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State Responsibility in the Regulation of Pharmaceutical Preparations and Pharmaceutical Personnel Comparison of Indonesia and Chile

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Abstract

The state is responsible for pharmaceutical preparations to realize and ensure the implementation of quality, correct and useful pharmaceuticals, it is necessary to build an integrated system starting from the upstream process, namely the existence of strong regulations as a legal basis in the form of implementable laws and regulations, which can be applied properly. In the practice of regulating pharmaceutical preparations, there is a difference where the Law mandates to realize the resilience of pharmaceutical preparations, the Central Government and Regional Governments are responsible for independence in the field of domestically produced pharmaceutical preparations for national resilience and progress, on the other hand, in the implementing regulations regulations are in the form of facilitating the implementation of imports. The difference in the regulation of pharmaceutical preparations that are inconsistent, it is necessary to take a comparative approach by comparing regulations in the form of regulations that are substantially related to the implementation of pharmaceuticals between Indonesia and Chile, when compared with the practice of regulating pharmaceutical preparations with Chile fully regulating the authority given to the government to protect public health by ensuring the availability of drugs starting from storage, distribution, Setting prices until imports are carried out, import needs are based on procurement transparency, supply control, and community needs. Pharmaceutical preparations are the responsibility of the state to ensure that every citizen has the right to receive health services, as a policy to realize a resilient and responsive health system , regulating the import of pharmaceutical preparations is in contrast to the independence of downstream the domestic pharmaceutical industry.

Keywords: *state responsibility, pharmaceutical regulation, pharmaceutical personnel, indonesia chile*

A. INTRODUCTION

The state has a responsibility in pharmaceutical preparations which are a very fundamental part of the health sector which is inseparable from health services carried out both

by the state and organized by the community, so the state has an obligation to produce cheap but high-quality pharmaceutical products. For this reason, the state through the constitution mandates that every citizen has the right to receive services and state responsibility for the provision of health services organized by the Central Government, Regional Governments, communities, and health service facilities must prioritize the use of domestic pharmaceutical preparations while still paying attention to quality, quality, safety and benefits (Amalia, 2018).

The implementation of health services by the Central Government, Regional Governments and the Community with the National Health Insurance (JKN) program currently managed by the Health Social Security Maintenance Agency (BPJS) has played an important role in ensuring access to quality medicines for all Indonesian people. In the implementation of JKN, the Government strives to provide safe and effective essential medicines for participants of the BPJS Kesehatan program. Data from the National Social Security Council (DJSN) through the National Social Security System (SJSN) for Health, until July 31, 2025, the coverage of JKN membership As of July 31, 2025 reached 280.7 million people or 98.7% of the total population of Indonesia. (BPJS Kesehatan, 2025) Meanwhile, the budget allocated for drug procurement will reach 40.33 billion in 2024 and 54.60 billion in 2024 (Perencanaan, 2025).

The regulation of the implementation of quality, correct and useful pharmaceutical preparations, and the need to build an integrated system starting from the upstream process, namely the existence of strong regulations as a legal basis in the form of implementive laws and regulations, can be applied properly. The promulgation of Law Number 17 of 2023 concerning Health (Law No. 17 of 2023), on August 8, 2023, is a codification of 11 (eleven) laws related to health that have been repealed and no longer applicable, so that the implementation of health system transformation requires capacity in an integrative and holistic manner in 1 (one) law (UU Kesehatan, 2023).

The Government of the Republic of Indonesia's policy promises to strengthen pharmaceutical resilience through the implementation of supply chains from upstream to downstream. Access to pharmaceutical preparations, especially drugs and medicinal ingredients, is a human right of every human being who until now there are still many people who have not received essential treatment, because in addition to the reason for unaffordable prices, one of the main reasons is the lack of access to information on the supply chain of pharmaceutical preparations has become a problem in Indonesia (Meliawati, 2020).

The causes of the shortage of pharmaceutical preparations, especially drugs, are grouped into three, namely: 1) economic and regulatory reasons; 2) business issues; and 3).

manufacturing and supply chain issues. First , economic and regulatory problems can cause a shortage of drug supply, including strict fiscal policies, changes in government policies, increased regulations related to requirements and changes in drug demand due to new drug applications. *Second*, business-related reasons, which cause a shortage of drug supply, namely increasing prices, declining margins, increasing dominance by a number of manufacturers, and a tender system that supports large manufacturers. *Third*, namely problems related to manufacturing and supply chains. Some of the main problems related to manufacturing are the problem of adaptation to increasingly strict government policies, long production waiting times, increasing barriers to raw materials, and quality-related production failures (Beck, M., Buckley, J., & O'Reilly, 2020).

The need for pharmaceutical preparations in order to increase productivity and competitiveness through efforts to achieve economic independence by mobilizing priority industries to meet national and export needs, it is necessary to accelerate the development of the pharmaceutical industry. That for the development and improvement of the production capacity of medicinal raw materials and traditional medicinal raw materials, arrangements are needed to support the pharmaceutical industry to transform into a research-based priority industry (Seto, 2001).

Planning for pharmaceutical supply needs is a process of activities in selecting the type, quantity and price of pharmaceutical supplies in accordance with needs and budgets, to avoid drug vacuums by using responsible methods and predetermined planning basics, including consumption, epidemiological (disease spread), combination of consumption and epidemiological methods adjusted to the available budget (Herlambang, 2016). The government through the Ministry of Health of the Republic of Indonesia (Kemenkes RI) in priority programs for the 20024-2025 fiscal year from the budget allocation for the health security system allocation in 2024 of 145.25 billion increased the allocation in 2025 to 358.1 billion sourced from the State Expenditure Budget which consists of resilience: medical devices, drugs and vaccines (Perencanaan, 2025).

The choice of arrangement to shorten the supply chain in the context of the pharmaceutical industry in Indonesia is so widespread, because the longer the supply chain causes the greater the costs to be incurred. Regulation so that pharmaceutical preparations in the Health Law are the most important part that is carried out by the Government, Regional Governments, and/or the community in its implementation. While the regulation of pharmaceutical preparations in Chile is regulated in Law 20.850, known as the "Ricarte Soto Law" in honor of the late Don Luis Ricarte Soto Gallegos, the law aims to ensure the financing

of diagnosis and treatment based on drugs and medical devices because they are high cost must be efficacious and proven, to protect the public from unaffordable costs (Cenabast 20.850, 2025)

The problem of regulating pharmaceutical preparations in Indonesia can be examined in Law Number 17 of 2023 concerning Health, distorted by its Implementing Regulations, namely Government Regulation Number 28 of 2024 concerning Implementing Regulations of Law Number 17 of 2023 concerning Health (PP No. 28 of 2024), which is related to the facilitation of the implementation of imports for Fulfillment of pharmaceutical preparations and under certain conditions pharmaceutical practices can be carried out by other health workers. The issue of norms in the law with the norms of implementing regulations is contradictory, insynchronous and unclear the legal basis for the regulation resulting in a defect in the norm so that it can add legal uncertainty, injustice and do not provide benefits because the norms in Law No. 17 of 2023 do not regulate the facilitation of the implementation of the import of pharmaceutical preparations but in Government Regulation No. 28 of 2024 regulates the facilitation of the implementation of imports, Similarly, in pharmaceutical practice by pharmacists under certain conditions, pharmaceutical practices can be carried out by health workers, including doctors and/or dentists, midwives and nurses. The existence of this norm is that castration of pharmaceutical preparations is carried out through the development and strengthening of the pharmaceutical preparation supply chain governance from upstream to downstream in an integrated manner by prioritizing the use and fulfillment of domestically produced for national health resilience and progress and ignoring pharmaceutical practices that must be carried out by pharmaceutical personnel (UU Kesehatan, 2023).

B. MATERIALS AND METHODS

In this study, it is carried out methodologically to obtain valid and correct data and information, and the value is more rational and logical research approach by departing from philosophical, sociological, juridical constitutional paradigms, the right to obtain health services and the aspirations of the legal needs of the community. The method of this research study is to compile systematic results by minimizing problems in the implementation of pharmaceuticals with an emphasis on basic research, applied research, and policy or evaluative research (Lubis, 2013).

In basic research, it is carried out through literature studies that examine secondary data, both in the form of primary legal materials, secondary legal materials, and tertiary legal materials. Furthermore, applied research is carried out through literature studies carried out by examining various secondary data such as policies in the form of related laws and regulations,

both at the level of laws and implementing regulations and various legal documents that are related to pharmaceutical issues. As for completing the literature and literature study, discussions and data collection were also carried out with various interested parties or related *stakeholders*. The literature study is carried out by collecting data in literature research using document studies with the acquisition of data sources from:

1. Primary Legal Materials, which are binding legal materials in the form of the 1945 Constitution of the Republic of Indonesia, Laws and Regulations and other legal documents related to pharmaceuticals in general and the implementation of pharmaceuticals; and
2. Secondary Legal Materials, which are explanations of primary legal materials such as research results, studies, and other references related to the identified problems. Discussions were held with various related parties in order to sharpen the study and analysis. In addition, a comparative approach is carried out by substantially comparing the regulation and implementation of Pharmaceuticals in Indonesia and Chile. The data processing is carried out qualitatively. The various written legal materials that have been collected are then systematically analyzed to answer the problem as a result of research to be discussed and then conclusions are made.

C. RESULT AND DISCUSSION

The regulation of pharmaceutical preparations is regulated in Law No. 17 of 2023 concerning Health, and the implementation regulations are regulated in Government Regulation No. 28 of 2024, which is considered to make government regulatory policies difficult in the implementation of health efforts between the use and security of pharmaceutical preparations. The level of public awareness in using drugs that is increasing and supported by the increase in people's purchasing power has caused a positive impact on the growth of the pharmaceutical industry in Indonesia. However, the government is obliged to ensure that the pharmaceutical industry in drug manufacturing must meet the quality standards that have been set, namely to improve the highest degree of public health (Amalia, 2018).

The Constitution of the Republic of Indonesia obliges the state through the Government, in this case, the Ministry of Health of the Republic of Indonesia to guarantee the supply of pharmaceuticals, because the state guarantees the right of every citizen to realize a good, healthy, and prosperous life in the body and mind for the achievement of the national goal of protecting the entire Indonesian nation and all Indonesian bloodshed to advance the general welfare and educate the life of the nation as mandated in Article 28H paragraph (1) The 1945 Constitution of the Republic of Indonesia (1945 Constitution of the Republic of Indonesia)

guarantees, "Everyone has the right to live a prosperous life in birth and mind, to live, and to have a good and healthy living environment and the right to receive health services" as well as in Article 43 paragraph (3) of the 1945 Constitution of the Republic of Indonesia states, "The State is responsible for the provision of health service facilities and proper public service facilities" (Indonesia, 2002).

The universal implementation of pharmaceutical preparations based on the principles of non-discrimination, participation, protection and sustainability is very important for the formation of Indonesian human resources, increasing the nation's resilience and competitiveness and national development. To realize quality, correct and useful pharmaceutical preparations, it is necessary to build an integrated pharmaceutical and pharmaceutical personnel preparation system starting from the very upstream, namely strong regulations as a legal basis in the form of laws and regulations that do not contradict each other, and can be implemented with plenary, then The Government is obliged to protect the public from the use and service of pharmaceutical preparations, which are detrimental and/or harmful, through the supervision of pharmaceutical preparations that meet the standards and requirements (Pengawasan Sediaan Farmasi, n.d.)

1. Regulation of Pharmaceutical Preparations in Indonesia

The provisions of Article 28 H paragraph (1) of the 1945 Constitution of the Republic of Indonesia states that, "everyone has the right to live a prosperous life in birth and mind, to live, and to have a good and healthy living environment and to the right to receive health services" (Indonesia, 2002). The Indonesian Government's anxiety about the rising prices of pharmaceutical products should be welcomed as a positive signal. Indonesia's pharmaceutical industry has been so poor that it has failed to produce cheap but high-quality pharmaceutical products. The intention of the Indonesian government, through the Minister of Health, to reduce the price of (generic) drugs will always be difficult. This will continue as long as the structure of the pharmaceutical industry in Indonesia does not undergo reform of this phenomenon, exacerbated by inconsistencies carried out by the Government itself due to the tug-of-war in it (Mustamu, 2007).

Our Constitution has mandated in Article 34 paragraph (3) of the 1945 Constitution of the Republic of Indonesia, stating: "The State is responsible for the provision of health service facilities and good public service facilities" (Indonesia, 2002). These norms are interpreted as including the state is responsible for the fulfillment of pharmaceutical preparation services that must be safe, efficacious/useful, quality, and affordable. So that the Government is obliged to foster, regulate, control, and supervise its procurement, storage, promotion, and distribution.

For this reason, the Government is obliged to ensure the development and maintenance of pharmaceutical preparations for all Indonesian people The lack of government policy on the distribution of pharmaceutical preparations distributors in Indonesia is one of the obstacles for the government in distributing drug distribution equally (Mudin, 2018).

A good and implementable law is certainly born from the process of forming a good law, so that in the context of the formation of this law, according to Lon Fuller, which Shidarta was quoted as suggesting that every process of forming laws and regulations must consider at least two things, namely (1) the need for a general principle and not an unpredictable momentary interest and (2) reaching for the future. Especially the point of reaching the future, a legal product must be able to answer current and future challenges and conditions so that it is implementable and sustainable (Shidarta, 2014).

A law can be said to be of good quality and has sustainable characteristics, it can be seen from the point of view of success in achieving goals (*doeltreffendheid*), implementation (*uitvoerbaarheid*), and law enforcement (*handhaafbaarheid*) but determined by its existence rather than the law itself (Yuliandri, 2011). At this time, in Indonesia, the regulation that is the main legal umbrella act for pharmaceutical preparations is Law No. 17 of 2023 concerning Health, while the regulation of pharmaceutical preparations is regulated in Chapter IX of Pharmaceutical Resilience and Medical Devices, in that chapter to the entire body of article after article there is no provision for facilitating the implementation of the import of pharmaceutical preparations, Generally, the Pharmaceutical chapter regulates the standards, systems, and governance of pharmaceutical preparations, medical devices, and other health supplies in emergencies, disasters, extraordinary circumstances or outbreaks (UU Kesehatan, 2023).

Facilitation of the implementation of the import of pharmaceutical preparations is regulated in Article 943 paragraph (3) letter d of Government Regulation No. 28 of 2024 as an implementing regulation of Law No. 17 of 2023, so as an effort to meet the needs of pharmaceutical preparations can be in the form of: facilitation of the implementation of imports, these provisions are very beneficial for business actors who own pharmaceutical companies. At this time there are at least 12 pharmaceutical companies, 2 of which are State-Owned Enterprises (SOEs), namely PT. Indofarma Tbk and also PT. Kimia Farma Tbk., the rest of the private pharmaceutical companies with conditions and potential losses due to higher business continuity operations and production costs, are very profitable for the facilitation of import implementation under the pretext that pharmaceutical raw materials are very expensive in the

country and the fulfillment of insufficient pharmaceutical preparations in the country (Wiarta et al., 2022).

The absence of provisions on content that regulates and orders the facilitation of the implementation of the import of pharmaceutical preparations in Law No. 17 of 2023 concerning Health, can be considered as deliberate negligence or not because it has gone through such a long formation process from planning, drafting, harmonizing, discussing, ratifying and promulgating can be considered not to meet the aspects of good law formation, including: 1) *legal needs*), 2) social *conditions,* and 3) social *capital*, so the content material that regulates is not in accordance with the principles of good legislation and regulation (Kurnia, 2007). On the other hand, the regulation of facilitating the implementation of imports is regulated in Government Regulation No. 28 of 2024, because in Law No. 17 of 2023 there are no norms that regulate or order it can be considered as non-compliance with the Law, because the Health Law does not delegate. If the reason for the complexity of regulating pharmaceutical preparations is spread across various laws and regulations, including the Job Creation Law, the Health Law, the Psychotropics Law, the Narcotics Law, Government Regulations, the Regulation of the Minister of Health and the Regulation of the Food and Drug Supervisory Agency, as a legal basis for justifying the facilitation of the implementation of imports in Government Regulation No. 28 of 2024, in order to answer the needs of pharmaceutical law in Indonesia is very inappropriate, If the pretext is to achieve the goal *of doeltreffendheid* (efficiency/adequacy) to protect the pharmaceutical industry as a business actor to be more efficient and can make the price of pharmaceutical products as products more profitable because of the guarantee of distribution and the market that buys (Windha & Andriati, 2023).

The implementation of pharmaceutical preparations, inseparable from business practices in the pharmaceutical industry, especially in Indonesia with the price of drugs being so expensive that consumers are dependent, requires an increased level of public awareness in using drugs and supported by the increasing purchasing power of the public causing a positive impact on the growth of the pharmaceutical industry in Indonesia. Therefore, the government is obliged to ensure that the pharmaceutical industry makes fafaasi preparations in the form of drugs that meet the set quality standards. To ensure that pharmaceutical preparations are safe for the public, as *a guideline* the pharmaceutical industry is obliged to ensure quality management with adequate human resources, for this the Government is responsible for not needing to facilitate the implementation of imports in order to realize the independence of the national pharmaceutical industry with the availability of stock in various health facilities

according to the National Health System (SKN) as a form of subsystem, one of which is pharmaceutical preparations (Hani Putri Febriyanti et al., 2023).

Data on the import of pharmaceutical preparations as published by the Ministry of Health of the Republic of Indonesia in 2024 related to the importance of domestic pharmaceutical independence, found that around 90% of Medicinal Raw Materials (BBO) are still imported and product data published in the e-catalog around 34.7% are imported products. The existence of the pharmaceutical industry in Indonesia is highly dependent on BBO from China and India, so that more than three hundred pharmaceutical industries in Indonesia rely on production in these two countries. It is very unreasonable if the limited scale of production and the lack of incentives for the pharmaceutical industry cause the price of domestic BBO to be more expensive, when compared to the price of imported BBO as a justification for the policy of facilitating the implementation of imports (KIPPRA, 2022).

The government has a great responsibility to educate and supervise pharmaceutical preparations as an effort to protect the public, the government is obliged to carry out comprehensive supervision of the production and distribution of pharmaceutical preparations, to ensure that every product in circulation has a valid distribution permit, and conduct periodic inspections of production and distribution facilities (Sari et al., 2025). The state is obliged to fulfill the right to health is a constitutional mandate that progressively, structurally, regulates the resilience of pharmaceuticals and medical devices produced domestically in Law No. 17 of 2023 by delegating to implementing regulations as derivative regulations, not negating each other, namely:

1. Government Regulation Number 28 of 2024 concerning Health, which emphasizes the importance of research, development of medicinal raw materials, utilization of local resources and domestic production;
2. Presidential Regulation Number 12 of 2021 concerning the Procurement of Government Goods/Services, which requires the use of domestic products with a minimum TKDN level of 40%;
3. Presidential Instruction Number 6 of 2016 concerning the Acceleration of the Development of the Pharmaceutical and Medical Device Industry;
4. Regulation of the Minister of Health Number 62 of 2017 concerning the Implementation of the Production and Distribution of Medical Devices.

The hierarchical regulatory framework is analyzed from the impact of a regulation, especially Law No. 17 of 2023, which was formed as a legal umbrella for pharmaceutical preparations, how good and clean governance can be applied as the main key to openness in

policy-making. The occurrence of overlap, conflict, harmony and insynchronization between the parent norm and the derivative norm of the pharmaceutical preparation regulation is due to pseudo-public participation and lack of openness in decision-making (Ruben, 2025).

2. Pharmacy Personnel Practice Arrangement

The practice of pharmaceutical preparations and pharmacists in pharmaceutical service facilities which is a part of Law 17 of 2023 concerning Health which regulates the use and security of pharmaceutical preparations, Article 199 aya (5) of the Health Law introduced the types of health workers who are included in the group of pharmaceutical workers consisting of pharmaceutical vocational personnel, pharmacists, and specialist pharmacists who are expected to be able to controlling the quality of pharmaceutical preparations, security, procurement, storage and distribution or distribution of drugs, drug management, drug services on a doctor's prescription, drug information services, and the development of drugs, medicinal ingredients and traditional medicines. However, no less important in pharmaceutical preparations, the role of pharmaceutical personnel is both in the form of pharmaceutical preparation management standards and clinical pharmacy service standards to the public (Supardi et al., 2019) .

The regulation of pharmaceutical practices is intended for pharmaceutical workers, but the regulations in Law No. 17 of 2023 and Government Regulation No. 28 of 2024 provide a gap for other health workers to carry out pharmaceutical practices to the community. The provision of opportunities for medical personnel, health workers and midwives to carry out pharmaceutical service practices is very detrimental to pharmaceutical personnel in the practice of implementing the law is considered discriminatory and facultative to meet the wishes of interested parties. As a result, the application of the law will be different, the uncertainty of the regulation results in arbitrariness by certain parties even under the pretext of certain circumstances. Deviations in pharmaceutical implementation practices result in confusion for pharmaceutical personnel in implementation in the field, so the government must be responsible for pharmaceutical preparations in accordance with procedures, addition or procurement of human resources as well as changes in administration and accreditation (Muhammad Ikhsan & Sabda Wahab, 2021).

The government, in this case, the Ministry of Health must realize that pharmaceutical services are a direct and responsible service of a pharmacist to patients related to pharmaceutical preparations intended to achieve definite results to improve the quality of life of patients. The existence of pharmaceutical service facilities is a means used to provide pharmaceutical services, one of which is a pharmacy. Basically, the existence of pharmaceutical personnel is very strategic in the selection of the type of drug that can be determined by all pharmacy

officers. However, in monitoring and determining the final result, the Pharmacist and the Pharmacy and Therapy Team (Kencana et al., 2023). Furthermore, to find out the regulation of pharmaceutical practices that are considered detrimental to pharmaceutical personnel, it can be done by medical personnel and health workers, see the following table:

Table I
Comparison of Provisions for Regulating Pharmaceutical Practice

Law Number 17 of 2023 Article 145 paragraph (1)	**Government Regulation Number 28 of 20204 Article 428**
(1) Pharmaceutical practice must be carried out by pharmaceutical personnel in accordance with the provisions of laws and regulations.	(1) Pharmaceutical practices include production, including quality control, procurement, storage, distribution, research and development of pharmaceutical preparations, and pharmaceutical management and services.
(2) Pharmaceutical practices as intended in paragraph (1) include production, including quality control, procurement, storage, distribution, research and development of Pharmaceutical Preparations, as well as pharmaceutical management and services.	(2) Pharmaceutical practices as intended in paragraph (1) must be carried out by pharmaceutical personnel in accordance with the provisions of laws and regulations.
(3) Under certain conditions, pharmaceutical practices as intended in paragraph (1) may be carried out by other health workers on a limited basis other than pharmaceutical personnel. **Explanation** of Paragraph (3) What is meant by "certain conditions" is the absence of pharmaceutical personnel, the need for government programs, and/or in the conditions of KLB, Outbreaks, and other disaster emergencies. Other health workers, among others, are doctors and/or dentists, midwives, and nurses.	(3) In carrying out pharmaceutical practices as intended in paragraph (2), pharmaceutical personnel can be assisted by Health Support Personnel.
(4) Provisions regarding pharmaceutical practices as referred to in paragraphs (1) and (2) are regulated by Government Regulations.	(4) Under certain conditions, pharmaceutical practices are limited to pharmaceutical service facilities can be carried out by Medical Personnel and Health Workers.
	(5) Certain conditions as referred to in paragraph (4) include: a. Absence of pharmaceutical personnel in a region; b. Government program needs; c. Handling of medical emergencies; and/or d. Outbreak KLB, and other disaster emergencies.
	(6) Medical Personnel and Health Workers as intended in paragraph (4) include doctors, dentists, nurses, or midwives who provide pharmaceutical services within certain limits.
	(7) Further provisions regarding pharmaceutical practices on a limited basis are regulated by Ministerial Regulation.

Based on the table, it is known that the important role of pharmaceutical personnel should be the Government together with the House of Representatives as the lawmakers, that pharmaceutical personnel are the main actors in planning and implementing pharmaceutical preparation practices, including: First, the expertise of pharmaceutical personnel can be applied in developing treatment management, selection of drugs and medical devices, quality assurance of drugs and medical devices, as well as distribution guarantees. Second, pharmaceutical personnel can be involved in every stage of disaster management according to their expertise, and Third, in pandemic conditions, pharmaceutical personnel can play a role in providing education about disease prevention and detection (Faradilla, 2018).

The imbalance in the need for pharmaceutical personnel can be illustrated in a disaster situation, the estimated number of health workers needed is 2 (two) pharmacists per 10,000-20,000 residents or refugees (Depkes, 2007). This need is unfair, with the role of pharmacists as pharmaceutical personnel in pharmaceutical preparations, especially medicines, playing a crucial role in efforts to maintain and restore public health. The need for pharmaceutical personnel consisting of pharmacists and Pharmaceutical Technical Personnel (TTK) must have the qualifications of Pharmaceutical Service Standards in Pharmacies which includes two activities, namely managerial in the form of pharmaceutical preparation management standards and clinical pharmacy service standards, if the pharmaceutical profession is discriminated against and distorted by the regulations of Law No. 17 of 2023 and Government Regulation No. 28 of 2024, So the threat of failure of pharmaceutical services haunts people who are entitled to health services as they should (Supardi et al., 2019).

3. Pharmaceutical Preparations Setup in Chile

As a comparison or comparison with the practice of regulating pharmaceutical preparations between Indonesia and Chile, in Chile pharmaceutical preparations are fully the responsibility of the government through *the Ministerio de Salud* or the Ministry of Health as the regulator, then the implementation of pharmaceutical preparations is carried out by *the Central de Abastecimiento del Sistema Nacional de Servicios de Salud (*CENABAST) with its duties and functions to protect public health by ensuring the availability of drugs from storage, distribution, setting prices to imports, import needs are based on procurement transparency, supply control, to community needs mandated by the Ministry of Health (Cenabast, 2025).

The responsibility of pharmaceutical preparations in Chile by CENABAST as set forth in *La ley 21.198, connu como Ley Cenabast* or Law No. 21.198 on CENABAST, authorizes CENABAST to act as an intermediary of medicines through pharmaceutical warehouses, private pharmacies, and free health care facilities. The CENABAST Law, passed and published

on January 08, 2020, with the main objective of reducing the price of medicines and consequently, reducing the personal expenditure of people, especially the most vulnerable groups. The existence of the Law, protects and serves every citizen by prioritizing the principles: universality, solidarity, transparency and social participation by placing the main emphasis on the universal component that leads to equal access and opportunities for health care, territorial order, efficient and transparent public management, as a priority according to the level of care as an effort to achieve infrastructure standards, equipment, human resources, especially medicines (Ley Num, 2019).

The implementation of *La ley* 21.198, *Cenabast* is an ongoing challenge for CENABAST, efforts have begun to bear fruit from limited planning and implementation time, improvements continue to be made to ensure the success of this Law to protect and serve its citizens prioritizing the principles: universality, solidarity, transparency and social participation by placing the main emphasis on the universal component that leading to equal access and opportunities for health care, territorial order, efficient and transparent public management, making the service of drug needs a priority according to the level of care to achieve the standards of infrastructure, equipment, human resources, especially medicines (Gracia, 2021).

The institutional structure in the health sector in Chile consists of *the Ministerio de Salud* assisted by CENABAST, a National Health Service System Central Procurement Agency, *the National Health Service System* (FONASA), a National Health Service Center System Agency, *the Instituto de Salud Pública (ISP),* a National Health Fund Management Center Agency and also health services in every province, municipality, and university. In addition to health care centers from companies and other private sectors that consist of foundations, organizations that offer health care and several entities as a mixed subsystem (Ministerio de Economía - Fomento y Turismo, 2013).

The regulation of pharmaceutical preparations in Chile in addition to *La ley* 21.198, *Cenabast* also contains the Law on Health Products and Other Supplies, which essentially mandates the responsible national health authorities throughout the country to verify compliance with the provisions issued by the Act. In the case of the existence of the FONASA health service agency and the ISP health fund management agency directly under *the Ministerio de Salud*, its existence is responsible for ensuring that the public consumes quality, safe and efficacious products, by carrying out quality control for medicines in the pharmaceutical market, through testing and analysis carried out by reference laboratories, while the main task of *ISPs* maintain cooperation agreements and exercise control of permitted pharmaceutical companies (OECD, 2016).

Regarding pharmaceutical preparations in Chile, the arrangement is by having a low ratio of population per pharmacy compared to other countries in the world, and stands out as one of the countries with the highest ratio in Latin America. The implementation of pharmaceuticals in Chile has an ideal system, both in terms of regulation and in practice in the implementation of pharmaceutical preparations from the results of the study showing a negative correlation between the level of household income and the number of population per pharmacy, as well as a positive correlation between the number of population per pharmacy and the level of regional poverty. Furthermore, of the 96 poor, remote and densely populated municipalities rarely do not have pharmacies, as they are one of the most politically, economically and socio-culturally stable countries in the Latin American region (Cenabast, 2021).

CENABAST's existence is recognized nationally and internationally for its existence in supply service management, through innovative processes and high-impact strategies, with a team of experts and specialists working in a harmonious and coordinated manner, committed to the equality and well-being of the population and the mission of contributing to the well-being of the population by ensuring the availability of medicines, food, supplies, and equipment for the health network through the management of supply services that are superior, efficient, and high-quality, to improve the health of the entire Chilean population, and aims to improve access to medicines, supplies, medical devices, and food in accordance with the health policy issued by *the Ministerio de Salud*, through the efficient supply of products to ensure sustainable supply to the country's health system as a functionally decentralized public institution, with its own assets and financing. Since Chile has a vast and complex geography (4,329 km long), the first priority is to analyze the distribution of pharmaceutical preparations and to socialize the *Ley de Fondo Nacional de Medicamentos de Alto Costo* or Law 20,850, otherwise known as the *Ricarte Soto* Law or the National Drug Fund Act (Esteban, 2022).

In the same context, there are three interesting perspectives to consider in Article 70 *of La ley* 21.198, that CENABAST performs fulfillment functions in pharmacies, logistics and products, plus the challenge of building traceability that allows data analysis and generates useful information, such as the public value that this public policy can create for citizens. Therefore, the challenge remains on setting maximum prices that encourage pharmacies to act as intermediaries while remaining low for the public, while ensuring a logistics system tailored to the needs of private pharmacies and pharmaceutical warehouses, as well as non-profit health institutions (Ley Num, 2019).

The existence of Private Pharmacies in Chile by CENABASTin the Private Pharmacy Procurement Service is empowered by Law 21.198 which allows CENABAST to supply private

pharmacies and non-profit organizations, setting maximum retail prices. Participation in the *Lista de Medicamentos Esenciales* (LME) or List of Essential Drugs, in the Chilean Health Services Budget Law it is mentioned that at least 80% of the quantity and 40% of the quantity of medicines are determined by the National Health Service System Supply Center and the Secretariat of the Help Network, having a high turnover, from health services, dependent companies, self-managed companies of the ministry of health, requesting CENABAST, Determine the list of drugs called LME needs from a year loaded with a list of budgets that have been set. The needs of drug consumption and health care, as well as technical feasibility are determined by CENABAST after coordinating with *the Ministerio de Salud* to respond to and comply with the company's requests for drug needs (Cenabast, 2022).

In Chile the profession of pharmacist as a specialty of pharmaceutical prescriptions is mandatory in the public and private sectors, according to the Law on the Promotion of the Use of Drugs, related to the sale of drugs with generic names and with the active principles listed in the LME List, allowed both in state-owned pharmacies and in private ones, with the guarantee that the pharmacist is obliged to comply with the guidelines established in the law, namely regulating the gradual incorporation of clients according to their type, that is, independent pharmacies that are smaller or unique in their territory, then regional network pharmacies and, finally, networks of pharmacies and non-profit organizations, which range from 90 days to 24 months from their enactment, depending on the type of establishment. The promotion or advertising of drugs by the mass media is regulated based on Laws and Regulations (Gracia, 2021).

The Chilean government, through the *Ministerio de Salud*, has the main function of making policies and regulations, such as the provision of the National Health System Law and the Health Products Law, for pharmaceutical preparations in the market based on pharmacist technical standards and guidelines for pharmaceutical practice. In Chile, pharmacist services provide health care services are responsible for technical, scientific, and administrative activities, procedures, and interventions related to drugs and health supplies used, in order to make a harmonious and comprehensive contribution to improving the quality of health services (Cenabast, 2022).

The legal protection of the Chilean government against the national drug needs aimed at ensuring access, quality, safety, efficacy and rational use of drugs is the responsibility of *the Ministerio de Salud*, through agencies including: CENABAST, FONASA, ISP and *the Superintendencia de Salud* or the Health Supervisory Agency. Policies in the form of regulations on national pharmaceutical preparations policy were formed, based on studies with

the aim of establishing guidelines that lead to the achievement of equal access for all people to essential, safe, effective and quality medicines, as well as the promotion of their rational use within the framework of health policies and strategic plans (Cenabast, 2021).

The Chilean government in pharmaceutical preparations coordinates with the technical analysis group of the document, as a strategy of access to health and universal health coverage", in which the context of the importance of access to safe medicines is emphasized effective and quality, since pharmaceutical problems are very complex and are the responsibility of the state, through *the Ministerio de Salud*, to ensure such access at all levels of society. The National Constitution of the Republic of Chile stipulates, "health shall be protected and promoted as a fundamental right of the individual and for the benefit of society, strengthening the functioning of the national health system by designing health policies and agreements and coordinating resource programs from the public and private sectors" (*The Case of CENABAST in Chile*, n.d.).

Medicine as a priority dimension of health policy requires a universal approach with a comprehensive approach to address a wide range of interdependent issues and, at the same time, involve all direct stakeholders. Chile's national pharmaceutical policy proposes its formulation guidelines incorporating general strategies, such as the selection of essential drugs, the acquisition of appropriate quality drugs based on health needs and education and training in various elements of the pharmaceutical program. For this reason, the updated national drug policy is prepared as an instrument of health care planning, related to timely and sustainable financing to ensure safe and effective access to medicines, to be used rationally in the framework of new challenges and reforms with the participation of the private sector, as well as as as an expansion of access to the list of basic medicines in first-level services through the Family Health Unit, through the implementation of a new service model based on the Primary Health Service strategy (Cenabast, 2021).

The National Medicines Policy is a priority axis of the Health System in Chile:

1. To be a formal declaration of intentions, values, aspirations, goals, decisions and commitments of the government in the medium and long term with the health of individuals, families and communities, based on national goals and objectives for the pharmaceutical sector and its priorities as well as maximum service by pharmacists or pharmaceutical personnel.
2. Develop the necessary strategies to meet these objectives and identify the various parties responsible for implementing the key components of the policy in importing according to market demand from existing data.
3. The integration of responsible actors, and pharmaceutical arrangements are necessary for their respective fulfillment, in order to effectively implement established guidelines through strategies supported by resources and access to essential medicines to obtain equity and sustainability from health outcomes and health impacts.

As a feedback effect of the comparison of the regulation of pharmaceutical preparations between Indonesia and Chile, although there are differences in the regulation of each country, essentially legal and political in their respective practices, has created a law in the form of a law as a power and interest to submit to the politics of arguments that refer to the prevailing norms, so that in this area the law gives structure to politics in various ways depending on the form relevant rules as well as on the facts and situations of legal necessity (Christian Reus-Smith, 2017).

In the CENABAST Law regulating future governance, CENABAST is authorized to publish and periodically update information on its website, in order to contribute to transparency. Regarding accountability, the supervisory and sanctioning process has been established for regulated parties, but not for regulatory bodies. Participation arrangements are made by technical entities, without a wider community engagement process, for integrity, pricing decisions are the responsibility of CENABAST and the decision-making process in practice is not defined in the rule of law. Regarding capacity, the institution is expected to have the resources to carry out this task, considering that this is an expansion of the tasks and authorities it has. The lack of regulation of pharmaceutical preparations in Chile on a scale of coverage is limited to the number of products required, but the potential benefits of the CENABAST Act can be understood if applied on a larger scale (*The Case of CENABAST in Chile*, n.d.).

D. CONCLUSION

Pharmaceutical preparations are the responsibility of the state, in this case the Government of Indonesia through the Ministry of Health related to the security and use of pharmaceutical preparations regulated in Law Number 17 of 2017 concerning Health, its implementation by Government Regulation No. 28 of 2024. Uncertainty and inconsistency of norms in the regulation of imports and pharmaceutical personnel, if there is no legal politics to revise the Health Law and its regulations, then it has great potential to cause uselessness, injustice and uncertainty in the future, because it is not in line with health development so as to weaken health resources and not open health management, lowering the degree of public health because it is not in line with health development. In accordance with the principles of welfare, equity, non-discrimination, participatory and sustainable, if left unchecked, it threatens the fulfillment of quality and productive human resources, increases inequality, weakens health services, reduces health security and weakens the nation's competitiveness so that the goals of national health development are not achieved, because the benefits and ease of facilitation of the implementation of the import of pharmaceutical preparations are only enjoyed by a few

people by harming the public, then it is better that the regulation of facilitating the implementation of imports in Government Regulation Number 28 of 2024 be revoked and declared invalid.

Pharmaceutical practices must be carried out by pharmaceutical personnel which includes production, including quality control, procurement, storage, distribution, research and development of pharmaceutical preparations, as well as pharmaceutical management and services. By Law No. 17 of 2023 and Government Regulation No. 28 of 2024, castrated on the grounds of certain conditions, pharmaceutical practices can be carried out by other health workers on a limited basis other than pharmaceutical workers. As a reason for certain conditions with the absence of pharmaceutical personnel, the need for government programs, and/or in exceptional conditions, outbreaks, and other disaster emergencies. Other health workers are doctors and/or dentists, midwives, and nurses. Regulatory norms that provide loopholes in other professions or health workers as well as pharmaceutical workers result in malpractice and maladministration.

On the other hand, the Chilean government's policy on pharmaceutical preparations due to the limitation of raw materials, so importing as stipulated in *La ley* 21.198 authorizes CENABAST to act as an intermediary for pharmaceutical warehouses, private pharmacies, and non-profit health facilities. CENABAST permits the import of medicines, pharmaceutical and laboratory equipment, surgical materials and other instruments needed for health services, CENABAST is authorized to regulate prices as it is responsible for determining the maximum retail price of medicines. The CENABAST Law in setting prices in stages to include partners based on their type: first, smaller independent pharmacies or are the only pharmacies in a region; second, pharmacies that are members of the regional network; and third, pharmacy networks and non-profit organizations, requests for pharmaceutical preparations are made within 90 days to 24 months, depending on the need. The CENABAST Law requires every pharmacy to have a pharmacist with the main task of recommending the needs of pharmaceutical preparations needed, developing research results, selling medicines at the maximum price set by pharmacies, and obliged to sell pharmaceutical preparation products from CENABAST to consumers.

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