

Construction of Consumer Rights and Business Liability for Losses Resulting from Defective or Dangerous Medicines and Medical Devices in Indonesian Positive Law

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ABSTRACT

This study examines the construction of consumer rights and the basis for business actor liability regarding damages arising from defective or hazardous drugs and medical devices within the framework of Indonesian positive law. The primary focus is directed toward two issues: how consumer rights to security, comfort, safety, and information are constructed as standards of protection, and how the basis for compensation claims is formulated through a synthesis of consumer protection regimes, civil law, and health regimes. The analysis is conducted using a normative juridical approach, positioning norms as the primary object, particularly provisions concerning consumer rights, prohibitions on the circulation of goods that do not meet standards, labeling and warning obligations, recovery mechanisms, and causal relationships in evidentiary processes. The results of the study indicate that consumer rights bind the entire supply and distribution chain, allowing accountability to be drawn from producers, importers, and distributors, to service providers distributing the products, according to the relevant point of failure. The classification of design defects, manufacturing defects, and instruction defects serves as a juridical mapping tool to determine standards of care and appropriate forms of compensation. Regarding evidentiary aspects, a layered burden of proof model is considered most adequate: consumers prove the loss and exposure, while business actors demonstrate compliance, quality control, and corrective responses through technical documentation as well as administrative evidence of licensing and oversight. Damage assessment is directed toward adequate recovery through compensation, replacement, and health-related expense financing, including fairly assessed immaterial damages. Multiple forum options are available, through the Consumer Dispute Settlement Agency (BPSK), general courts, class action lawsuits, or alternative dispute resolution, supported by administrative enforcement for corrective actions such as product recalls. This study underscores the importance of harmonizing safety norms, information honesty, and the effectiveness of recovery procedures so that consumer protection for health products is measurable and executable.

INTRODUCTION

The development of health products, including drugs and medical devices, expands public expectations for recovery, improved quality of life, and disease prevention. Concurrently, the relationship between consumers or patients and producers, importers, distributors, health service facilities, and healthcare professionals has become increasingly dense with transactions, information, and promises of quality and safety.

At this point, compensation claims are not merely technical civil issues, but part of risk governance in health services and health product supply chains. Patient satisfaction with the quality of health services at public health centers shows that aspects of service quality and health product safety significantly influence the level of public trust (Darmawan et al., 2022). When defective or hazardous products cause injury, disability, or death, what emerges is not just a clinical issue, but

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a juridical question regarding the basis of business actor liability, standards of proof, measurement of damages, and dispute resolution channels accessible to consumers. Experience from various jurisdictions shows that injuries due to errors and failures in safety systems can occur at many points, from design, production, and labeling, to use in health facilities, making legal responsibility often difficult to place on a single actor (Institute of Medicine, 2000).

In the health sector, the nature of risk is unique. Consumers often face information asymmetry, dependence on professional personnel, and limited ability to assess the safety of products used on the human body. Challenges and changes in national health development from the perspectives of law, service access, and the management of infectious diseases require serious attention from all parties (Harianto et al., 2024). In drugs, risks can arise from contamination, discrepancies in active ingredient levels, unanticipated interactions, or misleading labeling. In medical devices, risks can stem from design defects, material failure, software errors, or inadequate instructions for use. This problem becomes more acute because health products are often used in urgent situations and on vulnerable groups, so delays in product recalls, limited reporting of adverse events, or the distribution of products without adequate monitoring have the potential to increase the number of victims. From a juridical standpoint, these circumstances demand clarity regarding appropriate standards of care, the scope of the duty to provide information, and the causal relationship between product defects and the losses suffered by consumers. The patient safety agenda provides policy language to identify sources of risk, but compensation settlement requires firm normative construction so that the restoration of consumer rights does not end merely with social sympathy (Institute of Medicine, 2004).

The Indonesian legal system regulates health, drug distribution, and medical devices through various norms that govern licensing, post-market surveillance, reporting, and administrative and criminal sanctions. Nevertheless, when losses occur to consumers, the questions that arise often revolve around the basis of the lawsuit and the burden of proof. Consumers can sue through civil paths, pursue consumer protection mechanisms, or utilize administrative oversight and enforcement mechanisms. However, practice shows that access to technical evidence, the accuracy of identifying

responsible actors, and the differences in standards of proof between forums can influence claim outcomes. Losses related to health products often have complex technical traces, such as specific production batches, distribution chains, storage, or usage that deviates from instructions. Therefore, the discussion of the juridical aspects of consumers must carefully assess how norms regarding quality, safety, information, and responsibility are read together within a layered legal architecture, including the relationship between patient rights, health facility obligations, and the responsibility of business actors in the supply chain.

Beyond normative aspects, there is a dimension of human experience that influences compensation claims. Consumers who suffer injuries due to health products often face emotional burdens, worries about long-term health conditions, uncertainty regarding treatment costs, and the pressure of dealing with institutions that possess greater resources. The regulation of medical product advertising and the protection of patients as consumers of health services also need attention within a broader legal framework (Sahidu et al., 2023). The power imbalance between consumers and business actors, or between patients and health facilities, can make the complaint process feel overwhelming, especially if risk communication is poor, medical documentation is difficult to access, or families do not understand the options for legal recourse. At this stage, law functions as a device for recognizing losses and a tool for recovery, but its effectiveness depends on the clarity of norms and the consistency of their application. Therefore, normative research is necessary to formulate a map of obligations, the basis of liability, and evidentiary instruments that can reduce positional inequality without sacrificing the accuracy of scientific assessment regarding the cause of the loss.

Ultimately, the issue of defective or hazardous health products places the intersection of consumer protection and health governance at the forefront. Health products differ from ordinary consumer goods because they touch upon bodily safety and human dignity. When failure occurs, liability cannot be read simply as an exchange of goods and money; there are layers of professional standards, production standards, surveillance standards, and information standards. This research is directed toward mapping the juridical construction of compensation claims for

consumers for losses due to defective or hazardous drugs or medical devices, and explaining how existing norms provide pathways for recovery that are appropriate, accessible, and commensurate with the degree of loss. With such mapping, the discourse on health law acquires a more structured basis of argument to assess the adequacy of norms, the suitability of mechanisms, and the critical points that cause the right to compensation to remain merely a normative promise.

Compensation claims due to defective or hazardous health products are faced with complex issues of attribution of liability. In the supply chain, there is the manufacturer that designs and produces, the importer or distributor that transports and distributes, the pharmacy or health facility that stores and dispenses, and the healthcare professional who selects and uses the product. Hospital legal liability for service disruptions due to information system failures demonstrates the complexity of accountability in the health sector (Yatno et al., 2023). When injury occurs, consumers often struggle to determine the legally relevant point of failure. With drugs, for example, injury can stem from production defects, inadequate contraindication information, or a combination of drugs that trigger serious reactions. With medical devices, failure can arise from unsafe design, component damage, or unclear instructions. The law requires a framework to link defects, negligence, or breaches of information obligations to the resulting consequences, but proving causation often demands scientific knowledge and data that are beyond the reach of consumers. In patient safety literature, many injuries are born from a series of system errors, making the search for a single actor often inadequate to describe the cause of the incident (Institute of Medicine, 2000).

The next problem is the inequality of information and access to evidence. Technical documents regarding batches, quality test results, adverse event reports, distribution records, and post-market surveillance data are usually controlled by business actors or health service institutions. Consumers seeking compensation must transform their experience of loss into a juridical narrative that can be tested, while the primary elements of proof reside with the opposing party. Consequently, claims can be stalled at the initial stage, either due to the unavailability of evidence, limited funds to present experts, or difficulty in understanding technical terms. In the realm of patient safety, research

emphasizes the importance of reporting and learning systems so that incident evidence is collected and can be used for correction. However, from the perspective of litigation or dispute resolution, reporting systems can cause tension between the need for learning and the need for proof. The remaining question is how the law provides a path for consumers to obtain reasonable access to decisive information without undermining the goal of service quality improvement (Institute of Medicine, 2004).

Another issue is the assessment of damages and appropriate forms of recovery. Losses due to defective or hazardous health products often exceed direct medical costs. There are lost earnings, long-term rehabilitation needs, disability, family care burdens, psychological suffering, and decreased quality of life. Factors such as advanced age and stress determinants also need to be considered in public health policy (Issalillah & Aisyah, 2022). In the civil system, the measure of damages requires justifiable parameters, while consumer protection mechanisms have variations in forms of recovery and procedures. At the same time, dispute resolution in the health sector demands attention to aspects of safety and the prevention of recurrence, so financial recovery needs to be understood alongside corrective obligations such as product recalls, safety warnings, or changes to instructions for use. Literature in health ethics and law emphasizes that fair recovery requires recognition of the injury as well as respect for individual autonomy, but the design of recovery mechanisms often lags behind the complexity of the actual losses suffered by victims (Kuhse & Singer, 2007).

The circulation of drugs and medical devices is becoming increasingly diverse, including high-tech products and those entering through cross-regional distribution networks. This diversification expands the potential for a variety of defects, ranging from labeling errors to software failures. Simultaneously, consumers are becoming more active in seeking information and are increasingly emboldened to demand recovery when losses occur. The law needs to provide a clear map regarding claim paths, standards of proof, and the relationship between administrative product oversight mechanisms and the civil rights of consumers. A structured normative study helps to avoid the oversimplification of issues into mere financial disputes, as in the health sector, what is at stake

is bodily safety and trust in the service system.

This examination is also important because unclear dispute resolution can result in two equally detrimental states: consumers find it difficult to obtain appropriate recovery, while business actors and service providers face uncertainty regarding the standards of liability applied. The quality of service and patient satisfaction with public health services show that complete and integrated information strongly determines the level of public trust (Khayru & Issalillah, 2022). Such uncertainty can encourage defensive behavior, reduce information openness, and weaken efforts to learn from adverse events. By testing the juridical basis of compensation claims for defective or hazardous health products, this research can provide a more organized foundation for assessing whether existing norms have provided protection that is aligned with the risk characteristics of health products.

This research aims to formulate a normative mapping of consumer rights, the basis of liability, and the relevant juridical consequences in compensation claims resulting from defective or hazardous drugs and medical devices, as well as to formulate an analytical framework regarding proof, assessment of damages, and the choice of dispute resolution forums that are aligned with the risk characteristics of health products. The theoretical contribution is directed toward sharpening the construction of liability and causation in health product disputes, while the practical contribution is directed toward providing a reference framework for policymakers, law enforcement officials, and healthcare practitioners when assessing appropriate recovery for consumers.

RESEARCH METHOD

This research employs a normative juridical method with a qualitative literature study design. Primary legal materials include legislation governing consumer protection, health, pharmacy, and medical devices, including norms that encompass the obligations of business actors, information duties, safety standards, oversight, and sanctions. Secondary legal materials include academic books and journal articles discussing product liability, consumer protection, patient safety, and legal research methodology. The processing of materials is conducted through critical reading to assess the consistency of norms, the relationships between norms, and the construction of liability that may arise when

defective or hazardous health products cause loss. This framework positions legal texts as the primary object of analysis, while academic literature is utilized to strengthen the rationality of interpretation and clarify technical terms that frequently appear in health product disputes. To maintain the rigor of reasoning, the researcher implements a systematic source organization step and strict citation recording as recommended in literature review reporting guidelines.

The literature search strategy is conducted through academic databases and official publisher portals using keywords tailored to the two research questions. Inclusion criteria cover reputable scholarly works relevant to the issues of product liability and recovery mechanisms, as well as those containing accountable methodological explanations. Exclusion criteria cover popular writings without peer review, sources without clear publisher identities, and sources that do not provide adequate bibliographic metadata for verification. Synthesis is performed through thematic synthesis, which involves grouping literature findings into conceptual themes such as the basis of liability, information obligations, causation, the burden of proof, and the mapping of dispute resolution forums. This thematic approach follows thematic analysis practices that emphasize coding consistency, theme tracking, and the traceability of analytical decisions (Braun & Clarke, 2006).

RESULT AND DISCUSSION

The Concept of Consumer Rights and Liability for Defective or Hazardous Health Products

Aspects of security, comfort, and safety are rights that must be granted to consumers by health product business actors, as they are fundamental principles of human rights protection. Consumer rights to security, comfort, and safety in the use of drugs and medical devices stem from the basic guarantee of the right to health and a sense of security recognized in the 1945 Constitution of the Republic of Indonesia, particularly the recognition of every person's right to live in physical and spiritual prosperity and to obtain healthcare services. Beyond these basic regulations, legal guarantees for patients are crucial to ensure they feel calm and protected from any form of negligence that might be committed by healthcare personnel (Lethy et al., 2023). This constitutional guarantee directs that the circulation of health products is not merely an economic activity, but one that entails an obligation to protect humans as

legal subjects. Within this framework, consumer rights function as a standard for assessing whether a product is fit to be offered, handed over, promoted, or used. Because drugs and medical devices touch the human body, safety and security parameters become mandatory measures, not options that can be negotiated through advertisements or unilateral contract clauses. The construction of these rights requires operational devices, and in Indonesia, the primary device is Law Number 8 of 1999 concerning Consumer Protection. Through regulations regarding the right to truthful, clear, and honest information, the right to choose, the right to be heard, the right to advocacy, and the right to compensation, damages, and/or replacement, these norms affirm that consumers harmed by defective or hazardous health products have a protected position and legitimate pathways for recovery. Such protection demands information transparency, traceability, and the accountability of business actors throughout the entire distribution chain. Therefore, for legal purposes, any violation by a business actor that harms a consumer gives the harmed consumer the right to demand accountability and compensation for the losses experienced (Rumiarta & Indradewi, 2020). Thus, consumer rights regarding health products are positioned as fundamental rights that demand active legal protection.

The normative foundation of consumer protection is strengthened through the regulation of the relationship between consumers and business actors. Law Number 8 of 1999 concerning Consumer Protection provides a firm normative foundation regarding who the consumers are, who the business actors are, and how the legal relationship between them is assessed when losses arise. A crucial factor in observing the extent to which legal protection is applied in health affairs is the fulfillment of patients' rights, including their right to information (Pratyanti et al., 2023). In the matter of drugs and medical devices, the right to truthful, clear, and honest information must be understood as the business actor's obligation to convey facts relevant to safety, such as composition, legitimate benefits, directions for use, usage limitations, contraindications, side effects, warnings, storage, and expiration dates. The right to choose means consumers have the right to determine products based on reasonable information, so any promotional practice that conceals risks or exaggerates benefits can undermine the process of choosing freely and

safely. The right to compensation, damages, and/or replacement positions recovery as a legal consequence when a product causes loss. The right to advocacy and dispute resolution provides channels so that consumers are not forced to negotiate directly with business actors who hold a resource advantage. This construction confirms that public safety is a material standard, while transparency and accountability are procedural standards that must be present in production, distribution, advertising, after-sales service, and product recall actions when defects or hazards are found. Thus, consumer rights regarding health products rely on a combination of substantive and procedural rights that reinforce one another, forming a protective framework that is both repressive and preventive.

In addition to rights, the consumer protection system places strict obligations on business actors. On the obligation side, Law Number 8 of 1999 concerning Consumer Protection prohibits the circulation of goods that do not meet or are not in accordance with required standards, do not comply with labeling provisions, do not include expiration dates, do not include instructions for use, or do not contain appropriate warnings and risk information. These prohibitions are significant in drug and medical device cases because some hazards are latent, appearing only after use or accumulation. With these prohibitions, positive law establishes a standard of care that must be met before a product enters the market, including the obligation for feasibility testing, quality control, and change management governance. If a business actor continues to trade products that do not meet standards or provides misleading information, then that act has violated the prohibitory norms designed to prevent injury. From the perspective of compensation claims, these prohibitions help consumers build arguments that the loss is not merely a medical misfortune, but the result of a breach of legal obligations. At this point, accountability does not stop at the manufacturer. The importer, distributor, or party placing the product on the market can have their responsibility traced according to their role in the distribution chain. The obligation to provide after-sales service, complaint channels, and corrective actions, including recalls, becomes part of the compliance standard assessed when consumers demand recovery. These normative prohibitions function as both prevention instruments and a basis for accountability.

Civil liability serves as the primary means of

recovering consumer losses due to problematic health products. The construction of liability for losses resulting from defective or hazardous drugs and medical devices meets the general civil regime in the Civil Code. In a sales relationship, the obligations of the seller and the party handing over the goods concern the fulfillment of performance, the conformity of goods with the agreement, and the guarantee that the goods can be used for the promised purpose. If a health product is non-conforming, for example, a medical device does not function safely according to specifications or a drug does not meet the required dosage, the claim can be structured as breach of contract because the performance was not fulfilled or was fulfilled defectively. The mental health of a patient, especially during pregnancy, is also heavily influenced by the social-psychological conditions of their environment (Issalillah, 2021). Patient protection is also closely related to issues of compliance with medical ethics. Cases of patient neglect, the use of medicines not in accordance with procedures, or medical actions that do not meet ethical standards are clear evidence that patient protection must be the main focus in every healthcare service (Prayuti et al., 2024). Beyond contractual relationships, the tort opens space for accountability when there is an act or omission that violates the general duty of care, causing loss. In health product disputes, the tort path is relevant when the consumer does not have a direct contractual relationship with the manufacturer, or when losses arise from misleading promotion, inadequate labeling, or distribution that ignores storage standards. From the perspective of evidence, the civil construction requires a causal link between the defect and the loss. However, positive law also recognizes that the violation of safety and information obligations can be a strong indicator of negligence; thus, circulation records, label completeness, distribution logs, and compliance with recall procedures become important materials for testing a business actor's standard of care. The quality of drinking water consumed must also be ensured to be safe so that public health is maintained (Issalillah et al., 2022). This framework positions consumer protection as an integral part of the civil liability regime.

Health regulations strengthen safety standards relevant to consumer claims. In the health sector, the general framework is reinforced by Law Number 17 of 2023 concerning Health, which places the protection of patients and the public as the goal of health administration, including

regulations regarding pharmaceutical preparations and medical devices. This law provides a basis that drugs and medical devices must meet requirements of quality, safety, and efficacy, and their circulation must be supervised. In compensation claims, health laws serve as a normative reference to assess whether a product and its distribution governance have met mandatory requirements. When loss occurs, consumers can use health norms to affirm that the risks that emerged are not reasonable risks of therapy, but risks stemming from violations of quality, safety, or governance requirements. Health laws also reinforce the importance of correct information and education in healthcare services, so liability can flow from the business actor to the service provider when products are used without proper information, or when health facilities ignore storage procedures that affect drug quality. Thus, consumer claims regarding defective products lie at the intersection of two pillars: consumer protection as a transaction regime and health law as a public safety regime. Combining both helps assess the appropriate standard of conduct for business actors and parties distributing products to the public. This sectoral reinforcement ensures that public safety becomes the primary benchmark for legal assessment.

Implementing regulations provide concrete metrics for assessing negligence. Further detailed implementation of Law Number 17 of 2023 concerning Health is directed through Government Regulation Number 28 of 2024. Additionally, royalty costs in the health business must be considered so as not to burden public access to such services (Putra & Wibowo, 2023). This government regulation operationalizes many obligations related to the administration of health, including the strengthening of quality governance, safety, licensing, oversight, and corrective actions against products that have the potential to cause harm. In the construction of liability, the existence of implementing regulations is important because it provides a more concrete measure of what is considered appropriate and what is considered negligent. The obligations of oversight, traceability, recording, and response to findings of defects or hazards become measures of the accountability of business actors in a system that demands the prevention of injury. In recall cases, for example, implementing regulations allow for the assessment of response speed, notification mechanisms, the scope of the recall, and the recovery steps offered to consumers. If a business

actor delays or conceals information, such a delay can be assessed as negligence that exacerbates losses. Government regulations also provide a basis for administrative actions by the government to stop circulation, order repairs, or impose sanctions. For consumers, these administrative actions can become legal facts that strengthen the argument that the product is indeed problematic, thus providing support for compensation claims through the state's assessment of product risk. Thus, administrative norms contribute directly to civil evidence.

A risk-based licensing approach further reinforces the duty of care for business actors. Within the layer of business licensing governance, Government Regulation Number 5 of 2021 concerning the Organization of Risk-Based Business Licensing provides a framework that production, distribution, and circulation activities of drugs and medical devices are subject to licensing requirements adjusted to the level of risk. This risk-based construction has legal consequences for consumer claims, as business actors are considered to know that the health product sector has high risks, so standards of compliance and quality control must be stricter. If a business actor carries out activities without proper permits, violates commitments to meet standards, or ignores obligations inherent to the risk classification, such a violation can be viewed as a breach of administrative norms that intersects with the civil duty to exercise care. Risk-based licensing also reinforces the importance of internal control systems, supplier audits, and process documentation that can be traced when harmful incidents occur. In losses due to medical device malfunctions, for example, traceability of serial numbers, distribution records, and maintenance evidence are important to map the point of failure. In losses due to drugs, batch traceability and storage chains become central elements. These cases not only harm consumers directly but also raise public doubt toward health services and the quality of medicines sold (Wirasto et al., 2024). Therefore, the protection of patients' personal data in financial or fintech systems must also be regulated very strictly (Aziz et al., 2023). When business actors fail to provide a trail of compliance, that failure can lead to a negative assessment of the standard of care, while making it difficult to defend that the loss occurred outside of reasonable control. This construction positions administrative compliance as an indicator of care.

The role of the pharmaceutical profession also

determines product safety at the service stage. In the field of pharmacy and drug distribution, health company leaders also hold great responsibility if there is a failure in the business they run (Saputra et al., 2024). Government Regulation Number 51 of 2009 concerning Pharmaceutical Work stipulates that activities related to drugs must be carried out by authorized personnel and in accordance with professional standards, including procurement, storage, distribution, and submission to patients. For the construction of consumer rights, this regulation shows that health product safety is not detached from professional governance. Even drugs that meet production standards can become dangerous if stored incorrectly, handed over without proper information, or if errors occur in preparation. We are also reminded to be ethical in disseminating information about accident victims on social media so as not to violate the law (Muhammad et al., 2023). In compensation claims, this regulation helps distinguish the responsibility of business actors who produce or distribute from the responsibility of parties who carry out the submission and provision of information. When losses arise due to expired drugs that are still in circulation, or due to the submission of drugs without explaining relevant contraindications, the error may lie in a breach of pharmaceutical work governance, not merely a production defect. The Consumer Protection Law does not regulate the definition of defective products in either the general provisions chapter or the definition of various terms; the law only stipulates that business actors provide compensation for damage, pollution, and/or consumer losses resulting from consuming the goods and/or services produced, as emphasized in Article 19 (Utomo, 2019). Thus, business actors in the distribution chain, including pharmaceutical service facilities, can be held accountable according to their roles. This regulation also reinforces the need for documentation, recording, and compliance with procedures as part of the duty of care, so that consumers have a normative basis to demand that a proper system should have prevented dangerous drugs from reaching the hands of the user. The use of telemedicine must also be continuously supervised so that patient safety remains the priority (Sasmita et al., 2023). Thus, it can be understood that responsibility does not necessarily stop at production alone.

Classifying product defects will help map the sources of failure. Grouping defects into design defects, manufacturing defects, and instruction

defects aids normative analysis on the basis of liability. Even nurses working in hospitals need clear legal protection when carrying out their medical duties (Yulius et al., 2023). A design defect refers to a situation where a product by design carries dangers disproportionate to the promised benefits, so that even units produced according to specifications still contain unreasonable risks. A manufacturing defect refers to process deviations that make some units deviate from safe design, such as contamination, dosage inaccuracies, or component damage to medical devices in specific batches. Patients' rights must remain protected through a combination of legal rules and medical ethics applicable in Indonesia (Herisasono et al., 2023). An instruction defect refers to a failure to provide adequate instructions, warnings, and information so that the user is unable to avoid preventable risks. Law Number 8 of 1999 concerning Consumer Protection provides a firm foundation for instruction defects through obligations regarding labels, usage instructions, and risk warnings. Legal protection is also provided for the community participating in immunization programs if unexpected side effects occur (Riyanto et al., 2023). Law Number 17 of 2023 concerning Health, along with its implementing regulations, affirms quality, safety, and oversight requirements as measures for design and manufacturing defects. In compensation claims, this classification helps map which party is closest to the source of failure, whether it be the manufacturer, importer, distributor, service facility, or a combination of parties. Damages that can be claimed include treatment costs, lost income, subsequent damage, as well as immaterial losses assessed by the court, provided that the causal relationship and breach of legal obligations can be proven appropriately. Finally, the use of electronic medical records must be managed properly in accordance with applicable health laws (Kholis et al., 2023). This classification can facilitate the determination of which subjects should be held responsible.

The basis of liability can be constructed through either a fault-based approach or a risk-based approach. The accountability of business actors within the framework of positive law can arise through either basis, depending on the norms applied, the nature of the defect, and the facts of circulation. On the fault basis, consumers emphasize negligence in testing, quality control, distribution, storage, labeling, or response to

reports of loss. The Civil Code provides tools to assess negligence through standards of propriety and the duty of care, as well as providing consequences for compensation when negligence causes loss. On the risk basis, the mindset focuses on the fact that business actors who introduce risky products into the market bear the burden of responsibility to guarantee user safety and provide recovery when products cause injury, especially if the business actor violates the prohibition on trading goods that do not meet safety standards as formulated in Law Number 8 of 1999 concerning Consumer Protection. Although debates regarding the boundaries may arise in practice, the normative framework provides direction that consumers should not be burdened with all technical risks that are under the control of the business actor. Therefore, quality documentation, registration evidence, proof of standard compliance, and records of corrective actions become important means to assess whether the business actor has fulfilled the appropriate standard of care or has instead ignored it. This approach confirms the balance between consumer protection and business certainty.

Efforts to enforce consumer rights are carried out through a combination of private and public law. The enforcement of consumer rights combines private and public channels. On the private path, consumers can file civil lawsuits based on breach of contract or tort in accordance with the Civil Code, and utilize dispute resolution mechanisms provided by Law Number 8 of 1999 concerning Consumer Protection, including through the Consumer Dispute Settlement Agency. This mechanism is relevant when consumers need a faster and simpler forum to obtain replacement, repair, or other forms of compensation. On the public path, the state, through its health oversight authority, can take administrative action based on Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024, for example, stopping circulation, mandatory corrective actions, and administrative sanctions. In cases involving hazardous products, administrative actions and findings of violations can be material for consumers to demonstrate that the risk causing the loss has been institutionally recognized. Regarding evidence, consumers will be aided by documents such as distribution permits or licensing evidence, distribution records, laboratory test results, marketing communication evidence, product labels, purchase records, and medical records. However, the burden of proof in

practice is often heavy for consumers, so a normative construction that emphasizes the obligation of business actors to provide information and a trail of compliance becomes crucial to maintaining access to justice. The combination of these mechanisms broadens recovery opportunities for consumers.

Furthermore, contractual and non-contractual relationships have equal relevance in health products. In the contractual realm, business actors can be held accountable for the non-fulfillment of quality guarantees and usage conformity that is reasonably expected of the goods traded. When drugs or medical devices are marketed with specific claims regarding benefits, safety, or performance, those claims can be read as representations that create legitimate expectations. If the product deviates, then breach of contract can be proven through the non-conformity of goods with the specifications or the informed intended use. In the non-contractual realm, tort provides space to sue parties with whom there is no direct contractual relationship, including manufacturers that supply to various channels. In health products, limitation of liability clauses often included in marketing documents or purchase receipts need to be tested against the mandatory nature of safety obligations. Law Number 8 of 1999 concerning Consumer Protection places safety and the right to information as mandatory standards, so clauses that remove liability for injuries due to product defects potentially conflict with consumer protection principles. At the same time, Law Number 17 of 2023 concerning Health asserts that health products must meet quality and safety requirements, so limitations of liability that obscure this obligation can be assessed as not in line with legal obligations. Such construction directs that consumer recovery should not be diminished by unilateral contract devices that weaken public safety standards. Through this approach, it is emphasized that consumer safety cannot be negotiated through contracts.

The legal system forms a unified entity of consumer protection for health products as a whole. Systemically, Indonesia's positive legal framework combines substantive norms in the form of safety, quality, and information honesty with procedural norms in the form of licensing, oversight, recording, reporting, and product recalls. The 1945 Constitution of the Republic of Indonesia provides the direction for the basic values of human protection. Law Number 8 of 1999 concerning Consumer Protection provides a set of

rights, obligations, prohibitions, and recovery mechanisms. The Civil Code provides a basis for compensation through breach of contract and tort. Law Number 17 of 2023 concerning Health and Government Regulation Number 28 of 2024 provide health sector measures regarding quality, safety, and distribution governance. Government Regulation Number 5 of 2021 regulates risk-based licensing which reinforces the appropriate level of care. Government Regulation Number 51 of 2009 regulates pharmaceutical work which affects drug safety at the service stage. From this combination, the construction of consumer rights and the basis of business actor liability becomes clear: business actors are obligated to ensure products are safe according to their purpose, information is not misleading, and corrective responses are carried out when defects or hazards are found; when those obligations are violated and loss occurs, consumers have the right to demand compensation through mechanisms provided by law. The entire framework shows that consumer protection is an integrated and layered legal obligation.

Evidence, Assessment of Damages and Choice of Forum in Claims for Compensation for Medical Products

Evidence in consumer disputes regarding health products must be positioned as a structured and rational normative process. Proof in cases involving defective or hazardous drugs and medical devices must be built as a series of normative arguments stemming from consumer rights to safety, information, and compensation under Law Number 8 of 1999 concerning Consumer Protection. From the perspective of civil procedure, these rights require evidence linking three core elements: the existence of actual loss, the occurrence of exposure or use of a specific product, and a reasonable causal relationship between the product defect or breach of legal duty and the loss incurred. This framework prevents claims from turning into mere accusations based on suspicion while maintaining space for consumers to obtain recovery when technical evidence is within the control of the business actor. In the initial stage, consumers typically prove product identity through packaging, distribution permit numbers, batch or serial numbers, purchase receipts, handover records, and medical records showing the time and manner of use. Subsequently, the proof shifts to the quality of information and product quality, such as label compliance,

instructions for use, warnings, expiration dates, and the validity of promotional claims. The Consumer Protection Law establishes truthful, clear, and honest information as a core obligation; thus, the absence of safety-relevant information can be treated as a strong indicator of a violation of consumer protection norms, which strengthens the basis for compensation claims. This framework ensures that consumer claims are tested proportionally without closing off access to recovery.

The choice of the basis of the lawsuit determines the direction and techniques of proof that will be used by the consumer. In the civil realm, the basis of a lawsuit usually moves along two different but complementary paths: breach of contract and tort. The Civil Code provides normative references via Article 1243 for claims of loss due to breach of contract, and Article 1365 for claims due to tort. In the breach of contract path, the focus of proof places the engagement and the content of the performance as the starting point for example, when a specific guarantee regarding quality, function, safety, or usage conformity is not met. In the tort path, the focus shifts to the violation of a general duty of care or the breach of prohibitory norms in the Consumer Protection Law that cause loss. This distinction impacts the strategy of proof: breach of contract requires proving the existence of a promised or agreed-upon standard, whereas tort requires proving an act or omission that violates the law, the existence of loss, a causal relationship, and fault. For health products, both paths are often used alternatively or cumulatively to ensure the consumer has a sufficient foundation, especially when there is no direct contractual relationship with the manufacturer, or when losses arise from misleading promotional information. By choosing the correct construction, the evidentiary process becomes more focused, and the judge's assessment of causality and the standard of care becomes more organized. Through such construction, the judge will obtain a clear foothold in assessing liability.

Civil procedural law provides evidentiary instruments relevant to technical disputes. Civil procedural law provides the format and limitations regarding what can be accepted as evidence and how judges weigh it. The *HIR/RBg* (Indonesian civil procedure regulations) recognize evidence such as documents, witness testimony, presumptions, admissions, and oaths, while judicial practice places expert testimony as an essential instrument for disputes requiring

specialized knowledge. Consumer dispute resolution requests must accurately and completely contain information in accordance with Article 16 of the Decree of the Minister of Industry and Trade Number 350/MPP/Kep/12/2001, including the identity of the consumer, the identity of the business actor, the goods/services being complained about, proof of acquisition, the location and time of acquisition, witnesses who observed the acquisition, and photos of the goods and the implementation process (Nisantika & Maharani, 2021). In drug and medical device cases, documentary evidence often becomes the backbone, covering packaging and labels, brochures, advertisements, purchase records, medical records, laboratory results, complaint correspondence, and after-sales service documents. Witnesses can strengthen the chronology of use, storage methods, or changes in health conditions after using the product. Experts are needed to assess whether the symptoms and medical losses are aligned with plausible mechanisms, whether there is an instruction defect in the manual, or whether laboratory findings indicate a quality deviation. Studies on the falsification of health certificates from the perspective of criminal law and professional ethics show that patient protection requires firm law enforcement against various forms of violation (Hartika et al., 2023). Presumptions in the *HIR/RBg* allow judges to infer the existence of certain facts from a series of consistent circumstances, for example, many reports of similar losses regarding a specific batch circulating in the same period. This structure of proof demands traceability, so each document must be linked to the product identity and the chronology of use. If documentary evidence is complete but the causal relationship is still debated, expert testimony becomes the determinant to bridge medical facts with liability norms. A systematic arrangement of evidence will strengthen the legitimacy of the resulting verdict.

The distribution of the burden of proof must be arranged fairly between the consumer and the business actor. A fair framework of proof in health product disputes needs to place the burden of proof in layers. Consumers generally prove the loss and product exposure, while business actors demonstrate their standard of care through safety testing, standard compliance, quality control systems, and corrective responses when loss reports emerge. The legal rights of patients,

including those who are less fortunate, must be guaranteed protection in every healthcare service provided (Noor et al., 2023). Law Number 8 of 1999 concerning Consumer Protection demands truthful, clear, and honest information regarding matters relevant to safety, so information violations can strengthen the suspicion of fault. Normatively, when labels cover important contraindications, obscure side effects, or contain claims exceeding the permit, it is difficult for a business actor to claim that the consumer made a decision consciously regarding a reasonably known risk. This situation serves as an incentive for business actors to disclose data within their control, such as batch records, test documents, distribution procedures, complaint records, and logs of corrective actions. If a business actor is uncooperative, the judge can assess such non-cooperation as a circumstance that weakens the business actor's defense, provided the assessment remains within the limits of civil evidentiary procedures. With such a design, the consumer's position is not trapped by an inability to access technical data, while the business actor is still given space to prove that they have worked according to appropriate standards. This approach prevents structural inequality without eliminating the right to defense for business actors.

Administrative oversight acts as a source of objective legal facts. Administrative oversight in the health sector provides highly valuable sources of evidence for civil cases, as it shows an institutional assessment of product and business actor compliance. Law Number 17 of 2023 concerning Health confirms the regulation of quality, safety, licensing, and oversight of pharmaceutical preparations and medical devices. Government Regulation Number 28 of 2024, as an implementing regulation, operationalizes these obligations through more technical requirements, including registration, compliance with standards, reporting, and recalls when safety issues arise. In practice, post-market surveillance data, sampling and testing results, safety alerts, and recall records coordinated with the authorities become administrative evidence that can be used to assess whether a product is indeed in a problematic status, or whether the business actor was negligent in responding to danger signals. Administrative evidence does not automatically replace the proof of individual causality, but it can strengthen the chain of evidence that a product defect is real and relevant to the loss suffered by the consumer. If the distribution permit is problematic, labels are non-

compliant, or there is an order to stop circulation, such facts add weight to the argument that the business actor has violated legal obligations directly related to safety. Thus, administrative and civil paths can run in parallel, and the information generated from public oversight helps ensure that consumer recovery has a justifiable basis. The interconnection between these two paths will strengthen the consistency of law enforcement.

Assessing causality requires the integration of legal reasoning and health sciences. Determining the causal relationship in cases involving drugs and medical devices requires measured medico-legal reasoning, as health injuries often have multiple potential causes. Normatively, causality testing can be structured through a series of indicators: the temporal relationship between exposure and the onset of symptoms, a reasonable biological or mechanical explanation, consistency of clinical findings, and efforts to rule out reasonable alternative causes. The legal rights of persons with disabilities in accessing healthcare services demonstrate that clear and accessible information is a vital element in an inclusive health system (Subiakso et al., 2023). This framework aligns with the needs of civil evidentiary proceedings, which require a judge's conviction based on the balance of probabilities rather than criminal standards. In medical device cases, reasoning may include the evaluation of design and performance, the conformity of usage with instructions, and whether the failure occurred during foreseeable normal use. In drug cases, reasoning may include dosage, interactions, comorbid conditions, and the adequacy of contraindication information and warnings on the label. Violations of prohibitory norms in Law Number 8 of 1999 concerning Consumer Protection, such as misleading labels or the absence of critical information, can make causality more readily accepted if the resulting loss is a type of injury that is common and foreseeable from such a lack of information. With this approach, causality is not understood as an absolute certainty which is difficult to achieve in health sciences but as a relationship that can be reasonably accepted for the purposes of civil liability. This probabilistic approach maintains the balance between legal certainty and medical reality.

The calculation of damages serves as the bridge between the violation and recovery. The assessment of damages in health product cases must rely on the recovery formulas provided by consumer protection law and general civil law.

Article 19 of Law Number 8 of 1999 concerning Consumer Protection affirms the obligation of business actors to provide compensation, damages, and/or replacement for losses arising from the consumption of goods or services. Normatively, the form of recovery may include refunds, product replacement, healthcare, compensation, or other equivalent forms, depending on the nature of the loss. The Civil Code (provides the foundation for material losses, such as medical costs, costs of follow-up procedures, rehabilitation costs, lost income, caregiver costs, and expenses related to supporting equipment. Non-material losses can be assessed when an injury causes suffering, reasonable anxiety, or a tangible decline in the quality of life. To ensure the assessment of damages does not become speculation, consumers need to compile billing evidence, clinical records, therapy plans, expert testimony regarding prognosis, as well as evidence of income before and after the incident. In long-term losses, projections of future costs can be justified as long as they are built using reasonable and transparent methods. Thus, appropriate recovery is directed toward approaching the state before the loss occurred, to the extent that it is achievable through compensation instruments. Accordingly, damages are directed toward real and measurable recovery.

However, the temporal dimension of recovery also requires proportional interpretation. Article 19 of the Consumer Protection Law (*UUPK*) also contains a time dimension that is often understood as an impetus for prompt recovery. The formulation of the obligation to provide damages within a certain period after a transaction is frequently debated in health cases requiring clinical verification, because losses may arise after a delay or require follow-up examinations to confirm the cause. Social support plays an important role in reducing anxiety, for instance, in pregnant women before giving birth, which shows that psychological aspects also need to be considered in health recovery (Issalillah & Khayru, 2022). Normatively, this tension can be unraveled by distinguishing between recovery obligations that are immediate and simple such as replacing a proven defective product and recovery that requires medical assessment, such as losses due to serious side effects. In the latter category, a reasonable delay for verification can be justified; however, the business actor remains obligated to act quickly in data collection, risk communication, and providing temporary solutions that protect the

consumer, such as suspending use and providing healthcare referrals. The assessment of "appropriate" recovery demands calculation transparency and good faith, so that consumers understand the basis of the nominal amount offered and can test its adequacy. If a business actor refuses to provide recovery without a justifiable reason, it can strengthen the consumer's decision to pursue the adjudication path. Consumer protection norms position safety as the standard; therefore, clauses limiting liability that eliminate damages for health injuries should be strictly tested, especially if those clauses reduce rights that are mandatorily protected by the *UUPK*. This interpretation maintains the balance between certainty and substantive justice.

Furthermore, consumer disputes in health product issues often involve collective interests. Health product cases frequently have a mass dimension, such as many consumers experiencing similar losses from a specific batch of drugs or a specific medical device. Under these circumstances, the individual lawsuit mechanism can result in high evidentiary costs and inconsistent outcomes. Supreme Court Regulation Number 1 of 2002 concerning the Procedures for Class Action Lawsuits provides a path for collective action when there is sufficient commonality of facts or legal grounds, allowing for the common proof of causality regarding product defects and violations of obligations to be conducted more efficiently. A class action does not eliminate the need to prove loss for each individual member, but it helps consolidate evidence regarding the defect, negligence, and the breached compliance standards. This aligns with government efforts in providing legal guarantees for children's rights to ensure they receive proper healthcare services from an early age (Hariani et al., 2021). Law Number 8 of 1999 concerning Consumer Protection recognizes the existence of LPKSM (Consumer Protection Agency) as a reinforcement of the consumer's position, including in filing lawsuits for the benefit of consumers. In collective recovery, forms of remedy may include replacement programs, refunds, financing for health examinations, or structured compensation according to the level of injury. Aggregate assessment can utilize distribution data and documented adverse event data, provided that the calculation method is explained and testable. Additionally, the use of technologies such as artificial intelligence is expected to help make this data collection process more accurate in the future

(Khayru, 2022). Normatively, the collective path affirms that appropriate recovery is not measured solely by the nominal amount, but by the ability of legal mechanisms to reach victims in large numbers in a manner that is fair, consistent, and executable. Class actions expand access to recovery without sacrificing the accuracy of evidence.

One part of the recovery strategy is the selection of a dispute resolution forum. The choice of forum must be understood as a strategic decision that remains aligned with the goal of equitable recovery. Law Number 8 of 1999 concerning Consumer Protection provides the Consumer Dispute Settlement Agency, which is authorized to handle disputes through mediation, conciliation, or arbitration. Patient satisfaction based on service quality and the location of health facilities indicates that accessibility and service quality strongly determine the level of public trust (Mardikaningsih, 2022). Normatively, the BPSK is suitable for cases requiring rapid recovery, relatively simple proof, and a value of loss that can still be handled through summary proceedings. However, health product cases can be highly technical, so it must be evaluated whether the BPSK is capable of adequately facilitating expert examination and technical evidence evaluation. Compared to systems formed by several countries that adopt common law systems, where dispute resolution cases are handled by specialized courts called Small Claims Courts, the construction of the BPSK in Indonesia is quite vague. Although it uses the terminology of arbitration, the BPSK does not have an arbitration mechanism because, in practice, it examines consumer disputes and operates formally as a court (Matnuh, 2021). Such legal uncertainty needs to be corrected so that the general public feels that their rights are truly protected by the state (Nalin et al., 2022). If a consumer seeks a more comprehensive ruling, such as for long-term medical losses or complex causality issues, general courts are often chosen because they provide a broader space for examination and rulings that are both declaratory and condemnatory. At the same time, the choice of forum does not close the path for filing complaints with health authorities or drug supervisors, because administrative steps such as safety alerts or product recalls are aimed at protecting the public and can run in parallel with civil disputes. Within a normative framework, consumers should choose a forum based on evidentiary needs, the need for speed of recovery, the need for enforceability, and the need to encourage

measured corrective actions from business actors. With the right selection of a forum, it is hoped that there will no longer be cases of fraud or falsification of health data that harm the industry and the public (Setiawan et al., 2023). Considerations regarding the selection of the appropriate forum will ultimately determine the effectiveness of the dispute resolution outcome.

Alternative dispute resolution offers flexibility, yet its selection still requires caution. Resolution through litigation institutions is often considered less efficient in terms of time, cost, and energy, which is why dispute resolution through non-litigation institutions is often chosen by the public (Agyarossa & Apriani, 2023). This choice is also influenced by how the public views the reputation of a health institution based on news that goes viral on social media (Taufik et al., 2022). Alternative dispute resolution outside of court finds its basis in Law Number 30 of 1999 concerning Arbitration and Alternative Dispute Resolution. Arbitration provides a private process with binding rulings, but it requires the existence of an arbitration agreement or a consensus between the parties after a dispute arises. In consumer transactions, the will behind an arbitration clause needs to be tested, as consent born from a standard form can raise questions regarding voluntariness. For service providers, it is important to measure service quality regularly so that customer satisfaction is maintained and disputes can be avoided (Essa & Mardikaningsih, 2022). For health product cases, arbitration might be attractive to business actors who desire time certainty, but for consumers, it can be burdensome if costs are high or access to experts is limited. Outside of arbitration, other alternative forms such as facilitated negotiation can result in recovery in the form of compensation programs, follow-up care, or device replacement, provided that the terms are transparent and do not negate consumer rights. The norms in the Consumer Protection Law (UUPK) regarding the right to dispute resolution provide a foundation that the choice of Alternative Dispute Resolution (APS) must expand access, not lock consumers into procedures that weaken their position. Therefore, the normative understanding emphasizes two things: first, peace agreements must be based on sufficient information regarding risks and losses; second, the peace outcome must be executable and contain a commensurate measure of recovery. Many consumers today are also starting to turn to health products that are environmentally friendly because they are

increasingly concerned about their long-term impact (Fachrurazi et al., 2022). Thus, APS becomes a functional recovery instrument, not merely a tool to delay accountability. Alternative dispute resolution will function optimally if placed as an equal means of recovery.

Mediation conducted in court requires good faith and openness. The litigation process in civil courts is also influenced by the obligation of mediation as a procedural prerequisite. Supreme Court Regulation (*Perma*) Number 1 of 2016 concerning Mediation Procedures in Court encourages parties to seek resolution at the initial stage, before the full evidentiary examination takes place. In this process, the honesty of a doctor in filling out medical records is very helpful in finding a fair middle ground for patients (Mubarak et al., 2023). In health product disputes, mediation can be beneficial if the business actor is willing to open technical data, offer health examinations, and provide a clear compensation scheme. However, mediation can fail if the business actor blocks access to information, or if the consumer requires a more formal expert assessment to test causality. This is because a diagnosis error made by a doctor can be fatal and must be accounted for legally (Setiyadi et al., 2023). Normatively, mediators and judges need to ensure that mediation does not sacrifice consumer safety, for example, by encouraging the cessation of circulation or product recalls as part of the agreement if there is an indication of widespread danger. *Perma* 1/2016 provides space for creative solutions but still requires voluntariness and good faith. The resulting agreement can be strengthened into a deed of settlement, thus possessing executorial power. In cases involving medical losses, the formulation of an ideal agreement should contain: medical verification mechanisms, payment schedules, the party responsible for health service costs, the form of product replacement, and follow-up clauses if health conditions worsen. With such a design, mediation performs a tangible and measurable recovery function and reduces the burden of long trials without lowering the standard of justice for consumers. Mediation is ideally conducted to accelerate recovery without blurring accountability.

Civil evidentiary construction is enriched, among other things, through administrative compliance. Compliance within the health sector regarding licensing and operational standards provides relevant supplementary evidence, especially when the point of contention is whether

a business actor has implemented appropriate risk control measures. Government Regulation Number 5 of 2021 concerning the Organization of Risk-Based Business Licensing provides a structure wherein high-risk activities demand stricter requirements and oversight. The equitable distribution of health services through telemedicine demonstrates the importance of innovation in reaching the public across various regions (Khayru & Issalillah, 2022). In disputes involving health products, failure to meet licensing obligations or commitments to standard compliance can be read as an indicator that the business actor has disregarded administrative obligations that are closely linked to safety. Although a civil lawsuit still requires proof of loss and causality, evidence of licensing violations strengthens arguments regarding fault or negligence. At the drug service stage, Government Regulation Number 51 of 2009 concerning Pharmaceutical Work is relevant for assessing whether the delivery, storage, and provision of information have been carried out by authorized parties and in accordance with procedures. For disputes involving drugs damaged due to improper storage or delivery, this norm helps map appropriate standards as well as the types of evidence that should be requested, such as temperature records, stock records, expiration logs, and counseling notes. Thus, the evidentiary process does not stop at "this product is harmful," but moves toward "the legally mandated procedures were not followed," allowing appropriate recovery to be supported by more robust normative reasoning. This approach links procedural failure to legal liability.

The entire evidentiary mechanism is aimed at achieving appropriate recovery. Ultimately, appropriate recovery for consumers in cases involving defective or hazardous health products requires a balance between the thoroughness of proof and the affordability of the process. Law Number 8 of 1999 concerning Consumer Protection affirms the right to compensation and dispute resolution, so evidentiary procedures must provide a realistic path for victims who lack access to technical data. The legal implications and challenges of using medical records as evidence in the Indonesian judicial system also show that procedural and evidentiary aspects play a key role in health law enforcement (Ustani et al., 2024). The Civil Code provides a basis for damages through breach of contract and tort, so causality and fault continue to be tested

reasonably. The *HIR/RBg* (civil procedure regulations) provide a framework for evidence that maintains the order of examination, while *Perma* 1 of 2016 and the Alternative Dispute Resolution (APS) mechanism in Law Number 30 of 1999 open faster solution paths when parties act in good faith. For mass losses, *Perma* 1 of 2002 and the strengthening of LPKSM (Consumer Protection Agency) in the Consumer Protection Law provide more efficient collective means. In the health sector, Law Number 17 of 2023 along with Government Regulation Number 28 of 2024, coupled with the risk-based licensing framework in Government Regulation Number 5 of 2021, enrich the standards for assessing compliance and provide relevant sources of administrative evidence. When all these instruments are utilized appropriately, recovery does not stop at a monetary figure, but encompasses commensurate replacement, necessary treatment, and the guarantee that the same risk will not be repeated for other consumers. This framework affirms that the evidentiary process is a means of achieving justice, not a barrier in the recovery process. Consumer protection and the legal liability of business actors in the sale of medicines above the highest retail price in pharmacies demonstrate that price oversight and compliance with regulations are crucial in protecting consumers (Baktiasih & Mardikaningsih, 2024).

CONCLUSION

The construction of consumer rights regarding drugs and medical devices in Indonesian positive law rests on the guarantees of safety, security, comfort, and the right to information that is truthful, clear, and honest. This framework positions the consumer as a subject entitled to make rational and safe decisions regarding the use of health products, and entitled to compensation when products cause harm. These rights simultaneously establish a standard of obligation for business actors to ensure the fulfillment of quality, safety, efficacy, labeling compliance, and risk management throughout the entire supply chain, including corrective obligations when defects or hazards are identified.

The basis of business actor liability in compensation claims for losses due to defective or hazardous health products can be constructed through both consumer protection channels and general civil law channels. Consumer protection channels emphasize the prohibition on trading goods that do not meet standards, do not contain

critical information, or are misleading, making the violation of safety and information obligations the primary foundation of liability. General civil law channels strengthen claims through breach of contract and tort, primarily to examine negligence, the breach of the duty of care, and the causal relationship between the defect and the loss. The classification of design defects, manufacturing defects, and instruction defects helps map the point of failure, determine the responsible parties, and assess the level of accountability based on legally mandated standards of compliance.

Evidence, damage assessment, and the choice of dispute resolution forum must normatively be directed toward guaranteeing a recovery that is appropriate, measurable, and executable. Evidence demands the interconnection between product exposure, defects or breaches of legal obligations, and the losses suffered, utilizing documentary evidence, witness testimony, expert statements, as well as administrative evidence from the health sector's licensing and oversight systems. The assessment of damages includes both material and immaterial losses, calculated reasonably with the support of medical documentation and financial records. The choice of forum is diverse, ranging from quick out-of-court resolution mechanisms to civil litigation for complex disputes, including class action lawsuits for mass losses, while maintaining parallel space for administrative actions that protect the public.

A recommendation for business actors is to build a tested compliance system through quality control, batch or serial number traceability, safety test documentation, label and instruction clarity, and responsive complaint-handling mechanisms. In the event of a defect or hazard, business actors need to execute corrective actions that are prompt, transparent, and verifiable, including public notification and clear remediation programs, so that consumer recovery does not depend solely on lengthy dispute processes.

A recommendation for regulators and oversight authorities is to strengthen public information transparency regarding safety alerts and product recalls, improve the integration of post-market surveillance data, and ensure that compliance documentation and corrective actions can be accessed proportionately for the purposes of civil proof. Strengthening reporting standards and the handling of adverse events will improve the quality of prevention and strengthen the legitimacy of recovery when disputes occur.

A recommendation for dispute resolution

institutions and the judiciary is to encourage examination practices that balance the need for technical precision with access to justice, particularly through the use of credible experts, the structuring of proportional evidence, and rigorous testing against practices of misleading information and non-compliance with safety standards. In mass cases, the use of class action mechanisms and collective recovery schemes should be encouraged so that recovery is more consistent, efficient, and reaches victims more broadly.

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