

The Impact Of The Ratification Of The Job Creation Law Regarding Business Permits For Supervision And Enforcement In The Drug And Food Sector

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Abstract

UU no. 11 of 2020 concerning Job Creation provides changes to regulations related to improving the investment ecosystem by changing, removing, and forming new norms from various sectoral regulations. The ratification of the Job Creation Law related to business licenses has had a significant impact on drug and food supervision carried out by the Food and Drug Supervisory Agency (BPOM). Using qualitative descriptive research methods with data collection methods through interviews and focus group discussions (FGD) with BPOM, academics, practitioners, and literature review. There are findings that there is an increase in the circulation of illegal drugs through e-commerce and the challenges of industry 4.0, making it challenging to monitor and enforce the circulation of illicit drugs in Indonesia. By using the precautionary principle theory and national security, preventive measures are needed before implementing an evaluation in handling various cases related to drugs in Indonesia, granting permits, and consuming drugs on the market when facing different emergency conditions in Indonesia. Differences in interpretation at the ministries and institutions make efforts to protect the community neglected. Harmonization of rules is needed to create legal certainty. So that in the short term, the government needs to harmonize the regulations related to business licenses regarding drugs and food. Differences in interpretation at the ministries and institutions make efforts to protect the community neglected. Harmonization of rules is needed to create legal certainty. So that in the short term, the government needs to harmonize the regulations related to business licenses regarding drugs and food. Differences in interpretation at the ministries and institutions make efforts to protect the community neglected. Harmonization of rules is needed to create legal certainty. So that in the short term, the government needs to harmonize the regulations related to business licenses regarding drugs and food.

Keywords: Job Creation Act Law, BPOM, National Security, Precautionary Principle

Introduction

The Indonesian government and the DPR formed the Omnibus Law through Law no. 11 of 2020 concerning Job Creation; in this Law, some regulations regulate the improvement of the investment ecosystem by changing, removing, and forming new norms from various sectoral regulations (Suntoro, 2021). One form of increasing investment is contained in Chapter III of the Job Creation Law on improving the investment ecosystem and business activities which includes (i) Application of risk-based business licensing; (ii) Simplification of the basic requirements for business licensing; (iii) Simplification of sector business licensing and (iv) Simplification of investment requirements. Business

licenses are a form of legality given to business actors to start and run their businesses or business activities. Indirectly, simplification and licensing of risk-based businesses also increases the risk in monitoring and licensing the distribution of business products. The ratification of the Job Creation Law, especially the regulations governing business permits, has brought severe implications for the supervision and enforcement of the drug and food sector, especially for the Food and Drug Administration (BPOM). BPOM is a non-ministerial government agency that carries out government duties in Drug and Food supervision. BPOM also has additional authority and plays an essential role in monitoring and issuing distribution permits for drugs and food after ratifying the Job Creation Act. Therefore, it is necessary to look at the impact of the ratification of the Job Creation Act related to the regulation of business licenses for supervision and enforcement of the drug and food sector carried out by BPOM in supporting the health of the Indonesian people further.

Theoretical Framework

Precautionary Principle

The term "precaution" is etymologically derived from Latin, which means "prae," which means "before", and "cautio," which means "security". A deep understanding is needed to define the precautionary principle, not only a "be careful" or "alert before it is too late" view, but in essence, this principle talks about actions taken with complete consideration as a form of prudence so as not to have a detrimental impact (Latifah Emmy, 2016). This principle was first proclaimed in 1971 in the German environmental protection program, namely the German Program of Environmental Protection of 1971 as "Vorsorge". The term "Vorsorge" in English is defined as "foresight" which means a review of the future while "vorsorgeprinzip" in English means "foresight principle," which is the principle or concept of foresight (Latifah Emmy, 2016)

Of the many regulations passed, the precautionary principle is also one of a series of established regulations. This incident has made this principle famous throughout Europe, such as Denmark, contained in the Consolidated Act of Denmark No. 583 of July 9, 1993. Sweden as contained in the Environmental Code of 199. And France, which is known in the French Environmental Code of 2000. Since then, this concept has become one of the basic foundations of European Union Environmental Law. In addition, the precautionary principle formulation is also often adapted to be used as material for public policies and even contained in international agreements such as the Ministerial Declaration of the North Sea, Helsinki Convention, Rio Declaration, and many more (Latifah Emmy, 2016). This precautionary principle is implemented in all corners of the world as a preventive measure; it is unknown how much impact the risks will pose to maintain environmental quality. This principle is applied as an effort to overcome the possibility of severe damage, and although there is no solid scientific evidence, this is not allowed to be used as an excuse not to make arrangements (Farihah & Angraini, 2012).

Initially, science and technology were believed to be tools used to bridge decision-making in predicting hazards. However, as the times progress, we are challenged to agree and limit the danger. The approach taken by this principle uses more assumptions to make decisions (Hanna, Evans, & Booth, 2020). By observing various factors suspected of having the potential to trigger damage, caution is needed in formulating public policies regarding an event or a product that is potentially dangerous but uncertain due to the lack of strong scientific evidence, so that the expected outcome is that

policymakers can be wise in their decision making. Take responsible decisions by maintaining the quality of the environment to reduce the incidence of damage (Latifah Emmy, 2016).

There are several elements contained in the precautionary principle, including:

- **Risk Ambiguity**

This concept has a deeper meaning than just preventive measures. This concept describes actions prior to the occurrence of a causal relationship of a policy or event that has a potential value to have a harmful impact but is not based on sufficient scientific evidence.

- **Assessment of potential risks that arise**

All data that has the potential to pose a risk as a result of an event or product that may disrupt the stability of the health and environment of the community is determined and collected first by several competent experts in their respective fields. This precautionary is solely done as a precautionary measure to prevent misuse of precautionary principles such as excessive decision-making. It is hoped that this assessment of potential risks can be used as a reference for policymakers in making responsible decisions.

- **Serious damage potential**

The predicted impact of damage must be able to be classified. Damage is classified as severe if the resulting impact is capable of causing loss of life, disturbing the health, life of species, and vital resources such as water, soil, and air. Appropriate parameters are needed to determine this type of damage because the level of damage between people's cultures is often different. In this case, the precautionary principle is applied to deal with hazardous conditions that have high intensity with a long enough time to minimize the impact of damage caused by an event or product.

- **Proportionate preventive action**

Not every condition that can pose a risk needs to implement this precautionary principle. This concept is intended to reduce the number of risks exposed, budget losses and to reduce the number of fatalities. In food and medicine, this principle can be applied by conducting regular monitoring or screening, checking to label, conducting trials before being released on the market so that the impact of damage that is calculated to occur can be reduced (Latifah Emmy, 2016).

National defense theory

According to the National Resilience Institute, National Resilience is defined as a dynamic condition of the Indonesian nation that contains tenacity and resilience in facing and overcoming all threats, disturbances, obstacles, and challenges both coming from outside and from within the country directly or indirectly that can endanger the integrity, identity as well as the survival of the nation and the state (Taufiq, 2013). The impact ratification of the Job Creation Act also impacts public health. According to WHO, public health is defined as the art and science of preventing disease, prolonging life, and promoting health through organized community efforts. The overall vision is to promote

better health and well-being sustainably while strengthening integrated public health services and reducing inequality. To achieve this vision, approaching public health involves working with other sectors to address the broader determinants of health and with health professionals in their fields (WHO, 2012).

Research methods

This research uses a qualitative descriptive research type. Qualitative research describes variations in a phenomenon, situation, problem, or event (Widi, 2018, p. 59). Qualitative research adherents of the phenomenological school emphasize scientific research activities by decomposition and understanding the observed social phenomena (Ahyar et al., 2020, p. 41). Researchers collected primary data by conducting interviews and focus group discussions (FGD) with BPOM on collecting data related to drug and food supervision after the Job Creation Act. In addition, the authors also collect secondary data obtained from official documents, books, journals, online media, and news. This method is carried out to describe the impact of the ratification of the Job Creation Act on business licenses on drug and food control in Indonesia.

Results and Discussion

After ratifying the Job Creation Act, Chapter III of the Job Creation Law contains articles to improve the investment ecosystem and business activities. In-Law no. 11 of 2020 concerning Job Creation, article 6 contains an increase in the investment ecosystem and business activities which are described as covering (i) the application of risk-based business licensing, (ii) simplification of the basic requirements for business licensing, (iii) simplification of sector business licensing and (iv) simplification of investment requirements. In the Job Creation Law, risk-based business licensing is applied based on determining the risk level and business scale rating of business activities. The determination is carried out by assessing the hazard level to aspects of health, safety, environment, and resource utilization and management. The hazard level assessment also considers the type of business activity, criteria for business activities, location, limited resources, and risk of volatility. The division of risk level and business scale rating of activities is determined to be low, medium, and high-risk business activities. The granting of business activity licenses, both low, medium, and high, will be given in the form of a business registration number that becomes the legality of the implementation of business activities and a standard certificate. Business standard certificates are issued by the central government or local governments based on verification of business activities implementation standards by business actors. Further provisions regarding this business permit are regulated in government regulation.

Government Regulation Number 5 of 2021 regulates the implementation of risk-based business licensing. In this PP, the implementation of risk-based business licensing covers 16 sectors, and one of them is health, medicine, and food. Medicine and food are two products that are the primary needs of the Indonesian people. The existence of medicine and food is a determinant of human survival. The condition of the drug and food industry in Indonesia is experiencing obstacles due to several reasons. The decline in the rupiah exchange rate has impacted the processed food and drug industry, which still relies on imported raw materials. Then, the difficulty of traditional medicine to the world market is still not based on clinical trials to the global food industry that emphasizes food safety and health (DPR RI, 2019).

Regulations related to the health, drug, and food sectors are listed in PP No. 5 of 2021, the eleventh part of articles 119 to 133, which regulates business licensing covering the health sub-sector and the drug and food sub-sector. Business licensing for the drug and food sub-sector includes permits and standard certificates for medicine and food. Business Licensing is established to support business activities in the drug and food sub-sector, including drugs and medicinal ingredients, traditional medicines, health supplements, causative drugs, cosmetics, and processed food. Standard requirements for drugs and drug ingredients must include the safety, efficacy, quality, and product information specified. After ratifying the Job Creation Act, BPOM, as a government agency authorized to supervise and issue distribution permits in drugs and food, has additional business licenses. BPOM is only authorized to supervise drugs and food circulated (pre-market) and after circulating in the community (post-market). However, there are obstacles as to whether the Ministry of Trade, Industry, Ministry of Health, and the National Police Headquarters has the same interpretation regarding granting business and distribution licenses related to drugs and food.

Based on the findings of the SKSG team through a focus group discussion with the POM, academics, and practitioners involved in the drug sector, it was found that the business license issued by BPOM after the Job Creation Act did not reduce the legality of the distribution permit. However, in a related case, some victims are affected by toxic effects due to consuming illegal drugs based on the new regulations, which can hinder the investigative activities of investigators from the POM and law enforcement officers due to changes in offenses and nomenclature. The increasing digital economic activity in society and the increasing need for drugs have opened up space for the circulation of illegal drugs, which has become difficult to control by the relevant authorities, so it is necessary to strengthen the drug and food regulatory agency. Another finding is that there are still traces of non-prescription drug sales transactions in e-commerce because the BPOM does not have the power to ask the platform owner to handle the case. After all, the owner of e-commerce argues that transaction activities are returned to the user. Moreover, the high activity of raids carried out by the competent body shows that it is easy to obtain hard drugs without a prescription in the community. This problem of an online transaction then becomes some of its challenges for drug and food control in Indonesia.

There has been an escalation of crime in Indonesia's Drug and Food sector since 2016-2019. In 2016, drug and food violations were recorded as 250 cases and increased to 293 cases. In 2017, 302 cases, then in 2018, increased with a total number of cases. In 2019 as many as 335 cases with a total economic value of Rp. 345.52 billion (BPOM, 2019). To ensure drugs and food circulating in the community meet safety and health standards, the government established the Food and Drug Supervisory Agency (BPOM). BPOM is authorized by Law to carry out work in issuing distribution permits, monitoring, and taking action. According to WHO in the Effective Drug Regulation (A Multicountry Study), surveillance activities aim to ensure the safety, efficacy, and quality of drugs available to the public. So that supervision needs to be regulated in legislation in the field of medicine that comprehensively regulates requirements related to products, and the entire series of activities that must be carried out before and after the product is circulated, including all aspects of activities related to production, importation, distribution including distribution, and product promotion activities (DPR RI, 2019).

The Food and Drug Supervisory Agency (Badan POM) has an important position in Indonesia, so its birth was based on Presidential Decree Number 103 of 2001 concerning Positions, Duties, Functions, Authorities, Organizational Structures, and Work Procedures of Non-Departmental Government Agencies. Subsequently, there were changes several times, and the latest was

Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Supervisory Agency. Based on this regulation, the Head of the POM Agency issues Regulation of the Food and Drug Supervisory Agency Number 26 of 2017 concerning the Organization and Work Procedure of the Food and Drug Supervisory Agency (BPOM, 2021b).

One of the biggest challenges in monitoring drug distribution is monitoring the supply chain and drug supply chain. The supply chain emphasizes an integrated pattern regarding the flow of medicinal products from suppliers, manufacturers, retailers to the final consumer. Supervision along this supply chain has complex problems, as evidenced by the many regulations related to the circulation of medicinal products. There is a link between one supervisory department involving the pharmaceutical industry, wholesalers, pharmaceutical service facilities, and retailers before drugs reach consumers (BPOM, 2019). In its implementation, violations were found in rampant drug distribution at facilities that did not have the expertise and authority (TKK). Circulation of drugs at TTK facilities takes place offline and online, where hard drugs are sold at unlicensed facilities or drug stores without a doctor's prescription. E-commerce, social media, personal portals are the means for drug distribution at TTK facilities. Then there is the phenomenon of "wasting drugs," which is clear evidence of deviations in drug distribution channels involving the pharmaceutical industry as the product owner. The phenomenon of drug distribution irregularities is also inseparable from community involvement. People's tendency to want to self-medicate, ease of transactions, the efficiency of time and energy, and lifestyle changes are factors that support the rapid pace of trade transactions both through offline and online media. This trend will undoubtedly significantly impact the supply chain, especially in the drug distribution channel (BPOM, 2021b).

In the context of national resilience, public health and safety is top priority that deserves the government's attention. Although the government is trying to increase the pace of industrialization by cutting down on overlapping regulations, the government must not ignore the aspect of public safety. Along with the increasing digital economic activity in society and the increasing need for drugs, there is an open space for the circulation of illegal drugs that the relevant authorities cannot control. The issuance of increasingly complex permits requires stricter supervision and distribution permits to prevent the circulation of illegal drugs in the market.

Regulations related to business permits in the Job Creation Law have become a challenge for BPOM, where it is necessary to have policies that can strengthen the role of BPOM in supervising and controlling the distribution of food, especially illegal drugs in the community. Thus, BPOM certainly needs to strengthen its roles and duties in carrying out drug and food supervision after implementing the Job Creation Law in creating a safe and healthy environment for the community to support the health of the Indonesian people. The purpose of the creation of the Job Creation Law is, of course, aimed at improving the welfare of the Indonesian people as part of achieving national security,

However, in the 2020-2024 RPJMN, it is also stated that the Drug and Food Control system has not run optimally; this is due to various challenges faced. BPOM also needs to develop strategic steps that refer to national development priorities as national resilience. These strategic steps include efforts to develop human resources for Drug and Food Control that focus on employees as human capital, community empowerment (social capital), cross-sectoral networks including the domestic and foreign private sector, infrastructure utilization, and information technology-based technology (BPOM, 2021a).

After ratifying the Employment Copyright Act, in terms of business licenses and distribution permits, the drug qualifications must be based on the nature of their toxicity. Differences in interpretation at the ministries and institutions make efforts to protect the community neglected. In addition, the harmonization of the rules is needed to create legal certainty by having the same interpretation of the existing rules in various regulations by various agencies and stakeholders. The POM Agency, as an institution that is mandated to supervise drug and food when dealing with cases in the field, experiences problems in the field of human resources; therefore, efforts are needed to increase the number of BPOM human resources so that they can monitor, detect, and take action against violations of the Law—related to Drugs and Food. Moreover, in the Job Creation Law, the granting of business licenses is categorized as risky, which requires a lot of human resources who can speed up the business permit process with precise calculations. A solid legal law is needed in responding to various problems such as globalization, the development of science and technology, the industrial revolution 4.0 such as transactions carried out through e-commerce, as well as tight competitiveness with foreign countries regarding the circulation of illegal drugs on the market, so a Bill on Drug and Food Control is needed. In the right to grant business licenses in the Drug and Food sector as well as ease of access and matters related to sanctions. The development of science and technology, the industrial revolution 4.0, such as transactions carried out through e-commerce, and tight competitiveness with foreign countries related to the circulation of illegal drugs on the market so that a bill on drug and food control is needed. In the right to grant business licenses in the Drug and Food sector as well as ease of access and matters related to sanctions. The development of science and technology, the industrial revolution 4.0, such as transactions carried out through e-commerce, and tight competitiveness with foreign countries related to the circulation of illegal drugs on the market so that a bill on drug and food control is needed. In the right to grant business licenses in the Drug and Food sector as well as ease of access and matters related to sanctions.

The method developed in decision-making must be based on democratic values by prioritizing a mature mindset in considering scientific evidence when estimating uncertainty so that the possible risk of loss can be minimized as much as possible. The policies outlined must go through various stages of sorting in interpreting the possibility of damage that can occur. Assistance from various parties is needed in complying with the precautionary principle by not ignoring or trivializing related matters. BPOM itself is required to be able to interpret this principle by being selective and careful in submitting a business license or distribution of drugs and food in Indonesia while still prioritizing aspects of health, economy, environment, and continuous supervision; this is solely done to be able to prevent the rise of arbitrary exploitation by irresponsible persons. The reason is that the threats that arise from various oppositions can undermine the level of guarantee for the welfare of the people.

Therefore, by implementing the policy function, it is hoped that BPOM, as the agency responsible for drug and food regulation in Indonesia, can provide good health services to the broader community and equally value the economy in Indonesia. The issuance of the legality of a business actor is obtained through several procedures, with the final result in the form of a business standard certification issued by the government. This certification includes the level of danger of the type of business, the results of verification of business implementation standards, and a business registration number. Government regulations regulate this business license.

Conclusion

The impact of the ratification of the Job Creation Law related to business permits in drug and food control can be seen from the increasingly complex rules related to the issuance of risk-based permits, which are not balanced with the current capabilities of BPOM. In the short term, the government needs to harmonize regulations related to business licenses regarding drugs and food. Moreover, there is still no agreement on understanding the rules in the Job Creation Law from each agency regarding the formulation of future policies. Not to mention the differences in interpretation at the ministry and agency levels, efforts to protect the community was neglected. In addition, the harmonization of the rules is needed to create legal certainty. So that in the short term, the government needs to harmonize the regulations related to business licenses regarding drugs and food.

References

- Ahyar, H., Maret, US, Andriani, H., Sukmana, DJ, Mada, UG, Hardani, S.Pd., MS, Nur Hikmatul Auliya, GCB, Helmina Andriani, MS, Fardani, RA, Ustiawaty, J. , Utami, EF, Sukmana, DJ, & Istiqomah, RR (2020). Qualitative & Quantitative Research Methods (March Number).
- BPOM. (2019). Strategic Plan of the Deputy for Enforcement for 2020-20204. In POM Agency. https://www.pom.go.id/new/files/2020/renstra/center/FINAL-11.00_Edit_140720_Deputy_Strategic_Plan_4_2020-2024_Review2.pdf
- BPOM. (2021a). Performance Report 2020. Deputy for Processed Food Supervision of the Food and Drug Supervisory Agency. https://www.pom.go.id/new/files/2021/LAPKIN2020/1.Echelon_I/DEPUTY_III/LAPKIN_DEPUTY_FOR_PROCESSED_FOOD_SUPERVISION_FY_2020_FINAL.pdf
- BPOM. (2021b). Annual Report of the Directorate of Security of the POM Agency 2020. In the Language Development and Development Agency of the Ministry of Education and Culture of the Republic of Indonesia (Vol. 0).
- DPR RI. (2019). Academic Paper of the Draft Law on Drug and Food Control.
- Fariyah, L., & Angraini, F. (2012). Prinsip Kehati-hatian dan Kerugian Potensi Dalam Perkara Tata Usaha Negara Terkait Lingkungan Hidup. *Jurnal Yudisial* , 241-260.
- Hanna, T. P., Evans, G. A., & Booth, C. M. (2020). Cancer, COVID-19, and the precautionary principle: prioritizing treatment during a global pandemic. *Nature Reviews | Clinical Oncology*, 268-270.
- Latifah Emmy. 2016. Precautionary Principles the Foundation in Formulating Public Policy. Eleven Maret University Faculty of Law.
- Suntoro, A. (2021). Progressive Implementation of Achievements in the Omnibus Law on Job Creation. *Human Rights Journal*, 12(1), 1. <https://doi.org/10.30641/ham.2021.12.1-18>
- Taufiq, M. (2013). Increasing the Prevention of Radicalism for the Stability of Homeland Security in the Context of National Defense. National Defense Library RI. <http://lib.lemhannas.go.id/public/media/catalog/0010-011160000000134/swf/3767/mobile/index.html#p=1>
- WHO. (2012). Public health services. World Health Organization; World Health Organization. <https://www.euro.who.int/en/health-topics/Health-systems/public-health-services/public-health-services>
- Widi, RK (2018). Invigorate Research; Introduction and Guidance for Research Implementation.

Depublish. <https://books.google.co.id/books?id=1QODDwAAQBAJ>