E-ISSN: 2962-2816 P-ISSN: 2747-1985



JLPH: Journal of Law, Politic and Humanities

https://dinastires.org/JLPH

DOI: https://doi.org/10.38035/jlph.v5i5 https://creativecommons.org/licenses/by/4.0/

Legal Protection Analysis of Consumers Against Traditional Medicines Containing Pharmaceutical Chemical Substances (BKO) in Digital Markets

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Abstract: Pharmaceutical Chemical Substances (BKO) are chemicals added to traditional medicines to enhance their efficacy and accelerate healing. A 2015 BPOM (Indonesian Food and Drug Authority) report found 54 traditional medicine products containing BKO circulating in digital markets, posing potential risks such as liver and kidney damage. This study examines the legal protection of consumers against traditional medicines with BKO in digital markets and evaluates BPOM's role in prevention. The research uses a normative juridical method with a statute approach, analyzing secondary data qualitatively. Findings show that consumer protection for traditional medicines with BKO in digital markets is regulated under Law No. 8 of 1999 concerning Consumer Protection (UUPK), particularly Article 19, which prohibits businesses from making false or misleading claims. The Electronic Information and Transactions Law (UU ITE) also applies, particularly Article 9, requiring full disclosure to consumers regarding the substances, approval, form, efficacy, and side effects of the medicine. Sanctions for businesses selling traditional medicines with BKO in online markets can be imposed to protect consumer rights. Consumers are entitled to legal protection for purchasing traditional medicines not registered with BPOM. Articles 60 to 63 of the UUPK specify administrative and criminal sanctions, with Article 60 outlining administrative sanctions and Articles 61 and 62 detailing criminal penalties. BPOM issued Regulation No. 8 of 2020 to supervise online food and drug distribution, aiming to prevent the circulation of traditional medicines with BKO. BPOM Regulation No. 14 of 2024 revokes the previous regulation, expands commodity coverage, and clarifies procedures for monitoring and withdrawing illegal products based on online verification.

Keyword: Traditional Medicine, Pharmaceutical Chemical Substances, Consumer Protection.

INTRODUCTION

The advancement of information technology has become a highly effective instrument in product marketing activities and facilitates transactions for consumers. This development allows the purchase of goods and services to be conducted online more conveniently. However,

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behind these conveniences, electronic transactions also present various challenges, one of which is the risks to consumers due to the circulation of products that do not comply with applicable regulations. This non-compliance can affect safety, security, and public health. The World Health Organization (WHO) also advises the use of traditional medicine in the prevention, maintenance of health, and treatment of diseases (Sari & Wiryawan, 2018). In Indonesia, BPOM (Indonesian Food and Drug Authority) specifies that traditional medicines are natural mixtures of plants, animals, minerals, or galenic preparations used for medicinal purposes passed down through generations. Traditional medicine holds a special place in Indonesia as part of the nation's cultural heritage, especially in health care (Pidada & Sutama & Priyanto, 2019). According to BPS data, 27.57% of the population uses traditional medicine for promotional, preventive, and curative purposes. The most important aspect in realizing these health improvement efforts is medicine. Many individuals, particularly those who wish to appear perfect, are willing to spend money on various medications to achieve that perfection (Arnawa & Dharmawan, 2018). Medicines contain substances that alter biological functions through chemical reactions (Pratiwi & Amalia & Hasanah, 2017).

Pharmaceutical Chemical Substances (BKO) are chemicals commonly added to traditional medicine to enhance the medicine's indications and produce strong, rapid therapeutic effects (Pradika, 2023). Some of the common pharmaceutical chemicals added include Sodium Diclofenac, Phenylbutazone, Paracetamol, Antalgin (Metamizole/Metampiron), Piroxicam, Prednisone, Dexamethasone, Sibutramine HCl, Sildenafil Citrate, Glibenclamide, and Theophylline. These chemicals are added to accelerate the therapeutic effects or claimed benefits of traditional medicines, making the products appear more effective. However, this is dangerous to health, as these pharmaceutical chemicals may cause side effects, ranging from mild to severe, which can harm consumers when used excessively (Nichairin, 2023). Generally, side effects from consuming traditional medicines containing harmful chemicals include gastrointestinal distress, gastrointestinal bleeding, and gastric ulcers. Traditional medicines containing pharmaceutical chemicals have circulated widely, including in regions such as East Java and West Java, and globally, such as in the United States, Australia, and other parts of Asia. The number of such medicines has increased annually from 43 traditional medicines containing pharmaceutical chemicals to 50-53 such products.

BPOM has identified approximately 54 traditional medicines that contain pharmaceutical chemicals and are deemed unfit for consumption, with 7 of them having had their distribution permits revoked. A 2015 BPOM finding noted 54 pharmaceutical chemical products circulating in digital markets that, if consumed, could potentially cause serious side effects, including liver and kidney damage. The lack of transparency regarding the composition, efficacy, and side effects in digital markets worsens the situation, as consumers may unknowingly consume harmful products. Both the Electronic Information and Transactions Law (UU ITE) Article 9 and Minister of Health Regulation No. 06 of 2012 Article 33a mandate the provision of complete and accurate information. Government Regulation No. 80 of 2019 and BPOM Regulation No. 8 of 2020 also regulate online distribution supervision. Furthermore, BPOM, through its cyber patrol mechanism, has seized 658,205 illegal traditional products and/or those containing pharmaceutical chemicals between October 2021 and August 2022, valued at IDR 27.8 billion, and blocked 82,995 digital market links offering harmful products (POM, 2023). The circulation of these products clearly violates consumers' rights to safety and security.

The circulation of traditional medicines containing pharmaceutical chemicals without distribution permits not only violates consumers' rights to safety and security (Law No. 8 of 1999 on Consumer Protection), but also constitutes a health crime (Article 435 of Law No. 17 of 2023), with penalties of up to 12 years in prison and/or a fine of IDR 5 billion. This situation emphasizes the need for stricter BPOM supervision, improved consumer literacy, and adequate legal certainty. Therefore, this study will examine: 1. legal protection for consumers of

traditional medicines containing pharmaceutical chemicals in digital markets, and 2. the role of BPOM in preventing and reducing the circulation of traditional medicines containing pharmaceutical chemicals in digital markets.

METHOD

This journal research is carried out using normative legal research methods. Normative legal research involves the identification and examination of legal norms, doctrines, and principles, which serves as a process to derive arguments, concepts, or new theories that can provide guidance in resolving legal issues (Marzuki, 2011). In this context, the normative legal research method is utilized to address and elaborate on the issue of legal protection for consumers of traditional medicines, particularly by focusing on applying the principles and norms found in positive law. The research primarily employs statutory regulations as the main legal source, as these form the foundation of the legal framework being studied. Secondary legal sources, including books, papers, and research journals, are also consulted to enrich the understanding of the subject matter and provide supporting arguments. The primary objective of using these legal sources is to ensure a comprehensive analysis of consumer protection laws and their implementation in the context of traditional medicines that contain pharmaceutical chemical substances.

Furthermore, this research uses a conceptual approach, which involves analyzing legal materials to develop a deeper understanding of the issues at hand. This approach is coupled with the "statute approach," which focuses on the examination of existing legislation, regulations, and legal texts that directly impact the topic under investigation. By applying this approach, the study aims to evaluate how legal frameworks address the challenges surrounding consumer protection in the digital marketplace, with specific reference to traditional medicine products. This method ensures that the research is grounded in established legal norms and allows for the development of legal arguments, theories, and recommendations that are both academically rigorous and practically applicable in the context of consumer protection in Indonesia's digital economy.

RESULTS AND DISCUSSION

Legal Protection for Consumers in the Distribution of Traditional Medicines Containing Pharmaceutical Chemical Substances (BKO) in the Digital Marketplace

Law serves as a fundamental system for the exercise of authority and power within the institutions of the state and government in a narrow sense. It provides a legal framework and imposes limitations upon the government in formulating legal norms and policies aimed at advancing and ensuring legal protection, legal certainty, justice, and the protection of legal interests for all citizens, while upholding human rights (Azharie, 2023). Legal protection for consumers is a fundamental right guaranteed under various legal regulations in Indonesia. Such protection can be realized in many forms, including safeguarding the rights and interests of consumers. In general terms, a consumer is defined as any individual who utilizes goods or services available within society to meet personal needs, the needs of others, or other living beings, for various purposes, without engaging in the resale of such goods or services.

The notion of legal protection for consumers is thus directed toward individuals as the end-users of a product—either goods or services—and not those who use them as raw materials for producing other products in a manner that contravenes the law and subsequently trades them for profit (Sunarjo, 2014). Legal protection for consumers also extends to the health sector, such as in the area of pharmaceuticals. In the context of the trade in traditional medicines through digital marketplaces, such protection becomes critically important due to the high risk associated with the circulation of products that unlawfully contain pharmaceutical chemical substances. In the commercial distribution chain, products rarely reach consumers directly from the producers; instead, they often pass through multiple intermediaries such as agents,

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wholesalers, distributors, and retailers (Rajagukguk, 2000). This complexity creates legal challenges, particularly when a consumer suffers harm and is uncertain as to which business actor should be held accountable (Syawali, 2000).

In Indonesia, the use of traditional medicines has shown a significant increase over the years. According to the National Socio-Economic Survey (SUSENAS), the utilization of traditional medicines rose from 19.8% in 1980 to 32.8% in 2004 (Siti Fadilah Supari, Minister of Health, 2007). In the most recent survey, 27.57% of the Indonesian population reported using traditional medicines for promotive, preventive, and curative purposes. The consumption of traditional medicine is a cultural heritage embedded within Indonesian society, offering substantial potential for the growth of the traditional medicine market. This potential is reflected in the increasing availability of traditional medicinal products, both in conventional markets and online platforms such as digital marketplaces. The Central Statistics Agency (Badan Pusat Statistik/BPS) conducted a survey and recorded a 48% increase in online sales in April 2020 (BPOM, 2025). The growing consumer interest in traditional medicines has unfortunately been exploited by unscrupulous business actors who distribute traditional medicine products that in fact contain pharmaceutical chemical substances, posing serious risks to public health.

Pharmaceutical chemical substances are chemical compounds commonly added to traditional medicinal preparations with the intent to enhance the perceived therapeutic indications of such products, producing stronger and faster pharmacological effects in treating illnesses (BPOM, 2025). Among the chemical substances frequently added is Paracetamol. Paracetamol is classified as an over-the-counter (OTC) drug. Also known as acetaminophen (N-acetyl-p-aminophenol), it is a synthetic, non-opioid derivative of p-aminophenol. Paracetamol is one of the most commonly used medications in the treatment of migraines and is widely administered as an antipyretic and analgesic (Hidayati & Kustriyani, 2020).

The addition of pharmaceutical chemical substances into traditional medicines is often aimed at accelerating the claimed therapeutic effects of these products, thereby making them appear more effective or potent. However, such substances are frequently added without proper formulation standards or medical oversight. This practice poses serious health risks, as pharmaceutical chemicals are known to have side effects ranging from mild to severe, and excessive or improper use can endanger consumer health (Nichairin & Mita, 2023). In general, adverse effects associated with the consumption of traditional medicines containing hazardous chemical substances may include gastrointestinal distress, gastrointestinal bleeding, and gastric ulceration (Priyana, 2023). The unauthorized inclusion of pharmaceutical compounds in traditional medicinal products constitutes a violation of health regulations and consumer protection norms, given the potential harm to public health and the deceptive nature of such practices.

To reinforce the regulation of trade conducted through online platforms, the Government of Indonesia enacted Government Regulation Number 80 of 2019 concerning Trade Through Electronic Systems (Perdagangan Melalui Sistem Elektronik/PMSE). The provisions of this regulation emphasize the importance of consumer protection and mandate that business actors provide accessible mechanisms for online dispute resolution. Meanwhile, the Indonesian Food and Drug Authority (BPOM) issued Regulation Number 8 of 2020 concerning the Supervision of Drugs and Food Circulated Online, which establishes procedural requirements for monitoring product distribution, including the obligation to verify product legality. However, weak enforcement at the operational level has resulted in the continued proliferation of traditional medicinal products containing pharmaceutical chemicals across various digital marketplaces (Latianingsih, 2019).

The lack of transparency in product information further exacerbates the risks faced by consumers, who often find it difficult to distinguish between legally registered and illegal products. Consequently, legal protection must not merely exist in normative form but must be supported by effective regulatory enforcement and enhanced consumer awareness.

The Indonesian Food and Drug Authority (BPOM) reported that 50 types of traditional medicines containing pharmaceutical chemicals were distributed via digital marketplaces between September 2022 and October 2023. These accounted for over one million illegal product units, which were subject to takedown and recall measures. The trend of adding pharmaceutical chemicals to traditional medicines has been dominated by substances such as sildenafil citrate and tadalafil (promoted as male performance enhancers), dexamethasone, phenylbutazone, and paracetamol (marketed for pain relief), and sibutramine (promoted for weight loss). Other identified substances include ephedrine, pseudoephedrine hydrochloride, ibuprofen, diclofenac sodium, mefenamic acid, prednisolone, vardenafil hydrochloride, and yohimbine hydrochloride.

The inclusion of such pharmaceutical chemicals can cause adverse effects such as vision and hearing disturbances, chest pain, dizziness, heart attacks, kidney disorders, hormonal imbalances, hepatitis, and even death (BPOM, 2022). These practices reflect the negligence of business actors in safeguarding consumer safety and health, as the incorporation of hazardous substances into traditional medicines poses significant risks to the human body. Furthermore, many of these products are not registered with or authorized by BPOM, and therefore lack any guarantee of safety. Such misuse not only harms consumers but also undermines public trust in traditional medicines, which are expected to be safe and naturally derived. For this reason, stricter regulatory oversight and consumer education regarding the identification and selection of legally registered and safe traditional medicinal products are of critical importance.

Although the majority of Indonesia's 200 million residents are consumers, it was only on April 20, 1999, that the Indonesian Government enacted Law Number 8 of 1999 on Consumer Protection (Undang-Undang Perlindungan Konsumen/UUPK). In the words of the law: "You can never stop being a consumer." (Widjaja & Yani, 2000). Through the enactment of the UUPK, Indonesia established a legal framework to protect buyers from fraudulent business practices. Historically, consumers have been viewed as occupying a weaker bargaining position than producers. To balance this disparity, the UUPK was introduced as a strategic measure to ensure that consumers possess an equal and fair voice in relation to business actors.

Consumer rights are explicitly provided under the UUPK, particularly in Article 19, which prohibits business actors, in the course of offering goods and/or services for trade, from making false or misleading representations regarding:

- a. the price or rate of any goods and/or services;
- b. the usefulness of any goods and/or services;
- c. the condition, warranty, guarantee, rights, or compensation related to any goods and/or services;
- d. offers of discounts or attractive prizes; and
- e. the dangers associated with the use of goods and/or services.

Therefore, legal protection for consumers must be enforced as stipulated in Article 19 of Law Number 8 of 1999 on Consumer Protection (UUPK), which provides as follows:

- 1. Business actors shall be held liable to compensate for damages, pollution, and/or consumer losses arising from the consumption of goods and/or services produced or traded.
- 2. Compensation as referred to in paragraph (1) may take the form of a refund, replacement of goods and/or services of the same type or equivalent value, medical treatment, and/or financial indemnity in accordance with the prevailing laws and regulations.
- 3. Compensation shall be provided within a period of seven (7) days from the date of the transaction.
- 4. The provision of compensation as referred to in paragraphs (1) and (2) shall not eliminate the possibility of criminal charges based on further evidence of fault.
- 5. The provisions of paragraphs (1) and (2) shall not apply if the business actor can prove that the fault lies with the consumer.

Accordingly, one of the fundamental benefits of integrating consumer protection with public safety objectives is to ensure the security and well-being of consumers. Traditional medicine products consumed by the public must not cause harmful side effects that result in material or psychological harm to consumers.

In addition, Article 9 of the Electronic Information and Transactions Law (Law No. 11 of 2008 as amended) stipulates:

"Business actors who offer products through Electronic Systems must provide complete and accurate information relating to the terms of contract, the manufacturer, and the product being offered."

Consumers must receive full disclosure regarding the active pharmaceutical substances, marketing authorization, dosage form, therapeutic claims, and potential side effects based on actual conditions. The imposition of sanctions on business actors who market traditional medicines containing pharmaceutical chemicals through online platforms is necessary to safeguard consumer rights. Every consumer is entitled to legal protection in connection with the purchase of unregistered traditional medicine products not authorized by the National Food and Drug Authority (BPOM).

The imposition of sanctions on business actors who market traditional medicine products containing pharmaceutical chemicals through online trade may also be carried out as a means to uphold consumer rights (Mahesti & Laksana, 2019). Every consumer is entitled to legal protection in connection with the purchase of traditional medicines that are not registered with the National Agency of Drug and Food Control (BPOM), pursuant to Articles 60 to 63 of Law Number 8 of 1999 concerning Consumer Protection (UUPK), which regulate the following types of sanctions:

1. Administrative Sanctions

Sanctions constitute an essential component of the law. Legal provisions concerning sanctions are intended to ensure that all prescribed requirements are enforced in an orderly manner and are not violated (Susanto, 2019). Article 60 of the UUPK governs the imposition of administrative sanctions. The UUPK confers a "special authority" upon the Consumer Dispute Settlement Body (Badan Penyelesaian Sengketa Konsumen – BPSK), which has the responsibility and competence to resolve consumer disputes outside the court system. Article 60 stipulates:

"Business actors who violate the provisions of Article 19 paragraph (2) and (3), Article 20, Article 25, and Article 26 may be subject to administrative sanctions in the form of compensation orders of up to IDR 200,000,000 (two hundred million rupiah)." (Wignjosumarto, 2014).

Thus, in the event that consumers suffer adverse effects or incur losses due to the consumption of traditional medicines containing harmful substances sold via e-commerce, business actors shall be held liable to provide compensation in accordance with Article 19 of the UUPK.

2. Criminal Sanctions

Criminal sanctions are categorized into two types: principal criminal sanctions and additional criminal sanctions. Principal criminal sanctions are imperative and may be imposed independently by the court. The provisions on principal criminal sanctions are set forth in Articles 61 and 62 of the UUPK. Meanwhile, additional criminal sanctions, as explained by Andi Hamzah, are facultative in nature, meaning that they must be imposed in conjunction with principal criminal sanctions. In other words, additional sanctions may only be imposed alongside a principal sanction (Hamzah, 2008). Additional criminal sanctions are regulated under Article 63 of the UUPK.

Although Law Number 8 of 1999 on Consumer Protection does not provide a specific definition of a "consumer dispute," it is evident that conflicts may arise between consumers and business actors. Such disputes may result in harm or loss to either party. Consequently, every

issue or disagreement between the parties must be resolved appropriately. According to the UUPK, consumer disputes may be resolved through two mechanisms (Sudewi et al, 2020):

- a. Litigation / Judicial Process
 - Consumers who have complaints or are involved in disputes may seek redress through the general court system. The provisions of Article 45 of the UUPK apply in such cases. However, litigation often involves high costs, lengthy proceedings, and in some instances, may be detrimental to both parties. Therefore, litigation should be considered as a last resort.
- b. Non-Litigation / Out-of-Court Settlement
 - The Consumer Dispute Settlement Body (BPSK) was established to promote consumer protection efforts. One of BPSK's roles is to provide advice and recommendations to the government in the development of consumer protection policies. BPSK is authorized to resolve consumer disputes through mediation, conciliation, or arbitration, thereby facilitating a more efficient and accessible dispute resolution process outside the courts (Hassanah, 2005).

The Health Law also provides protection to individuals who consume traditional medicines containing pharmaceutical chemicals by imposing sanctions on business actors. Article 435 and Article 196 of Law Number 17 of 2023 concerning Health stipulate criminal sanctions in the form of imprisonment of up to 12 (twelve) years and/or fines of up to IDR 5,000,000,000 (five billion rupiah). In addition, Article 196 of the Health Law provides as follows:

"Any person who intentionally manufactures or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements of safety, efficacy or usefulness, and quality as referred to in Article 98 paragraphs (2) and (3), shall be subject to imprisonment for a maximum of 10 (ten) years and a fine of up to IDR 1,000,000,000 (one billion rupiah)."

The referenced Article 98 paragraphs (2) and (3) set forth standards for healthcare services, specifically that healthcare efforts must fulfill minimum service standards, and the implementation of such standards shall be further regulated by legislation.

Preventive legal protection efforts by the government have not yet been realized optimally. A specific regulation governing the distribution of medicines—particularly traditional medicines containing pharmaceutical chemicals—through digital marketplaces remains necessary and must be formulated with direct input from consumers, considering the lack of transparency and weak supervision. The practice of selling traditional medicines adulterated with pharmaceutical substances through digital marketplaces poses a serious threat to consumer safety, as consumers are often unaware of the true ingredients. Moreover, the Consumer Protection Law (UUPK) does not yet specifically regulate electronic transactions.

Therefore, public complaints should serve as a basis for drafting more responsive regulations that uphold the rights and interests of digital consumers. It is expected that such regulations would reduce the occurrence of the aforementioned cases and ensure that consumers feel safe when using traditional medicinal products

The Role of BPOM in Preventing and Reducing the Circulation of Traditional Medicines Containing Chemical Drug Substances (CDS) in Digital Marketplaces

The National Agency of Drug and Food Control (Badan Pengawas Obat dan Makanan/"BPOM") plays a strategic role as the government's representative institution responsible for monitoring and supervising the distribution of traditional medicines, both offline and online through digital marketplaces, as mandated by BPOM Regulation Number 8 of 2020. This regulation serves as the legal basis for online surveillance of drug and food products, encompassing tracing, verification, and the imposition of administrative sanctions. It also stipulates that each traditional medicine must obtain marketing authorization and comply with established standards of safety, efficacy, and quality. Consumers have reported that the use of

modern medicines often causes direct or indirect side effects, possibly due to their chemical contents, and may lead to dependency. Medicines containing harmful chemicals are detrimental to human health if consumed continuously. The more frequently such chemical-based medicines are used, the more the body builds resistance, thereby reducing the effectiveness of treatment (Munaeni et al, 2022).

BPOM Regulation Number 14 of 2024 revoked the previous regulation, expanded the scope of commodities, and clarified procedures for monitoring and withdrawing illegal products based on online verification results. However, the implementation of this regulation faces challenges due to limited resources, the complex nature of digital market ecosystems, and the necessity for intensive coordination among BPOM, digital marketplaces, and the Ministry of Communication and Information (Kemenkominfo). Therefore, continuous collaboration and active public participation through reporting mechanisms are crucial to ensure the safety and quality of traditional medicines distributed online.

One of BPOM's concrete efforts includes conducting regular cyber patrols to identify and take action against the distribution of illegal products in digital marketplaces. BPOM recorded that from October 2021 to August 2022, a total of 658,205 pieces of illegal traditional medicines and/or those containing chemical drug substances were confiscated, with an estimated economic value of IDR 27.8 billion. Additionally, 82,995 digital marketplace links offering illegal products were blocked. These cyber patrols represent the implementation of BPOM Regulation Number 8 of 2020, which mandates online supervision of drugs and foods. Nevertheless, due to limitations in human resources, rapid technological advancements, and the open nature of digital platforms, BPOM's supervision tends to be more reactive than preventive.

In addition to its supervisory function, BPOM also undertakes preventive measures through public education. Preventive legal protection is conducted by BPOM and other related agencies to prevent the circulation of traditional medicines containing chemical drug substances, which includes public outreach regarding the consumption of traditional herbal products. BPOM's Communication, Information, and Education (KIE) Program aims to improve consumer literacy on the importance of verifying product legality, understanding product composition, and being cautious of misleading advertisements. Empowering the public to be more critical in selecting health products is essential so that consumer protection does not rely solely on the state but is also supported by collective awareness.

BPOM is obligated to handle events that infringe upon consumer rights, especially those relating to drug and food products. One of the most fundamental rights is the right to accurate information (Kesuma & Atmadja, 2016). Article 14 paragraph (1) of the Health Law stipulates that "the government is responsible for planning, regulating, organizing, fostering, and supervising the implementation of health efforts that are equitable and accessible to the public." Hence, BPOM, as a governmental institution, is also obliged to prevent and reduce the circulation of traditional medicines containing chemical drug substances in digital marketplaces. In this regard, the government, represented by BPOM, is designated under Government Regulation Number 72 of 2009 on the Security of Pharmaceutical Availability as the competent authority in drug supervision. Preventive actions must be taken to eliminate traditional medicines containing CDS that do not meet safety, quality, and efficacy standards in order to protect public health. The following are some roles and actions already taken by BPOM:

- 1. BPOM has enacted regulations on the supervision of drugs and foods distributed online. Article 13 paragraph (2) of BPOM Regulation Number 8 of 2020 stipulates that "Business actors are obligated to ensure that traditional medicines distributed online comply with statutory provisions on safety, efficacy/benefit, and quality requirements." This regulation aims to protect consumers from substandard products.
- 2. BPOM mandates that every traditional medicine product must obtain a marketing authorization. As stipulated in BPOM Regulation No. HK.00.05.41.1384 Chapter I Article

- 1: "Marketing Authorization refers to the form of approval issued by the Head of the Agency for the registration of traditional medicines, standardized herbal medicines (OHT), and phytopharmaceuticals for distribution within the territory of Indonesia." This regulation reflects the view that the issuance of marketing authorization by BPOM prior to public availability is a preventive measure to ensure consumer protection. A valid marketing authorization serves as a guarantee that the product meets safety and efficacy standards.
- 3. To control the distribution of traditional medicines and prevent the circulation of those containing CDS in digital marketplaces, BPOM has conducted regular enforcement actions since 2011 through "Operation Pangea." According to BPOM, "Operation Pangea is an operation regularly conducted since 2011." Based on the findings of Operation Pangea VIII in 2015, 293 websites were identified as involved in the sale of counterfeit or illegal medicines and medical equipment, of which 233 were taken down. The remaining websites were connected to transactions conducted through digital marketplaces and social media platforms such as Facebook and Twitter. Evidence seized during Operation Pangea VIII amounted to IDR 27.6 billion in economic value. Compared to the results of Operation Pangea VII in 2014, this figure reflects a 269% increase (BPOM, 2015).
- 4. BPOM Regulation on the Withdrawal and Destruction of Traditional Medicines That Do Not Meet Requirements stipulates in Article 3 that "Traditional medicines which do not meet quality, efficacy/benefit, and safety standards must be withdrawn from circulation." Prior to the destruction of traditional medicines containing chemical substances, BPOM is required to conduct testing and examination. Upon confirmation of non-compliance with standards, BPOM must withdraw the product from the market, issue warnings to all relevant stakeholders including business actors and distributors, and notify the public about the defective goods. The destruction of such products is intended to serve as a deterrent to those marketing dangerous and chemically adulterated traditional medicines.

Based on the findings of the research on consumer legal protection against traditional medicines containing medicinal chemicals (Bahan Kimia Obat or BKO) distributed through digital marketplaces, it can be concluded that legal protection for consumers has, in fact, been sufficiently regulated under various legislative instruments in Indonesia. These include, inter alia, Law No. 8 of 1999 on Consumer Protection, Law No. 11 of 2008 on Electronic Information and Transactions, as well as specific regulations issued by the National Agency of Drug and Food Control (BPOM), such as BPOM Regulation No. 8 of 2020 and BPOM Regulation No. 14 of 2024. These regulations govern consumers' rights, business actors' obligations, and administrative as well as criminal sanctions for violations.

Nevertheless, in practice, the enforcement of such legal protection remains suboptimal. The circulation of traditional medicines containing medicinal chemicals through digital marketplaces persists due to weak regulatory oversight, a lack of transparency in product information, and low consumer literacy concerning the dangers posed by such chemical substances. Moreover, business actors frequently evade sanctions through various methods, thus continuing to expose consumers to health and economic risks.

While BPOM has undertaken supervisory and enforcement measures—including the blocking and withdrawal of illegal products—these efforts continue to face significant challenges, especially in terms of monitoring the vast and dynamic scope of online distribution. Therefore, to strengthen the implementation of existing regulations, the following measures are necessary:

- 1. Enhancing the effectiveness of BPOM's supervisory mechanisms and cyber patrols;
- 2. Fostering cross-sectoral collaboration between BPOM, the Ministry of Communication and Information Technology (Kominfo), and law enforcement authorities;
- 3. Developing more technical implementing regulations to address digital enforcement, including mechanisms for automatic withdrawal of illegal products, mandatory verification

- of BPOM marketing authorization before products are displayed on digital marketplaces, and stricter sanctions for repeated violations by business actors;
- 4. Promoting legal education and awareness among the public to ensure consumers are more vigilant and capable of choosing lawful and safe products.

Accordingly, consumer legal protection against traditional medicines containing medicinal chemicals in digital marketplaces can be better ensured if all relevant stakeholders perform their respective roles effectively, and are supported by regulations that are adaptive to technological developments and evolving patterns of digital commerce.

CONCLUSION

Legal protection for consumers in relation to traditional medicines containing medicinal chemicals (BKO) is carried out by the Government in cooperation with the National Agency of Drug and Food Control (BPOM) of the Republic of Indonesia through oversight of the manufacturing and distribution processes of traditional medicines, with the aim of safeguarding public health against harmful substances. This protection begins with ensuring compliance with regulatory requirements, including the production process in accordance with BPOM standards, administrative procedures, and control measures up to the point at which the product is circulated in the community. The responsibility borne by producers or business actors manufacturing traditional medicines containing medicinal chemicals is stipulated under Article 19(2) of Law No. 8 of 1999 on Consumer Protection (UUPK), which governs the types of compensation to be provided to consumers. Sanctions applicable to such violations are set forth in Articles 60 to 63 of the UUPK, comprising both administrative and criminal sanctions.

The Government is expected to act more firmly and consistently in addressing the production and distribution of traditional medicines containing medicinal chemicals to prevent their widespread circulation within society. Business actors are likewise expected to exercise due diligence before marketing goods or services intended for consumer use, particularly by providing truthful and accurate information regarding the marketed products. This is necessary to ensure the health and safety of all consumers who consume or use such goods. In addition, the public is encouraged to take a more active and careful role when purchasing traditional medicines available in the market by thoroughly examining the eligibility and safety of such products. In doing so, consumers may better exercise their rights and actively contribute to the advancement of consumer protection in Indonesia.

REFERENCE

Arnawa, Eka Putra and Ni Ketut Supasti Dharmawan. (2018). "Pengawasan Terhadap Perusahaan Yang Mengedarkan Obat-Obatan Impor Tanpa Izin Edar." Jurnal Kertha Semaya 6, No. 1-15.

Az, Nasution. (2024). Hukum Perlindungan Konsumen: Suatu Pengantar, Jakarta: Diadit Media.

Azharie, Ade. (2023). Pemanfaatan Hukum Sebagai Sarana Untuk Mencapai Keadilan Sosial. Lex Aeterna Law Journal, 01(02).

Erman Rajagukguk, (2000). Hukum Perlindungan Konsumen, Bandung: Mandar Maju.

Hamzah, Andi. (2008). Hukum Acara Pidana Indonesia, Sinar Grafika.

Hassanah, H. (2005). Metode Alternatif Penyelesaian Sengketa. Bandung: Universitas Komputer.

Hidayati.,H.,B., Kustriyani., A., (2020). Paracetamol, Migraine And Medication Overuse Headache (MOH), Neurology Department, Medical Faculty, Airlangga University, Dr. Soetomo General Hospital, RESEARCH ARTICLE, Surabaya, Vol.1 No.1, Hlm. 1.

Husni Syawali, (2000), Hukum Perlindungan Konsumen, Bandung: Mandar Maju. Kesuma, Gede Jaya, and Ida Bagus Putra Atmadja. (2016). "Peran Bpom Provinsi Bali Dalam

- Memberikan Perlindungan Terhadap Konsumen Berkaitan Dengan Peredaran Obat Yang Mengandung Zat Berbahaya (Policresulen)." Jurnal Kertha Semaya 4, No.3,1-13.
- Latianingsih, Nining. (2019). Hukum Perlindungan Konsumen dalam Transaksi Elektronik. Jakarta: PNJ Press.
- Mahesti, Indira Putri, and I. Gusti Ngurah Dharma Laksana. (2019). "Perlindungan Hukum Terhadap Pengguna Jasa Titip Online." Kertha Negara: Jurnal Kertha Negara 7, No.10, 1-17.
- Marzuki, Peter Mahmud. Penelitian Hukum, (Surabaya, Kencana, 2011). Perkembangan dan Manfaat Obat Herbal sebagai Fitoterapi. 2022. (n.p.): Tohar Media
- Nichairin., W., Mita., S., R., (2023) Review Artikel Identifikasi Bahan Kimia Obat (BKO) Dalam Sediaan Obat Tradisional, Program Studi Profesi Apoteker, Fakultas Farmasi, Universitas Padjajaran, Farmaka, Bandung, Volume 21 Nomor 2, Hlm. 156.
- Ni Kadek Ayu Padmi Ari Sudewi, dkk. (2020). Perlindungan Hukum Badan Pengawas Obat dan Makanan (BPOM) Terhadap Peredaran Produk Jamu yang Mengandung Bahan Kimia Obat Berbahaya", Jurnal Analogi Hukum, Vol. 02, No. 02.
- Prayoga.,D.,A.,Husodo.,J.,A.,Maharani.,A.,E.,P.,(2023) Perlindungan Hukum Terhadap Hak Warga Negara Dengan Berlakunya Undang-Undang Nomor 23 Tahun 2019 Tentang Pengelolaan Sumber Daya Nasional, Universitas Sebelas Maret, Souvereignty: Jurnal Demokrasi dan Ketahanan Nasional, Surakarta, Volume 2, Nomor 2, Hlm. 4.
- Pradika.,Y.,(2023) Analisis Bahan Kimia Obat Dalam Jamu Tradisional Pegal Linu Kemasan Yang Beredar Di Marketplace, Program Studi Teknologi Laboratorium Medis, Sekolah Tinggi Ilmu Kesehatan Kesetiakawanan Sosial Indonesia, Jurnal MedLab, Jakarta, Indonesia, Vol 2 No.2 Hlm. 19
- Pratiwi, Hening, Nur Amalia, and Warsinah. "Pengaruh Edukasi Apoteker Terhadap Pengetahuan dan Sikap Masyarakat Terkait Teknik Penggunaan Obat." Jurnal Ilmiah Farmasi 5, No.2 (2017): 44-49.
- Priyana.,P.,(2023) Sosialisasi Bahaya Obat Kimia pada Obat Jamu Tradisional dipandang dari Aspek Hukum Kesehatan, Fakultas Hukum, Universitas Singaperbangsa Karawang, Jurnal Pengabdi Masyarakat, Karawang, Indonesia, Vol. 3 No. 1, Hlm. 186-189
- Pidada, Ida Ayu Laksmi, Ida Bagus Putu Sutama, and I Made Dedy Priyanto. (2019). "Peranan Badan Pengawasan Obat Dan Makanan (BPOM) Terkait Dengan Peredaran Obat Tradisional Legal Moktail Di Kpta Denpasar. "Jurnal Kertha Semaya 7, No. 9. 1-13.
- Sari, Ni Komang Ayu Wade and I Wayan Wiryawan. (2018). "Pengaturan Perlindungan Hukum Atas Obat Tradisional Berdasarkan Perspektif Hak Kekayaan Intelektual." Jurnal Kertha Samaya 6, No.2.1-15.
- Sunarjo., (2014) Perlindungan Hukum Pemagang Kartu Kredit Sebagai Nasabh Bank Berdasarkan Perjanjian Merchant, Fakultas Hukum Universitas Merdeka Malang, Malang, Jurnal Cakrwala, Vol.5, No.2, Hlm. 180-196.
- Susanto, Sri Nur Hari. (2019). "Karakter Yuridis Sanksi Hukum Adminitrasi: suatu pendekatan komparasi." Jurnal Adminitrasi Pemerintahan 2, No.1, 126-142.
- Widjaja, G., Yani, A. (2000). Hukum tentang perlindungan konsumen. Indonesia: Gramedia Pustaka Utama.
- Wignjosumarto, P. (2014). Ganti rugi dan sanksi administratif menurut Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen. Jakarta: Tatanusa.