

***JURIDICAL REVIEW OF LAW NUMBER 6 OF 2023 CONCERNING
EMPLOYMENT COPYRIGHT ON THE IMPLEMENTATION OF RISK-BASED
BUSINESS LICENSING IN THE HEALTH SECTOR IN THE FIELD OF
PHARMACY***

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Abstract

The fulfilment of medicines has become important in health development in Indonesia due to the increasing public awareness of health. Pharmacies are an important tool in the provision of medicines and health services. However, establishing a pharmacy business has high risks and requires a business licence and pharmacist practice permit. However, Law No. 11 of 2020 on Job Creation was rejected by the Constitutional Court, which resulted in the reissuance of the regulation in Law No. 6 of 2023. This has also impacted the regulations governing business licences, especially in the health sector such as pharmacies. Digital technology is also applied in implementing business licences with the OSS System. For the pharmacy business, business actors must understand the appropriate KBLI code and the correct licensing application procedure. Therefore, this research aims to analyse the impact of the reissuance of the rules in Law Number 6 of 2023 on the pharmacy business licensing rules. This research uses a form of normative juridical research that refers to developing legal norms, such as laws and court decisions. The approach methods used are statute approach and conceptual approach. The data to be used is secondary data from primary legal materials, secondary legal materials, and tertiary legal materials, such as laws, regulations, books, papers, journals, and other sources. The data collection technique that will be used is document study. The method of analysis that will be used is the qualitative analysis method to analyse the social aspects of the implications of Law Number 6 of 2023 on the Implementation of Risk-Based Business Licensing in the Health Sector for Pharmacies based on legal materials. After the issuance of Law Number 6 of 2023, there have been significant changes to the business licensing mechanism in Indonesia. Risk-based business licensing is enforced to support job creation and empowerment of micro, small and medium enterprises. The licensing process is based on the level of risk, with NIB as the legality to start and run a business. This concept regulates the function of NIB and other business licensing facilities from the government. Permenkes Number 14 of 2021 regulates the standards of business activities and products in the implementation of risk-based business licensing in the health sector, including pharmacies. So pharmacy business actors are encouraged to adjust to business licensing regulations and ensure legal certainty in pharmacy business licensing.

Keywords: Job Creation, Business Licensing, Risk-Based, Health Sector, Pharmacy

INRODUCTION

National development is currently an important concern, especially in the health sector. Efforts to fulfil medicines are very significant in achieving optimal health for the population. Pharmacies are one of the important elements in the provision of medicines and health services that are directly related to the community. The pharmacist is the person responsible for the management and operation of the pharmacy, and a pharmacy business licence (SIA) and pharmacist practice licence (SIPA) are required.

In Indonesia, pharmacies are the main platform for medicine trade and are a fast-growing retail business. Despite its bright prospects, setting up a pharmacy business also comes with high risks. For this reason, a licence is required to certify the legality and safety of the business.

In the context of the law, pharmacy business actors are required to take care of their business licences so that they are not considered illegal. Risk-based business licensing is also needed to ensure the legality of the business being opened. The OSS system allows business actors to register their business to obtain a business licence.

The KBLI code used for the pharmacy business is 47721, which is included in the retail trade category of pharmaceutical goods and drugs. However, in practice, the law on which the licence simplification was based was declared conditionally unconstitutional by the Constitutional Court, so the government re-issued a work copyright regulation with similar regulatory material in Law Number 6 of 2023.

Thus, to analyse the implications of Law Number 6 of 2023 on the Implementation of Risk-Based Business Licensing in the Health Sector, especially Pharmacies, is an interesting thing to investigate in a research. Changes in rules and policies will have a direct impact on the health sector, especially pharmacies, so further study to understand the impact and implications of these changes is very important.

LITERATURE REVIEW**Legal Concept of Licensing**

At present, the definition of licence is still not agreed upon by experts as the focus of their respective fields affects their perceptions. The difficulty in defining a permit is due to the differences in opinion among experts. Sutedi (2011) equates permit with vergunning and defines it as an approval from the authorities based on the law to deviate from the statutory prohibition. The difference between permits and licensing is also explained by Sutedi (2011), with licensing defined as a form of implementation of the regulatory and control functions owned by the government towards community activities. Atmosudirdjo (1994) also views the licensing system as a form of government intervention in the process of community activities. N.M Spelt and J.B.J.M ten Berge (Hadjon, 1993) divide the notion of permit in a broad and narrow sense. In a broad sense, permits are used by the government as a means of controlling community behaviour. Whereas in the narrow sense, permission serves to regulate certain actions determined by law in order to generate supervision. The purpose of a permit (in the narrow sense) is to grant an exemption from a prohibition in special circumstances. Thus, a permit has a purpose to be achieved from a permit. Therefore, permits have an important role in controlling and regulating community activities.

The Function of Granting Permits

Sutedi (2019) asserts that permits have three main functions. The first function is to bring order so that each permit or place of business does not contradict each other, thus creating order in community life. The second function is to regulate so that permits can be implemented in accordance with their designation, so that there is no misuse of permits. The last function is to foster, by granting permits, business actors are recognised as having the competence to conduct business practices, and the government has the responsibility of providing guidance to business actors who have obtained permits before.

Purpose of Granting Permits

Permit granting according to Sutedi (2019) is to control government activities in certain matters. The purpose of the permit is seen from two different sides, namely from the government side (implementing regulations and as a source of regional income) and from the community side (legal certainty, certainty of rights, and making it easier to get facilities).

Elements of Licensing

The government has the duty and authority to maintain order and security and seek public welfare. One of the juridical instruments used in licensing is a decree, which can create new rights or allow something that was previously not allowed. Laws and regulations form the basis for the authority to make and issue licence decrees, and licensing decisions can be influenced by the government's discretionary power. However, the sheer number of government organs authorised to grant licences can cause activities to be impeded, hence deregulation to reduce state interference. Licensing consists of prohibitions, approvals that form the basis of exemptions, and conditions associated with licences. Licensing processes and procedures vary depending on the type of licence and the licensing agency, and must be in line with applicable laws and regulations. Every legal action of the government must be based on the authority granted by laws and regulations, and a permit is a form of government decree as a legal instrument. Government agencies also play an important role in licensing actions, and must be well organised in order to achieve objectives efficiently and effectively. Certain requirements must also be met by the applicant to obtain the licence applied for. (Hadjon, 1993).

Business Licensing System

Business licensing is the legality or basis for business actors in starting and carrying out their business activities. The government is expected to be able to support increased investment in Indonesia through the ease of business licensing. Registration to obtain a business and/or activity licence can be done online through the Online Single Submission System (OSS). Law Number 11 of 2020 concerning Job Creation states that the risk-based OSS is prepared to implement the use of information technology in business licensing services. The use of the OSS system is mandatory for business actors before starting business activities in Indonesia. Local and Central Governments are refined PTSP services to be more efficient, serve, and modern. Business licensing through OSS can be accessed through www.oss.go.id. The birth of OSS plays an important role in the infrastructure development sector in Indonesia. The types of licences issued through the risk-based OSS include business licences, commercial or

operational licences, and licence commitments. The implementation of risk-based OSS is intended to make it easier for business actors, both individuals and non-individuals, to start a business in Indonesia. To date, there are 1,702 business activities integrated into the risk-based OSS system.

Trade Distribution Channels in Indonesia

Trade in ancient times was carried out by the trade-exchange system. Over time, trade has become more modern with stages of production, distribution, and consumption. Trade now means mediating between producers and consumers to facilitate buying and selling. Distribution is a significant process in channelling goods or services from producers to consumers, now done digitally and globally. Through technology, distribution can be done efficiently and profitably for businesses. With efficient distribution, business profits will be maximised. Distribution also serves to smoothen the flow of goods and services and promote products. However, spending a lot of money on distribution does not always guarantee marketing success. Therefore, the success of businesses is greatly influenced by proper distribution activities.

Pharmacy in Indonesian Law

Pharmacy comes from the Greek *apotheca*, which means 'store'. In Dutch, a pharmacy is called an *apotheek*, a place to sell and concoct medicine. The definition of a pharmacy has been regulated in Government Regulation No. 51 of 2009, which is a place where pharmaceutical practice is carried out by pharmacists. Pharmacies have the aim of improving the quality of pharmaceutical services, providing protection for patients and the public, and ensuring legal certainty for pharmaceutical personnel. Pharmacies are also a place for pharmacists to perform professional services, as well as produce and distribute medicines, medicinal raw materials, and cosmetics. The establishment and licensing of pharmacies is regulated in Government Regulation No. 51 of 2009. Regarding the establishment of pharmacies, it is regulated in Article 25 of Government Regulation No. 51 of 2009.

Overview of Licences and the Operation of Pharmacies

A Pharmacy Licence, abbreviated as SIA, is written evidence given by the district/city government to a pharmacist to operate a pharmacy. The location of the pharmacy establishment must fulfil environmental health requirements and the local district / city spatial plan. The building, facilities and infrastructure, equipment and spatial arrangement of the pharmacy must pay attention to its functions such as security, health, comfort, and safety protection. Based on the Regulation of the Minister of Health of the Republic of Indonesia Number 14 of 2021 concerning Business Activity and Product Standards in the Implementation of Risk-Based Business Licensing in the Health Sector, prior to operations, pharmacies are required to install a signboard containing the name of the pharmacy, the pharmacy licence number, and the pharmacy address. Pharmacies must also meet organisational standards, have a pharmacist in charge, and pharmaceutical personnel who have a license to practice. Pharmacies are responsible for organising pharmaceutical services to ensure the availability of quality, safe and useful medicines. Pharmacies can also deliver pharmaceutical preparations to other pharmacies, health centres, hospitals, and clinics. However, pharmacies are prohibited from distributing drugs in large quantities and must provide pharmaceutical services at

an additional cost. The implementation of pharmacy operational activities is carried out in accordance with effective and documented standard operating procedures. The central government, provincial governments, district/municipal governments, and community health centres participate in supervising the operation of pharmacies since the pharmacy licence is issued. Pharmacies can also provide pharmaceutical services to patients at an additional cost that must be paid by the patient.

Theoretical Overview

The legal theories used in this research are agreement theory and legal expediency theory. Legal certainty is a clear condition, provision, or circumstance that demands that the law must be certain and fair (Rato, 2010). Legal certainty is mandatory in carrying out the code of ethics in achieving justice in the nation. Normative law is the law that must be realised in the norms set out in the regulations that apply in a country. Normative law is a rule about what to do, and only through deliberate human action are norms created. Law is also able to bring even and comprehensive certainty so that legal development is well-conceptualised and well-organised. The conception of law also includes general rules that allow individuals to know what actions can or cannot be enforced, as well as legal protection against the government. Legal certainty is born and comes from jurisprudence in decisions issued by judges (Marzuki, 2008). The purpose of this law is to maintain public order by creating legal certainty. As a result of the lack of legal certainty and the resulting uncertainty, the demand for legal certainty is the existence of a norm that is clearly and logically regulated in its implementation in society (Mertokusumo, 1998). This does not also cause a conflict in the midst of society, where the axis of implementation is carried out in a certain and consistent manner and is not influenced by subjective circumstances.

Utilitarianism theory is a simple concept of how to maximise the usefulness of an action to bring benefits, advantages, happiness, and enjoyment. It also aims to minimise pain, evil and suffering. Law is important to provide security, order, and welfare for society, and also regulates human relations. However (Mertokusumo, 2011), the development of the times makes the validity of the law not always relevant to the needs of society. Therefore, there must be contextual laws that can accommodate social practices in society. The legal doctrine applied must create a correlation between the law and society, in order to reflect happiness for the community. According to the utilitarianism school, the purpose of law is to benefit all people, by prioritising the greatest possible happiness for the community (Erwin, 2011). Jeremy Bentham is the main figure in the utilitarianism school who applies this principle to the environment. The purpose of legislation according to Bentham is to create happiness for society. Therefore, legislation should endeavour to provide a living, abundant food, protection, and equality for society (Rasjidi & Rasjidi, 2012). Thus, the law should be flexible and adaptable to the needs of society and reflect the happiness of society as its main goal.

RESEARCH METHOD

The research to be conducted by the author is a normative juridical research that refers to the developing legal norms, such as laws and regulations and court decisions. In this research, the author will use a statute approach and conceptual approach. The author will use secondary data sourced from books, official documents, research results, theses, theses, dissertations, and laws and regulations. The data sources are divided into

primary legal materials, secondary legal materials, and tertiary legal materials. The author will use data collection tools in the form of document studies. The analysis method that will be used by the author is a qualitative analysis method. In this research, the author will analyse a social aspect, namely the Implications of Law Number 6 of 2023 on the Implementation of Risk-Based Business Licensing in the Health Sector for Pharmacies based on legal materials and will be written systematically so that conclusions can be drawn. By using a statutory approach and conceptual approach, and using a qualitative analysis method, the author hopes to answer the formulation of problems based on applicable laws and regulations.

RESULTS AND DISCUSSION

Risk-Based Business Licensing After the Enactment of Law Number 6 of 2023 Concerning the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 on Job Creation into Law

The Job Creation Law in Indonesia's Business Licensing Mechanism

The Job Creation Law was issued to make changes related to improving the condition of hyper-regulation in Indonesia. This can be seen from the legal politics contained therein. The basic policy on which the law is based is the simplification of regulations and deregulation of regulations that support job creation and empowerment of micro, small, and medium enterprises. The Law also supports the economic reforms undertaken by the House of Representatives and the government. Deregulation to create a good business climate is reflected in the principles in the Job Creation Law. The enactment of the Job Creation Law has led to fundamental and strategic changes in the field of business licensing in Indonesia. Business licensing is the legality given to business actors to start and run their business and/or activities. Business actors are individuals or business entities that conduct business and/or activities in certain business fields. The business licensing process is carried out based on the application of risk-based business licensing. The Job Creation Law aims to create jobs and increase investment and business activities in Indonesia.

Implementation of Risk-Based Business Licensing

GR 5/2021 provides exceptions for business actors who have obtained business licences before this regulation comes into effect. PP 5/2021 is a derivative of the Job Creation Law and adopts a new concept in risk-based business licensing. Business actors can easily process business licences through the electronically integrated OSS system. Convoluted licensing mechanisms can disrupt the company's business activities, therefore the Government of Indonesia offers the concept of omnibus law in Law Number 11 of 2020 on Job Creation and its derivative regulations which are expected to simplify business licensing and improve economic development.

Prior to the enactment of the Job Creation Law, the concept of licensing in Indonesia was considered too much bureaucracy and too long. Therefore, the government tried to simplify the licensing flow to make it easier but still pay attention to important matters

such as Health, Safety, Security, and Environment (HSE), as well as resource utilisation or management. Government Regulation No. 5 of 2021 on the Implementation of Risk-Based Business Licensing creates a new paradigm that grants licences based on other legalities that must be fulfilled simply by business actors. One form of new legality is the Business Identification Number (NIB) which is proof of registration/registration of Business Actors to conduct business activities. The process of issuing business licences is carried out by several institutions in accordance with their respective authorities listed in the appendix to Government Regulation Number 5 of 2021. This PP also explains the role of NIB and the functions of NIB, including to apply as an Import Identification Number, register business actors for BPJS Health and BPJS Employment, get halal certificate assistance, record business actor data, and obtain financing facilities from banks. In addition, GR 5/2021 also regulates the implementation of risk-based business licensing which includes business licensing arrangements, norms, standards, procedures, OSS system services, supervision procedures, evaluation, funding, problem solving, and sanctions. The main objective of GR 5/2021 is to improve the investment ecosystem and business activities through the issuance of business licences in a more effective, simple, and transparent manner in accordance with the provisions of laws and regulations. Hopefully, this will encourage a good investment climate and have a positive impact on the Indonesian economy. However, this positive impact needs to be studied more deeply to ensure that the Job Creation Law provides real benefits for companies in carrying out their business activities and businesses.

The Government of Indonesia has transformed the concept of business licences through GR 5/2021 on Risk-Based Business Licensing as mandated by the Job Creation Law. Previously, an Industrial Business Permit was a licence granted to any person to carry out industrial activities without any division of risk levels. Then, Government Regulation No. 24/2014 on Electronic Integrated Business Licensing Services (GR 24/2014) is intended to accelerate investment and business through several stages, such as registration, issuance of Business Licences, and issuance of Commercial/Operational Licences. On the other hand, GR 5/2021 divides licensing based on the level of risk, namely low risk, low medium risk, high medium risk, and high risk. This latest conception is also based on the trust but verify principle, where the Government gives trust to business actors by simplifying the business licensing process but followed by the implementation of supervision by the Government. This principle is based on basic risk criteria consisting of health, safety, environment, and limited resources. In the risk division, GR 5/2021 divides licensing based on each Indonesian Standard Industrial Classification (KBLI) regulated in the Central Bureau of Statistics Regulation. In GR 5/2021, there are business licence registrations for business activities with low and medium-low risk levels, and business licence registrations for business activities with high and medium-high risk levels. There is also a grandfather clause that allows old rules to apply to some ongoing situations or contexts when new rules are made for all future situations and contexts. Despite the change in rules, the grandfather clause principle ensures that the old rules still apply to legal subjects who carried out activities before the new rules.

Law Number 6 of 2023 on the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 on Job Creation on Risk-Based Business Licensing Mechanism in Indonesia

Law No. 11/2020 on Job Creation is facing implementation challenges, including a lawsuit to annul the law at the Constitutional Court. The Constitutional Court partially granted the request for a formal review on 25 November 2021, stating that the establishment of the law was contrary to the Constitution of the Republic of Indonesia. The government responded to this by issuing Government Regulation in Lieu of Law Number 2 Year 2022 on Job Creation to ensure the law's enforceability. The government also passed Law No. 6 of 2023 regulating the Government Regulation in Lieu of Law No. 2 of 2022 on Job Creation, making business licensing easier for low, medium, and high risk businesses. Businesses are expected to register their Business Identification Number (NIB) through the Online Single Submission (OSS) agency to obtain legality and legal protection. The determination of the business risk level affects the licensing process, where low risk allows operations after obtaining the NIB, while high risk requires prior verification before an operational permit is granted. The Job Creation Law also simplifies business licensing for micro and small businesses, ensuring compliance with the Indonesian National Standard (SNI) and Halal Product Guarantee Certification, as well as environmental approvals by only requiring a statement from the business actor.

Implementation of Health Sector Risk-Based Business Licensing for Pharmacies as Retailers After the Enactment of Law Number 6 of 2023 on Job Creation

Through Law Number 11 of 2020 on Job Creation, there are 79 laws combined into one law with 11 different clusters. This law aims to absorb labour, provide ease of licensing, empower cooperatives and MSMEs. In Law Number 6 of 2023 on the Stipulation of Perpu into the Job Creation Law, the authority to issue business licences is carried out by the OSS Institution managed by the Ministry of Investment/Investment Coordinating Board. For the health sector, the Government issued Government Regulation Number 5 of 2021 which regulates the Implementation of Risk-based Licensing.

This GR is followed by Minister of Health Regulation No. 14 of 2021 which regulates the standards of business activities and products in the implementation of risk-based business licensing in the health sector. With this PP and Permenkes, the licensing implementation is carried out through an integrated business licensing system with an electronic system (OSS) to make the licensing process simpler and more effective. Then, large and small risk businesses must register their business legality or register a Business Identification Number for their business. Minister of Health Regulation Number 14 of 2021 also regulates pharmacy business standards and licences in the form of NIBs and pharmacy standard certificates.

Pharmacies can be organised by individual or non-individual business actors and must fulfil all pharmacy business licensing requirements issued by the District / City Health Office. Prior to Minister of Health Regulation 14/2021, the establishment of pharmacies was regulated under Minister of Health Regulation Number 26/2018 which only regulated that pharmacies were organised by individual business actors, namely pharmacists with their own capital and / or capital from capital owners. However, with the existence of Minister of Health Regulation 14/2021, pharmacies must be in the form of legal entities, such as Limited Liability Companies, Foundations, and / or Cooperatives, causing problems for business actors who renew their licences.

Limited Liability Companies according to the Job Creation Law are divided into Limited Liability Companies and Individual Companies that fulfil the criteria of Micro and Small Enterprises as regulated in laws and regulations. It is further explained that a Limited Liability Company is a legal entity that is a capital partnership established on the basis of an agreement, which has an authorised capital that is entirely divided into shares to carry out its activities. A

Limited Liability Company is a legal entity, established by two or more persons by notarial deed, where the status of this legal entity will be obtained after being registered with the Minister and obtaining proof of registration. The period of establishment can be limited or unlimited as stated in the articles of association, and has an authorised capital of at least IDR 50,000,000.00 (fifty million rupiah). So that with the existence of Permenkes 14/2021, the expansion of business licences like this creates problems for pharmacy business actors, especially for licence renewal because many processes are hampered because most pharmacies are not legal entities and the form of cooperation between pharmacists and capital owners is only a cooperation agreement ratified by a notary. In addition, changing the form of business to a legal entity also raises objections for pharmacy business actors..

CONCLUSION

Law Number 6 Year 2023 on Job Creation has successfully simplified and deregulated business licensing by implementing a risk-based licensing mechanism. This is demonstrated by the issuance of Government Regulation Number 5 Year 2021 which regulates the Implementation of Risk-Based Business Licensing. This regulation makes it easier for businesses to start and run their businesses by considering the level of business risk.

This Government Regulation adopts a new concept of business licensing based on the level of risk. Businesses must apply for a licence based on the risk of the business they are running, with certain criteria such as the type of business activity, business activity criteria, location, and limited resources. The regulation also covers the granting of NIB which has multiple functions, including acting as an Import Identification Number, customs access rights, business registration for BPJS Kesehatan and BPJS Ketenagakerjaan, and more.

The Government Regulation also categorises licences based on their risk level, from low to high risk, and provides ease of business licensing for micro and small businesses through a single licence in the form of an NIB. This concept is designed to make it easier for businesses to run their businesses. Nevertheless, the government still accommodates business actors who have obtained licences based on old regulations by applying the grandfather clause principle.

Law Number 6 of 2023 on the Stipulation of Government Regulation in Lieu of Law Number 2 of 2022 on Job Creation into law has resulted in the derivative regulations of the Job Creation law remaining in effect. There is a risk assessment and business scale rating of business activities, and the OSS Institution has the authority to revoke NIBs if business actors do not comply with the provisions.

The Government Regulation also provides standards for business activities and products in the implementation of risk-based licensing in the health sector. In this case, pharmacy business actors must have a licence that complies with the standards of pharmaceutical business activities, medical devices, and household health supplies issued by the Regency/City Health Office. A pharmacy licence is valid for a maximum of 5 years and needs to be renewed after that.

However, Permenkes 14/2021 also creates problems for non-individual business actors, especially regarding the extension of pharmacy licences. Many licence renewal processes are hampered because most pharmacies are not legal entities. The requirements that must be met by non-individual business actors have caused problems in the community. Dalam Lampiran I Peraturan Pemerintah Nomor 5 Tahun 2021, apotek memiliki tingkat risiko tinggi dengan mencakup seluruh skala usaha, yang

berarti skala usaha untuk pendirian apotek dapat berbentuk usaha mikro, kecil, menengah, ataupun besar. Dengan begitu, penerapan mekanisme perizinan berbasis risiko telah membawa perubahan signifikan pada perizinan berusaha di sektor kesehatan.

SUGGESTION

Pharmacy business actors are expected to be able to adjust to well-regulated business licensing regulations. Law Number 11 of 2020 concerning Job Creation has been replaced by Law Number 6 of 2023 concerning the Stipulation of Perpu into a Job Creation Law that Regulates Business and Product activity standards in the Implementation of Risk-Based Business licensing in the Health sector. This is intended so that business licences and drug distribution will not cause problems in the future. Permenkes 14/2021 raises problems for pharmacy business actors, especially regarding license renewal because many processes are hampered and objections for pharmacy business actors regarding changes in business form to become legal entities. Clear legal certainty is needed to overcome this problem. Drug consumers/patients need to pay attention to legal pharmacy business licences and pharmacist licences in order to measure legal certainty in pharmacy business licensing. If you find irregularities or discrepancies, you can immediately report to follow up on the case.

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