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The Effectiveness of Regional Government Empowerment on Pharmaceutical Wholesaler Licenses on The Bali Province

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ABSTRACT

Pharmaceutical wholesalers (PBF) that are already licensed by Indonesian government have complied with the pre-operational business standard requirements and during operations are required to comply with the standards of good drug distribution procedures. However, there have been some cases of PBFs that have been licensed infringing on their business licensing obligations. These infringements will affect the quality of drugs and/or drug substances which could endanger consumers. Based on this phenomenon, monitoring by regional governments is important in maintaining businesses' compliance with business standards. The objectives of this research were to examine and analyze several factors affecting the effectiveness of regional government supervision of PBF licenses in Bali Province. The method used is empirical legal method. To address the issues within this research, the author utilizes a sociological approach, a legal regulation approach, and a conceptual approach. Furthermore, this research indicated that Bali Provincial Health Office supervision is ineffective in assuring compliance in the fulfilling of requirements and obligations by businesses. These conditions have been affected through legal substantial factors, legal structure, and legal culture.

Keywords: *Pharmaceutical Wholesaler, Regional Government, Supervision*

INTRODUCTION

Health supplies, such as pharmaceutical preparations, particularly medications, are necessary to attain the highest possible level of health for the community. Pharmaceutical wholesalers (PBF), companies that function as distributors in the health sector, are involved in the distribution of pharmaceutical preparations. One of the companies impacted by the Job Creation Law is PBF. Business licensing for PBF is classified as high risk according to the risk analysis in the attachment to Government Regulation No. 5/2021 concerning the Implementation of Risk-Based Business Licensing (hereinafter referred to as Licensing Regulations), which is a derivative regulation of the Job Creation Law. When a PBF operates, it must adhere to the Food and Drug Supervisory Agency's Standards for Good Medicine Distribution Methods (also known as CDOB) if it has permission from the government. Prior to operations, the PBF must meet the business standard requirements (BPOM).¹

Every distribution company is required to maintain a good system that comprises operational, operational, and risk management procedures related to the services offered, according to CDOB's technical recommendations. The distribution business is responsible for ensuring that the drug and/or drug product quality and the system's overall health are maintained during the distribution process. However, in reality, there are instances where PBFs with permits break their license requirements for businesses. The quality of medications and/or therapeutic components that also contain alcohol will be impacted by such infractions, putting patients at risk. A incidence of dispensing counterfeit medications was reported in 2019 involving PT Jaya Karunia Invesindo (JKI), one of the PBFs in Jakarta. The perpetrators targeted 197 pharmacies in the Jabodetabek area in all. Two PBFs will have their CDOB certificates revoked by BPOM in 2022. According to the Head of BPOM, it was established that the two PBFs were dispensing solvent raw materials for propylene glycol that were tainted with EG and DEG and did not adhere to regulations.

In order to determine if implementation in the field complies with the laws, supervision is obviously required given the circumstances in the community. In order to address mistakes or deviations made by PBF business actors, the government must make significant modifications if the implementation does not follow the established plan. To guarantee the efficacy, safety, and quality of medications, strict oversight must be undertaken during distribution. Here, monitoring is an endeavor to safeguard customers under the law. Both preventive (prevention) and repressive (coercion) protection of legal subjects' rights are the goals of legal protection. An abundance of people can feel secure under well-

¹ Menteri Hukum dan Hak Asasi Manusia Republik Indonesia, *Peraturan Pemerintah Republik Indonesia Nomor 5 Tahun 2021 Tentang Penyelenggaraan Perizinan Berusaha Berbasis Risiko* (Jakarta, 2021).

crafted legal rules.² Article 1504 of the Civil Code establishes PBF's obligation to be held accountable for any hidden defects in the goods. In the event that the goods are defective, PBF, as the seller, is entitled to a price refund for the returned goods or the right to keep the goods after receiving compensation from the seller.³ When a product has a long expiration date but is still unusable, for instance, product replacement is the most common type of responsibility that arises from product faults in practice.⁴

In addition to prioritizing assessment and corrective actions for the output produced, supervision is an activity that is used to determine whether an activity is in line with the plan based on its application. In this regard, supervision can be compared to Das Sein & Das Sollen corrections, where Das Sollen (the plan) is required. Das Sein (actuality) is synchronous.⁵ One tactic for implementing risk-based business licensing in the context of enhancing the investment ecosystem is supervision, according to the Job Creation Law. According to Government Licensing Regulations, the Central Government, Regional Government, KEK Administrators, and/or the KPBPB Concession Agency are responsible for overseeing risk-based business licensing in compliance with their respective jurisdictions. In order to carry out supervision, business actors' compliance level is taken into account. As part of their separate jurisdictions, the governor, regent, and/or mayor exercise the authority of the Regional Government, which is supervision.

Bali Province is one of the provinces in Indonesia that has PBF. There are 17,726 Medicine and Food Products circulating in Bali province consisting of 3,595 Medicinal products, 1,752 Traditional Medicine products, 326 Quasi-Medicine products, 876 Health Supplement products, 6,183 Cosmetic products, and 4,994 Processed Food products. In 2022, the National Center for Drug and Food Control in Denpasar will supervise 19 PBFs in Bali Province, namely 16 PBFs in Denpasar City and 3 PBFs in Badung Regency. From the total of PBF inspected, 12 facilities (63.2%) met CDOB requirements and 7 facilities (36.8%) did not meet CDOB requirements. The types of violations found included distributing drugs not in accordance with CDOB principles and storing drugs not in accordance with the temperature required on the label.⁶

² I Made Arjaya, Ni Komang Mahyuni Gita Paramita, and I Made Suwitra, "Perlindungan Hukum Bagi Pembeli Berdasarkan Akta Perjanjian Pengikatan Jual Beli," *TUTURAN: Jurnal Ilmu Komunikasi, Sosial, dan Humaniora* 1, no. 2 (2023).

³ Deddy, Annalisa Yahanan, and Iza Rumesten, "Tanggung Jawab Hukum Pedagang Besar Farmasi Terhadap Distribusi Obat Generik Kepada Apotek," *Lex LATA: Jurnal Ilmiah Ilmu Hukum* 3, no. 3 (2021).

⁴ I Putu Gede Wiramahendra, I Nyoman Putu Budiarta, and Ni Komang Arini Styawati, "Pelaksanaan Perlindungan Hukum Bagi Konsumen Terhadap Peredaran Makanan Yang Telah Kedaluwarsa Di Pasar Kereneng Denpasar," *Jurnal Analogi Hukum* 3, no. 3 (2021).

⁵ Angger Sigit Pramukti and Meylani Chahyaningsih, *Pengawasan Hukum Terhadap Aparatur Negara* (Pustaka Yustisia, 2016).

⁶ Balai Besar Pengawas Obat dan Makanan (BBPOM), *Laporan Tahunan 2022 Balai Besar Pengawas Obat Dan Makanan Di Denpasar* (Denpasar, 2022).

Previous research mostly discussed the role of the Food and Drug Supervisory Agency (BPOM) in monitoring good drug distribution methods by PBF and distribution of drugs without distribution permits. There has been no research examining local government supervision of PBF permits, especially in Bali Province. Researchers believe that local governments have a very important authority and role in supervising PBF. Based on the data presented previously, it appears that this role has not been optimized by local governments. It is important to study PBF supervision in Bali Province in more depth because there is an increase in the number of PBFs and there are phenomena related to violations of PBF business licensing obligations in Bali Province based on data from the National Center for Drug and Food Control in Denpasar. Based on this, research regarding the effectiveness of local government supervision of PBF permits in Bali Province is important to carry out. The aim of this research is to analyze the effectiveness of local government supervision of PBF permits in Bali Province and the factors that influence the effectiveness of local government supervision of PBF permits in Bali Province.

RESEARCH METHODOLOGY

This research involves empirical legal research. It focuses on the behavior that develops in society or it can be asserted that the concept of this research is a real behavior that comprises the deeds and their consequences in the relationship of community life.⁷ This research is intended to analyze legal problems, such as the disparity between *Das Sollen* and *Das Sein*, harmonization and imbalance between existing policy arrangements and the actual circumstances occurring in the field. Furthermore, the researcher uses a sociological approach, legislative approach and conceptual approach to discuss the problems contained in this research. Primary data is field data, which is gathered from interviews related to the implementation of regional government supervision of PBF licenses in Bali Province. Meanwhile, secondary data is obtained from literature research which includes books/literature, written works such as essays, theses, dissertations and journals (library research) and the legislations. In collecting secondary data, it is accomplished by documentation study technique. The Bali Provincial Health Service, based at St Melati No. 20 Denpasar, is the provincial apparatus organization in the regional government that oversees PBF permits. This addresses the location of the research.

When we complete gathering and organizing the data in a methodical and consistent manner, both primary and secondary data are processed using qualitative descriptive analysis, which produces a qualitative analysis that gives solution on the issues presented. During processing, the data is connected to legal

⁷ Ishaq, *Metode Penelitian Hukum: Penulisan Skripsi, Tesis, Serta Disertasi*, 1st ed. (Bandung: Alfabeta, 2017).

theory, guidelines, and expert opinions to derive definitive conclusions that are then presented as explanations to address the formulation of the problem.

RESULT AND DISCUSSION

Empowerment of Regional Government Supervision towards Pharmaceutical Wholesaler Licenses on Bali Province

The Job Creation Law has a significant impact on business and investment by simplifying regulations massively from 79 laws into 1 law which aims to create a quality business and investment climate for business actors, including MSMEs and foreign investors.⁸ The Government Regulation on Licensing prescribes that PBF licenses are classified under KBLI (Indonesian Standard Industrial Classification) code 46441 entitled “Wholesale Trade in Pharmaceutical Drugs for Human Being.” KBLI 2020 is the Wholesale Trade Business Sector, which means it is impossible to be operated in the Retail Trade Business Sector simultaneously, as stipulated in Government Regulation No. 29/2021 on the Administration of Trading Sector. Based on the risk analysis listed in the Annex of Licensing Regulation which is a derivative regulation of Job Creation Law, business licensing for PBF is classified into high risk category so the forms of business licensing are Business Identification Number and PBF Permit.

Based on business classification, PBF is classified into two, which are central PBF and subsidiary PBF. Subsidiary PBF is a sub-branch of PBF that is licensed to procure, store, distribute drugs and/or drug ingredients in substantial quantities as required by applicable regulations. Both central PBFs and subsidiary PBFs can only distribute drugs to central PBFs or other branch PBFs, pharmaceutical service facilities such as pharmacies, hospital pharmaceutical installations, health centers, clinics, and drug stores; as well as scientific institutions. Meanwhile, drug ingredients can only be distributed to the pharmaceutical industry, PBF or other PBF branches, pharmacies, hospital pharmaceutical installations, and scientific institutions. The PBF profile in Bali Province from 2019 to November 2023 can be found in the following table.

Table 1. The Profile of Pharmaceutical Wholesaler in Bali during 2019-2023

No.	Districts/Cities	The Total of Pharmaceutical Wholesaler				
		2019	2020	2021	2022	2023
1	Buleleng	1	1	1	1	1
2	Jembrana	-	-	-	-	-
3	Tabanan	1	1	1	3	4
4	Badung	7	5	6	6	6
5	Denpasar	51	50	43	55	55
6	Gianyar	2	2	2	3	5

⁸ Hari Agus Santoso, “Efektifitas Undang-Undang Cipta Kerja Terhadap Peningkatan Investasi,” *Jurnal Hukum Positum* 6, no. 2 (2021).

7	Klungkung	-	-	-	-	-
8	Bangli	-	-	-	-	-
9	Karangasem	-	-	-	-	-
Total		62	59	53	68	71

Source: Health Department at Bali Province

The Licensing Regulation in Article 23 stipulates that entrepreneurs must comply with the requirements and/or business license obligations as listed in Appendix II of the Government Regulation. The business licensing obligations and compliance period that must be fulfilled by PBF entrepreneurs are required to fulfill the Good Drug Distribution Method (CDOB) standards set by the Food and Drug Supervisory Agency (BPOM). Based on BPOM Regulation No. 9/2019 concerning CDOB Technical Guidelines which was amended to Head of BPOM Regulation No. 6/2020, there are several aspects in it, which are (1) quality management; (2) organization, management, and staff; (3) construction and equipment; (4) operations; (5) self-inspection; (6) complaints, drugs, and/or drug ingredients suspected of being counterfeit and recalls; (7) transportation; (8) distribution facilities under contract; (9) documentation; (10) special provisions for drug ingredients; (11) special provisions for cold chain products; and (12) special provisions for narcotics, psychotropic substances, and pharmaceutical precursors.

Supervision is all activities intended to ensure and guarantee that tasks or assignments have been completed in accordance with established intentions, policies that have been outlined and orders (rules) that have been assigned.⁹ The Licensing Regulation stipulates that supervision is an effort in ensuring business activities are implemented in accordance with the standards for implementing business activities through a risk-based approach and obligations that must be completed by entrepreneurs. Supervision is performed by determining the compliance level of entrepreneurs. The types of supervision in the Licensing Regulation are routine supervision and incidental supervision. Routine supervision is performed with a regular basis based on the level of business activity risk and considering the level of cooperation of entrepreneurs. Occasional supervision is supervision conducted by ministries/institutions, provincial governments, regency/city governments, KEK (Special Economic Zone) administrators, and/or KPBPB (Free Trade Zone and Free Port) Concessionaires at certain times.

The concept of effectiveness is something that implies the occurrence of an intended outcome or consequence in organizational and management theory when

⁹ Iswandir, "Dasar-Dasar Proses Pengawasan Dalam Organisasi," *Journal Universitas Dirgantara Marsekal Suryadarma* 1, no. 1 (2021): 1–9.

someone executes an action with a specific goal that is genuinely desired.¹⁰ Therefore, if someone generates or serves the intended purpose, they have been deemed effective. According to this definition, the researcher determines that something is effective if it achieves the intended results. It means that accomplishing the thing during the moment entails accomplishing the objective of implementing the necessary steps to accomplish it.

Following Soerjono Soekanto's statement, an attitude of legal behavior is deemed effective only when it results in the desired goal, i.e., if another person obeys to the regulations. If someone asserts that a law has succeeded or failed in accomplishing its goals, this usually depends on how effectively its impact has controlled particular attitudes or behaviors to make them consistent with those goals. Behavior or actions that contribute to the goal are referred to as positive, while those that do the opposite are typically referred to as negative. It must be underlined that the term "purpose" refers to the legislator's goal.¹¹ When it comes to the durability of the law, Hans Kelsen clarified that people actually obey the law because they are required to do something to ensure that the law is actually applied and followed.¹² These are the purposes of government licensing was regulations-based business license supervision:

1. Verify that business actors are adhering to their obligations and requirements;
2. Gather information, proof, and/or reports about additional risks that might develop from the execution of business operations; and
3. referrals for advice or the application of administrative charges for infractions of business licenses.

The primary data collection results indicate that the Bali Provincial Health and Safety Service's implementation of supervision has not been successful in ensuring business actors' compliance with requirements and obligations. It is evident that annual routine supervision reveals continued non-compliance with requirements and obligations by business actors. After speaking with Ni Made Dian Utami, S. Farm Apartments on 7 November 2023, it was found that, although routine monitoring had previously revealed non-compliance with business obligations and had provided field guidance, some PBFs continued to violate these obligations. In an interview on 8 November 2023, with Dra. Desak Ketut Andika Andayani, Apt., who works as an Associate Expert Pharmacy and

¹⁰ Gracelia Friska and Drs. Eko Pudjolaksono, "The Effect of Profitability, Liquidity, Leverage, Sales Growth on Financial Distress in Consumer and Non-Consumer Cyclical Companies Listed on The IDX During The 2019-2021," *Utsaha (Journal of Entrepreneurship)* 2, no. 3 (2023).

¹¹ Soerjono Soekanto and Sri Mamudji, *Penelitian Hukum Normatif: Suatu Tinjauan Singkat* (Jakarta: Rajawali Pers, 2015).

¹² Suharyanti Asti Oktavia, Cicilia Julyani Tondy, and Amelia Nur Widyanti, "Pembatasan Kriteria Tidak Mampu Yang Wajib Diberikan Jasa Hukum Cuma-Cuma Oleh Notaris Berdasarkan Pasal 37 Undang Undang Jabatan Notaris," *SENTRI: Jurnal Riset Ilmiah* 2, no. 9 (September 5, 2023): 3548–3555, <https://ejournal.nusantaraglobal.ac.id/index.php/sentri/article/view/1499>.

Food Supervisor at the Center for Drug and Food Supervision (BBPOM) in Denpasar, it was revealed that the supervision's findings indicated that PBF violations of the guidelines in the Good Medicine Distribution Methods (CDOB) were still occurring, with some violations occurring more than once. PBF has received a strong warning letter from the Food and Drug Monitoring Center (BBPOM) in Denpasar regarding these persistent violations. On the 7th of November 2023, it was learned through an interview with Dr. Ni Wayan Murdani, MAP, Head of Health Resources at the Bali Provincial Health Service, that the outcomes of the supervision conducted by the organization had evolved into a source of direction. For example, in 2021, guidance was carried out regarding the fulfillment of Good Medicine Distribution Methods (CDOB) by the Center for Drug and Food Control in Denpasar for the person in charge of technical PBF because many violations were found regarding these business obligations. Researchers are of the opinion that the implementation of regional government supervision carried out by the Bali Provincial Health Service regarding PBF permits in Bali Province is ineffective because it has not fulfilled the objectives of supervision of business permits in the Government Licensing Regulations in the first policy, namely ensuring compliance with the requirements and obligations by business actors.

Influential Factors of Regional Government Supervision over Pharmaceutical Wholesaler Licenses on Bali Province

Lawrence Friedman as explained in the Legal System Theory asserted that the elements in the legal system are legal substance, legal structure, and legal culture.¹³ The three elements can be used as guidelines for a country on determining the proper way of law to be implemented.¹⁴ There are three factors that can affect regional government supervision of pharmaceutical wholesaler licenses to be ineffective, such following below:

1. Legal Substance

The legal substance that can affect Regional Government supervision of Pharmaceutical Wholesaler Licenses in Bali such following below:

- a. No arrangements related to supervision results assessment and types of sanctions that can be imposed on business license obligation violations.
- b. No technical arrangements related to coordination between regional authorities in Bali on the implementation of PBF license supervision.

¹³ Lawrence M. Friedman, *Sistem Hukum: Perspektif Ilmu Sosial*, Cetakan VI. (Bandung: Penerbit Nusa Media, 2018).

¹⁴ Yulianta Saputra, "Pengawasan DPRD DIY Terhadap Pemerintah Daerah Dalam Penggunaan Dana Keistimewaan," *Widya Pranata Hukum : Jurnal Kajian dan Penelitian Hukum* 1, no. 2 (October 2, 2019): 86–107, <http://ejournal.widyamataram.ac.id/index.php/pranata/article/view/48>.

2. Legal Structure

The legal structures that can affect regional government supervision of PBF licenses in Bali are described below:

- a. Supervisors of pharmaceutical wholesalers in Bali have not received sufficient knowledge and trained in supporting the implementation of supervision.
- b. The quantity of PBF supervisors in Bali Province is not sufficient to be able to supervise the whole Bali Province.
- c. There is an inadequate budget to supervise, which includes supervisory staff welfare.
- d. Supporting supervisory infrastructure such as business reporting information systems and submitting supervisory reports by supervisory staff.

3. Legal Culture

Legal culture is the most important aspect in legal socialization. Legal culture describes individual behavior patterns as community members that illustrate the same response (orientation) against legal livelihood, which is respected by the community concerned.¹⁵ These are several points of legal culture which affects local government supervision of pharmaceutical wholesaler licenses in Bali Province, such following below:

- a. The pharmaceutical wholesalers in Bali Province have not socialized their responsibilities which must be implemented consistently after getting a business license.
- b. Their commitment is inconsistent due to the lack of administrative sanctions and the tendency to make profits from their transactions without calculating the quality and safety of the drugs they manage.
- c. Entrepreneurs are bothered when inspectors do field inspection.

CONCLUSION AND SUGGESTION

Conclusion

The law is perceived to be effective if these attitudes and behaviors can be implemented to accomplish the intended purposes. In Government Regulations governing Business Licensing Supervision, it is designed to ensure compliance with the fulfillment of requirements and obligations by businesses; to obtain data, evidence, or reports when there are possible threats in safety, healthy, environmental, and other risks occurring as the implementation of business

¹⁵ Lalu M. Alwin Ahadi, "Efektivitas Hukum Dalam Perspektif Filsafat Hukum: Relasi Urgensi Sosialisasi Terhadap Eksistensi Produk Hukum," *JURNAL USM LAW REVIEW* 5, no. 1 (April 14, 2022): 110, <https://journals.usm.ac.id/index.php/julr/article/view/4965>.

activities; and referrals for assistance or imposition of administrative sanctions against business licensing infringements. However, interviews conducted with the concerned Health Office have not led to proper outcomes and are still ineffective in ascertaining compliance with the fulfillment of requirements and obligations of businesses since the supervision objectives have not been accomplished. This was discovered because there are still many infringements on the business obligations of PBFs in Bali, such as license changes due to the turnover of pharmacists responsible and branch heads that have not been submitted through OSS RBA; incomplete warehouse stock cards; expired fire extinguisher; broken building walls and ceilings; and uncalibrated thermometers.

There are several factors that can affect regional government supervision of pharmaceutical wholesaler licenses to be ineffective, which are legal substance, legal structure, and legal culture. Issues in legal substance are unclear supervision policy arrangements, for example coordination between regional apparatus; and arrangements for the sanctioning of business obligation infringements. While the issues in legal structure, such as supervisor who has not received supervisory training, no budget and facilities support. In addition, there is a lack of socialization regarding business obligations that should be implemented consistently if they have obtained a business license. This is caused by the reluctance of the pharmaceutical wholesaler owners.

Suggestion

The Indonesian Health Ministry is expected to arrange regulations on technical guidelines for controlling pharmaceutical wholesaler licenses, both at the central and regional branches, which regulate supervision indicators, evaluation of offense levels, and imposition of administrative sanctions. Then, for Regional Government of Bali Province is expected to formulate policies related to collaborative implementation of supervision among regional government agencies in an integrated manner so as to reduce the frequency of regional government authorities' supervisory activities that are not available to Pharmaceutical Wholesaler. The integrated supervision is expected to strengthen the investment climate as stipulated in Job Creation Law. It is expected that the Health Department of Bali Province will be consistent in supervising and socializing business obligations to PBF from the leadership to the executive staff. Furthermore, supervisory training in the health sector is also expected to be conducted for supervisors who will be assigned to supervise Pharmaceutical Wholesaler licenses. Implementers of PBF business in Bali are expected to be more committed in fulfilling the requirements and obligations of PBF business by supporting facilities and other resources as required by PBF business obligations.

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