

Law Enforcement by the National Food and Drug Control Agency (BPOM) on the Sale of Vitamin D3 without a Distribution Permit in the Digital Marketplace

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Abstract— Technological developments are utilized by business actors to sell vitamin D3 pharmaceutical products online in the digital marketplace. In accordance with the facts that have occurred, 19,703 links have been circulated that sell vitamin products without a distribution permit or legality. The National Food and Drug Control Agency (BPOM) is one of the parties responsible for the circulation of drugs and food in Indonesia. The purpose of this study is to examine the supervision and law enforcement regulations by BPOM against the sale of Vitamin D3 without a distribution permit in the marketplace. BPOM supervision of the sale of vitamin D3 in the marketplace is regulated in Article 25 of BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online. BPOM supervision in the marketplace emphasizes the form of post market supervision. Law enforcement efforts carried out by BPOM in the marketplace can use preventive efforts and repressive efforts.

Index Terms— Law Enforcement, National Drug and Food Control Agency, Vitamin D3, Distribution Permit, Digital Marketplace.

1. Introduction

Advances in science and technology have developed very quickly and dynamically. Business actors take advantage of technological developments by creating platforms that are used for buying and selling online. Digital marketplace is one of the platforms created to bring together sellers and buyers online [16]. Digital marketplace is a commercial transaction platform that provides and makes it easy for buyers and sellers to do business online. This means that a marketplace can be likened to a market, but it is done online without directly bringing the parties together. If the conventional market transactions between sellers and buyers are carried out directly through the physical market while the digital marketplace transactions are carried out virtually. The existence of a marketplace allows consumers to carry out shopping activities without being limited to space and time, anytime, anywhere, and at any time [2].

Currently, health issues are of great concern to the

community. One of the things needed is supplements as an immune enhancer for the human body. The neurosensum survey noted that 73% of Indonesians consume a lot of supplements compared to before the covid 19 pandemic [4].

The high demand for supplements is utilized by business actors to sell their products through the digital marketplace. Supplements as one of the pharmaceutical products sold through the digital marketplace certainly provide convenience for consumers because consumers can choose supplement products with many choices, lower prices and without a doctor's prescription. However, this convenience is utilized by business actors to distribute low-quality products without paying attention to the efficacy, safety, and benefits of the supplement products being traded.

As in Article 18 paragraph (2) of BPOM Regulation No.32 of 2022 concerning Criteria and Procedures for Registration of Health Supplements, there is a safety requirement, namely "Supplements circulated by business actors must obtain a distribution permit". The requirement to obtain a distribution permit can be said to be a drug and food registration approved by the head of the agency (BPOM) to be circulated throughout Indonesia. However, according to the facts that occur, there are still circulating vitamin D3 products without a distribution permit, especially through the marketplace.

Cyber patrol surveillance during 2021-2022 has found the circulation of vitamins without BPOM distribution authorization circulated in the digital marketplace. The findings were in the form of 22 items, mostly vitamin D3, from 19,703 links that sold vitamin products without a distribution permit [15]. The total findings amounted to 718,791 pieces with an economic value of Rp.185.2 billion. This finding is certainly detrimental to the government and the people of Indonesia.

The National Food and Drug Control Agency or commonly referred to as BPOM is an institution mandated to carry out government affairs in the control of drugs and food in the territory of Indonesia. In accordance with its authority, BPOM has the authority to issue distribution licenses and supervise the circulation of drugs in the territory of Indonesia. In addition,

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BPOM has one of the functions to take action against violations in the field of drug and food control.

Vitamin D3 products are not only sold conventionally, but have been circulated online through marketplaces. Supervision and law enforcement on the sale of supplements in the marketplace should be a concern for BPOM. This is because supplements are an item that is consumed and enters the human body. If the goods consumed contain harmful ingredients, it will have an impact on human health and life.

2. Research Methods

This research uses normative juridical research type. The approaches used are statutory and conceptual approaches. The statutory approach is carried out by understanding all laws and regulations related to the legal issues being studied. The conceptual approach is carried out by emphasizing the legal principles contained in the views of legal experts or legal doctrine [7]. The legal materials used are primary legal materials and secondary legal materials using the method of collecting legal materials for literature studies (Library Research) with research analysis using the deductive method.

3. Results and Discussion

A. Supervisory Regulation by the National Food and Drug Control Agency (BPOM) on the Sale of Vitamin D3 in the Marketplaces

In the modern era, business actors do not only rely on capital in order to build their business, but by sharing information with those who need it with technological applications [8]. Vitamin D3 is used to maintain bone health and endurance obtained through animal foods such as salmon, tuna, fish oil, and processed milk [5]. Currently, vitamin D3 health products are widely traded in the form of supplements or capsules online through the digital marketplace. However, there are still business actors who sell vitamin D3 products without a distribution permit from BPOM. The target of business actors is of course consumers who certainly have a lower level than business actors.

With the issuance of Presidential Regulation of the Republic of Indonesia No. 80/2017 on the Food and Drug Control Agency, the government has established an institution in Indonesia, namely BPOM (Food and Drug Supervisory Agency). BPOM is an institution that functions to oversee drugs and food in the stages of production, distribution and circulation of products. This is done to avoid fraud in the circulation of goods which will certainly harm consumers.

Supervision is carried out in accordance with predetermined stages [6]. The Food and Drug Supervisory Agency (BPOM) in carrying out supervision has various systems, forms and procedures. In accordance with Article 4 letter d of Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Control Agency, it is explained that the supervision carried out by BPOM can be divided into 2 (two) forms, namely Pre Market and Post Market [13].

- a. Assessment or Pre Market evaluation is an assessment of products before obtaining a distribution license

number that is used for distribution in the community. Products are tested through laboratories to determine whether drugs and foods are suitable for consumption. Laboratory test results are used as samples to determine whether the product is eligible or not. Evaluation is carried out centrally so that products that have a distribution permit can apply nationally.

- b. Post-market surveillance is conducted to see the consistency of product safety and information. This supervision is carried out by sampling drug and food products that have been circulated. In addition, inspection of the place of production and distribution of drugs and food supervision of labels/advertisements. This supervision is carried out in a tiered, consistent and structured manner.
- c. Law enforcement in the field of food and drug control is based on data from testing results, inspections and preliminary investigations. The law enforcement process is not complete until administrative actions are taken such as restriction of circulation, withdrawal from circulation, revocation of distribution license, or confiscation for destruction. The perpetrator can be processed civilly, administratively, or criminally if the violation falls into the criminal realm.

If it is related to the form of BPOM supervision of vitamin D3 sales in the digital marketplace, it can be explained First, pre-market supervision (before circulation), then vitamin D3 products circulated through the digital marketplace should have fulfilled the method of making good drugs and obtained a distribution permit. Supervision is used to ensure that supplement products that are circulated have quality, efficacy, safety and benefits for the people who consume them [9].

Second, Post Market is supervision carried out by BPOM on the circulation of vitamin D3 products in the digital marketplace. In 2020 the Food and Drug Control Agency (BPOM) issued a regulation through Article 25 of BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online. Inspections can be carried out by BPOM through supervisors. The regulation was issued to keep up with the development of information technology and the needs of the public for online circulation of drugs and food.

Article 25 paragraph (2) of BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online explains that BPOM has the right to inspect and monitor the circulation of Drugs and Food online including accompanying advertisements on electronic systems, Social Media, and other Internet Media Furthermore, it is further regulated in Article 25 paragraph (4) which explains that BPOM in the examination has the following authority.:

- a. Trace suspected drug and food distribution sites by collecting samples of ingredients and food, or to document all activities related to online distribution;
- b. Examine electronic systems used to distribute drugs and food, as well as data, information, documents or records that may provide information about the online

distribution of drugs and food, including by copying or quoting such data; and/or;

- c. Take pictures or videos of all or part of the equipment and infrastructure used to distribute food and medicine online.

Vitamin D3 products that are considered not in accordance with the legality and specified requirements, BPOM can photograph, record and take product samples for laboratory examination. This is done in connection with providing assurance to consumers that the products circulated have quality and efficacy that are safe for consumption. BPOM post market supervision can be carried out periodically to conduct post market checks in the marketplace.

The National Food and Drug Control Agency (BPOM) in monitoring vitamin D3 in the marketplace can coordinate with other parties. This is regulated in paragraph (3) which states that supervisors in supervising the circulation of drugs and food online can coordinate with ministries, local governments, and electronic system organizers. Based on these provisions, it can be understood that BPOM in supervising drugs and food still requires cooperation with parties including ministries and electronic system organizers. The supervision of these parties can be explained as follows:

1) *Ministry*

The ministries have the right to oversee trade conducted electronically. The ministries referred to here are the Ministry of Communication and Information Technology (Kominfo) and the Ministry of Trade. Article 35 paragraph (2) of the Government Regulation on the Implementation of Electronic Systems and Transactions states that supervision includes monitoring, control, examination, tracing, and security. Furthermore, Article 78 Paragraphs (1), (2) and (3) of Government Regulation Number 80 of 2019 concerning Trade through electronic systems states that the minister can appoint supervisors in the field of trade who are assisted by an assistance team to prioritize the protection and security of national interests from the negative impact of trade through electronic systems.

2) *Electronic system organizer (Marketplace)*

Electronic system operators also have the right to monitor the products circulated on their platforms. As stated in Article 23 of Government Regulation Number 80 of 2019 concerning Trade through electronic systems, to avoid or respond to the existence of illegal electronic information content, the organizer of trade through domestic or foreign electronic systems is obliged to present terms of use or agreements and provide means of technological control or means of receiving reports or complaints from the public about the existence of illegal information content or misuse of space on the electronic system it manages.

Post market supervision carried out by BPOM cannot be carried out independently by BPOM. However, it must be carried out in collaboration between agencies that have the authority. BPOM must continue to conduct supervision in coordination with the parties. However, supervision is not only carried out to business actors, but the community must receive supervision. Another study stated that as many as 52% of

respondents studied did not know about the legality and registration number of drugs [14]. From this data, supervision should not only be carried out to business actors, but consumers who buy must also receive supervision from BPOM. Supervision is carried out such as providing socialization, education, guidance and knowledge for consumers regarding the legality of drugs and food that are circulated both conventionally and online. This is because if the circulation of supplements without a distribution permit is still an attraction for consumers because the price is cheaper, then business actors continue to do various ways to take advantage of opportunities to obtain maximum profit. In addition, BPOM can socialize to the public regarding the characteristics or characteristics of vitamin D3 products that have safe efficacy and quality. This is done to prevent consumers from avoiding vitamin products produced by business actors who do not have good faith.

BPOM must conduct balanced supervision of business actors and consumers. The high demand for vitamin D3 without being balanced with good supervision can certainly be used by business actors to circulate products that endanger consumers. As explained in the provisions of the BPOM Regulation that in online drug and food supervision can be emphasized in the form of post market supervision in collaboration and coordination with other parties including the Ministry of Communication and Informatics (Kominfo), the Ministry of Trade, and the marketplace as the organizer of the trading system through an electronic system.

B. Law Enforcement by the National Food and Drug Control Agency (BPOM) on the Sale of Vitamin D3 without a Circulation Permit in the Digital Marketplace

The issue of selling vitamin D3 without a distribution license in the marketplace should not be seen as an ordinary action. This is because the vitamin D3 that is circulated does not have a feasibility test for efficacy, safety and benefits which results in harm to the health of the human body. Law enforcement must be carried out as an effort to punish business actors who do not have good faith. Law enforcement is an activity that combines the values contained in the applicable norms or rules to create, maintain peace and order in society [10].

Law enforcement can be carried out against business actors who sell vitamin D3 in the digital marketplace. Law enforcement must be carried out systematically, purposefully and based on a clear concept, and high integrity [1]. In addition, law enforcement must be shown to increase legal guarantees and certainty in society. Good law enforcement will create justice and legal protection for people's lives. Weak supervision and law enforcement will certainly be utilized by business actors to continue selling vitamin D3 products without distribution permits in the digital marketplace. The state must provide balanced action between legal protection and forms of punishment for violations.

The Indonesian state has actually regulated law enforcement against the sale of supplements or vitamins including Law Number 17 of 2023 concerning health and BPOM Regulation No.32 of 2020 concerning changes to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated

online. However, until this year the practice of selling vitamin D3 in the marketplace still continues to occur

BPOM as a drug and food control agency also has the duty and authority to enforce the law on drugs and food. Law enforcement is carried out by civil servant investigating officials from BPOM. This provision is regulated in Article 424 paragraph (3) of Law Number 17 of 2023 concerning health and Article 4 of Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Supervisory Agency. BPOM can impose administrative sanctions as an effort to enforce the sale of vitamin D3 without a distribution permit in the digital marketplace.

In accordance with Article 32 paragraph (2) of BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online, there are administrative sanctions for electronic system organizers (PSE) and business actors including:

- a. Rebuke
- b. Harsh rebuke
- c. Recommendations for closing or blocking Electronic Systems owned by Pharmacies, Electronic Systems owned by the Pharmaceutical Industry, Electronic Systems owned by Pharmaceutical Wholesalers, merchants in Electronic Systems owned by PSE, Social Media accounts, Daily Deals, Classified Ads and other internet media used for e-commerce activities;
- d. Recommendation to revoke the license of a pharmaceutical service facility;
- e. Temporary prohibition of distribution; and/or;
- f. Recall of drugs and food that have been distributed.

However, administrative sanctions apply more to business actors in the form of a stern warning and a recommendation to close the electronic system owned by the pharmacy and merchant. Meanwhile, for electronic system organizers only in the form of reprimands and stern warnings. Therefore, in the circulation of vitamin D3 without a distribution permit in the digital marketplace, it is still necessary to increase law enforcement and stricter rules from the Food and Drug Administration in coordination or cooperation with the police and the authorized ministries.

Law enforcement against business actors who distribute vitamin D3 through the marketplace has yet to have a deterrent effect. This is evidenced by the circulation of vitamin D3 without a distribution permit that is sold freely in the marketplace. Business actors still easily sell vitamin products without a distribution permit in the marketplace without clear legality. This shows that law enforcement is still weak.

The government can pursue law enforcement proactively. There are two efforts in law enforcement, namely preventive efforts and repressive efforts [11]. Preventive efforts are preventive measures that aim to prevent business actors from violating the law. Meanwhile, repressive efforts are enforcement efforts carried out forcibly on actors who violate the law.

Preventive efforts that can be used in law enforcement of

vitamin D3 sales in the marketplace include **First**, increasing coordination between sectors. The position of the National Food and Drug Control Agency (BPOM) in law enforcement cannot be processed independently. In an effort to overcome the circulation of vitamin D3 without a distribution permit in the digital marketplace, BPOM must continue to work with the Police, the Ministry of Communication and Information, the marketplace. BPOM can increase cooperation with agencies or institutions in the form of agreements or MOUs. This collaboration is carried out because BPOM still needs other institutions to examine and take action against the perpetrators. So that in the prevention stage and the process of monitoring the circulation of vitamin D3 in the digital marketplace must be carried out with coordination between parties.

Second, creating law enforcement resources according to the times. Trading vitamin D3 in the marketplace is different from conventional trading. Online trading can be done quickly without directly bringing together sellers and buyers. Business actors often distribute vitamin D3 products without a distribution permit in the digital marketplace not only have one account, but have several backup accounts that are used when the main account is blocked. This makes it difficult to track down business actors who sell vitamin D3 without a distribution permit. Thus, the process of monitoring, preventing and tracking sellers of vitamin D3 without a distribution permit in the marketplace must be balanced with the completeness of cyber tools and BPOM human resources as law enforcers who understand the use of technology in accordance with the times.

Third, improving public education and awareness. Vitamin D3 or supplements are needed by the public to support endurance and strengthen bones. However, people often only see the price value of a product without knowing the legality that guarantees the efficacy, safety, and benefits of the product. BPOM must provide education to the public regarding the importance of the legality of drugs and supplements to the efficacy and safety of a product. Thus, consumers can know the importance of the legality of vitamin D3 pharmaceutical products that meet health standards.

Fourth, prohibit the circulation of pharmaceutical products in the digital marketplace. This is because pharmaceutical products are one of the sensitive products and if misused can endanger and threaten human life. The government can create a separate container related to the circulation of pharmaceutical products. one of them is vitamin D3 which is sold online must have its own separate place with the digital marketplace. In accordance with the mandate of Article 25 of Law Number 17 of 2023 concerning health, Indonesia has developed the use of technology in the form of telemedicine which is integrated with the national health information system. Trade in pharmaceutical products should only be through the telemedicine application as a place to sell drugs and supplements or other pharmaceutical products online. Thus, not all business actors can freely distribute vitamin D3 products in online markets or digital marketplaces.

Repressive efforts can also be used in law enforcement against business actors for the sale of vitamin D3 in the marketplace. Repressive law enforcement efforts such as the

following **First**, strengthening the position of the Food and Drug Supervisory Agency (BPOM) as a law enforcer in the field of drugs and food. In accordance with the mandate of Law Number 17 of 2023 concerning health and Presidential Regulation of the Republic of Indonesia Number 80 of 2017 concerning the Food and Drug Supervisory Agency has the right to enforce the law. However, in accordance with Article 424 paragraph (6) the position of PPPNS BPOM as a law enforcer is still under the supervision and coordination of the police. In addition, to overcome the circulation of vitamin D3 in the marketplace must require permission from the Ministry of Communication and Informatics for tracking and blocking accounts. This causes the process of prosecution and sanctioning to be more complicated because there are many processes that must be carried out by BPOM. There should be a legal umbrella that regulates BPOM to become an independent law enforcer in the field of food and drug health. This is done to create effectiveness and efficiency in law enforcement in the health sector.

Second, provide additional sanctions in the form of fines and compensation as a form of protection for victims. The sanctions contained in BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online are not sufficient to provide a deterrent effect. Some criminal sanctions and administrative sanctions established by the government have not yet created a deterrent effect for business actors. The government can make a regulation that adds sanctions in the form of fines and compensation to companies and business actors who distribute pharmaceutical products without a distribution permit in the digital marketplace. The marketplace as the organizer of the electronic system has the responsibility to filter the products that enter its platform. Law enforcement against the marketplace is important to protect the public from the risk of harm [12]. There should be additional sanctions in the form of fines and compensation for business actors and marketplace companies that fail to prevent the trade of vitamin D3 pharmaceutical products without a distribution permit through their platforms. The imposition of fines and compensation is expected to have a deterrent effect on business actors and marketplace companies to further increase restrictions and filter products that enter their platforms.

Strict law enforcement will create a sense of security and peace in people's lives.. Actions that violate the law will develop following the times. In accordance with its nature, the law is dynamic. This causes law enforcement to follow the changes in people's lives due to the times. The law enforcement process in this modern era certainly requires good human resources, large costs and longer time. The sale of vitamin D3 without a distribution permit in the marketplace has proven that law violations do not only occur conventionally, but can be done online. The success or failure of the law enforcement process is determined by the governing law and the authorities as law enforcement. The case of vitamin D3 circulation in the marketplace is still a task that must be completed by BPOM civil servant investigators as law enforcers in the field of drug and food circulation. This law enforcement is certainly carried

out to eradicate and protect the public from the harmful effects of vitamin D3 sold in the marketplace.

4. Conclusions

Regulations on the Supervision of the National Food and Drug Control Agency regarding the Sale of Vitamin D3 through Marketplaces are regulated in in Article 25 of BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online. BPOM supervision has 2 systems, pre market and post market. BPOM supervision of the sale of vitamin D3 without a distribution permit in the marketplace can be emphasized through post market supervision in coordination with the Ministry of Communication and Information, the Ministry of Trade and electronic system administrators (marketplace). Supervision carried out by BPOM will be more effective if balanced with firmer supervision of both business actors and electronic system organizers (platform marketplace)..

The Food and Drug Supervisory Agency (BPOM) has the task of enforcing the law on the circulation of drugs and food through Civil Servant Investigators (PPNS). Law enforcement against business actors selling vitamin D3 without a distribution permit has not been enough to cause a deterrent effect and still needs legal reform. The government can use preventive and repressive law enforcement efforts. That can preventive law enforcement efforts include creating law enforcement resources according to the times, increasing coordination between sectors, banning the circulation of pharmaceutical products on digital marketplaces, improving public education and awareness. Repressive law enforcement efforts are carried out by adding sanctions of fines and compensation to business actors and marketplaces and strengthening the position of BPOM as an independent law enforcer in the field of food and drug health.

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