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Legal Regulations Related To Medicinal Products And Capsule Shells In Indonesia

1st Fitri Rafianti
Prodi Ilmu Hukum
universitas Pembangunan panca budi
Medan, Indonesia
fitrirafianti@dosen.pancabudi.ac.id

2nd Irsyam Risdawati
Prodi Magister Hukum Kesehatan
universitas Pembangunan panca budi
Medan, Indonesia
isryamrisdawati@dosen.pancabudi.ac.id

3rd Muhammad Andafi
Prodi Ilmu Hukum
universitas Pembangunan panca budi
Medan, Indonesia
andafiandrian@gmail.com

Abstract*— A topic of significant concern in the pharmaceutical industry, legal regulation plays a crucial role in overseeing and controlling the production, distribution, and consumption of medicinal products, including capsule shells used as packaging materials. By exploring this aspect, it is hoped to provide a deeper understanding of how the rule of law influences and shapes the sector. As such, this paper will present a comprehensive and informative analysis of the legal regulations applicable in Indonesia in relation to medicinal products and capsule shells. One of the good and responsive laws and regulations in the health sector is one that fulfills the sense of justice and expectations of the community. This research is a normative legal research where normative legal research takes data with a statutory approach, looks for the meaning and source of value of the law, only legal concepts are used and the steps taken are normative steps". The statute approach in legal research is used to observe the results of human behavior. To make regulations derived from the Health Act, various parties affected by this Act need to participate because the regulations derived from the law will be more practical. The initial phase and is expected to look at the Health Law, because, this Law is an OBL Law, which can run well if we understand not only laws related to certain fields but also related to funding, human resources, and other aspects In order to implement Food and Drug supervision, strong regulations are needed, as a non-ministerial government agency that has technical duties, not only technical regulations must be fulfilled, but administrative and strategic regulations are needed. Food and Drug Supervision is a government task that cannot be done alone, and in practice it requires cooperation with many related sectors, both government and private. Meanwhile, the capsule shell as part of a drug instrument where the capsule shell is used as a drug container is an innovation that helps in the effective administration and use of drugs. The capsule shell can protect the drug content from damage, facilitate dose measurement, and extend the shelf life of the drug. Therefore, the regulations and related instruments must be supported and run in tandem in order to create a sense of justice, comfort and order regarding legal arrangements in the health sector.

Keywords— Regulation, Medicinal product, capsule shell

I. INTRODUCTION

The relevance of law in the health sector has a very strategic function. Therefore, the formulation of legislation in the field of health that is good and responsive, should meet the sense of justice and expectations of the community, an integral part of the Ministry of Health's Strategic Plan is to support the implementation of health in Indonesia, one of which is related to the need for "medicine" as another health support tool, the Ministry of Health (Kemenkes) of the Republic of Indonesia issued new technical guidelines for the preparation of drug requirement plans (RKO), which aim to ensure access to quality, safe, and effective essential medicines for all Indonesians. drug supply planning must consider all factors that can cause differences between drug planning and procurement. For this reason, all lines must work together to realize the implementation of drug regulations in Indonesia so that there is no overlap and chaos in Indonesia.

II. DISCUSSION

A. Law No.17 of 2023 Concerning Health

Specifically for legislation in the health sector, we know that there is Law No.17 of 2023 concerning Health. On August 8, 2023, it was ratified by the President of the Republic of Indonesia in a Plenary Meeting of the House of Representatives on July 11, 2023. The newly enacted Health Law has become a hot issue in the world of health. This law provides a new direction in the regulation of the health system in Indonesia.

The Health Law is a regulation that governs various aspects of the health system in Indonesia. It covers matters such as promotive, preventive, curative, and rehabilitative efforts. The aim is to improve the quality of health services, protection for the community, and regulate the authority and responsibilities of health workers. There are a number of aspects that will be improved with the implementation of this Health Law, including:Business Licensing Services was issued which regulates the provisions regarding:

1) Changing the focus from treatment to prevention.
2) Facilitate access to health services.
3) Preparing a disaster-resilient health system.
4) Improving the efficiency and transparency of health financing.
5) Fixing the shortage of health workers.
6) Encourage the health industry to be independent in the country and encourage the use of the latest health technology.
7) Simplify the health licensing process.
8) Protect health workers in particular.
9) Integrate health information systems.

This law provides a clear and comprehensive framework for health workers in carrying out their duties and responsibilities. However, in its implementation, there is a need to revise and clarify several articles that still create confusion. This will help health workers to perform their duties better and avoid different interpretations.

What can be concluded in the meantime is that the new health law has become an important issue in the Indonesian health scene. Health workers' attitudes towards the law vary, but in general, they accept it as a step forward in improving the health system. Nonetheless, there are still issues that need to be addressed, such as the regulation of the use of technology and the implementation of excessive sanctions. In the view of professionals, the law provides a clear framework, but there needs to be revisions and clarifications to ensure proper implementation. The new Health Law is an important foundation for health workers in providing quality services to the people of Indonesia. This law regulates health by setting limits on the terms used in its regulation. This law contains general provisions, rights and obligations, responsibilities of the central government and regional governments, health administration, health efforts, health service facilities, health human resources, health supplies, pharmaceutical and medical device security, health technology, health information systems, extraordinary events and outbreaks, health funding, coordination and synchronization of health system strengthening, community participation, guidance and supervision, investigation, criminal provisions, transitional provisions and closing provisions.

Law No. 17 of 2023 is stipulated with the following considerations

a. that the state guarantees the right of every citizen to realize a good, healthy, and physically and mentally prosperous life in order to achieve national goals in protecting the entire Indonesian nation and the entire Indonesian blood spill to advance welfare.

b. that public health development requires health efforts, health resources, and health management to improve a. the highest degree of public health based on the principles of welfare, equity, nondiscrimination, participation, and sustainability in the context of developing quality and productive human resources, reducing disparities, strengthening quality health services, increasing health resilience, ensuring a healthy life, and advancing the welfare of all citizens and the competitiveness of the nation for the achievement of national development goals.

c. that health problems and disorders in the community will reduce productivity and cause losses to the state so that health transformation is needed to achieve an increase in the degree of public health.

d. that public health development is getting better and more open so as to create independence and encourage the development of the national health industry at the regional and global levels and encourage the improvement of safe, quality and affordable health services for the community to improve the quality of life of the community.

e. whereas to increase health capacity and resilience, it is necessary to adjust various policies to strengthen the health system in an integrative and holistic manner in 1 (one) comprehensive law.

f. that based on the considerations referred to in letter a, letter b, letter c, letter d, and letter e, it is necessary to form a Law on Health.

b. Novelty Aspects of the Health Law

Several arrangements that distinguish the Health Law from previous laws (especially laws that have been repealed by this Health Law) include:

1) Health care facilities can provide Telehealth and Telemedicine services. Telemedicine services include: between health care facilities and between health care facilities and the community.

2) Reinforcing the obligations of health care facilities related to emergency conditions. In emergency conditions, health care facilities are prohibited from refusing patients, asking for advance payments, and prioritizing all administrative matters that cause delays in health services.

3) Hospital leaders can be: Medical personnel, Health personnel, or professionals who have competence and hospital management.

4) Hospitals are required to implement a hospital information system that is integrated with the National Health Information System (SIKN)

5) Teaching hospitals can organize specialist/subspecialist programs as the main organizer of education (college based), provided that: based on the permission of the Minister of Education and Culture and only for specialist and subspecialist education programs.

6) Health Human Resources can be divided into three parts which include: Medical Personnel (consisting of doctors and dentists), Health Workers (consisting of 11 groups of Health Workers); Health support or support personnel (personnel working in health service facilities or other institutions in the health sector).

7) Registration Certificate (STR) is issued by the Council on behalf of the Minister of Health and is valid for life.

8) Practice License (SIP) is granted by the Regency/City Government or the Minister of Health under certain conditions and does not require recommendations from professional organizations.

9) The utilization of Medical and Health Workers of Indonesian Citizens (WNI) and Foreign Citizens (WNA) graduated from abroad can be done through portfolio assessment for those who have practiced for at least two years (for Indonesian citizens) and five years (for foreigners) or are experts in certain superior fields in health services.

10) Enforcement of Medical and Health Worker Discipline is carried out by a Tribunal established by the Minister of Health. The Tribunal may be permanent or ad hoc and its decision may be reviewed by the Minister of Health.

11) Medical Personnel or Health Personnel who are suspected of committing unlawful acts in the implementation of health services that can be subject to criminal sanctions, must first request a recommendation from the Assembly.

12) Allocation of the Health Budget by the Central Government and Local Governments is set out in the Health Sector Master Plan with Performance Based Budgeting. Related to this, there are three recommendations that need to be submitted regarding the Health Law.

Referring to the opinion of Gustav, a German jurist and philosopher who also served as Minister of Justice of Germany. He stated that law has three values, namely justice, legal expediency, and legal certainty.

1. First, in its implementation, the Health Law must continue to be guarded in order to realize the value of the law.

2. Second, the government must be wise and prudent in receiving input related to the implementation of the Health Law.

3. Finally, as long as the legal process is still left to the General Court, it is difficult to realize justice, certainty and legal benefits, especially for medical personnel.

The establishment of this "Specialized Judicial Body" must be based on the Law. The Ministry of Health is transforming itself to accelerate health reform by activating many of the policy buttons set out in the Health Act. This is why the Omnibus Health Law is referred to as a reformist health law. Based on this law, The Ministry of Health is committed to transforming the health system where one of the pillars is related to the drug and medical device industry.

Starting with the mapping of pharmaceutical elements that require regulations derived from the Health Law with a total of 121 regulations. Among them, there are 8 Learning Implementation Plans needed in the field of pharmacy about:

1. Security of pharmaceutical preparations, medical devices, and PKRT
2. Pharmaceutical practice
3. Availability, equity, and affordability of health supplies
4. Classification of drugs, prescription drugs, and non-prescription drugs
5. Classification of natural medicine
6. Implementation of research, development, utilization, and maintenance of natural ingredients medicine
7. Acceleration of the development and resilience of the pharmaceutical and medical device industry; and
8. Standards, systems and governance of pharmaceutical preparations, medical devices, and other health supplies in emergencies, disasters, outbreaks, or epidemics.

In relation to the classification of pharmaceuticals and the classification of drugs, drugs are divided into prescription drugs and non-prescription drugs. Article 320 states that in addition to over-the-counter drugs and limited over-the-counter drugs, certain hard drugs can be dispensed by pharmacists. This provision provides space for pharmacists to move in areas that have been "gray", but the government needs to establish clearer and more detailed indications and provisions. An explanation of the different concepts of drug services (prescription-based treatment, non-prescription treatment, and self-medication) is also needed in the regulations derived from the Health Law. Then in Chapter IX of the Health Law regarding pharmaceutical and medical device security, which contains 11 articles, namely articles 322-333. Indonesia is still experiencing the problem of dependence on imports of medicinal raw materials (BBO) and medical devices, where BBO imports reached more than 90% in 2020. In addition, Indonesia faces the main challenge of developing traditional medicine production, namely producing traditional medicines that meet standards, both in terms of safety, quality and efficacy, with quality and quantity that meet the needs. Indonesia is also still importing medical devices, reaching 91.5% in 2020. Looking at these problems and challenges, the proposal for derivative regulations of the Health Law related to the production of BBO and medical devices is the need for explanation and confirmation of matters relating to:

1) Safeguarding pharmaceutical preparations, medical devices, and PKRT
2) Pharmaceutical practice
3) Availability, equity, and affordability of health supplies
4) Classification of drugs, prescription drugs, and non-prescription drugs
5) Classification of natural medicine
6) Implementation of research, development, utilization, and maintenance of natural ingredients medicine
7) Acceleration of the development and resilience of the pharmaceutical and medical device industry; and
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equipment is the need for explanation and confirmation of matters relating to:

1) Efficacy, safety, and quality standards for pharmaceutical and medical devices products that are developed, produced, and used in treatment.
2) Strengthening cooperation between supporting components in the ABG system for the independence of pharmaceutical preparations and medical devices
3) Strengthening and facilitating the utilization of new technologies in the production process of pharmaceutical preparations and medical devices; and
4) Emphasizing the use of information technology in efforts to increase the resilience of pharmaceutical and medical supplies.

Thus, serious work needs to be done to make derivative regulations of this Health Law. Various parties affected by this law need to participate because the derivative regulations will be more practical. That this is the initial phase and is expected to scrutinize the Health Law. This is because this law is an OBL law, which can run well if we understand not only laws related to certain fields but also related to funding, human resources, and other aspects. Minister of Health Regulation Regulation of the Minister of Health of the Republic of Indonesia Number 3 of 2021 concerning Changes in the Classification, Restrictions, and Categories of Drugs has gone through a careful and thorough study so that it is in accordance with the needs and legal developments in the classification and restriction of drugs as well as the classification of drugs. aims to ensure patient safety and protect the public from the circulation of drugs that do not meet the requirements of safety, quality and usefulness, as well as increase public access to safe, quality, and useful drugs. The list of changes to the classification, restrictions, and categories of drugs is attached in the Appendix as an integral part of this draft regulation of the Minister of Health. There are 13 points of changes to drug classification and changes to drug restrictions, as well as 3 points of changes to drug categories.

b. Food and Drug Administration Regulation No. 17/2019 on Quality Requirements for Health Supplements

In an effort to improve the performance of Food and Drug Control, (hereinafter referred to as BPOM) has carried out an organizational restructuring process which has an impact on increasing workload. It can be seen that to accommodate the workload related to the organizational restructuring, 7,380 employees are needed, while the number of available human resources is currently only 3,784 people. For this reason, an additional 3,596 employees are still needed. The identification of potential and problems of BPOM is carried out to analyze the problems, challenges, opportunities, weaknesses and potentials that will be faced by BPOM in order to carry out the assignment of RPJMN 2015-2019. The identification of these problems includes internal and external factors as material for formulation in planning for 2015-2019. In an effort to achieve BPOM's performance goals and objectives, it is necessary to conduct a comprehensive and integrated analysis of environmental factors including strategic issues that can affect the achievement of performance goals and objectives. In order to carry out the task of supervising Food and Drugs, strong regulations are needed. As a non-ministerial government agency that has technical duties, not only technical regulations must be fulfilled, but administrative and strategic regulations are needed.

Food and Drug Monitoring is a governmental task that cannot be done alone, and in practice requires cooperation with many related sectors, both government and private. For this reason, regulations need to be designed in such a way that they are in line with the task of Food and Drug supervision. Currently, the implementation of Food and Drug supervision still encounters obstacles related to coordination with stakeholders. In the regions, in carrying out Food and Drug supervision, the Center for Food and Drug Control often has to coordinate with the local district/city health office. In carrying out their duties and functions, government agencies must pay attention to concurrent legislation, namely government affairs that are divided between the central government and provincial and district / city regions, where the affairs handed over to the regions become the basis for implementing regional autonomy. For this reason, BPOM establishes norms, standards, procedures and criteria (NSPK) which then become guidelines for the regions in order to organize regional policies that will be formulated. Food and Drug Supervision is an important aspect. In terms of health, Food and Drugs indirectly affect the degree of public health, not only the degree of health, but also human life. Food and Drugs cannot be underestimated and considered inferior to other factors that determine the degree of health. The supervision of Food and Drugs is of a national strategic nature in an effort to protect and improve the quality of life of the Indonesian people and support national competitiveness and has a direct impact on national resilience and is an effort to fight crimes against humanity, which is directly related to aspects:

i. Health;
ii. Social/Humanitarian;
iii. Economy; and
iv. Security and Public Order.

Thus, the supervision of Food and Drugs is multi-sectoral and multi-level of government that is interrelated and contributes importantly in realizing effective and integrated Food and Drug supervision in national development. In connection with this, Presidential Instruction No. 3/2017 on Improving the Effectiveness of Food and Drug Supervision has been issued, which instructs K/L/D to take steps in accordance with their respective duties, functions, and authorities to improve the effectiveness and strengthening of Food and Drug supervision, including:

1) Pharmaceutical preparations, which consist of drugs, medicinal substances, traditional medicines, and cosmetics
2) Extracts of natural ingredients
3) Health supplements
4) Processed food; and
5) Hazardous materials that have the potential to be misused;

In accordance with the provisions of laws and regulations. Presidential Instruction No. 3/2017 instructs the Head of BPOM to:

a. Develop and improve regulations related to the supervision of Food and Drugs in accordance with its duties and functions;

b. Synergize in developing and improving the governance and business processes of Food and Drug supervision;

c. Develop a Food and Drug supervision system;

d. Developing guidelines to increase the effectiveness of Food and Drug supervision;

e. Providing technical guidance and supervision in the field of Food and Drug supervision;

f. Coordinating the implementation of Food and Drug supervision with relevant agencies.

Considering the challenges of multi-sectoral and multi-level government supervision of Food and Drugs and optimally implementing the Presidential Instruction, institutional strengthening is required. Institutional strengthening of BPOM has received support from stakeholders, including recommendations based on the results of the performance audit from the Indonesian Supreme Audit Agency, Hearings with Commission IX of the House of Representatives, the Corruption Eradication Commission, and Working Visits of the Head of BPOM to various Ministries/Institutions/Departments, it was concluded that it was necessary to strengthen the BPOM organization in accordance with organizational needs and the strategic environment. Institutional strengthening efforts and to follow up on stakeholder expectations are implemented through Presidential Regulation No. 80/2017 on the Food and Drug Supervisory Agency. The substance regulated in Presidential Regulation No. 80/2017 in principle includes sharpening the duties, functions, and authorities of BPOM in the context of strengthening BPOM institutions. In addition, it also strengthens the role of the Government Internal Supervisory Apparatus (APIP) through the development of the Inspectorate into the Main Inspectorate and strengthens the functions of deterrence, investigation, and investigation of violations. The target for the Percentage of Food and Drugs in 2019 has decreased compared to the previous year. This is due to changes in the flow of Drug and Food inspection which starts from sampling to testing. Sampling is carried out not only limited to the types of drugs and food that are tested in supervision, but includes all types of drugs and food in circulation and become the supervisory authority of BPOM. For this reason, a review process of BPOM's existing key performance indicators (KPI) has been carried out, namely the Percentage of Qualified Drugs and Food. The scope of the indicator does not only include test results, but also includes products that do not have a distribution permit number (NIE) illegal products including counterfeit, do not meet labeling/marking requirements, expired products, and damaged products. With the globalization of the economy through free market trade, it will have an impact on various fields and one of them is related to the supervision of Food and Drugs because there is a thinning entry barrier in the trade flow of goods from within and outside the country. This has resulted in an increase in the amount of drug circulation, both in type and volume, which is both domestically produced and imported from abroad, which will have its own consequences for drug control. . An important thing that must be considered is the establishment of drug standards that will affect the competitiveness of drugs in the free market. Substandard products will have an impact on health risks and weaken the competitiveness of the drug product itself, so in this case it is necessary to strengthen the standard function for screening unqualified drugs. The establishment of standards for the safety, efficacy, and quality requirements of a product will be an important reference for the industry or manufacturer in the manufacture and development/innovation of a product. From the government side, setting standards for safety, efficacy, and quality requirements of a product is a reference in assessing products before they are allowed to circulate in Indonesia and in monitoring drugs in circulation, which is carried out through laboratory testing of samples of products in circulation. To measure the success of this activity, a performance indicator is formulated, namely the percentage of drug standards, narcotics, psychotropic drugs, precursors, and addictive substances that are utilized with a target of 80 percent by the end of 2019.

C.Capsule Shell as Part of Medicine from a Legal Perspective

The capsule shell from the perspective of Indonesian health law refers to the legal framework that regulates aspects of health in Indonesia. The use of capsule shells as drug containers is an innovation that helps in the effective administration and use of drugs. The capsule shell can protect the drug content from damage, facilitate dose measurement, and extend the shelf life of the drug. In addition, capsule shells also allow drugs to be better digested by the body. In Islam, maintaining a healthy body is part of a Muslim's duty. By using capsule shells, medicine can be taken easily and consumed in a more convenient way. Although the materials used to make capsule shells are usually made from animal materials, such as gelatin, Islamic law allows their use. This is because the gelatin used in capsule shells has undergone adequate processing, so it is no longer considered a haram material. Capsule shells are an important part of medicine that is often used in modern medicine.

In the perspective of Islamic law, the use of capsule shells in medicines is not contrary to the principles of religion.In conclusion, the use of capsule shells in medicines is not contrary to the principles of Islamic law. The capsule shell is actually made of gelatin material that is safe for the body.Gelatin is a substance obtained by extracting collagen from cartilage or animal skin.So gelatin in capsule drug packaging is safe for consumption.Drugs in capsule form have the aim of regulating the working period of drugs in the body.This means that the drug will be absorbed slowly over a certain period of time.With the capsule wrapper, the drug will dissolve and be absorbed for 12 to 24 hours.Meanwhile, drugs in tablet or powder form can be absorbed quickly, which is only 5 to 10 minutes.

The capsule shell from the perspective of health law in Indonesia also includes aspects of protection of patients' rights, such as the right to information about disease and treatment, the right to receive humane and dignified treatment, and the right to give consent or refuse treatment or certain medical actions. the capsule shell from the perspective of health law in Indonesia also contains aspects of supervision of health practices, including supervision of health workers, supervision of drugs and medical devices, and supervision of

health service places. the capsule shell from the perspective of health law in Indonesia covers various aspects including the rights and obligations of the community in the health sector, protection of patients' rights, supervision of health practices, and sanctions for violations of health regulations.

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