNES Law Review* 6, no. 3 (2024): 8660–75.

[3] Christina Clarissa Intania, "Analisis Hukum Pembentukan UU Kesehatan Dan Perbandingan Pengaturan Profesi Dan Penyelesaian Perselisihan Dalam UU Kesehatan," *The Indonesian Institute Indonesia Report*, 2023.

achieve the objectives of the currently applicable Health Law, simplification has been carried out through the Omnibus Law method.

The Omnibus Law is a method of forming regulations or legal norms in which a single regulation contains the substance or material needed to repeal previous legal norms dispersed across several regulatory instruments. With the enactment of this regulation, the material contained in the previous regulations is revoked.[4] Its implementation in the Health Law is used as a regulatory transformation measure aimed at simplifying rules in the health sector. This approach is viewed as a solution to regulatory overlap and complexity, which have long hindered the effectiveness of health policy.

The application of the Omnibus Law in the Health Law continues to face considerable debate and problems within society. The use of the Omnibus Law concept is considered inconsistent with the civil law system adopted by Indonesia. This is evident in the law-making process, which has been assessed as failing to observe the principles of legislative formation. This view has emerged from public statements asserting that the government did not fulfill public participation by directly involving the public in the formulation and planning of the provisions of the Health Law.

This has raised public concern that the omnibus law method applied in the Health Law will narrow public participation and prioritize only certain parties. In fact, public participation is a crucial element in ensuring that a law truly reflects public needs and aspirations. If public participation is not involved, the condition tends to indicate that the public rejects laws considered inconsistent with societal needs.

Another problem arising from the omnibus law method in the Health Law concerns changes in substance. Professional organizations, both in the medical profession and among health workers, consider that the substance of the Health Law is contradictory and has the potential to reduce the quality of health received by the public.[5] This arises because the Health Law revokes eleven sectoral laws, thereby making the substantive changes perceived as too general and insufficiently detailed in regulating standards of medical practice.[6]

A study related to this issue was also conducted by Ety Retno Setyowati, Sri Karyati, Sukarno, and Ainuddin in a scientific article entitled "The Application of the Omnibus Method in the Formation of Law Number 17 of 2023 concerning Health: A

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[4] Rudy Rudy, *Model Omnilaw: Solusi Pemecahan Masalah Penyederhanaan Legislasi Dalam Rangka Pembangunan Hukum*, 2021, http://repository.lppm.unila.ac.id/41696/1/MODEL%20OMNILAW.pdf.

[5] Zakiyah Maulida Kertawirja et al., *Analisis Keterlibatan Berbagai Aktor Di Luar Dewan Perwakilan Rakyat (DPR) Dalam Proses Legislasi RUU Kesehatan*, 2025, https://www.jurnal.upgriplk.ac.id/index.php/morality/article/download/1127/294.

[6] Yudhi Hertanto and Yana Chaeru, "Paradoks Yudisial Omnibus Law: Analisis Komparatif Putusan Uji Formil Dan Uji Materiil Undang-Undang Kesehatan No. 17 Tahun 2023," *Al-Zayn: Jurnal Ilmu Sosial & Hukum* 4, no. 1 (2026): 5592–97.

Reflection." This study focuses on the fact that the Health Law does not fulfill the principle of transparency as regulated in Law Number 12 of 2011 concerning the Formation of Laws and Regulations, and highlights weaknesses in the application of the Omnibus Law in the Health Law.[7]

However, this study does not explain or emphasize the assumption that the weaknesses of the Health Law reduce legal protection for medical personnel. This raises the question of whether such weaknesses arise from the law-making mechanism using the Omnibus Law approach or from the implementation of medical actions carried out by medical personnel.

Another study related to this writing was conducted by Ardhy Damanhury, Mardi Candra, and Rotua Valentina Sagala in an article entitled "The Application of the Omnibus Law Method in Law Number 17 of 2023 concerning Health." Their discussion focuses on the formation of the Health Law using the Omnibus Law method as an effort to simplify provisions in the health sector by merging several previous health laws into a single Health Law.

However, the study only focuses on the formation of the Health Law using the Omnibus Law method. It does not specifically focus on substantive changes in the Health Law after the application of the Omnibus Law method. Based on a review of previous studies, there are still limited studies that specifically examine the Health Law in relation to its substantive changes and the implications of forming the Health Law through the Omnibus Law method.

2. Metode

This study employs a normative juridical method that focuses on the examination of positive legal norms related to health provisions in Law Number 17 of 2023 concerning Health. The approaches used include the statute approach and the conceptual approach.[8] The statute approach is carried out by systematically examining Law Number 17 of 2023 and its implementing regulations, particularly Government Regulation Number 28 of 2024, with an emphasis on identifying substantive changes through comparison with previous provisions. Meanwhile, the conceptual approach is used to analyze the concept of the Omnibus Law and the principles of legislative formation in the Health Law.

The issues examined are determined based on their relevance to substantive changes, including the formation process and normative changes related to health services and the protection of health workers. The legal materials used consist of primary legal materials, namely laws and regulations, and secondary legal materials, namely books, journals, and other articles, which are analyzed qualitatively through normative interpretation. This study also applies deductive reasoning to examine the relationship between general concepts and specific provisions, thereby systematically explaining the changes and implications in the Health Law.

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[7] Ety Retno Setyowati et al., "Penerapan Metode Omnibus Dalam Pembentukkan Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan: Sebuah Refleksi," *Journal Kompilasi Hukum* 10, no. 1 (2025): 115–28.

[8] Irwansyah Irwansyah, "Penelitian Hukum: Pilihan Metode & Praktik Penulisan Artikel," *Yogyakarta: Mirra Buana Media* 8 (2020).

3. Analysis or Discussion

3.1. The Concept of the Omnibus Law in Law Number 17 of 2023 concerning Health.

Indonesia is known as a state governed by law that is more closely aligned with the concept of Rechtsstaat, a term derived from the Continental European legal tradition. This concept has shaped Indonesia's legal system to the present day. Within this framework, Indonesia can be categorized as a state that adheres to the civil law system or the continental legal system. The main objective of this system is to ensure legal certainty. Such legal certainty can only be realized through the regulation of human life by written legal rules.[9] This system has a main characteristic in the form of the codification of laws and regulations established by the state through official institutions, particularly the executive and legislative branches.

These institutions produce various types of regulations, ranging from laws, government regulations, ministerial regulations, to regional regulations.[10] Overall, all legal rules are not left to stand independently, but are collected and systematically arranged into a codified form. Hans Kelsen's theory explains that the constitution constitutes the highest legal norm. Every legal rule must be based on a higher rule, thereby forming a hierarchical legal pyramid.[11]

The meaning of Omnibus Law in Black's Law Dictionary, Ninth Edition, by Bryan A. Garner is stated as: "relating to or dealing with numerous objects or items at once; including many things or having various purposes," which means dealing with many objects or matters simultaneously, encompassing many things, or having various purposes.

It can be seen that the Health Law introduces reform through the omnibus law concept by fully revoking nine laws in the health sector, namely Law Number 4 of 1984 concerning Infectious Disease Outbreaks, Law Number 29 of 2004 concerning Medical Practice, Law Number 36 of 2009 concerning Health, Law Number 44 of 2009 concerning Hospitals, Law Number 18 of 2014 concerning Mental Health, Law Number 36 of 2014 concerning Health Workers, Law Number 38 of 2014 concerning Nursing, Law Number 6 of 2018 concerning Health Quarantine, and Law Number 4 of 2019 concerning Midwifery. The Health Law contains numerous objects that are systematically arranged into 20 chapters and 458 articles.

The explanatory section of the Law concerning the Formation of Laws and Regulations states that the Omnibus method in the formation of laws and regulations has been incorporated from the planning stage in legislative planning documents. Subsequently, the process continues to the stages of drafting, discussion, approval or ratification, and promulgation. This is carried out by observing the principles of legislative formation.

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[9] E. Fernando M. Manullang, *Selayang Pandang: Sistem Hukum Di Indonesia* (Kencana, 2017), https://books.google.com/books?hl=id&lr=&id=Pfq2DwAAQBAJ&oi=fnd&pg=PR4&dq=Buku+Ajar+Sistem+Hukum+Indonesia&ots=LEo6J_NH0K&sig=_AammUNP0LFWLVT54rp__eMNtm4.

[10] Ahmad Redi and I. S. Chandranegara, *Omnibus Law Diskursus Pengadopsiannya Ke Dalam Sistem Perundang-Undangan Nasional, Depok: PT* (Raja Grafindo Persada, 2020).

[11] Muhammad Suhenriko, "Implementasi Teori Hierarki Hans Kelsen Terhadap Perumusan Kebijakan Di Indonesia," *Jurnal Ilmiah Multidisipin* 1, no. 2 (2023): 64–71.

Jimly Asshiddiqie explains in detail several advantages of applying the Omnibus Law method in the formation of laws and regulations. Among them is the creation of harmony in regulatory provisions that are formulated in a more consistent and integrated manner. Provisions that were previously contained in separate sectoral health laws can be integrated into the currently applicable Health Law. This facilitates the process of dissemination and understanding for all levels of Indonesian society. Thus, all levels of society will obtain legal certainty that can be felt through the harmony and integration of provisions in the Health Law produced through the Omnibus Law method. Government policies also become easier to understand and implement in society because they are designed using the Omnibus Law method.[12]

The advantages of the Health Law are perceived only in terms of its outcomes. However, in the process of forming the Health Law, there were shortcomings in relation to the principles of legislative formation. Jimly Asshiddiqie, in his book, also explains the weaknesses of using the Omnibus Law method. The highlighted weakness is that public participation in the formation of laws and regulations may be reduced because the deliberation process takes a long time.[13]

The application of the Omnibus Law concept in the health sector has generated various challenges and debates. The formulation of the Health Law was carried out through closed meetings, which the public perceived as a barrier between the government and society. One of the main concerns is the reduced space for public participation in the law-making process. A rushed legislative process often causes opinions and input from various stakeholders, including the general public, to be inadequately accommodated.

This condition may result in policies that are less comprehensive and do not fully reflect the needs and aspirations of society. This is where the normative weakness in the application of the Omnibus Law method in the Health Law lies, namely the lack of attention to the principles contained in the Law concerning the Formation of Laws and Regulations. One of the principles of concern is the principle of public participation, which emphasizes the importance of public involvement in the legislative process.[14]

In practice, public participation is not sufficient if it is limited merely to the normative level, but must also be directly involved in the implementation of the Health Law within society. Involving the public in the implementation of the Health Law plays an important role in opening perspectives from various public opinions regarding health implementation. Thus, the public can convey suggestions, criticism, and input on health measures implemented by the government, which may improve health services and future health policies.

Accordingly, the government can conduct a review or evaluation of the Health Law as experienced by the public, and assess whether the Health Law that has been formulated and enacted is in line with the needs of all members of society or instead

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[12] Jimly Asshiddiqie, *Omnibus Law Dan Penerapannya Di Indonesia* (Konstitusi Press, 2020), 20–26, https://cir.nii.ac.jp/crid/1970304959899660417.
[13] Asshiddiqie, *Omnibus Law Dan Penerapannya Di Indonesia*.
[14] Setyowati et al., "Penerapan Metode Omnibus Dalam Pembentukkan Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan."

benefits only a small segment of society. Therefore, public participation serves as an actor in optimizing the implementation of the Health Law.[15]

The omnibus law concept in the Health Law affects the deliberation stage, which tends to be brief. Indirectly, the focus is directed more toward meeting the time target than toward the quality of the provisions of the Health Law itself. This indicates an influence on the formulation of the objectives and substance of the regulation as a whole. It results in provisions in the law that are less in-depth and less specific, because they must accommodate many sectors, ranging from medical personnel, health workers, health service facilities, to various medical actions performed. This situation may lead to the formation of regulations that do not fully reflect the needs and aspirations of society. Public participation is essential in a democratic law-making process to ensure that regulations provide legal certainty and are in line with the public interest.

The application of the Omnibus Law method must observe the principles of transparency and participation in order to maintain good legislative practices, particularly in relation to the Health Law. Based on this statement, the Omnibus Law is generally used as a policy instrument to address the large number and overlap of regulations within a state, and is often considered a fast means of resolving problems in the field of legislative formation.[16] Ideally, this simplification is not only related to quantity, but also encompasses the consistency and integration of regulatory substance. Thus, the Omnibus Law can be understood as a law-making mechanism aimed at creating a simpler, more effective, and more harmonious regulatory system.

3.2. Substantive Changes in Law Number 17 of 2023 concerning Health

The Health Law serves as the basis for the provision of health services that ensure quality and safety.[17] Therefore, the Health Law indicates a transformation in health-sector regulation and serves as a guideline for the provision of various aspects of health services to the public. The application of the Omnibus Law in Indonesia's health sector covers several important aspects, including the most prominent changes related to the role of health professional organizations, the distribution of medicines and medical devices, the legality of pharmacists' practice, and nursing practice.

First, the role of professional organizations is to provide a forum for health workers and medical personnel according to their respective fields and to provide essential support to the state in the delivery of health services. Prior to the latest Health Law, health professional organizations had a close relationship with the Indonesian government in carrying out health services. This can be seen in the

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[15] Tulia G. Falleti and Santiago L. Cunial, *Participation in Social Policy: Public Health in Comparative Perspective* (Cambridge University Press, 2018), https://www.cambridge.org/core/elements/participation-in-social-policy/2663DD5AA71E953F1A0AFB0AD74AACCB.

[16] Fuji Syifa Safari et al., "Problematika Metode Omnibus Law Dalam Pembentukan Peraturan Perundang-Undangan: Analisis Terhadap Undang-Undang No. 13 Tahun 2022 Dan Urgensi Pembentukan Badan Regulasi Nasional Di Indonesia," *Prosiding Seminar Nasional Ilmu Hukum* 1, no. 1 (2024): 29–40, https://doi.org/10.62383/prosemnashuk.v1i1.21.

[17] Ibid.

process of formulating health policies, in which health professional organizations were consistently involved in reviewing and formulating health policies.

Health professional organizations include the Indonesian Medical Association (IDI), the Indonesian Midwives Association (IBI), the Indonesian Pharmacists Association (IAI), the Indonesian Dental Association (PDGI), and others. Each health professional organization was granted authority by the government to perform its professional functions, such as regulating the ethics of medical personnel and health workers and providing protection to its members when facing medical disputes. This is carried out through case assessment based on facts and through ethics hearings. If, in such cases, medical personnel and health workers are proven not guilty, the professional organization may issue a recommendation letter to release them from all medical disputes.[18] Therefore, the authority granted by the government to manage its members indicates that health professional organizations play an active role in ensuring national health.

The relationship between health professional organizations and the government, which had previously been mutually supportive, has shifted into a tense situation following the enactment of the latest Health Law using the omnibus law method.[19] Health professional organizations argue that this law may restrict their independence. One example can be seen in Article 311 paragraph (1) of the Health Law, which states that medical personnel and health workers may establish professional organizations. Professional organizations consider that the use of the word "may" indicates that medical personnel and health workers are not required to establish professional organizations, but instead have the option or freedom to do so.[20]

This is what has caused tension due to changes in the authority of professional organizations. This condition raises concerns regarding the independence of professional organizations in carrying out their functions, especially because the Health Law gives the government a greater role in medical practice and health workers. This change has the potential to affect the autonomy of professional organizations, while also raising issues regarding their ability to maintain their roles and functions in regulating the medical profession and health workers in Indonesia amid continuously evolving regulatory dynamics. In addition, there is also the potential for overlapping authority, which may reduce the effectiveness of supervision over medical practice in Indonesia.[21]

For example, in medical organizations, when compared with the previous regulation, namely the Medical Practice Law, professional organizations had very broad authority in carrying out guidance and supervision. Meanwhile, under the

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[18] Selvi Relita Fitri and Zainal Arifin Hoesein, "Urgensi Pembaharuan Hukum Dalam Perlindungan Tenaga Kesehatan Sebagai Tinjauan Terhadap Undang-Undang Nomor 17 Tahun 2023," *Jurnal Retentum* 5, no. 1 (2025): 169–87.

[19] Wahyu Widodo, "Dampak Undang-Undang Kesehatan No. 17 Tahun 2023: 'Perampasan Legal' Kewenangan Organisasi Profesi," *Jurusan Farmasi*, April 24, 2025, https://pharmacy.uii.ac.id/dampak-undang-undang-kesehatan-no-17-tahun-2023-perampasan-legal-kewenangan-organisasi-profesi/.

[20] Intania, "Analisis Hukum Pembentukan UU Kesehatan Dan Perbandingan Pengaturan Profesi Dan Penyelesaian Perselisihan Dalam UU Kesehatan."

[21] Yodi Mahendradhata et al., *The Republic of Indonesia Health System Review*, vol. 7 (WHO Regional Office for South-East Asia, 2017), https://iris.who.int/handle/10665/254716.

Health Law, the authority of professional organizations is transferred to councils and state institutions, such as in matters of competency certification, medical guidance, and professional ethics. With the enactment of the Health Law, professional organizations have limited authority and focus more on continuous professional development and member advocacy.[22]

In 2024, the government delivered positive news with the enactment of Government Regulation of the Republic of Indonesia Number 28 of 2024 concerning the Implementing Regulation of Law Number 17 of 2023 concerning Health, hereinafter referred to as the Implementing Regulation of the Health Law. This regulation provides more detailed provisions regarding the implementation of the Health Law, including provisions related to professional organizations. The government continues to grant independence to professional organizations in terms of supervision and guidance.

This can specifically be seen in Article 1148 of the Implementing Regulation of the Health Law, which states that professional organizations are involved in increasing access to and fulfilling health needs related to Health Resources and Health Efforts, implementing health efforts to improve the quality of health services and the competence of medical personnel and health workers, and protecting the public from various potential health risks. This article affirms that professional organizations continue to have a strategic role and legal responsibility in the national health system. It also emphasizes that professional organizations do not only function as membership forums for medical personnel and health workers in guidance and development, but also as government partners in public health development.

Article 1149 of the Implementing Regulation of the Health Law states that, in supervising health services, the government continues to exercise supervision by controlling health service providers so that services operate effectively and efficiently. In addition, the government also ensures that health services are carried out in accordance with laws and regulations in the health sector by all service providers and members of the public involved in health services.

This indicates that professional organizations are not part of the state structure, but may conduct external supervision, namely supervision carried out by institutions or organizations that are structurally outside the government.[23] The positive aspect of external supervision by professional organizations is that it can create the principle of good governance in health services, which requires supervision by external parties in order to prevent conflicts of interest in the internal management of the profession.

Second, supervision of medicines and medical devices has a central function in providing protection and improving public health and welfare. Therefore, supervision refers to the authority granted to state institutions to ensure that medicines and medical devices meet standards of quality, safety, and effectiveness before being distributed to the public. This supervision includes various activities,

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[22] Maria Merry et al., "Analisis Normatif Terhadap Ketentuan Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan: Rekonstruksi Kewenangan Organisasi Profesi Dan Kollegium Kedokteran," *Jurnal Kolaboratif Sains* 8, no. 11 (2025): 7353–60.

[23] Haji Rachmad Ridwan, *Hukum Administrasi Negara* (Raja Grafindo Persada, 2006), https://library.stik-ptik.ac.id/detail?id=28039&lokasi=lokal.

ranging from product registration and inspection of production facilities to the imposition of legal sanctions on parties that violate regulations.[24]

Supervision of medicines and medical devices is carried out by the Food and Drug Supervisory Agency, hereinafter referred to as BPOM. BPOM represents the implementation of higher laws and regulations and aims to provide protection to the public. In addition, BPOM has a strategic role in addressing the widespread circulation of illegal medicines in society.[25]

Preventive and anticipatory efforts carried out by BPOM include measures such as preventing the circulation of counterfeit medicines, the distribution of illegal medicines, the sale of medicines without authorization, and other related actions. However, supervision conducted by BPOM remains limited and is generally more focused on the stages of product testing prior to distribution and product registration. This is reflected in BPOM's supervisory practice, which still tends to be weak, as a number of medicines continue to circulate without meeting the established standards.[26]

In practice, amid the rapid development of the pharmaceutical industry, business actors registering medicinal products or medical devices often neglect or fail to meet safety standards, composition requirements, and applicable legal provisions. This phenomenon indicates a tendency among business actors to disregard the supervisory procedures established by BPOM prior to distribution in order to obtain economic benefits more easily.[27] Therefore, the government pays attention to the granting of distribution permits. If a medicine does not have a distribution permit and its origin is unclear, the party most harmed is the public. This is because the public will face difficulties in demanding accountability if the medicine consumed is found to contain harmful substances.[28] Against this background, the government expanded BPOM's authority to supervise medicines and medical devices after they have been distributed.

The Health Law grants broader authority to BPOM to control and monitor the circulation of pharmaceutical products and medical devices. This is regulated in Article 143 of the Health Law, which states that the circulation of medicines and medical devices must comply with norms, standards, procedures, and criteria, and must obtain a distribution permit. Furthermore, Article 403 of the Implementing Regulation of the Health Law states that medicines and medical devices must meet standards to ensure their safety, efficacy, and usefulness. To achieve this, Article 407 of the Implementing Regulation of the Health Law affirms that quality and safety assurance must be carried out from the production stage to distribution.

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[24] Sony Ruben, "Analisis Yuridis Terhadap Undang-Undang Nomor 17 Tahun 2023 Tentang Kesehatan Dalam Upaya Mewujudkan Ketahanan Farmasi Dan Alat Kesehatan Dalam Negeri," *HARISA: Jurnal Hukum, Syariah, Dan Sosial* 2, no. 2) (2025): 191–209.

[25] Novi Christi and Gatot P. Soemartono, "The Role Of The Drug And Food Control Agency (BPOM) In Addressing The Distribution Of Illegal Cosmetics," *JIHK* 6, no. 1 (2024): 9–24.

[26] TERESA WENSEN MARIA et al., "Peredaran Obat Terlarang Di Indonesia Dan Upaya Pencegahannya Oleh Badan Pengawas Obat Dan Makanan (BPOM)," *ALIANSI: JURNAL HUKUM, PENDIDIKAN DAN SOSIAL HUMANIORA Учредители: Asosiasi Seni Desain Dan Komunikasi Visual Indonesia* 1, no. 2 (2024): 175–81.

[27] Ibid.

[28] Muhammad Alfan Nur Zuhaid et al., "Perlindungan Konsumen Terhadap Peredaran Obat Tanpa Izin Edar Yang Dijual Secara Online Di Indonesia," *Diponegoro Law Journal* 5, no. 3 (2016): 1–12.

These provisions indicate BPOM's authority to conduct supervision prior to distribution, namely pre-market supervision, as a preventive form of control carried out before a product is marketed, with the aim of ensuring product safety and quality. This process is conducted through stages of permit application to BPOM, which include production facility permits, production permits, and food distribution permits before the product is released to the market. At this stage, the product first undergoes an evaluation process before obtaining an official distribution permit number from BPOM. After the permit is issued and stated on the label, producers are allowed to distribute their products, whether through stalls, retail outlets, distributors, or directly to the public.[29]

Subsequently, supervision after distribution, namely post-market supervision, is carried out after business actors submit product licensing applications to BPOM. These permits consist of two types, namely product permits and distribution permits for medicines and medical devices. This supervision is conducted through a sampling method on products that have already been marketed. Its purpose is to assess the durability of quality and the health-related quality of products produced by business actors.[30] This supervision enables BPOM, in ensuring safety, efficacy, and usefulness, to coordinate with health offices in conducting quality testing of medicines and medical devices consumed by the public.

Third, pharmacists' practice, in which pharmacists have a role in providing medication services, constitutes a form of professional service and responsibility carried out directly by pharmacists to improve patients' quality of life. Therefore, the role of pharmacists is highly vital in efforts to improve service quality in order to achieve optimal outcomes for the highest possible level of public health. Pharmacists, in carrying out their duties, have currently undergone changes. Initially, they only provided services in the pharmaceutical field, but they are now also required to interact and work directly with patients.[31] In practice, it has been found that many pharmacists experience unfavorable treatment when serving patients.

One issue experienced by pharmacists occurs when the number of prescriptions received by a pharmacy is very high while the available personnel are limited. This condition may encourage staff to work hastily in order to meet service demands. In addition, limited facilities and equipment for preparing, compounding, modifying, mixing, and storing medicines may also increase the risk of errors in administering medicines to patients.[32] Therefore, legal protection is required for pharmacists in

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[29] PUTRI UMAMI AZIZAH et al., "Implementasi Peran Pengawasan BPOM Terhadap Penjualan Makanan Dan Minuman Kemasan Rusak (Perspektif Hukum Perlindungan Konsumen)," *YUSTISI Учредителu: LPPM Universitas Ibn Khaldun Bogor* 11, no. 1 (2024): 148–61.

[30] Imam Suyudi et al., *Analisis Pengawasan Post-Market Badan Pengawas Obat Dan Makanan Pada Peredaran Kosmetik Berbahaya*, 6 (2022): 135–52.

[31] Andrii Zelinskyi, "On the Issue of Patient-Consumer Protection Guarantees When Performing Pharmaceutical Activities," *Law Ukr.: Legal J.*, 2022, 112.

[32] Wendi Muhammad Fadhli, *Tanggung Jawab Hukum Dokter Dan Apoteker Atas Permintaan Tertulis Oleh Dokter (Resep) Kepada Apoteker Dalam Pelayanan Kefarmasian* (Penerbit NEM, 2022), https://books.google.com/books?hl=id&lr=&id=S0BZEAAAQBAJ&oi=fnd&pg=PR1&dq=Tugas+Dan+Tanggung+Jawab+Hukum+Apoteker+Dalam+Pelayanan+Kefarmasian&ots=AMrcEsLnDh&sig=-wpXK9VpdWI2JxCHZBrxwrghIJ4.

carrying out their duties to ensure that their rights are protected and that they are free from violence, harassment, and bullying.

This can be seen in the rights of pharmacists, which must be upheld in carrying out their practice as regulated in the Health Law. The Health Law protects pharmacists under two distinguishable conditions. The first is normal conditions, which may be categorized as conditions in which pharmacists continue to carry out their duties in pharmacies and treat patients properly in accordance with their competencies. Specifically, Article 273 paragraph (1) of the Health Law states that pharmacists obtain legal protection while performing their duties in accordance with professional standards, professional ethics, and the health needs of patients. In carrying out their practice, pharmacists also receive protection in relation to occupational safety and health, security, as well as health and employment guarantees. This illustrates the existence of preventive protection to prevent conflicts arising from interactions or the performance of professional duties.

In addition to protection under normal conditions, pharmacists also receive protection under extraordinary conditions. This reflects a condition in which pharmacists may take actions beyond the limits of their obligations by prioritizing public safety in accordance with applicable procedures, and it must be supported by the fact that extraordinary conditions include pandemic conditions involving the spread of disease.

Article 393 of the Health Law states that pharmacists have the right to obtain legal protection, security, and health guarantees in carrying out their duties, including when performing community service and entering communities affected by diseases or health problems that may give rise to extraordinary conditions or outbreaks. However, in carrying out their duties, situations may arise in which members of the public engage in actions that undermine the dignity of the pharmacist profession.

Article 273 paragraph (2) of the Health Law states that pharmacists have the right to discontinue health services in response to conduct that is inconsistent with the dignity and honor of the pharmacist profession. This indicates that the government has made legal protection a state responsibility in protecting pharmacists in the performance of their duties, both under normal and extraordinary conditions, with the aim of fulfilling pharmacists' rights.

The government has regulated new provisions in the Health Law, in which it does not only consider the position of pharmacists, but also provides legal protection for patients if they suffer losses or harm as a result of pharmacists' actions.[33] One of the most significant risks is the possibility of misuse or errors in the use or provision of medicines to patients, which may potentially cause harmful side effects.

This is mandated in Article 306 of the Health Law, which states that pharmacists may be subject to professional disciplinary sanctions in the form of a written warning, an obligation to attend education or training, deactivation of the Registration Certificate (STR), and a recommendation for revocation of the Practice License (SIP). Article 310 of the Health Law affirms that if pharmacists commit

[33] Iqbal Sadjali Jayusman, "Upaya Perlindungan Hukum Bagi Pasien Terkait Kesalahan Pemberian Obat Oleh Apoteker," *Jurnal Tampiasih* 2, no. 1 (2023): 46–52.

errors in carrying out their professional duties, the settlement must be conducted through an alternative mechanism, namely dispute resolution outside the court.

Based on this, the government, through the Health Law, provides the principle of balance between protection for the pharmacist profession and protection of patients' rights. This means that the government not only regulates the authority and responsibilities of pharmacists in carrying out their profession, but also ensures that patients obtain legal protection if they are harmed by pharmacists' actions.

According to the Ministry of Health of the Republic of Indonesia, legal protection functions as both a guarantee and a motivation for pharmacists to provide the best pharmaceutical services to the public, as long as the practice is carried out in accordance with professional standards and Standard Operating Procedures (SOPs). The Health Law does not eliminate the right of patients or their families to pursue legal remedies.

However, the Health Law regulates that compensation for alleged professional violations committed by pharmacists may be resolved fairly, either through professional hearings, relevant institutions, or the judicial system. In addition, to avoid the potential criminalization of pharmacists in carrying out pharmaceutical practice, appropriate preventive measures are required.[34] These efforts include exercising caution in every action, strengthening professional regulations, cooperating with law enforcement officials, and deepening understanding of the professional code of ethics so that pharmacists can carry out their duties in accordance with applicable ethical and legal principles.

4. Conclusion

The application of the Omnibus Law in the formation of the Health Law constitutes a rapid state measure in responding to various regulatory problems in the health sector through the simplification and integration of provisions within legal norms. Substantively, this reform has brought important changes, particularly in strengthening supervision by professional organizations, providing legal protection for pharmacists and patients, and regulating the circulation of medicines through BPOM, all of which are directed toward the creation of a more efficient and adaptive health system.

However, this substantive success is not fully balanced by the ideal quality of the law-making process, particularly because of the weak implementation of the principle of public participation as mandated in the Law concerning the Formation of Laws and Regulations. Thus, health regulatory reform through this approach should not only be assessed from the results of substantive changes, but also from the process of forming the Health Law.

Therefore, it is necessary to review the use of the Omnibus Law method so that it remains in line with the provisions regulated in the Law concerning the Formation of Laws and Regulations. This study emphasizes the importance of further empirical research to examine the extent to which these substantive changes truly affect the effectiveness of pharmacist protection and its reciprocal impact on patients, the supervision of medical actions by professional organizations, and the governance of

[34] Piotr Lisowski, "Analysis of Legal Misuse by Pharmacy Inspectors in Relation to the Alleged Drug Mafia," *Journal of Forensic Science and Medicine* 11, no. 4 (2025): 340–50.

medicine circulation in society, thereby ensuring that the reform carried out is not only formal, but also real in its implementation.

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