Journal of Social Science Studies Vol. 4, No. 2, July 2024, pages 223 – 236

Legal Protection for Consumers in the Online Purchase of Personal Health Devices

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ARTICLE INFO

Article history:
Received 18 April
Revised 7 May
Accepted 15 May

Key words:
Consumer protection,
Personal health devices,
Online sale,
Distribution permit,
E-commerce,
Dispute Resolution,
Product Liability.

ABSTRACT

This literature study examines the legal framework for consumer protection regarding the online sale of personal health devices in Indonesia. Employing a normative juridical analysis, the research investigates the construction of business actor responsibility, the implementation of information obligations, and the effectiveness of dispute resolution mechanisms. The findings indicate that the legal framework is built on a convergence of three regimes: general consumer protection law, health sector regulations, and electronic transaction laws. While normatively comprehensive, the study identifies significant implementation gaps. The obligation to provide complete and honest information, including the display of distribution permits, is often unfulfilled in digital marketplaces. The complexity of the supply chain obscures clear accountability, and dispute resolution through the Consumer Dispute Settlement Agency (BPSK) or courts faces major procedural and evidentiary hurdles, particularly for proving device inaccuracy or health-related losses. The study concludes that strengthening protection requires specific technical regulations for online health device sales, enhanced verification and monitoring roles for e-commerce platforms, improved capacity of BPSK to handle technical disputes, and increased consumer literacy regarding health product safety in the digital marketplace.

INTRODUCTION

The development of digital technology and e-commerce has revolutionized many aspects of life, including the way people access health products. Personal medical devices, such as glucometers used to monitor blood glucose levels and digital blood pressure monitors used to measure blood pressure, are now increasingly traded through online platforms. This shift in distribution channels provides unprecedented convenience and accessibility, allowing consumers to obtain these devices without having to visit pharmacies or medical device stores physically. In addition, aspects of consumer personal data protection have also become important in online transactions, as highlighted by Aziz et al. (2023) regarding the effectiveness of data protection regulations in Indonesia's fintech sector. However, this transition toward electronic commerce also introduces several complexities and new risks that have not been fully anticipated by the existing regulatory framework. Health products, due to their direct relation to user safety and well-being, occupy a unique and sensitive position within the consumer ecosystem (Keselman et al., 2019). Therefore, an in-depth study is needed regarding the adequacy of legal protection for consumers purchasing personal medical devices online.

Personal medical devices function as diagnostic tools that support independent health monitoring (Guk et al., 2019). The accuracy and reliability of these devices are critical parameters, as incorrect measurement results may lead users to make improper medical decisions. For example, inaccurate glucometer readings may cause diabetes patients to incorrectly adjust their insulin dosage, potentially resulting in fatal consequences. Furthermore, research by Darmawan et al. (2022) indicates that service quality and patient satisfaction related to healthcare facilities are also influenced by the reliability of equipment and the information provided, which is relevant to the context of online medical device usage. In traditional sales channels, pharmacies or authorized distributors typically act as

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filters by ensuring that the products sold meet licensing requirements and standards. In the online environment, however, this filter often weakens or disappears entirely. E-commerce platforms that connect sellers and buyers may not have the capacity or legal obligation to verify the legitimacy and safety of every health product offered by third parties on their marketplaces. This situation creates an environment in which substandard, counterfeit, or unregistered products can circulate easily.

The consumer protection legal framework in Indonesia, primarily regulated by Law Number 8 of 1999, is designed to protect consumers from unfair trade practices and defective products (Izazi et al., 2024). This law establishes obligations for business actors to provide accurate, clear, and honest information, as well as to be responsible for losses caused by defective products. Research by Khayru and Issalillah (2022) emphasizes the importance of delivering clear information so that consumers can make informed decisions, which is particularly relevant to the presentation of online product information. However, the application of these general principles to online medical device transactions faces specific challenges. How are information obligations fulfilled within brief advertisements or product descriptions on e-commerce platforms? Who qualifies as the responsible business actor when the supply chain involves overseas manufacturers, importers, marketplace sellers, and the platform operators themselves? These questions indicate that the Consumer Protection Law needs to be interpreted and possibly supplemented with more specific sectoral regulations in order to remain effective in the digital era.

The relevant sectoral regulation primarily refers to the Ministry of Health Regulation concerning Medical Devices. This regulation establishes licensing requirements, standards, and supervision mechanisms for medical devices distributed in Indonesia. Every medical device, including those sold online, should have obtained a distribution permit from the Ministry of Health. In practice, however, the obligation to display and verify this distribution permit number is often ignored in online sales. Consumers, on the other hand, may not have sufficient awareness or tools to verify the authenticity of the permit number displayed. Meanwhile, Fachrurazi et al. (2022) demonstrate that consumer behavior and awareness of product quality significantly influence purchasing decisions, including for health products, making consumer education an important factor. The disruption brought by e-commerce business models, characterized by speed and high transaction volumes, challenges the effectiveness of traditional regulatory oversight models that are reactive and based on physical inspections. This creates a regulatory gap where products can circulate widely before recall or prohibition measures are implemented.

Therefore, this literature study aims to explore and analyze the intersection and gaps between the general consumer protection legal regime and specific medical device regulations governing the online sale of personal medical devices. The study will examine whether existing provisions are adequate to address the unique risks arising in electronic transactions, such as difficulties in verifying physical products prior to purchase, the potential for seller identity fraud, and challenges in cross-jurisdictional law enforcement. This aligns with findings by Harianto et al. (2024), which emphasize the importance of adapting national health regulations to technological developments and evolving access to services. By mapping the regulatory landscape and identifying protection gaps, this research is expected to provide recommendations for strengthening the legal framework that protects consumers without hindering innovation and the benefits provided by electronic commerce in the health sector.

The legitimacy and accountability of sellers represent the first crucial issue. In online transactions, the identity and credentials of sellers are often difficult for ordinary consumers to verify. A seller can easily create an account on a marketplace using unclear or false identities, offer medical devices at significantly lower prices, and disappear after the transaction is completed if problems arise. E-commerce platforms may only function as intermediary service providers without assuming full responsibility for the authenticity of products sold by third parties. This raises legal questions regarding the determination of the responsible legal subject when a medical device sold online turns out to be counterfeit, defective, or unlicensed. According to Hartika et al. (2023), unclear legal responsibility may open opportunities for document or certification forgery practices, which further increases risks for consumers. Should consumers pursue claims against individual sellers who are difficult to trace, or can the marketplace platform be held accountable for providing a space for the sale of illegal products? This ambiguity in the chain of responsibility leaves consumers in a vulnerable position when seeking dispute resolution.

The fulfillment of information obligations prior to purchase faces substantive challenges within the format of online sales. Consumer Protection Law requires clear and honest information. However, the information presented in online advertisements or product descriptions is often limited, promotional in nature, and potentially misleading. Claims such as "high accuracy" or "certified" may not be accompanied by documentary evidence that consumers can access. Crucial technical information, such as measurement error limits, required calibration, or compatibility with certain medical conditions, is often not provided. In addition, consumers do not have the opportunity to physically examine the product, read the instruction manual, or verify the packaging and distribution permit label before making a purchase. Esse and Mardikaningsih (2022) demonstrate that service quality and the provision of accurate information significantly influence consumer satisfaction, which is relevant in the context of online transactions. These limitations reduce consumers' ability to make truly informed choices, which constitutes a fundamental right within consumer protection law.

Dispute resolution mechanisms and law enforcement also face significant procedural obstacles. If consumers receive defective medical devices or products that do not match their orders, the refund or complaint process may become complicated and time-consuming, particularly if the seller is uncooperative. Although platforms usually offer guarantees or refund policies, these processes are not always smooth for products requiring technical verification, such as medical devices. Beyond platform mechanisms, formal legal avenues through the Consumer Dispute Settlement Agency (BPSK) or the courts face challenges related to evidence and jurisdiction. Proving that a product was defective from the outset may require expert examination, which can be expensive and difficult to access. If the seller is located in another region or even abroad, the legal process becomes even more complex. Lethy et al. (2023) emphasize the importance of legal protection for patients against negligence, which also applies to consumers of online medical devices. As a result, many consumers choose to give up, normalizing the risks as part of online shopping, which ultimately weakens the deterrent effect for dishonest business actors.

The rapid growth of the digital economy and the adoption of online shopping following the pandemic have consolidated e-commerce as a primary distribution channel, including for sensitive product categories such as medical devices. This trend is likely to continue and expand in the future. Therefore, critical academic studies of the regulatory framework governing this trend are urgently needed. In addition, environmental issues and consumer awareness of environmentally friendly products have begun to receive attention, as noted by Fachrurazi et al. (2022), which is also relevant to medical devices and online purchasing behavior. Without proper evaluation and regulatory adjustments, the gap between law and practice will continue to widen, potentially leading to serious public health consequences. This study seeks to provide a systematic preliminary mapping to identify priority areas that require regulatory intervention, whether through stricter enforcement, regulatory refinement, or consumer education.

Broader public health concerns also constitute a major consideration. The circulation of inaccurate or unsafe personal medical devices can have impacts beyond individual losses. Incorrect health data generated by personal monitoring devices may contribute to suboptimal management of chronic diseases at the population level, thereby increasing the burden on healthcare systems. Furthermore, the use of devices that are not sterile or are made from hazardous materials may create risks of infection or poisoning. Hariani et al. (2021) emphasize the importance of legal guarantees for children's rights in education and health, which can be extended to the protection of consumers of online medical devices. From a public health perspective, ensuring the safety and accuracy of medical devices in circulation, regardless of the sales channel, is imperative. This legal study therefore contributes to a broader discussion on the governance of health products in the digital era, which concerns patient safety and the overall quality of healthcare services.

Developments in international regulations and global standards also provide momentum. Many countries are facing similar challenges in overseeing the online sale of health products. Organizations such as the World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF) have begun issuing relevant guidance. This aligns with Khayru and Issalillah (2022) regarding the implementation of telemedicine to equalize access to healthcare services, which is also relevant to the cross-jurisdictional supervision of online health products. Examining the compatibility of Indonesia's legal framework with international developments and best practices can provide valuable insights for policymakers. Furthermore, as global markets become increasingly integrated through e-commerce, coordinated and robust regulatory

approaches are necessary to protect consumers from imported products that do not meet established standards. This study places national legal issues within a broader global conversation on consumers, digitalization, and the safety of health products.

This research aims to analyze the legal framework of consumer protection applicable to online transactions involving the sale of personal medical devices in Indonesia. The first objective is to examine the legal construction of business actors' liability, including manufacturers, importers, sellers, and e-commerce platform operators, based on Law Number 8 of 1999 concerning Consumer Protection and related regulations, in order to identify legal certainty and gaps within the chain of accountability. The second objective is to examine the implementation of information obligations and contractual clarity in the context of online sales, evaluating whether the format and substance of information provided to consumers are adequate to enable them to make well-informed purchasing decisions based on an understanding of product risks and specifications. The third objective is to evaluate the effectiveness of available dispute resolution mechanisms, whether through internal platform systems, the Consumer Dispute Settlement Agency (BPSK), or litigation channels, and to analyze law enforcement challenges against business actors who violate the law. Theoretically, this study is expected to develop an understanding of the application and adaptation of traditional consumer law principles within the e-commerce ecosystem for products that carry high levels of risk. Practically, the results of this research are expected to serve as recommendations for regulators, legal practitioners, and platform operators to strengthen consumer protection and ensure the safe and responsible distribution of medical devices in online marketplace.

RESEARCH METHOD

This research is a normative legal literature study using a qualitative approach that focuses on document analysis. The primary data sources used in this study consist of primary and secondary legal materials. Primary legal materials include relevant Indonesian legislation, namely Law Number 8 of 1999 concerning Consumer Protection, Law Number 11 of 2008 concerning Electronic Information and Transactions and its amendments, as well as sectoral regulations in the field of medical devices such as the Minister of Health Regulation on Medical Device Supervision. Secondary legal materials consist of legal textbooks, national and international scientific journal articles, previous research findings, and official publications from institutions such as the Food and Drug Supervisory Agency (BPOM) and the Ministry of Trade, which discuss legal aspects and the implementation of consumer protection in electronic commerce, particularly for health-related products. Data collection was conducted through systematic searches in legal and academic databases.

The data analysis technique applied in this study is qualitative content analysis using an interpretative approach. This method was selected to extract meaning, identify patterns, and develop a deeper understanding of the legal and academic texts collected. The analytical process follows the framework developed by methodological scholars such as Bryman (2016) and Schreier (2012). The initial stage involves repeated and in-depth reading to obtain a comprehensive understanding of the materials. Subsequently, a coding process is conducted to identify units of meaning related to the research variables, such as "manufacturer liability," "online information obligations," "platform roles," and "access to remedies." These codes are then synthesized into broader thematic categories that align with the research questions. These thematic categories are critically analyzed to identify relationships, contradictions, and gaps within the existing legal framework.

To ensure the validity and reliability of the analysis, this study applies triangulation of data sources and analytical methods. Source triangulation is carried out by comparing and confirming interpretations across various types of documents, such as regulations, academic literature, and policy reports. The analytical process is conducted explicitly and systematically to ensure that it is traceable and auditable. Furthermore, this study employs legal interpretation methods that include grammatical, systematic, and teleological interpretation to understand the intent and purpose of the legal norms being examined. Through this methodological approach, the research seeks to produce a comprehensive and analytical synthesis regarding the strengths and weaknesses of the current legal regime in protecting consumers of online medical devices, while also providing a strong foundation for future policy development recommendations.

RESULT AND DISCUSSION

Legal Construction and Liability of Business Actors in the Online Sale of Medical Devices

The increasing sale of personal medical devices through digital platforms raises legal consequences that require careful examination. The legal construction of business actor liability in the online

sale of personal medical devices in Indonesia is built upon the intersection of three legal regimes: consumer protection law, health law, and electronic transaction law (Nalin et al., 2022). The primary legal foundation that provides basic rights and guarantees for consumers is Law Number 8 of 1999 concerning Consumer Protection (UUPK). This law serves as the general framework establishing principles governing the relationship between business actors and consumers. In the context of medical devices, Article 4 letter (b) of the UUPK guarantees consumers the right to comfort, security, and safety in consuming goods and/or services. This right becomes particularly crucial because it concerns products whose functions are directly related to monitoring bodily conditions. Health products purchased via the internet may carry potential risks because information is often unavailable on foreign products, and many products are shipped without adequate ingredient composition, while the mixing of synthetic drugs has become a serious issue requiring adequate regulatory action (Alwhaibi et al., 2021). Article 4 letter (c) also guarantees the right to accurate, clear, and honest information regarding the condition and guarantees of goods. The fulfillment of this right in online transactions becomes a critical point, considering that consumers cannot conduct a physical inspection prior to purchase. In parallel, Article 7 of the UUPK establishes the obligation of business actors to be responsible for the goods they trade, ensure product quality, and provide adequate information. Violations of these obligations constitute the basis of business actor liability. Overall, these provisions position the UUPK as the initial normative foundation for assessing the legal relationship between sellers and consumers of online medical devices (Mardikaningsih, 2022).

The aspect of civil liability becomes an important component in ensuring compensation for losses experienced by consumers. Civil liability for compensation is explicitly regulated in Article 19 of the UUPK. This article states that business actors are responsible for providing compensation for damage, pollution, and/or consumer losses resulting from the consumption of traded goods. This responsibility is strict liability for losses arising from product defects, as stipulated in the Explanation of Article 19. For consumers of medical devices, this means that if a glucometer systematically provides incorrect readings due to a manufacturing defect, and this error leads the consumer to make an incorrect treatment decision that results in health losses, the manufacturer and/or seller can be directly held accountable. They cannot evade responsibility by arguing that they have conducted standard inspections. The concept of strict liability is particularly relevant for high-risk products such as medical devices (Muhammad et al., 2023). However, its application within a complex online supply chain, where the seller may only be a reseller who has no knowledge of the production process, raises questions about how compensation mechanisms can be practically accessed by consumers. This situation indicates a gap between the strength of legal norms and the challenges of their implementation in the digital commerce environment.

In addition to consumer protection, public safety guarantees are strengthened through sectoral regulations in the health sector. The second legal regime forming the construction of liability is health law, particularly those governing the circulation of medical devices. Law Number 36 of 2009 concerning Health, as amended by Law Number 17 of 2023, provides the legal basis. Article 98 of the Health Law states that medical devices distributed in the market must meet requirements of quality, safety, usefulness, and must possess a distribution permit. Medical device standards may be vertical, covering all safety requirements for specific products, but more often they are horizontal or process-based standards such as quality and risk management (Mkwashi & Brass, 2022). This provision is imperative and applies to all distribution channels, including online sales (Noor et al., 2023). The distribution permit issued by the Ministry of Health serves as administrative evidence that a product has been evaluated and meets established standards. Therefore, the online sale of personal medical devices without displaying or possessing a valid distribution permit constitutes a violation of health law. This violation is not merely an administrative breach but is also directly related to the obligation of business actors under the UUPK to ensure product safety. In other words, the absence of a distribution permit can serve as an initial indicator that the product does not meet safety standards, thereby strengthening the consumer's position when claiming compensation under the UUPK. In this context, health law functions as a preliminary filtering instrument to mitigate the risks posed by medical devices circulating in the digital marketplace.

Operational regulations are further elaborated in implementing rules at the ministerial level. At the technical level, Minister of Health Regulation of the Republic of Indonesia Number 62 of 2017 concerning the Supervision of Medical Devices regulates these matters in detail. This regulation reiterates the obligation to possess a distribution permit and

establishes the classification of medical devices based on their level of risk. Personal medical devices such as blood pressure monitors and glucometers generally fall within the low to medium risk classification, yet they still require a distribution permit. Importantly for online transactions, the regulation also stipulates that every party distributing medical devices, including sellers, must be able to demonstrate proof of a valid distribution permit (Sahidu et al., 2023). In the context of marketplaces, this creates an obligation for sellers to upload or provide distribution permit numbers in the product description. However, the regulation does not yet specifically regulate verification mechanisms by e-commerce platforms, thereby creating reliance on the initiative and good faith of individual sellers, which often becomes a weak point. This regulatory gap opens potential risks for consumers and poses challenges in supervising the circulation of medical devices in online marketplaces.

The legitimacy of online sales transactions is also supported by the legal regime governing electronic activities. The third legal regime is electronic transaction and e-commerce law. Law Number 11 of 2008 concerning Electronic Information and Transactions (ITE Law) provides legal recognition for electronic contracts, which form the legal basis for online sales transactions. Furthermore, Government Regulation Number 80 of 2019 concerning Trading Through Electronic Systems (PP PMSE) provides a more detailed operational framework. This regulation clearly defines the parties involved: Electronic Commerce Business Actors (PMSE sellers), Electronic System Trade Organizers (PPMSE or platforms/marketplaces), and Buyers (Putra & Wibowo, 2023). The regulation places primary responsibility on PMSE business actors, namely the sellers, to ensure that the products offered comply with applicable laws and regulations, including those in the health sector. Sellers of medical devices are therefore legally obliged to ensure that their products possess distribution permits and meet regulatory standards. Meanwhile, PPMSE (platforms) are required to verify the identity and completeness of sellers' business documentation and provide complaint-handling features. This distribution of responsibilities shows that e-commerce law functions primarily as a regulator of transaction governance rather than a guarantor of product substance.

When these three legal regimes operate simultaneously, a pattern of interrelated responsibilities emerges. Their interaction creates a layered construction of liability that may also lead to overlapping obligations. An online seller of medical devices is simultaneously bound by several obligations: the duty to provide information and strict liability for product defects under the Consumer Protection Law; the obligation to possess and display a distribution permit under the Health Law and Minister of Health Regulation No. 62 of 2017; and the obligation to ensure compliance with substantive legal requirements and identity verification under Government Regulation No. 80 of 2019. A violation of one regime may indicate a violation of another. For example, selling medical devices without a distribution permit violates health law and simultaneously constitutes a violation of the obligation to ensure product safety and provide honest information under the Consumer Protection Law. This construction theoretically provides consumers with multiple legal bases to file claims. However, its complexity may confuse ordinary consumers when determining the most effective remedy path. This situation requires adequate legal understanding so that consumer rights can be exercised optimally.

Within the digital ecosystem, e-commerce platforms occupy an increasingly strategic position. The role and responsibility of e-commerce platforms within this construction remain a developing issue. Government Regulation No. 80 of 2019 does not position platforms as guarantors of the quality of products sold by third parties. Platforms are primarily viewed as service providers required to conduct administrative due diligence on sellers (Setiawan et al., 2023). However, in enforcement practice, moral and social expectations often demand that platforms act more proactively. If a platform is deemed negligent in performing basic verification of sellers who later prove to sell illegal products, arguments may arise that the platform contributed to consumer losses by providing a marketplace for unlawful actors, even though primary legal responsibility remains with the seller. Several jurisdictions have begun developing doctrines of limited platform liability for high-risk products, a development that Indonesia's legal framework may need to anticipate. This debate illustrates the dynamic nature of law as it evolves alongside technological and market developments.

Law enforcement against violations in the online sale of medical devices may occur through various channels. Enforcement mechanisms and sanctions are therefore multiple. From the administrative health perspective, the Food and Drug Supervisory Agency (BPOM) may withdraw products from circulation and revoke distribution permits. From the

perspective of electronic commerce regulation, the Ministry of Trade may impose administrative sanctions on platforms or sellers who violate Government Regulation No. 80 of 2019. From the consumer protection perspective, in addition to civil compensation, the Consumer Protection Law also provides criminal sanctions (Article 62) for business actors who intentionally offer, produce, or trade goods that do not meet established standards (Setiawan et al., 2023). These criminal sanctions may also be combined with criminal penalties under the Health Law for distributing medical devices without permits. This layered sanction framework should theoretically create a strong deterrent effect, but its effectiveness largely depends on coordination among supervisory institutions and the ability to monitor activities within the vast digital space. Effective enforcement is therefore highly dependent on consistent supervision and synergy among relevant institutions.

The entire discussion above provides a comprehensive overview of the structure of legal liability that applies in this context. From this analysis, it can be concluded that the legal construction of business actor liability in the online sale of medical devices in Indonesia is normatively quite comprehensive (Issalillah & Aisyah, 2022). It is built upon general principles of consumer protection, reinforced by sectoral licensing requirements in the health sector, and facilitated or regulated through the legal framework governing electronic transactions. The strength of this construction lies in the multiple legal bases for claims and sanctions that are available. Its weakness lies in the potential fragmentation of enforcement, the difficulty consumers face in navigating a complex legal framework, and the absence of optimal regulation specifying the standard of care that e-commerce platforms must fulfill when filtering health products sold on their platforms. In the future, the integration and synchronization of these three regimes into practical technical guidelines that can be implemented by platforms and understood by consumers will be essential for improving the effectiveness of consumer protection. Clarifying this policy direction will be important to ensure sustainable protection for consumers of online medical devices.

Information Obligations and Transparency in Electronic Transactions of Personal Medical Devices

In digital transactions involving health-related products, the aspect of information plays a decisive role in shaping consumer decisions. The fulfillment of information obligations and clarity of agreements in online medical device transactions serves as a primary legal instrument to realize the principles of consumer awareness and freedom of choice, commonly referred to as informed consent. This principle, originally rooted in medical ethics, finds its resonance in consumer protection law through provisions that require business actors to provide accurate, clear, and honest information. In the context of electronic transactions for products with direct health implications, this obligation carries greater weight. Consumers are not merely purchasing a product; they are acquiring a device designed to generate diagnostic data or facilitate self-treatment. Therefore, the information provided must go beyond price specifications and general product descriptions; it must enable consumers to make an initial assessment regarding the safety, accuracy, and suitability of the medical device for their needs (Setiyadi et al., 2023). The absence of physical interaction between seller and buyer means that all written or visual information displayed on the product page functions as a substitute for direct explanation, making its completeness and honesty a determining factor in the validity of consumer consent to purchase. Governments must establish strict legal regulations to protect consumer rights and interests. Consequently, even though consumers may have limited medical knowledge and low price sensitivity, information about medical products must still be fully disclosed in accordance with legal provisions (Chen, 2021). Within this framework, the quality of information becomes the primary prerequisite for ensuring that consumer consent truly arises from adequate understanding.

The obligation to provide such information gains strong legitimacy within the prevailing positive legal norms. The normative foundation of this information obligation is generally regulated in Article 4 letter (c) and Article 7 of Law Number 8 of 1999 concerning Consumer Protection. These provisions require business actors to provide information regarding the condition, guarantees, and quality of goods. For medical devices, information regarding the "condition" must be interpreted broadly to include licensing status (distribution permit), risk classification, and intended medical use. Information concerning "guarantees" includes device warranties, availability of after-sales services, and complaint procedures if the product is defective. More specifically, Government Regulation Number 80 of 2019 concerning Trading Through Electronic Systems strengthens and operationalizes these obligations within the digital environment. This

regulation requires electronic commerce business actors (PMSE sellers) to provide accurate and clear electronic information about the goods offered. For medical devices, this provision can be interpreted as requiring the explicit inclusion of the distribution permit number issued by the Ministry of Health, the name and address of the manufacturer, and instructions for use or a link to such documentation. Without this crucial information, the product description may be considered incomplete and misleading, meaning that consumer consent to purchase could be regarded as defective because it was not based on a complete understanding. Consumer protection norms and electronic commerce regulations therefore reinforce one another in establishing minimum information standards that must be fulfilled.

The evolving digital business model also influences the complexity of legal relationships between business actors and consumers. The emergence of subscription-based transactions for medical devices such as periodic delivery of glucose test strips or medical masks adds another layer of complexity to information obligations. In this model, consumers do not merely agree to a one-time purchase but enter into an ongoing contractual relationship. Accordingly, the principle of informed consent must be applied at two stages: at the initial subscription and throughout the subscription period. At the initial stage, in addition to product information, business actors must transparently disclose all subscription terms. This includes total recurring costs, billing intervals, minimum contract duration (if applicable), accessible cancellation methods, and policies regarding future price increases. Such information must be presented clearly and not hidden within lengthy and complex terms and conditions pages. Consumer consent to subscribe should be express, for example by checking a separate confirmation box indicating that they have read and understood the terms, rather than merely being implied through the standard checkout process. Without transparency from the outset, subscription agreements risk placing consumers in an unequal bargaining position.

Clarity of contractual information is also closely related to restrictions on practices involving unfair contractual clauses. The clarity of subscription agreements is strongly linked to regulations governing standard clauses. Article 18 of the Consumer Protection Law explicitly prohibits standard clauses that disadvantage consumers, eliminate the liability of business actors, or state that consumers are subject to undisclosed rules. In online medical device subscription agreements, problematic clauses often include automatic renewal provisions that consumers may not realize, clauses that restrict the right to cancel subscriptions through overly complicated procedures, or clauses that release sellers from responsibility for the accuracy of medical devices after an extremely short warranty period. Such clauses contradict the law because they deprive consumers of the right to make ongoing informed decisions and shift the entire risk of using potentially defective products onto the consumer. Any clause that limits consumer rights to compensation under the Consumer Protection Law is considered null and void. Regulation of standard clauses thus serves as a corrective instrument to maintain balance in the bargaining positions of the parties.

Beyond contractual aspects, the dimension of usage safety also forms an inseparable part of information obligations. The principle of informed consent in the context of medical devices also requires information regarding limitations and risks of use. A pregnancy test or digital glucometer, for instance, is not a definitive diagnostic tool that replaces healthcare professionals. Business actors should therefore be obligated to include clear warnings stating that the results produced by such devices are indicative and must be confirmed by qualified medical personnel, along with instructions about situations in which users should immediately seek medical assistance. The inclusion of such information is not merely a matter of business prudence but represents fulfillment of the obligation to provide honest information about the "benefits" and "limitations" of the product, consistent with the spirit of medical device regulatory frameworks. Without this information, consumers may over-rely on device results and delay necessary medical treatment, potentially creating serious health risks (Setiyadi et al., 2023). Consequently, information obligations serve as a bridge between consumer law and considerations of patient safety. Emphasizing risks and limitations of use strengthens the preventive function of consumer protection law.

The effectiveness of fulfilling information obligations is also determined by how that information is presented to the public. Informed consumers must understand their rights, including the right to obtain accurate, clear, and honest information regarding goods and/or services provided by businesses (Kumurur & Kansil, 2022). The mechanism of presenting information itself becomes part of legal analysis. Legally valid information must be delivered in a manner that is

accessible and understandable to the average consumer. Placing critical information such as distribution permit numbers or health warnings in very small fonts, faint colors, or at the bottom of a page that can only be accessed after multiple scrolls may be considered a violation of the obligation of clarity.

The principle of prominent disclosure, which has developed in consumer protection practices in several jurisdictions, requires that material information be displayed conspicuously and before consumers make a purchasing decision. In online transactions, this may mean displaying distribution permit information and important warnings at the top of the product description, close to the "Buy" or "Subscribe" button, rather than hiding them within a PDF document that must be downloaded first. The prominent presentation of information thus becomes an important factor in assessing the good faith of business actors.

Consumer consent in online transactions must also be assessed from the perspective of contract law. With regard to electronic consent, the Information and Electronic Transactions Law recognizes its legal validity. However, the validity of electronic consent is not determined merely by the presence of a click, but also by the fulfillment of the substantive requirements of a contract under the Civil Code, including the legal capacity of the parties, a clearly defined object, and a lawful cause. In medical device transactions, a "clearly defined object" requires a highly detailed and accurate product description. If a product description merely states "accurate glucometer" without specifying its measurement error margin according to applicable standards, then the object of the agreement may be considered unclear. A consumer's click under conditions of incomplete information cannot be regarded as a fully conscious declaration of intent and may therefore provide grounds for contract annulment due to mistake (dwaling) regarding the essential characteristics of the goods. This illustrates that the validity of electronic consent is highly dependent on the quality of the information that precedes it (Ustani et al., 2024).

Within the digital ecosystem, e-commerce platforms also play a structural role in the flow of information. The role of e-commerce platforms as Electronic Commerce System Providers also carries a dimension of obligation to facilitate clear information. Government Regulation No. 80 of 2019 requires platforms to provide features that enable business actors to supply complete information. Platforms may be encouraged to create product description templates that require the completion of critical fields for medical device categories, such as "Distribution Permit Number," "Manufacturer Name," and "Medical Device Classification." By initiating standardized and mandatory information structures, platforms can help raise the standard of compliance with information obligations among sellers and make it easier for consumers to locate and compare material information. Without such facilitation, platforms may be considered passive and contributing to an inadequate information environment (Yatno et al., 2023). The facilitative role of platforms thus becomes an important element in strengthening consumer protection in the digital space.

All of these regulations demonstrate a legal orientation that increasingly places consumers as subjects who must be actively protected (Subiakso et al., 2023). Overall, the analysis shows that fulfilling the principle of **informed consent** in online medical device transactions requires a holistic and consumer-oriented information approach. This obligation is not satisfied merely by listing data, but by ensuring that the data are accurate (verification of distribution permits), presented in a clear and easily discoverable manner (prominent disclosure), and cover aspects that are material to health-related decision-making, including benefits, risks, limitations, and warnings. Subscription agreements must be managed with additional transparency, avoiding burdensome standard clauses and ensuring explicit consent mechanisms for every significant change. Only with high standards of information and meaningful consent procedures can the click of "buy" or "agree" in online medical device transactions truly represent the free and conscious will of consumers, which lies at the core of dignified legal protection (Taufik et al., 2022). With such an approach, consumer protection does not stop at legal formalities but reaches the substance of justice and safety.

Effectiveness of Dispute Resolution and Law Enforcement for Consumers

In the practice of digital consumer protection, the existence of dispute resolution mechanisms is an important indicator of how effectively the law functions. The effectiveness of dispute resolution and law enforcement mechanisms for consumers of online medical devices must be analyzed through the lenses of accessibility, speed, and the ability to provide adequate remedies. The legal framework provides several pathways that consumers may theoretically pursue, starting from internal platform

resolution, then proceeding to the Consumer Dispute Settlement Agency (BPSK), and ultimately to the courts. However, the effectiveness of each pathway varies significantly when dealing with the unique characteristics of medical device disputes, which often involve doubts about product accuracy, safety, and legality rather than merely physical defects or delivery delays.

The first and earliest pathway is the complaint and refund mechanism provided by e-commerce platforms. This mechanism is mandated by Government Regulation No. 80 of 2019 concerning Trade Through Electronic Systems, which requires Electronic Commerce System Providers to offer complaint-handling features. In practice, this process is relatively quick and informal, making it suitable for cases where goods are not delivered, arrive physically damaged, or clearly differ from their description. Nevertheless, its effectiveness decreases significantly when disputes are technical and require expert verification. Internal platform mechanisms function more as an initial screening process rather than as a comprehensive dispute resolution mechanism (Yatno et al., 2023).

The technical nature of medical devices reveals the limitations of overly simplistic dispute resolution approaches. In medical device disputes, consumer claims often involve allegations that a product produces inaccurate results, fails to function properly after several uses, or is suspected to be counterfeit. When defective products have been sold to customers, complaints become one way to address the issue and ensure that similar problems do not occur in the future (Ziarkiewicz & Górna, 2020). However, platforms generally lack the technical capacity or authority to conduct in-depth investigations into such claims. The resolutions offered are usually limited to refunds if the product is returned under certain conditions or the provision of replacement coupons. Such mechanisms fail to address immaterial or health-related losses that consumers may have suffered due to the use of defective or inaccurate products. Furthermore, platform policies that tend to favor sellers, or situations in which sellers become uncooperative or disappear after a transaction, can cause this internal mechanism to reach a dead end. Thus, although it serves as an important first point of contact, the effectiveness of platform-based mechanisms is limited and not designed to handle the complexity of disputes involving high-risk products. These limitations indicate that medical device disputes require dispute resolution forums with more adequate evidentiary capacity.

At the level of state institutions, the Consumer Dispute Settlement Agency (BPSK) is designed as a more balanced dispute resolution forum. If resolution at the platform level fails, consumers may submit disputes to BPSK. This institution was established under the Consumer Protection Law and is authorized to resolve disputes quickly, simply, and at low cost. The process may take the form of mediation, conciliation, or arbitration. The advantage of BPSK lies in its position as a forum that is more formal than platform mechanisms but less complex than court proceedings. BPSK may order compensation or certain actions from business actors. However, the effectiveness of BPSK in handling disputes involving online medical devices faces several serious challenges. First is the issue of jurisdiction and the presence of the parties. BPSK offices are located in provincial capitals and regency or municipal areas. Consumers must file applications with the BPSK located in their place of residence or the domicile of the business actor. If an online seller is domiciled in another city or even abroad, the process of summoning the parties and enforcing decisions becomes extremely difficult. This jurisdictional barrier significantly limits the reach of the legal protection promised by BPSK (Subiakso et al., 2023).

In addition to jurisdictional issues, evidentiary aspects present substantive challenges in medical device disputes. Second is the challenge of proof. In disputes regarding the accuracy of medical devices, consumers must demonstrate that the device is defective or does not meet applicable standards. Such proof may require expert testimony or laboratory testing from competent institutions, such as the Indonesian Institute of Sciences or laboratories designated by the Food and Drug Supervisory Agency (BPOM). The costs and time required to obtain such evidence are often disproportionate to the economic value of the medical device purchased, thereby becoming a significant barrier for consumers. The Consumer Protection Law recognizes strict liability, meaning that in cases of product defects consumers do not need to prove the fault of the business actor. However, consumers must still prove the causal relationship between the product defect and the loss suffered. Demonstrating that an inaccurate glucometer reading directly caused a specific health loss is a complex and costly task (Ustani et al., 2024). This situation places consumers in a disproportionate position when facing business actors.

The effectiveness of dispute resolution is also greatly determined by the ability to enforce

decisions. Third, this relates to the execution of decisions. Decisions issued by the Consumer Dispute Settlement Agency (BPSK) that have obtained permanent legal force are final and binding and may be enforced through the courts. However, if the business actor is a small-scale online seller with no clearly identifiable assets or who deliberately avoids responsibility, the execution of the decision becomes impractical. Sellers can easily close their online stores and reopen new accounts under different identities. The ineffectiveness of execution weakens the deterrent effect of the BPSK process and causes consumers to lose confidence in formal legal channels. As a result, many consumers choose to give up after their complaints through the platform fail, considering their losses as an unavoidable risk of online shopping (Yatno et al., 2023). Without effective enforcement mechanisms, legal decisions lose their protective power.

Another available alternative is dispute resolution through the general courts. The third pathway is litigation in the general court system. This pathway has the advantage of broader authority and decisions that can be enforced more strongly. Consumers may file claims based on breach of contract, unlawful acts (tort), or specifically under the Consumer Protection Law. However, its effectiveness is very low for medical device disputes with relatively small economic value. The lengthy judicial process, court fees, and attorney costs make this option economically irrational for most individual consumers. In addition, courts face similar technical challenges regarding proof of specific medical-related damages (Setiyadi et al., 2023). Litigation may only be appropriate for cases involving massive losses or fatalities, where the value of the claim becomes significant. Under such conditions, litigation becomes a last resort that is rarely chosen by individual consumers.

Beyond civil disputes, the state also provides other law enforcement instruments that are repressive in nature. Outside civil dispute resolution mechanisms, administrative and criminal enforcement pathways are available to complement consumer protection. Consumers may report the circulation of medical devices without distribution permits or counterfeit products to the Food and Drug Supervisory Agency (BPOM) and the Ministry of Health. These institutions have the authority to withdraw products from circulation, revoke permits, and impose administrative sanctions. From a public health perspective, this pathway is important for preventing the widespread distribution of dangerous products. However, from the perspective of individual consumers, this administrative route rarely produces direct remedies in the form of compensation. The process focuses on sanctioning business actors rather than restoring the losses suffered by victims (Subiakso et al., 2023). Nevertheless, successful enforcement actions by BPOM may provide leverage for consumers in civil proceedings or before BPSK, as administrative findings or decisions may be used as evidence. In this sense, administrative enforcement functions more as a protector of public interest than as a mechanism for individual compensation.

The separation of complaint-handling pathways also creates issues of institutional coordination. Coordination among institutions is often a determining factor in effectiveness but remains weak in practice. Consumer reports submitted to platforms, BPSK, BPOM, and the Ministry of Trade operate through separate parallel channels. There is no centralized system that integrates complaints and ensures comprehensive follow-up actions. A consumer who reports a seller to BPOM for selling unlicensed medical devices may not realize that they can also file a compensation claim before BPSK. Similarly, a BPSK decision finding a product defective does not automatically trigger an investigation by BPOM into the entire stock of similar products sold by the same seller. This lack of synergy results in fragmented and inefficient law enforcement efforts (Ustani et al., 2024). Such fragmentation weakens the overall impact of legal protection that should ideally function in a comprehensive manner.

All of these findings illustrate the current condition of consumer protection in the digital sphere. The conclusion of this analysis is that the effectiveness of dispute resolution mechanisms and law enforcement for consumers of online medical devices is currently at a low to moderate level. The normative framework exists and is relatively comprehensive, providing various options ranging from informal to formal mechanisms. However, implementation barriers that are procedural, economic, and technical in nature remain substantial. Access to justice is hindered by the high cost of obtaining evidence, the difficulty of locating business actors who can easily disappear, and the lengthy processes involved. To improve effectiveness, policy innovations are needed, such as the establishment of a fast-track mechanism within BPSK for disputes involving high-risk products, partnerships between BPSK and testing laboratories to facilitate affordable evidentiary processes, and increased obligations for platforms to act as limited guarantors when sellers

cannot be located. Without such structural breakthroughs, legal protection for consumers of online medical devices will remain largely declarative on paper rather than a practical reality that ensures substantive justice (Taufik et al., 2022). Therefore, strengthening dispute resolution mechanisms becomes an important agenda in the reform of digital consumer protection.

CONCLUSION

This literature review concludes that the legal framework for consumer protection in online transactions of personal medical devices in Indonesia has been constructed through the convergence of three main legal regimes: general consumer protection law, health law, and electronic transaction law. Normatively, this structure is relatively comprehensive. Consumer protection law provides the fundamental basis for rights and obligations, including strict liability for defective products and the obligation to provide honest information. The health law regime, through health legislation and ministerial regulations, adds imperative requirements such as distribution permits and quality standards that serve as objective parameters for product safety. Meanwhile, the electronic transaction regime establishes legal certainty for electronic transactions and contracts and sets specific obligations for sellers and digital platforms.

However, the implementation of this multidimensional legal framework faces significant challenges. Its effectiveness in providing real protection for consumers is constrained by the gap between normative provisions and practical realities, particularly in relation to the difficulty of verifying products within the digital environment, the complexity of proving damages especially those related to health impacts and the weak coordination and enforcement within existing dispute resolution mechanisms.

The findings of this study carry important implications for various stakeholders. For regulators and policymakers, the primary implication is the need to develop implementing regulations or technical guidelines that specifically govern the online sale of medical devices. Such guidelines should bridge the three legal regimes by regulating, for example, mandatory information standards that must be displayed on product pages, mechanisms for verifying distribution permits that can be integrated into e-commerce platforms, and fast-track dispute resolution procedures for high-risk products within consumer dispute settlement bodies. For e-commerce platform operators, the research implies the need to strengthen due diligence standards. Platforms can no longer remain passive as mere intermediaries; they should develop systems that require and verify the uploading of distribution permit documents by medical device sellers and provide complaint and remedy mechanisms that go beyond simple refund policies. For consumers and the general public, the key implication is the need to improve legal and health literacy. Consumers should be educated to always check and record distribution permit numbers, understand the limitations of self-use medical devices, and know the legal steps available when problems arise, starting from complaints to the platform and proceeding to formal dispute resolution mechanisms.

Based on these conclusions and implications, several strategic recommendations are proposed. First, the Ministry of Trade, together with the Ministry of Health and the national drug and food regulatory authority, should promptly issue a joint regulation or ministerial regulation specifically governing the sale of medical devices through electronic systems. This regulation should include explicit provisions on the obligation of platforms to verify and display distribution permit information, standards for electronic contracts that protect consumers, and an integrated reporting mechanism linking platforms, consumer dispute settlement bodies, and health sector regulators. Second, institutional strengthening and capacity development of consumer dispute settlement bodies are necessary. These institutions should be encouraged to establish panels of mediators or arbitrators with basic technical knowledge of health products and to collaborate with accredited testing laboratories to facilitate affordable evidentiary processes for consumers. Third, large-scale and continuous public education campaigns should be conducted by the government in collaboration with e-commerce associations and consumer organizations. These campaigns should focus on safe practices for purchasing medical devices online, the importance of verifying distribution permits, and the available complaint procedures. Finally, for future research, it is recommended to conduct empirical studies to map actual dispute patterns and barriers faced by consumers, as well as comparative analyses of regulatory frameworks in other jurisdictions that have implemented limited marketplace liability schemes for certain categories of products.

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