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Challenging The Form of Responsibility in Drug Policies That Adversely Affect Consumers

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Abstract. *This research examines the growing concern regarding the adverse effects of drugs in Indonesia, particularly in light of increasing health issues linked to low-quality pharmaceutical products. The study highlights the alarming rise in atypical progressive acute renal failure cases, attributed to contaminated drugs, despite regulatory inspections by the Food and Drug Supervisory Agency (BPOM). The research also delves into the evolving legal framework for consumer protection, particularly the role of Law Number 8 of 1999 on Consumer Protection, and critiques its application in addressing the gap between regulatory approval and consumer safety. Through the lens of causality theory, this study aims to analyze the responsibility of pharmaceutical companies and regulatory bodies in ensuring public health protection. The methodology employed is normative juridical, utilizing a comparative, conceptual, and statutory approach, with secondary data analyzed descriptively and qualitatively. Based on the theory of causality, in addition to pharmaceutical companies that can be charged with absolute liability in accordance with the provisions of Article 19 of the Consumer Protection Law, the Food and Drug Supervisory Agency (BPOM) can also be blamed, especially if the elements of abuse of duty and negligence are met based on Presidential Regulation No. 80 of 2017 concerning BPOM.*

Keywords: *Consumer; Drugs; Liability; Policy; Protection.*

1. INTRODUCTION

It is contradictory when it comes to the public that there is a dramatic increase in the adverse effects of drugs that threaten the health of drug consumers. Based on data reported by CNN Indonesia that in the results of tests conducted by the Food and Drug Administration (BPOM), the results of the outbreak of atypical progressive acute renal failure cases in a number of regions in Indonesia were found, to cause the growth of health polemics in the range of 245 cases in 26 provinces in Indonesia. This is certainly a sharp spotlight on the justification of regulations in consumer protection against the enigma of cases that occur. Given that everyone, at some point, whether alone or in a group, under any circumstances, must become a consumer for certain goods or

services, this is a very important concern for consumer protection.[1] In the context of consumer protection, the implementation of Law Number 8 Year 1999 on Consumer Protection (UUPK) is a step towards empowerment. With the emergence of the GCPL, the tendency of the caveat emptor principle to be applied to consumers and business actors who need to be careful has begun to reverse itself (caveat venditor).[2]

The legal umbrella for consumer protection itself has been explicitly designed with the objectives as stated in Articles 2 and 3 of the GCPL, which are the ultimate goals to be achieved in the implementation of development in the field of consumer protection law is the substance of national development. The protection subsystem of the GCPL as a whole should serve these six objectives for best results, without neglecting additional infrastructure or local conditions.[3] Thus, the government's implementation of health development initiatives thus far has been an integral component of national progress, as health permeates almost all aspects of human life and has effectively improved the overall health conditions of the people.[4] Although in general there has been a lot of progress in the field of health efforts that have succeeded in improving the degree of public health, the government is currently faced with new problems, namely the high level of serious / severe health problems against the background of the increasingly complex health problems faced, as has been stated above.

At this time there are many health drugs on the market, consumers become potential victims in the midst of the health drug trade because consumers are currently faced with drugs whose quality and quality must still be questioned. The development of increasingly sophisticated technology has had an impact on the accessibility of these medicines.[5] In some cases, certain therapeutic items have violated safety requirements as mandated by laws and regulations. There are case reports that are suspected to be due to the high contamination of solvents above the established threshold such as propylene glycol, polyethylene glycol, and others that have caused a drastic increase in health cases that have caused losses to consumers of the drugs they consume, even though the drugs have obtained distribution permits and passed the inspection of the Food and Drug Supervisory Agency (BPOM).[6] The existence of these problems in the field has posed a serious threat to health, such as the case that is being crowded at the end of 2022, namely the drastic increase in suspected acute kidney failure caused by children's syrup drugs, to be precise on October 15, 2022, which has been confirmed by BPOM.

The health threats that occur, which are clearly not in line with the pillars of health development and national development, of course, someone must be responsible for this. The Constitution has regulated this as outlined in the Law on pharmaceutical

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[1] Roihanah, R. (2019). Analisis Yuridis Perlindungan Konsumen Terhadap Peredaran Obat Tradisional Berbahan Kimia Obat. Kodifikasia , 13 (1), 123–147.

[2] Gautama, S. (2004). Hukum Perlindungan Konsumen Indonesia. Grasindo.

[3] Barkatullah, A. H. & others. (2017). *Framework Sistem Perlindungan Hukum bagi Konsumen di Indonesia*. Nusa Media.

[4] Sulaiman, E. S. (2021). Manajemen kesehatan: Teori dan praktik di puskesmas. Ugm Press.

[5] Aziz, A. (2020). Tugas dan Wewenang Badan Pengawas Obat dan Makanan (BPOM) dalam Rangka Perlindungan Konsumen. Al-Qanun: Jurnal Pemikiran dan Pembaharuan Hukum Islam, 23 (1), 193–214.

[6] Wensen, M. T., Mandiana, S., & Widjiastuti, A. (2024). Peredaran obat terlarang di Indonesia dan upaya pencegahannya oleh Badan Pengawas Obat dan Makanan (BPOM). Aliansi: Jurnal Hukum, Pendidikan dan Sosial Humaniora , 1 (2), 175– 181.

work, which is the manufacture, processing, compounding, changing the form, mixing, storage and delivery of drugs or medicinal. So relying on this, the pharmaceutical law has been violated, which clearly defines the compounding of drugs by pharmaceutical companies. However, before disseminating medicinal products, Pharmaceutical Companies will first go through an inspection process by BPOM (Food and Drug Supervisory Agency). BPOM is responsible for carrying out government responsibilities in the field of drug and food control, in accordance with the provisions of laws and regulations.[7] Drugs and Food cover a wide range of substances, including drugs, medicinal raw materials, narcotics, psychotropic substances, precursors, addictive substances, traditional medicines, health supplements, cosmetics and processed foods.

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2. RESEARCH METHODS

This research uses a normative juridical research methodology, which includes a comparative approach, conceptual approach, and statutory approach. This research is based on the use of secondary data sources. The data is analyzed descriptively and qualitatively.[9] The specification of this research uses descriptive analysis, which specifically focuses on the description of data to obtain a comprehensive understanding of certain legal events in society. Furthermore, this data was examined using relevant principles and guidelines.[10]

3. RESULT AND DISCUSSION

3.1. Drug Policy in Consumer Protection Law Decomposition

Indonesia, like other developing countries, has its share of problems in the area of consumer protection law. The fact that consumers in our country still often face

[7] Gondokesumo, M. E., & Amir, N. (2021). Peran Pengawasan Pemerintah Dan Badan Pengawas Obat Dan Makanan (BPOM) Dalam Peredaran Obat Palsu di Negara Indonesia (Ditinjau dari Undang-Undang Nomor 36 Tahun 2009 dan Peraturan Kepala Badan Pengurus Obat dan Makanan). Perspektif Hukum, 274–290.
[8] Umami, A. M., Al Qindy, F. H., Satriawan, H. A., & Wahyuddin, W. (2023). Tanggung Gugat Keperdataan Badan Pengawas Obat Dan Makanan (BPOM) Indonesia Dalam Peredaran Obat-Obatan Yang Menyebabkan Gagal Ginjal Akut Pada Anak. Jurnal Risalah Kenotariatan, 4 (1).
[9] Amiruddin, & Asikin,Z. (2012). Pengantar Metode Penelitian Hukum. PT RajaGrafindo Persada.
[10] Ramdhan, M. & others. (2021). Metode penelitian. Cipta Media Nusantara.

disadvantages suggests that they are in a weaker position than entrepreneurs and their organizations. Thus, consumer protection laws fill the gap left by the asymmetry in consumer power. The Consumer Protection Act is a piece of consumer law that sets out principles or regulations to safeguard the interests of consumers.[11]

A review of positive law reveals that consumer protection law, which is a body of legislation containing principles and rules relating to consumer relations and issues, is present in a number of procedural law settings, administrative law in a number of international conventions, and elsewhere.[12] The objectives of consumer protection, as outlined in Indonesian law, are multi-faceted and aimed at fostering a secure and ethical environment for consumers. First, they focus on enhancing consumer awareness, self-reliance, and the ability to defend themselves. Second, they seek to uphold the respect and dignity of consumers by preventing unfair access to goods and services. Third, consumer empowerment is emphasized, ensuring individuals can make informed choices, assert their rights, and participate actively in the market. Fourth, the law aims to establish a system that provides consumers with access to information, ensures transparency, and offers legal certainty. Additionally, it underscores the importance of promoting ethical business practices to cultivate corporate responsibility. Finally, the goal is to improve product and service quality, prioritizing consumer health, comfort, and safety while supporting the sustainability of businesses.

Consumer legal protection is a requirement of state law because almost all individual citizens are consumers of certain goods or services. In addition, the general public as customers require consumer protection laws. This is because consumers are in a weaker position than producers, who tend to produce goods and services that only aim for a certain level of productivity and effectiveness to meet corporate goals.[13] Given the fact that science and technology are key drivers for the productivity and efficiency of producers the goods and services produced to pursue and achieve these two goals are growing with ever-increasing statistics year on year, consumer protection is seen as materially and formally increasingly important.[14] Based on Article 7 letter (d) of Law No.8 of 1999 concerning Consumer Protection (UUPK), all drug industries in carrying out their business must pay attention to the obligations of business actors, namely:

> "Business Actors are obliged to guarantee the quality of goods and/or services produced and/or traded based on the provisions of the applicable quality standards for goods and/or services".

Pharmaceutical companies are required to comply with certain obligations as outlined in Article 7 of GCPL. This article mandates that such companies must conduct

[11] Prabowo, D., & Kurniawan, D. (2021). Pengaturan Pengawasan Badan Pengawas Obat Dan Makanan (Bpom) Dalam Perlindungan Konsumen Regulation Of Supervision Of The Drug And Food Control Agency (Bpom) In Consumer Protection. Jurnal Projudice, 2 (2).
[12] Sukma, L. (2016). Pertanggungjawaban Produk (Product Liability) sebagai Salah Satu Alternatif Perlindungan Konsumen. Dialogia Iuridica, 7 (2), 32–42.
[13] Simanjuntak, M.E.S. (2023). Perbandingan Perlindungan Hukum Konsumen Dan Penyelesaian Sengketa Cross Border E-Commerce Negara Indonesia Dengan Jepang. JISIP (Jurnal Ilmu Sosial Dan Pendidikan), 7 (3), 2033–2040.
[14] Firatmadi, A. (2017). Pengaruh kualitas pelayanan dan persepsi harga terhadap kepuasan pelanggan serta dampaknya terhadap loyalitas pelanggan. Journal of Business Studies, 2 (2), 80–105.

their business with integrity, provide accurate and transparent information regarding the terms and warranties of their products and services, and offer proper instructions for use, repair, and maintenance.[15] In addition, business actors must also pay attention to the quality and safety of medicinal products before they are distributed to the market. Violation of these obligations may result in legal sanctions, including fines and criminal action.[16]

3.2. Liability to Consumers of Bad and Harmful Medicines in the Eyes of Consumer Protection Law

According to the Big Indonesian Dictionary, responsibility is a state in which a person is required to bear everything, which makes the person responsible for the action obliged to bear everything in any scenario. The second result of the further exercise of these functions, whether in the form of rights, obligations, or newly acquired powers, is called legal responsibility.[17] Whereas in the civil context, liability is defined as the action that is required or must be taken because the action causes harm to others, usually in the form of payment of compensation.[18] So, from a legal relationship perspective, liability is the result of a party to an agreement, such as a traditional medicine sale and purchase agreement, violating the rights of another party.

There are two recognized categories when it comes to liability: strict liability and product liability. Product liability usually lies with the entity responsible for the manufacture, production, or sale/distribution of the product.[19]Based on the core of the problem in terms of responsibility for drugs that cause harm or adverse effects, this has been emphasized by the statement of the Law on pharmaceutical work which states that pharmaceutical companies are responsible for the production, processing, compounding, deformation, mixing, storage, and transportation of drugs and medicines. Therefore, based on this legal basis, the pharmaceutical company has violated the pharmaceutical law regarding drug compounding.

When referring to the theory of causality, in addition to the pharmaceutical company, BPOM should be drawn as a responsible party, because in its procedure before distributing medicinal products, the Pharmaceutical Company will first go through an inspection process carried out by BPOM. In accordance with the requirements of the legislation, BPOM is tasked with carrying out government obligations in the field of drug and food control. Drugs and Foods include prescription drugs, illegal drugs,

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[15] Nugroho, L. C. (2020). Tanggung Jawab Hukum Pelaku Usaha Farmasi Terhadap Izin Edar Obat. Jurnal Juristic , 1 (02), 177–196.

[16] Pesulima, T. L., Matuankotta, J. K., & Kuahaty, S. S. (2021). Perlindungan Konsumen Terhadap Peredaran Produk Kesehatan Ilegal di Era Pandemik Covid-19 Di Kota Ambon. Sasi , 27 (2), 160–171.

[17] Halim, A. R. (2020). Hukum Aministrasi Negara Dalam Tanya Jawab. Ghalia Indonesia.

[18] Novitasari, A. F., Rokiyah, R., & Muslim, S. (2022). Pertanggungjawaban Pelaku Usaha Terhadap Konsumen Terkait Produk Makanan. Y u ris p r u d e n : J u r n al F a k ult a s Hukum Universitas Islam Malang , 5 (1), 16–30.

[19] Ali, M. (2019). Konsep makanan halal dalam tinjauan syariah dan tanggung jawab produk atas produsen industri halal. AHKAM: Jurnal Ilmu Syariah , 16 (2), 291– 306. Ali, M. (2019). Konsep makanan halal dalam tinjauan syariah dan tanggung jawab produk atas produsen industri halal. AHKAM: Jurnal Ilmu Syariah , 16 (2), 291– 306.

psychoactive substances, precursors, addictive substances, over-the-counter drugs, herbal supplements, cosmetics, and processed foods.[20]

The legal liability of pharmaceutical companies for products that result in injuries, side effects, errors, health problems, or major problems is governed by the principle of strict liability or strict liability.[21] Pharmaceutical companies are fully responsible for drug information and advertising, which means that they are the businesses responsible for their products. However, businesses may be exempted from liability if the product was not intended for circulation, had a defect when it was supposed to be in circulation, had expired, or was defective due to consumer negligence.[22]

If in the course of the pharmaceutical company is proven to change the composition of the drug and does not notify BPOM, the pharmaceutical company can be held criminally liable based on Article 196 of the Health Law. Based on this, it is considered that the element of producing and distributing pharmaceutical preparations that do not meet the standards and / or requirements for safety, efficacy or benefits, and quality is fulfilled.[23] As a result, the perpetrator must bear the full brunt of all impacts resulting from his actions, including maximum fines, criminal penalties, and threats, as well as revocation of his production license.

Then this is inseparable from the contribution of BPOM, where BPOM has a role that cannot be eliminated, namely without the presence and function of BPOM, the drug cannot circulate. Thus, analyzed in more depth with reference to the theory of causality (cause and effect), BPOM can be drawn as a party who is responsible and can be blamed for being negligent. Then the form of responsibility that can be imposed on BPOM for drugs that cause adverse effects; losses; threaten health seriously, Liability and criminal law also apply if anomalies are found in the duties and activities of BPOM in accordance with Presidential Regulation Number 80 of 2017. This obligation specifically relates to BPOM units in charge of conducting pre- and post-circulation drug supervision, production supervision, and distribution supervision.[24]

Consumers who suffer losses caused by substandard products in circulation that can cause serious health problems (defects) and cause harmful things to consumers, can

[20] Tambuwun, T. T. (2020). Peranan Badan Pengawas Obat Dan Makanan (Bpom) Dalam Perlindungan Konsumen Yang Mengandung Zat Berbahaya. Lex Privatum , 8 (4).
[21] Atmoko, D., & Baihaki, A. (2024). Perlindungan Hukum Terhadap Konsumen Pada Produk Obat Tradisional yang Beredar di Masyarakat. Jurnal Cahaya Mandalika ISSN 2721 - 4796 (online) , 5 (2), 694–703.
[22] Ahmad, A., Krisyananti, N., Rumbia, M. R., Susanti, S., Rahim, M. A. F., Aslinda, A., Suherman, M. A., & Amalia, P. R. (2022). Tanggung Jawab Perusahaan Farmasi dan BPOM Terhadap Produk Obat Sirup Anak. Jurnal Litigasi Amsir , 118–123.
[23] Utami, A., & Herwastoeti, H. (2022). Perlindungan Hukum Terhadap Konsumen Atas Penjualan Obat-Obatan Ilegal Secara Online. Kla u s ula (Jurnal Hukum Tata Negara, Hukum Adminitrasi, Pidana Dan Perdata) , 1 (2), 93–116.
[24] Cahyono, I., Marsitiningsih, M., & Widodo, S. (2020). Peran Badan Pengawas Obat dan Makanan terhadap Peredaran Obat Tradisional yang Mengandung Bahan Kimia Obat Berbahaya dalam Perlindungan Konsumen. Kosmik Hukum, 19 (2), 110– 117.

be subject to strict liability.[25] Based on Article 19 of the Law, it is stated that business actors have the obligation to compensate customers for losses suffered as a result of consuming traded goods and services, which regulates the absolute liability of actors. UUPK with reference to paragraph (1) regulates several types of compensation, including refund of transaction money and provision of replacement products and/or services of comparable or equal value. With an estimated grace period of 7 (seven) days after the date of the transaction, fulfillment of the compensation must be paid against the compensation. In order to engage in the possibility of removal associated with the establishment of criminal charges based on additional evidence of the existence of an element of guilt, the payment of the compensation specified in paragraphs (1) and (2) shall be considered as fulfillment of civil liability. Tetaopi, if the fault resulting in errors and other damage to goods and services is proven to be the fault of the consumer, the provisions referred to in paragraphs (1) and (2) as previously indicated shall not apply.

4. CONCLUSION

Article 7 of the Consumer Protection Act underscores the importance of conducting commercial activities with good faith and providing clear, transparent, and accurate information regarding the condition and warranty of products, particularly medicinal goods. Companies are required to ensure the quality and safety of their products before market release, with legal sanctions imposed for violations. The Indonesian government has made significant efforts to safeguard consumer rights through various laws and regulations, with a strong focus on the principle of liability. The two key forms of liability—product liability and strict liability—highlight the need for clear categorization and careful assessment of responsible parties. Producers have clear obligations to consumers, including penalties, compensation, and potential legal actions. Therefore, the government must foster an inclusive and rigorous consumer protection policy, supported by preventive measures such as counseling and surveillance, to minimize risks and promote responsibility in drug consumption.

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