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Legal Protection of Consumers on the Sale of Vitamin D3 Without a Distribution Permit BPOM in the Digital Marketplace

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Abstract

Digital trade has resulted in many health products being sold online through marketplaces. According to the facts that have occurred, several vitamin D3 that do not have distribution permits or imitations are sold in the digital marketplace. Vitamin D3 without a distribution license or imitation certainly causes harm to consumers. This is because the products received do not contain the proper composition of vitamins and can endanger human health. The purpose of writing is to forms of legal protection for consumers who are harmed and settlement of consumer disputes that are harmed due to vitamin D3 without a distribution permit in the digital marketplace. The approaches used are statutory approach and conceptual approach. Internal legal protection is obtained from agreements in the marketplace. External protection for consumers who are harmed by vitamin D3 without a distribution permit can use Article 143 of Law No.17 of 2023 concerning Health and Article 4, Article 8, Article 19 of the of the Consumer Protection Law and Article 1365 of the Civil Code that business actors must be responsible and fulfill consumer rights in getting returns as before. However, consumer legal protection for the sale of vitamin D3 in the digital marketplace is not optimal because it is influenced by factors of legal substance, legal structure and legal culture. Dispute resolution can be filed by consumers in nonlitigation through BPSK and litigation through the court.

Keywords: Legal Protection; Consumer; Distribution License; Vitamin D3; Digital Marketplace

Introduction

In the era of society 5.0, all activities in the life sector cannot be separated from technological developments created by humans. Internet media is one proof of the manifestation of the results of technological progress. Trade is an economic sector that benefits from advances in information technology through internet media. Internet media provides updates for the world economy to move towards a more popular term, namely the digital economy.¹

The human desire to adopt a healthy life is utilized by several business actors to produce and distribute health products, especially online in the digital marketplace. One of the products circulated is

¹ Rizka Syafriana, Perlindungan Konsumen dalam Transaksi Elektronik, Journal De Lega Lata, Vol 1, No.2, 2016, p. 432

vitamin D3. People consume vitamin D3 with the aim of increasing calcium in the body and strengthening bones. However, business actors take advantage of opportunities to sell vitamin D3 products with low quality and lower prices. One of them is by circulating products without distribution permits and imitations that are not in accordance with applicable regulations.

The circulation of vitamin D3 in the marketplace should meet the requirements of safety and benefits for consumption. Distribution permit is one of the requirements that must be met by business actors. As in Article 18 paragraph (2) of BPOM Regulation No.32 of 2022 concerning Criteria and Procedures for Registration of Health Supplements, there are safety requirements, 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.

During October 2021-August 2022, cyber patrols Indonesia detected illegal vitamin distribution through digital marketplaces. The patrol found a total of 22 items of vitamin products in 19,703 links that sold vitamins without a distribution license. Randy, a private employee, was also stuck with vitamin D3 purchased in the digital marketplace. Randy bought vitamin D3 for Rp.150,000. After the product was received, there were irregularities, namely the contents were stuck together and the barcode scan did not match. He reported to the platfrom marketplace where the product was purchased, but did not get a response

A distribution permit can be said to be a drug and food registration issued by the Food and Drug Control Agency (BPOM) to ensure the efficacy, quality, and safety of products before they are distributed throughout Indonesia. According to Nur Inkandarsyah as Plt. Deputy of the National Food and Drug Control Agency (BPOM) said illegal vitamins are very dangerous for human health because the efficacy, safety and quality of the products are not guaranteed. Based on laboratory tests, BPOM confirmed that some illegal vitamin D3 products do not contain active substances like vitamin D3.⁴ Based on consumer complaints in one of the marketplace merchants, there are several consumers who complain of side effects after taking purchased vitamin D3 such as body itching, faster heartbeat, and difficulty sleeping.

The relationship between business actors and consumers is always evolving, so it requires rules to obtain legal protection to guarantee the rights and obligations between parties. Fulfillment of consumer rights in the sale of vitamin D3 for comfort, safety and security must be carried out in accordance with the mandate of Law No.8 of 1999 concerning Consumer Protection. So that with the development of technology in the trade sector from conventional to online, consumers can gain confidence in the vitamin D3 products sold without any sense of being cheated. Vitamin D3 without a distribution permit that harms consumers certainly still needs legal certainty and expediency to prevent goods from continuing to circulate in the digital marketplace.

Research Method

In this research the author 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

² Fika Nurul Ulya, Ratusan Ribu Vitamin Palsu Beredar di E-Commerce, ini Panduan Membeli yang terdaftar di BPOM,https://nasional.kompas.com/read/2022/10/06/15252371/ratusan-ribu-vitamin-palsu-beredar-di-e-commerce-ini-panduan-membeli-yang, accessed on February 16, 2023

³ Safrezi Fitra, Makin Marak Peredaran Obat dan Vitamin Palsu di Masa Pandemi, https://katadata. co.id/safrezifitra/in depth /613897dced0ea/makin-marak-peredaran-obat-dan-vitamin-palsu-di-masa-pandem, accessed on February 16, 2023

⁴ LPPOM MUI, Waspada Bahaya Vitamin Palsu,https://halalmui.org/waspada-bahaya -vitamin-palsu/, accessed on February 16, 2023\

⁵ Abdul Halim Barkatulah, Framework Sistem Perlindungan Hukum bagi Konsumen di Indonesia, (Bandung: Nusa Media, 2017), p. 100

emphasizing the legal principles contained in the views of jurists or legal doctrines. 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.

Discussions

1. Legal Protection of Consumers for Losses due to Vitamin D3 without a Distribution Permit Sold in the digital Marketplace

Lack of selective sense is one of the weaknesses of consumers caused by the low level of consumer awareness and education. Weak consumer knowledge regarding the side effects of vitamin D3 without a distribution permit can be used as an opportunity for business actors to continue circulating their products. The content of vitamin D3 without a distribution license does not guarantee human health and does not have vitamin content. In addition to material losses, consumers also receive losses to their health such as the appearance of allergies or itching on the skin and heart palpitations. Therefore, consumers who buy vitamin D3 without a distribution permit through the marketplace must have legal protection considering that vitamin D3 consumed will be harmful to the body.

Moch. Isnaeni has a theory that legal protection based on its source is divided into 2, namely legal protection internal and legal protection external.⁷ First, internal legal protection is established based on the agreement of the parties. Internal legal protection is established to avoid any type of risk by establishing clauses that are agreed upon and mutually agreed upon.. internal legal protection exists in the analyzed case regarding the seller of vitamin D3 without a distribution permit in the marketplace. During the bidding process, the products offered must be accessible, exhibited, guaranteed integrity, and can be accounted for to illustrate that the product or service meets the standards.⁸ The agreement that has been agreed by the parties is an electronic agreement with the form of marketplace terms and conditions that have been agreed by the parties before buying and selling. The terms and conditions of the shopee marketplace regulate the limitation of prohibited goods which states Types of drugs or other substances that are prohibited or restricted based on laws and regulations, including hard drugs, drugs with a doctor's prescription, slimming drugs and the like, drugs that do not have official permission from the Food and Drug Control Agency. Furthermore, in point number 7.1 of shopee terms and conditions, violations of this policy may result in various actions such as, delisting, restrictions imposed on account privileges, account suspension and termination, criminal prosecution, and civil action on claims for damages or temporary injunctive relief.9

Second, external protection is legal protection produced by the authorities through the making of laws and regulations aimed at the interests of weak parties. Legal protection for consumers in the sale of vitamin D3 in the marketplace must be carried out by the government. This is because consumers do not know whether the goods being traded are legally valid or not. The trade in drugs and food in the digital marketplace is specifically regulated in BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online. In accordance with Article 12, traditional medicines, quasi-medicines, health supplements and cosmetics must have a distribution permit and comply with good manufacturing methods. Vitamin D3 without a BPOM distribution permit sold in the marketplace is certainly contrary to applicable law. Vitamin D3 without a distribution permit does not have the safety, usefulness and quality requirements specified by laws and regulations.

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⁶ Kansil C.S.T,Pokok-Pokok Pengetahuan Hukum Dagang Indonesia, (Jakarta:Sinar Grafika,2013), p.210

⁷ Moch.Isnaeni, Pengantar Hukum Jaminan Kebendaan, (Surabaya: Revka Petra Media, 2016), p.159.

⁸ Farah Rasyiyqah Ahmad Riza, Audi H Pondaag, dan Reymen M.Rewah, Perjanjian Jual-Beli Melalui Internet Ditinjau dari Aspek Hukum Perdata, Lex Privatum, 2021, Vol. 9, No. 2, p:191

⁹ Shoope terms of service and conditions, https://help.shopee.co.id/portal/article/71187, accessed August, 2023.

The circulation of vitamin D3 in the marketplace has harmed the rights of consumers. Consumers who are harmed by the sale of vitamin D3 in the marketplace can claim their rights that are harmed in Law Number 8 of 1999 concerning Consumer Protection or commonly referred to as Consumer Protection Law. Article 1 paragraph (1) of the Consumer Protection Law states that consumer protection is intended to ensure the legal certainty of the rights owned by consumers. Consumer Protection Law not only provides material protection that seeks to prevent consumer harm, but also procedural or formal law that aims to facilitate consumers in litigating the recovery of their rights against business actors, both in court and outside the court.

Article 4 letter a of the consumer protection law explains that consumers are entitled to the right to safety, security and comfort. The actions of business actors who circulate vitamin D3 products without a distribution license have clearly violated the rights of consumers. Article 4 letter c of the consumer protection law explains that consumers have the right to receive correct, clear and honest information. Information can be conveyed to consumers in the form of benefits, warnings, instructions and legality. ¹⁰ Distribution permit from BPOM related to vitamin D3 products is very important as information to consumers. without a distribution permit, consumers do not get information related to the safety and usefulness of products in circulation.

Article 8 paragraph (1) letter a of the consumer protection law has explained that business actors are prohibited from trading and producing goods / and or services that are not in accordance with statutory provisions. It has been explained in Article 143 of Law Number 17 of 2023 concerning Health and Article 18 of the Food and Drug Control Regulation Number 11 of 2020 concerning criteria and procedures for supplement registration that pharmaceutical supplements must obtain a distribution license before being distributed in Indonesian territory. Vitamin D3 without a distribution license sold through the marketplace certainly violates the applicable regulations.

Vitamin D3 is one of the supplementary pharmaceutical products that should have maximum safety. Article 8 paragraph (3) of the consumer protection law explains that Business Actors are prohibited from selling damaged, defective, used, or contaminated pharmaceutical preparations and food with or without providing clear and correct information. According to Az. Nasution explained that a defective product is any product that is not in accordance with the purpose of its manufacture either due to intent or negligence or factors that occur in its circulation or does not provide security for humans or their property in its use as expected by people. In accordance with the expert opinion, vitamin D3 products without a distribution permit are one of the defective products circulated by business actors. Business actors try to circulate vitamin D3 goods. However, starting from the production process to its circulation is not in accordance with applicable procedures. Therefore, business actors who circulate vitamin D3 without a distribution permit have clearly violated Article 8 of the Consumer Protection Law

Article 19 paragraph (1) of the Consumer Prtection Law stipulates the responsibility of business actors to compensate consumers for pollution or losses due to consumption of products or services traded. Compensation can be in the form of money, suitable goods, or health care. Consumers who are harmed by the circulation of vitamin D3 can claim compensation for their losses to the business actor. responsibility in the circulation of vitamin D3 in the digital marketplace is borne by the business actor (merchant). In accordance with Article 23 of Government Regulation Number 80 of 2019 concerning Trade through electronic systems, the Marketplace as the organizer of the electronic system is only responsible for providing technological control facilities or facilities for receiving reports or complaints from the public about the existence of illegal information content or abuse of space on the electronic system it manages. If the report is received and the business actor is blocked, the platform marketplace is free from legal responsibility. Therefore, consumers who are harmed by vitamin D3 can only sue business actors to compensate for the products or services traded.

¹⁰ Fajar Nugruho Handayani dan Ahmad Haraap, Hukum Perlindungan Konsumen, (Bintang Pustaka Madani:,2021), p.38

¹¹ Celina Tri Siwi K, Hukum Perlindungan Konsumen, (Jakarta:Sinar Grafika,2016), p. 13

In addition, consumers in claiming compensation can use Article 1365 of the Civil Code regarding tort actions. Actions can be categorized as unlawful acts, then there are 4 elements that must be met, namely unlawful acts, fault, loss, and causal relationship between actions and losses. The circulation of vitamin D3 in the marketplace is against the law and business actors distribute it intentionally for personal gain. Losses arise to consumers, including consumers not obtaining the promised efficacy, but experiencing health problems such as body itching, insomnia and chest beats faster. The actions of business actors who sell vitamin D3 in the marketplace have fulfilled the elements of tort in Article 1365 of the Civil Code.

Legal protection has a function to protect parties from actions that violate their rights. One of the goals is that consumers do not receive losses for the circulation of vitamin D3 in the marketplace. However, the online circulation of vitamins or D3 supplements is still used by business actors to distribute products without a distribution permit. Legal protection must be balanced with the legal system.: According to Lawrence Friedman, there are 3 elements to determine the legal system which can be explained as follows ¹³

1) Legal Subtance

Legal substance has to do with legal products that apply in society. The weak strength of legal substance creates a gap for parties to commit acts that harm consumers. One of them is the circulation of vitamin products or D3 supplements without a distribution permit online through the marketplace. First, consumer protection law still regulates conventionally. The definition of business actors in consumer protection law must be expanded in accordance with the times. This is because Article 1 point 11 of Government Regulation No.80 of 2019 concerning Electronic Commerce states that the organizer of trade through electronic systems (marketplace) is a Business Actor providing Electronic Communication facilities used for Trade transactions. This provision will certainly expand the definition of business actors in consumer protection law which can affect the classification of liability. Second, BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online does not have much power in overcoming the circulation of drugs, supplements and food without a distribution permit circulated online. BPOM Regulation No.32 of 2020 concerning amendments to BPOM regulation No.8 of 2020 concerning supervision of drugs and food circulated online. regulates sanctions for electronic system operators and business actors. However, most of the sanctions are still imposed on business actors (merchants). In the current era, there must be strict and clear regulations aimed at electronic system operators who are obliged to prevent dangerous and illegal products. Therefore, there is still a need for legal reforms related to online pharmaceutical sales.

2) Legal Structure

The legal structure that has the right to tackle the circulation of supplements without a distribution license is the BPOM in collaboration with the Ministry and the police. In supervising the circulation of drugs and food online, of course, human resources and sophisticated tools are needed as a means of monitoring drugs and food online..Indonesia has tools regarding cyber equipment, but only focuses on the center as the capital city. This is one of the obstacles to tackling fraud through electronic transactions.¹⁴ Meanwhile, BPOM as a drug and food supervisor is not yet fully equipped with cyber equipment that can be used to monitor drugs and food online.

3) Legal Culture

People must be able to understand how the law is use or abused. Legal culture reflects the way

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¹² Indah Sari, Perbuatan Melawan Hukum (PMH) dalam Hukum Pidana dan Hukum Perdata, Jurnal Ilmiah Hukum Dirgantara, Vol.11, No.1, 2020, p.53.

¹³ Abdul R. Saliman, Hukum Bisnis Untuk Perusahaan Untuk Perusahaan Teori dan Contoh Kasus, (Jakarta: Kencana, 2015), p..4.

¹⁴ Hendy Sumadi, Kendala Dalam Menanggulangi kejahatan Penipuan di Sektor E- Commerce, Jurnal Wawasan, Volume, 33 No.2 September 2015, h. 175.

people perceive, understand, and appreciate the importance of consumer protection in economic activities. The increase in sales of supplements or vitamin D3 in the marketplace has certainly resulted in losses for consumers.. Consumers whose rights are violated still have the right to claim compensation. Susanti Nugroho in his book argues that consumers prefer to be victims rather than litigate in court which is considered a disgrace, a waste of time or complicated. This is because the amount of loss suffered is less than managing disputes outside and inside the court.

Legal protection is born from the rights and obligations that everyone has. So that in this paper, legal protection lies in the fulfillment of consumer rights and obligations that have been determined in laws and regulations. However, the existence of legal protection without a balanced legal system, the law that is formed cannot run optimally. Therefore, legal protection must run in balance with the legal system that has been determined.

2. Disputes Resolution for Losses Suffered by Consumer Due to Using Vitamin D3 without a Distribution Permit Sold in the Digital Marketplace

Disputes in the world of commerce are complex and evolve with the times. A dispute is the emergence of a conflict of parties that causes legal consequences and sanctions imposed on one of the parties between the other parties. One of the disputes that arises is the circulation of vitamin d3 without a distribution permit which can harm consumers both in terms of material and immaterial. Business actors who circulate illegal vitamin D3 products through in the digital marketplace are certainly very detrimental to consumers. Dispute resolution is intended to restore the rights of consumers that have been violated by business actors. Dispute resolution efforts are one of the rights of consumers as a guarantee of consumers to protect from actions that can harm them. The form of settlement and the amount of compensation are left to the parties provided that both parties have the same ethics and will. Therefore, parties who are harmed by vitamin D3 without a distribution permit can exercise their rights to obtain dispute resolution.

Article 45 paragraph (2) of the consumer protection law explains that dispute resolution can be pursued out of court or in court. Article 45 of the consumer protection law states that the choice of settlement is voluntarily submitted to the parties. Consumers who are aggrieved by vitamin D3 are free to resolve disputes outside the court or within the court. So, dispute resolution efforts are submitted based on the wishes of the parties without any element of coercion.

Consumers who suffer losses due to vitamin D3 products without a distribution permit can choose non-litigation dispute resolution. The dispute resolution effort is used to determine the results that satisfy the parties or win-win solution. Dispute settlement outside the court can be carried out through an agency that has been established by the government, namely the Consumer Dispute Settlement Body (BPSK). These provisions are included in Article 49 - Article 58 of the Consumer Protection Law. An aggrieved consumer can resolve the dispute by filing a lawsuit with the Consumer Dispute Resolution Agency. Article 58 of the Consumer Protection Law states that BPSK can resolve disputes through abritase, consialization, and mediation. ¹⁷

Consumers who are harmed by vitamin D3 without a distribution permit can first complain to the Consumer Dispute Settlement Body (BPSK). The consumer can explain the event based on the facts that have occurred. If BPSK has received a lawsuit and issued a decision, then the parties are obliged to obey it. As Article 56 paragraph (4) of the consumer protection law states that if the business actor does not

¹⁵ Hasbudding Khalid, Hukum dan Investasi: Aspek Perlindungan Hukum oleh Otoritas Jasa Keuangan bagi investor pasar modal, Unes Law Review, Vol.6 No.1, 2023, p.744

¹⁶ Dudi Badruzaman, Perlindungan Hukum Tertanggung dalam Pembayaran Klaim Asuransi Jiwa, Jurnal Ekonomi dan Keuangan Syariah, Vol.3, No.1, 2019, p.109.

¹⁷ Susanti Adi Nugroho, Proses Penyelesaian Sengketa Konsumen ditinjau dari Hukum Acara serta Kendala Implementasibya, Jakarta: Kencana, 2008,, P.98.

comply with the decision, BPSK is authorized to hand over the business actor to investigators for action in accordance with laws and regulations.

Consumers who are harmed by vitamin D3 without a distribution permit can also resolve disputes in litigation. Litigation dispute resolution efforts are carried out by the parties to face directly before the court to defend their rights which are carried out in accordance with the applicable civil procedural law in Indonesia. A lawsuit can be filed directly by the consumer or by an appointed attorney. If the consumer uses a power of attorney, it is mandatory to include a special power of attorney as a condition of registration at the registrar of the district court. In Article 46 of the consumer protection law, a lawsuit can be filed by the heirs of the consumer, a self-help consumer protection organization, and the government/agency if the loss is substantial.

A lawsuit may be filed by the parties to the district court in accordance with the consumer's domicile. Furthermore, the lawsuit can be forwarded to the head of the district court. After the lawsuit is received, the head of the court can appoint a panel of judges to examine, hear and give a decision on the case being examined. Consumers who sue can request both material and immaterial damages, provided that they must be in accordance with the evidence stipulated in the civil procedural law. If the trial process has explained the facts based on the evidence owned by the parties, the Panel of Judges can give a decision that is read out at trial. Therefore, consumers who are harmed by vitamin D3 without a distribution permit can claim their violated rights by filing a lawsuit for compensation in litigation to Court.

Conclusion

The form of legal protection for consumers who are harmed by the sale of vitamin D3 without a distribution permit in the digital marketplace is divided into two forms, namely internal legal protection and external legal protection. Internal legal protection of consumers who are harmed by the sale of vitamin D3 without a distribution permit through the marketplace can use the agreement clauses contained in the terms and conditions in the digital marketplace. External protection can be obtained through Article 143 of Law No.17 of 2023 concerning Health and Article 4, Article 8 of the consumer protection law. Consumers who suffer losses due to consuming vitamin D3 without a distribution permit are entitled to compensation from business actors as regulated in Article 19 of the consumer protection law and can file a lawsuit for compensation against business actors on the basis of Article 1365 of the Civil Code regarding unlawful acts. However, consumer legal protection for the sale of vitamin D3 in the digital marketplace is not optimal because it is influenced by factors of legal substance, legal structure and legal culture. Dispute resolution that can be carried out by consumers due to losses from the sale of vitamin D3 without a distribution permit based on Article 45 paragraph (2) of the consumer protection law can be carried out in non-litigation and litigation. Non-litigation dispute resolution can be carried out through the Consumer Dispute Resolution Agency (BPSK) or litigation dispute resolution can be carried out by filing a lawsuit to the general court.

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