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Legal Liability of Business Actors for Prohibited Products: A Juridical Review of the Consumer Protection Law and the Health Law

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Abstract

Ideally, business actors are obligated to ensure that all products they manufacture and distribute meet quality, safety, and legality standards in accordance with the provisions of the Consumer Protection Law (UUPK) and the Health Law. In reality, there are still business actors who distribute prohibited products that endanger consumer health and safety, such as the circulation of pharmaceutical preparations contaminated with hazardous substances. This study aims to analyze the forms and legal basis of business actors' liability for prohibited products within the framework of positive law in Indonesia. The method used is normative juridical with a descriptive qualitative approach through analysis of legislation and relevant case studies. The findings indicate that business actors can be held accountable under civil, criminal, and administrative law, applying the principles of strict liability and shifting the burden of proof, which strengthen the legal position of consumers. The study also highlights the necessity of active supervision by regulatory bodies such as BPOM to prevent the circulation of prohibited products.

Keywords: *Legal Liability, Prohibited Products, Business Actors*

Abstrak

Idealnya, pelaku usaha wajib menjamin bahwa seluruh produk yang diproduksi dan diedarkan telah memenuhi standar mutu, keamanan, dan

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legalitas sesuai ketentuan dalam Undang-Undang Perlindungan Konsumen (UUPK) dan Undang-Undang Kesehatan. Realitasnya, masih ditemukan pelaku usaha yang mengedarkan produk terlarang yang membahayakan kesehatan dan keselamatan konsumen, seperti kasus peredaran sediaan farmasi yang terkontaminasi senyawa berbahaya. Penelitian ini bertujuan untuk menganalisis bentuk dan dasar pertanggungjawaban hukum pelaku usaha terhadap produk terlarang berdasarkan kerangka hukum positif di Indonesia. Metode yang digunakan adalah yuridis normatif dengan pendekatan kualitatif deskriptif melalui analisis peraturan perundang-undangan dan studi kasus yang relevan. Hasil penelitian menunjukkan bahwa pelaku usaha dapat dimintai pertanggungjawaban secara perdata, pidana, dan administratif, dengan mekanisme strict liability dan shifting burden of proof yang memperkuat posisi hukum konsumen, serta perlunya peran aktif lembaga pengawas seperti BPOM dalam mencegah peredaran produk terlarang.

Kata Kunci: *Pertanggungjawaban Hukum, Produk Terlarang, Pelaku Usaha*

Introduction

In the modern era, characterized by technological advancements, industrialization, and market liberalization, trade and production activities have undergone massive expansion. This dynamic has opened up vast opportunities for business actors to increase economic profits and expand cross-sectoral business networks. However, alongside these developments, various forms of deviation and violations of business ethics have emerged, threatening consumer safety. Products that are produced or distributed without meeting safety, legality, and quality standards not only cause material losses but also pose serious risks to health and even life (Putri, 2022). The state, as the regulator and protector of its citizens, has enacted various legal instruments to ensure that business activities are conducted in accordance with principles of justice, safety, and social responsibility. In this context, consumer protection law and health law are two crucial aspects in structuring and balancing the relationship between business actors and consumers.

However, it is undeniable that in practice, many business actors deliberately violate legal provisions by producing, importing, or distributing products that are explicitly prohibited by legislation. Cases involving the distribution of mercury-containing cosmetics, pharmaceutical preparations contaminated with toxic substances such as ethylene glycol, and the sale of food containing hazardous substances have tainted business ethics and revealed weaknesses in the supervisory system (Eryansyah & Tanawijaya, 2023). Economic motives are often the primary driving force behind such violations, where short-term financial gain is prioritized over consumer safety and legal compliance. In such scenarios, the law no longer functions solely as a normative tool but also as a corrective instrument that must impose strict sanctions to safeguard market integrity and public rights.

Ideally, all business actors must comply with the regulations established by the state. Products produced or distributed must undergo processes that conform to the safety, quality, and feasibility standards set by the Food and Drug Supervisory Agency (BPOM), the Ministry of Health, and other regulatory institutions. Compliance with the Consumer Protection Law and the Health Law is an absolute prerequisite for conducting ethical and socially responsible business (Ngabito, 2025). Within this framework, legal accountability of business actors is not merely administrative or economic but also encompasses moral and criminal dimensions. Products that are declared prohibited by law must not be produced or distributed, and if this prohibition is violated, business actors must be held fully legally accountable.

However, the reality on the ground reveals a paradox between legal norms and business practices. Products that should be prohibited continue to circulate widely in society, even resulting in fatalities. This condition reflects the ineffectiveness of supervisory systems, weak law enforcement, and a high profit orientation among business actors. Many of them deliberately ignore legal provisions in pursuit of greater profit margins (Sembiring, 2023). In some cases, business actors claim ignorance of the presence of banned substances in their products, despite existing laws requiring quality testing and internal oversight. This issue highlights a systemic failure in integrating legal, ethical, and compliance aspects into business practices, making it a central problem that requires deeper juridical analysis.

This research aims to examine in depth the forms and mechanisms of legal liability that can be imposed on business actors for producing and distributing products explicitly prohibited by law. The main focus of the study lies on two key legal frameworks: the Consumer Protection Law and the Health Law, which serve as the foundation for enforcing legal responsibility for harm caused to the public. This study analyzes how civil, criminal, and administrative liabilities are applied in cases involving banned products, and how legal doctrines such as strict liability and product liability can be implemented to strengthen the legal position of consumers in asserting their rights.

Beyond merely identifying legal norms, this research also seeks to address the root causes that drive business actors to continue producing and distributing banned products despite the existence of clear regulations. These factors include weak oversight, loopholes in law enforcement, low legal literacy among business actors, and inadequate corporate accountability systems. By tracing business motives and patterns of regulatory failure, this study is expected to formulate new approaches to legally empower irresponsible business actors and propose concrete strategies to strengthen consumer protection systems.

The primary contribution of this research is to provide a more comprehensive understanding of the legal accountability of business actors in the circulation of prohibited products and to offer a critical evaluation of the effectiveness of existing regulations in addressing such violations. This study serves not only as an academic foundation but also as a practical reference for policymakers, law enforcers, and regulatory bodies in formulating more responsive and adaptive strategies to market dynamics. Furthermore, the findings of this study are expected to foster new awareness among business actors

regarding the importance of building a legal, ethical, and sustainable business system. Thus, this study is essential in bridging the gap between legal norms and business practices in society. In an ideal society, the law must be able to internalize the values of justice, safety, and social protection into every business activity.

Literature Review

The study of legal liability of business actors for prohibited products is not a new topic, as several researchers have previously discussed and published works on this issue using various methods and approaches. Ibrahim Nainggolan, in his work titled; *"Tanggung Jawab Pidana Bagi Pelaku Usaha Yang Menggunakan Bahan Tambahan Pangan (BTP) Berbahaya Pada Produk Pangan,"* discusses in depth the forms of criminal liability imposed on business actors proven to have used hazardous food additives in distributed products. In his study, Nainggolan emphasizes that business actors can be subjected to criminal sanctions based on proof of intent in violating food regulation provisions. His findings reveal that weak oversight and low awareness among business actors are the primary factors behind such violations (Nainggolan, 2018). The similarity with this study lies in the shared focus on legal issues regarding hazardous products and the liability of business actors. However, the difference lies in the approach and scope: Nainggolan emphasizes a purely criminal aspect, whereas this study also comprehensively explores civil and administrative aspects, integrating the Health Law as an essential part of the analysis.

Tri Sulismuji Wiyono, in his work titled; *"Perlindungan Hukum Konsumen Terhadap Produk Pangan Yang Mengandung Bahan Berbahaya,"* systematically explains the legal protection efforts for consumers harmed by food products containing hazardous substances. This research discusses the legal standing of consumers, producer liability, and the government's role in supervision. His findings underline the importance of regulatory enforcement and the need for consumer education (Wiyono, 2020). The similarity with this study lies in the focus on consumer protection and the legal position of victims. The difference, however, is in the primary focus of Wiyono's study, which highlights consumer legal protection, whereas this paper places business actors as the main subject in analyzing their forms of legal liability.

Rafyanka Ivana Putri Ngabito, in her work titled; *"Analisis Pertanggungjawaban Hukum Terhadap Pengedaran Produk Skincare yang Terbukti Overclaim,"* highlights the legal responsibility of business actors who distribute beauty products with exaggerated or misleading claims. The study shows that business actors can be held liable for misleading information that impacts consumer health. Her findings stress the need for strict supervision of cosmetic advertisements and labeling (Ngabito, 2025). The similarity with this study lies in the shared spirit of enforcing justice through legal accountability of business actors. However, the fundamental difference is the object of study: Ngabito focuses on overclaim issues in cosmetics, while this paper centers on products that are legally and medically prohibited, such as food and pharmaceuticals containing hazardous substances.

Based on the literature review, it is evident that although various studies have addressed business actors' legal responsibilities and consumer protection, no research has explicitly examined the normative correlation between the Consumer Protection Law (UUPK) and the Health Law in the context of prohibited products. This paper fills that gap by integrating these two major legal frameworks to comprehensively elaborate on civil, criminal, and administrative liabilities of business actors, and offers an analysis of how legal mechanisms such as strict liability and shifting the burden of proof are applied in consumer protection practices in Indonesia.

Research Methodology

This study employs a normative juridical approach with a qualitative-descriptive method. The normative juridical approach is chosen because the main focus of the research is to analyze applicable positive legal norms, particularly those found in the Consumer Protection Law (UUPK) and the Health Law, in relation to the legal liability of business actors for the distribution of prohibited products (Benuf & Azhar, 2020). The primary data sources in this study consist of primary legal materials such as laws and regulations, including the UUPK, the Health Law, the Criminal Code (KUHP), as well as technical regulations such as those issued by the Indonesian Food and Drug Authority (BPOM) and the Guidelines for Good Manufacturing Practices (CPOB). In addition, secondary legal materials such as academic literature, legal journals, and expert opinions are utilized to enrich the analysis. Data collection is conducted through literature study, with data analysis techniques involving interpretation of legal norms and juridical argumentation to explain the connection between normative provisions and relevant real-world cases.

In conducting the analysis, this study also applies conceptual and comparative legal approaches to explain legal liability concepts such as strict liability, product liability, and shifting the burden of proof within the context of consumer protection and health law. The study does not only aim to understand how legal norms are formulated and enforced, but also seeks to assess their effectiveness in practice by tracing cases involving violations committed by business actors who produce or distribute prohibited products. Data validity is tested through source triangulation and a critical understanding of the relevance of legal documents and their consistency in the enforcement process. Thus, this methodology is expected to provide a comprehensive and well-argued picture of how business actors' legal liability should be upheld in the context of the circulation of products prohibited by law.

Prohibited Products and Business Actors' Motives

In the landscape of Indonesian positive law, several provisions clearly prohibit the distribution of certain products that endanger public health, safety, and order. These prohibited products may include items containing hazardous substances, those without distribution permits, those that mislead consumers through labeling or information, or counterfeit goods that infringe intellectual

property rights. One of the fundamental legal bases for such prohibitions is Article 8 of Law Number 8 of 1999 concerning Consumer Protection (UUPK), which states that business actors are prohibited from producing and/or trading goods and/or services that do not meet or are not in accordance with the standards stipulated by statutory regulations (Yuliska, 2023). Other technical regulations, such as those issued by the Indonesian Food and Drug Authority (BPOM), the Ministry of Trade, and the Health Law, further expand the boundaries regarding prohibited products.

Products considered dangerous and banned from circulation include, among others, pharmaceutical preparations containing toxic chemicals, food or beverages containing dyes or preservatives exceeding safe limits, illegal cosmetics containing mercury, children's toys that do not comply with safety standards, and uncertified electronic devices. In the pharmaceutical sector, for instance, substances such as ethylene glycol (EG) and diethylene glycol (DEG) are banned in syrup-based medications due to their toxicity to the kidneys and liver and the potential to cause death if consumed in certain doses (Mayefis et al., 2025). Despite these clear prohibitions, incidents of such products entering the market still occur, even resulting in mass health tragedies, as seen in the child fatalities caused by acute kidney failure.

A critical question that arises is: why do business actors still choose to produce and distribute products that have been explicitly prohibited by law? The answer cannot be viewed solely from a legal-formal perspective but must be examined through the lens of the perpetrators' psychology, economic motives, weak oversight, and regulatory loopholes. The most dominant motive is economic. Business actors who ignore legal provisions are often lured by quick and substantial financial gain, especially when banned raw materials are significantly cheaper than those that meet the standard. For example, ethylene glycol is far cheaper than pharmaceutical-grade glycerin, making it attractive to cost-efficiency-driven business actors.

In addition to the lure of high profits, weak law enforcement also contributes to business actors continuing these illegal practices. In some cases, sanctions imposed are perceived as insufficient deterrents. When the potential profit far outweighs the risk of minor fines or penalties, perpetrators tend to make economically rational decisions to violate the law. Moreover, legal proceedings in civil or criminal domains often take a long time, require complex technical evidence, and suffer from limited oversight capacity (Handayani & Masri, 2023). The imbalance between the damage caused by violations and the capacity of the legal system to anticipate and respond creates room for repeated offenses. Another factor lies in the lack of information and competence within the businesses themselves. Many small and medium-sized enterprises are unaware of regulatory standards.

They often use uncertified suppliers without knowing that their materials contain banned substances. A lack of training, absence of internal testing labs, and a non-quality-based work culture make such businesses vulnerable to practices that endanger consumers. In these situations, the motive may not be intentional, yet the negligence still impacts public safety. In some cases, business actors are also driven by competitive market pressures. When markets are flooded with cheap products, businesses often feel compelled to lower their production

standards to stay price competitive. This phenomenon is referred to as a "race to the bottom," where competition forces businesses to reduce production costs to the point of sacrificing safety and quality standards. This not only harms consumers but also creates an unhealthy business climate and tarnishes the industry's reputation. In such ecosystems, law-abiding businesses may struggle to survive financially.

Meanwhile, another often-overlooked motive is the corrupt relationship between business actors and regulatory officials. Investigative reports have revealed cases where business actors exploit bureaucratic gaps or even bribe officers to smoothen licensing processes, avoid inspections, or erase violation records. Such practices blunt the force of regulation and turn it into a façade legitimizing dangerous products (Putra, 2024). When oversight is weakened by corruption, business actors feel emboldened to conduct irresponsible practices without fear of legal consequences. On the other hand, some large-scale business actors deliberately exploit regulatory complexity. They have the resources to manipulate production reports, deceive quality audits, or use third parties to obscure the distribution trail of hazardous products. In these cases, the motive transcends survival and becomes part of a systematic business strategy. These actors are aware of legal risks but prepare elaborate methods to evade them, including hiring skilled lawyers, establishing political networks, and controlling public opinion through media campaigns.

In another context, some actors are ideologically driven or harbor distrust toward the state legal system. These business actors view strict regulations as state interference hindering market freedom. They argue that as long as consumers continue to purchase and do not complain, there is no reason to tighten quality standards. This reflects a skewed business ethic where profit is prioritized above human safety. Such motives are difficult to address without fostering healthy business ideology and instilling values of social responsibility into business practices. These motives indicate that violations of product bans cannot be resolved solely through repressive measures (Saptono et al., 2024). Preventive approaches are also needed, including education, systemic oversight, licensing reform, and improved consumer literacy. When consumers are legally and quality-aware, the demand for unsafe products will significantly decline, compelling businesses to conform to higher standards. Additionally, incentive systems can be designed to reward businesses that comply with regulations, giving them competitive advantages in the market.

Within the ideal framework of legal protection, the state must be able to design mechanisms that not only punish violations after the fact but also prevent them from occurring in the first place. Pre-market inspections, mandatory certifications, supply chain monitoring, and self-reporting systems can be critical elements of a modern regulatory regime (Zafitriani & Khasanah, 2024). Moreover, the formation of dedicated agencies focused on the quality control of marketed goods can help close the regulatory gaps that business actors have long exploited. Thus, although certain products have been prohibited under current regulations, economic motives, weak law enforcement, ignorance, market pressure, and corruption remain the primary factors behind business actors' persistence in producing or distributing them. Countering these motives requires a holistic legal

approach—one that not only relies on civil or criminal sanctions but also fosters a transformation in legal culture and business ethics throughout Indonesia.

Business Actors' Accountability

In a complex and interconnected economic structure, business actors and consumers form two inseparable sides of market dynamics. Consumers are not merely buyers or end-users of products but are also key determinants of production direction, innovation, and the sustainability of business itself. Therefore, the relationship between the two demands a balance grounded in principles of justice and responsibility. To ensure this, the state, through its legal apparatus, has established regulations such as the Consumer Protection Act (UUPK), which not only details the rights and obligations of consumers but also emphasizes the accountability of business actors in every line of their economic activities (Kurniawan & Kahotimah, 2021). These regulations aim to create an economic order that is not only competitive but also healthy, transparent, and humane.

The accountability of business actors is a legal concept that places responsibility for actions or products produced on the authorized party, either individually or as a legal entity. In practice, this accountability involves the obligation of business actors to act in accordance with legal norms, business ethics, and compliance with established standards. Business actors cannot escape legal obligations by blaming others' negligence, as the principle of accountability inherently applies to every action and outcome originating from their business processes. Therefore, awareness of legal responsibility should be an inherent part of sustainable business practice. It is not enough to merely seek profit; business actors are obligated to ensure that the products or services they market do not cause harm or loss to consumers.

The case involving pharmaceutical preparations based on propylene glycol (PG) that were later found to be contaminated with ethylene glycol (EG) is clear evidence of a failure in accountability. Although the adulteration occurred at the distributor level, business actors are still obligated to test and verify each raw material used. This obligation is reinforced through BPOM Regulation No. 7 of 2024 concerning Good Manufacturing Practices (CPOB), which mandates strict quality control across all production processes. EG, as a toxic compound commonly used in non-health industries, is highly dangerous if ingested (Wulandari & Sayidin, 2022). Failure to identify this substance can result in loss of life, demonstrating the critical importance of precautionary principles in business practices, especially in industries affecting public health.

The acquisition of a CPOB certificate cannot be used as an excuse to evade responsibility. The certificate merely confirms that a facility met certain standards at a given time, but it does not guarantee that all products produced thereafter are safe without ongoing supervision. In the context of accountability, business actors are still required to implement continuous quality control systems. Failure to maintain the quality of raw materials, production processes, and distribution indicates a weak risk management system, ultimately leading to legal consequences. In this regard, the state, through UUPK, acts as the primary

guardian of consumer rights by emphasizing accountability in all forms—civil, criminal, and administrative.

Violating the principle of good faith in business is also a serious legal offense. Articles 7 and 8 of the UUPK explicitly stipulate that business actors must act in good faith in conducting their business activities, including ensuring that marketed products do not endanger consumer safety. When business actors neglect safety and quality aspects, they not only breach legal norms but also undermine public trust in the business sector itself. This highlights the importance of business actors' integrity in ensuring that the products they market meet safety expectations and standards (Karmila, 2023). In a complex market system, consumers are typically in a weaker position compared to business actors, both in terms of information access and quality control.

The UUPK serves not only as a regulatory tool but also as a mechanism to shape social awareness and ethical responsibility. Through its provisions, the UUPK aims to strengthen the consumer's position by granting them access to clear information and fair compensation in cases of violations. Furthermore, the UUPK encourages business actors to operate responsibly and transparently. The goals of consumer protection under Article 3 of the UUPK include increasing consumer awareness, preserving consumer dignity, and promoting the production of safe, high-quality, and standardized goods and services. This entire mission places accountability as the foundation for building a balanced and sustainable market system.

However, in certain cases such as poisoning caused by EG-containing drugs, traditional liability principles are insufficient. Therefore, the concept of strict liability is applied to ensure that business actors can still be held accountable even in the absence of direct fault. Strict liability places business actors in a position of automatic responsibility for damages caused by defective products, without the need to prove malice or negligence (Sinduningrum & Marlyna, 2023). This concept is highly relevant in high-risk industries such as pharmaceuticals, where even minor errors can lead to fatal consequences. In this context, business actors can no longer hide behind technical excuses or blame others, as the burden of proof is shifted from consumers to producers.

Black's Law Dictionary defines strict liability as a form of legal responsibility that arises without the need to prove fault. Within the consumer protection framework, this principle works effectively to dismantle the dominance of business actors who often have greater access to information and legal resources. Consumers, who typically lack the technical knowledge or resources to prove a manufacturer's fault, are protected through this principle. They need only demonstrate that they suffered harm from using a product, and the law automatically assumes the producer's responsibility (Sodikin, 2022). This creates a fairer balance of rights and obligations in a democratic market system. Alongside strict liability, the broader concept of product liability also applies, encompassing various product defects such as manufacturing defects, design defects, and labeling defects.

In the case of EG-contaminated drugs, the defect can be categorized as a manufacturing defect, as the hazardous substance entered the production chain without being detected or prevented. Thus, business actors remain liable even if

they claim to have followed procedures. Under product liability schemes, responsibility lies not only in the process but also in the final outcome that affects consumers. Accountability in this context is holistic and inseparable from the principle of precaution, which must permeate all stages of business (Wardana & Suhartini, 2023). If a defective or dangerous product causes harm, the business actor is legally obligated to provide compensation, whether in the form of restitution, refunds, or reimbursement of medical expenses and recovery costs. This aligns with Article 4(h) of the UUPK, which affirms consumers' rights to compensation for goods or services that fail to meet agreed or applicable standards.

In practice, the enforcement of this article is crucial in delivering substantive justice to victims. Business actors are not only morally but also legally responsible for restoring the rights of harmed consumers, while also using the experience as a basis for evaluating and improving their internal systems. Furthermore, in cases that harm the public at large, responsibility does not stop with business actors. Regulatory bodies such as BPOM, which hold authority and responsibility in ensuring the quality of pharmaceutical products, must also be held accountable if they are found negligent in performing their duties (Wulandari & Sayidin, 2022). In this case, accountability is structural and systemic, involving all actors in the supply chain and quality control process. BPOM as a regulator must ensure end-to-end oversight—from raw materials, through production, to distribution and sales. Failure to carry out these responsibilities can have fatal consequences and erode public trust in the national health protection system.

Forms of Business Actors' Legal Accountability

From a positive legal perspective, as stated in Article 1 point (2) of the Indonesian Consumer Protection Act (UUPK), a consumer is defined as an individual who utilizes goods and/or services available on the market for personal, family, or other living beings' needs, without the intention of reselling them. Meanwhile, Article 1 point (3) defines a business actor as any individual or entity, whether incorporated or not, established and operating within the jurisdiction of the Republic of Indonesia, either independently or jointly through agreements, who engages in business activities across various economic sectors. This definition shows that consumers and business actors are two legal entities with distinct rights and obligations, bound by a legal relationship that implies principles of justice and accountability (Sinduningrum & Marlyna, 2023). The affirmation of consumers as protected subjects and business actors as accountable parties illustrates the state's role in shaping an ethical and fair market ecosystem.

The explicit distinction of the term "end consumer" in UUPK should not be seen merely as a matter of wording but rather as a normative effort to determine who has the legal standing to claim protection. The end consumer in this context refers to the downstream party in the distribution chain who purchases and uses the product or service for their own benefit and not for commercial resale (Negara & Satria, 2021). This distinction is crucial in determining legal standing, as not every party interacting with a product or service qualifies as a consumer. By setting this boundary, consumer protection law can be more precisely targeted,

ensuring that lawsuits are brought by genuinely affected parties rather than other business actors engaging in commercial transactions.

As outlined in Article 46 paragraph (1) of UUPK, the right to file a lawsuit for losses caused by business activities is not limited to the consumers themselves but also extends to their heirs, groups of consumers with similar interests, eligible non-governmental organizations, and government agencies if the damage is widespread. Lawsuits may be based on two grounds: first, breach of contract (wanprestasi), where the business actor fails to fulfill contractual obligations to the consumer; second, tort (onrechtmatige daad), where the business actor violates general legal norms and causes harm without needing a prior contractual relationship (Kurniawan & Kahotimah, 2021). These two legal grounds expand the scope of consumer protection, covering both direct and indirect harm—physical, mental, or financial—and establish a strong legal foundation for achieving substantive justice.

In cases of loss due to defective products, positive law requires business actors to take responsibility for every product they circulate, both in terms of quality and safety. A product is categorized as defective if it contains flaws or inconsistencies that clearly endanger consumer safety. Product defects can be classified into three types: manufacturing defects, design defects, and informational or warning defects. Manufacturing defects refer to physical errors during the production process that result in non-compliance with expected standards (Nainggolan, 2018). Design defects stem from inherent flaws in the product's design that make it dangerous from the outset. Informational defects arise when a product lacks clear usage instructions, hazard warnings, or content details that could influence consumer decisions. In all these cases, the business actor is considered fully liable for the resulting harm, regardless of intent or negligence.

In real cases, such as the distribution of drugs contaminated with ethylene glycol (EG), as reported by *Liputan6*, business actors are considered to have failed in fulfilling their legal responsibilities, both in terms of good faith as mandated by Article 7 of UUPK and compliance with product quality standards as outlined in Article 8. Failure to implement precautionary principles and lack of internal quality control indicates weak enforcement of business accountability principles (Yusuf et al., 2022). In this case, the government—through the Deputy Head of BPKN—stated that the state should provide compensation for victims, but at the same time, guilty business actors must proportionally bear the burden of loss. This means business actors' liability is not only moral or administrative but can escalate into legal responsibility involving both civil and criminal sanctions.

Under civil law, every claim of liability requires a clear legal basis: a harmful act and a causal link between the act and the resulting damage. In consumer protection law, William C. Whitford classifies business actor liability into three categories: private remedies, hybrid remedies, and public remedies. Private remedies refer to direct consumer recovery, such as refunds or replacements (Asya, 2025). Hybrid remedies combine private and public rights, such as class actions with systemic impact. Public remedies involve state-imposed sanctions on business actors, such as license revocation or criminal penalties. This classification

reflects the complexity of the consumer protection system, where accountability is multidimensional depending on the scale and impact of the violation.

Normatively, civil liability is regulated under Article 19 paragraphs (1) and (2) of UUPK, which require business actors to compensate for losses due to defective products, including through product replacement, refunds, or equivalent services. If the damage involves health deterioration or death, the business actor must provide adequate compensation, including covering medical costs or offering restitution to the heirs. Although civil liability may be enforced, it does not exclude the possibility of criminal and administrative responsibility if gross negligence or violations of broader regulatory provisions are found (Wulandari & Sayidin, 2022). Thus, civil sanctions often serve as a gateway to a broader investigation of the business actor's overall accountability.

UUPK also provides space for litigation and non-litigation efforts to resolve consumer disputes through Article 23. Affected consumers may bring their cases to general courts or the Consumer Dispute Settlement Board (BPSK), allowing for equitable justice without excessive legal costs. This mechanism shows that the law is not merely normative but also offers concrete tools to address structural imbalances between business actors and consumers. However, in practice, the burden of proof often becomes a major barrier for consumers seeking justice. Therefore, a legal mechanism ensuring consumers' access to justice is crucial.

Aligned with progressive consumer protection principles, Article 28 of UUPK introduces the *shifting of the burden of proof*, where the burden no longer lies with the consumer but with the business actor. In other words, the business actor must prove that their product is safe and non-harmful. Failing that, legal responsibility is automatically imposed. This principle is a form of legal protection for consumers, who are structurally and informationally in a weaker position (Mugiono & Indradewi, 2025). Amid an asymmetrical legal relationship, this mechanism delivers more equitable procedural and substantive justice while encouraging business actors to be more transparent and cautious throughout their production processes.

Beyond civil liability, UUPK also includes criminal sanctions as stated in Article 62, which provides that business actors violating Article 8—such as producing substandard goods—may face up to five years of imprisonment or fines of up to two billion rupiah. If the violation results in death, criminal sanctions may be increased and refer to provisions of the Criminal Code (KUHP). In pharmaceutical contamination cases involving EG, these criminal sanctions are reinforced by the Health Law, which under Article 435 prescribes penalties of up to 12 years in prison or fines of up to five billion rupiah for those producing or distributing pharmaceutical products that fail to meet safety, quality, or efficacy standards (Yusuf et al., 2022). These criminal sanctions reflect the state's seriousness in protecting consumers from the consequences of corporate negligence.

In addition to criminal and civil penalties, positive law also provides administrative sanctions as regulated in Article 63 of UUPK and Article 448 of the Health Law. These sanctions may include product recalls, business license revocation, evidence seizure, cessation of business activities, and court decision publication. Furthermore, Article 143 paragraph (1) of the Health Law states that

business actors failing to comply with safety and quality standards may be subject to administrative penalties in accordance with prevailing licensing regimes (Wulandari & Sayidin, 2022). These administrative sanctions not only serve as a repressive measure but also function preventively to deter future violations. They are also an evaluation tool for internal improvement and sustainable implementation of precautionary principles by business actors.

Conclusion

Based on a juridical review of the Consumer Protection Act (UUPK) and the Health Law, it can be concluded that business actors bear inherent legal responsibility when they produce or distribute products that are explicitly prohibited by statutory regulations. This accountability encompasses three areas—civil, criminal, and administrative—which together form an integrated system of oversight and law enforcement. Products proven to contain hazardous substances or fail to meet quality standards carry serious legal consequences, including the obligation to compensate consumers, the imposition of criminal sanctions on individuals or corporations, and the application of administrative penalties such as business license revocation. In this context, provisions such as *strict liability* and *shifting the burden of proof* strengthen the consumer's position and affirm that business actors cannot evade responsibility merely by claiming ignorance or negligence.

Despite the existing legal framework, the effectiveness of enforcing business actors' legal accountability still faces significant challenges, particularly due to weak oversight, inadequate law enforcement, and low awareness among business actors regarding the importance of legal compliance. Therefore, there is a need to reinforce technical regulations, enhance the capacity of regulatory institutions, and conduct educational campaigns targeting business actors to promote not only profit-oriented practices but also uphold the values of consumer safety and justice. Consistent and firm legal enforcement against business actors proven to have produced prohibited products will demonstrate the state's presence in protecting its citizens while cultivating a business culture grounded in legal, social, and moral responsibility.

References

Asya, A. N. (2025). Perlindungan Hukum dan Dukungan bagi Korban Kekerasan dalam Rumah Tangga dalam Perspektif Viktimologi. *Akademik: Jurnal Mahasiswa Humanis*, *5*(1), Article 1. https://doi.org/10.37481/jmh.v5i1.1224

Benuf, K., & Azhar, M. (2020). Metodologi Penelitian Hukum sebagai Instrumen Mengurai Permasalahan Hukum Kontemporer. *Gema Keadilan*, *7*(1), 20–33.

Eryansyah, E. A., & Tanawijaya, H. (2023). Perlindungan Konsumen Terhadap Kosmetik Tanpa Izin Edar: Analisis Putusan Nomor 190/PID.SUS/2021/PT PAL. *Syntax Literate; Jurnal Ilmiah Indonesia*, *8*(6), 4536–4548. https://doi.org/10.36418/syntax-literate.v8i6.12657

Handayani, O., & Masri, E. (2023). Perlindungan Konsumen Produk Skincare Pada Penjualan Secara Online. *Krtha Bhayangkara*, *17*(3), 481–494. https://doi.org/10.31599/krtha.v17i3.781

Karmila, K. (2023). Tinjauan Hukum Penanggulangan Kejahatan Penjualan Produk Makanan Kemasan Yang Mengandung Bahan Kimia Berbahaya. *Innovative: Journal Of Social Science Research*, *3*(2), Article 2.

Kurniawan, A., & Kahotimah, N. (2021). Analisis Hukum Islam Tentang Perlindungan Hukum Terhadap Konsumen Menurut Undang-Undang No. 8 Tahun 1999. *Falah: Jurnal Hukum Ekonomi Syariah*, *1*(1), Article 1. https://doi.org/10.55510/fjhes.v1i1.43

Mayefis, D., Marliza, H., & Fadhil, M. (2025). Identifikasi Bahan Kimia Obat Sibutramin HCl pada Jamu Pelangsing yang Beredar di Kota Batam Menggunakan Spektrofotometri UV-Vis. *Jurnal Riset Kefarmasian Indonesia*, *7*(2), Article 2. https://doi.org/10.33759/jrki.v7i2.531

Mugiono, M., & Indradewi, A. A. (2025). Quo Vadis Regulasi dan Penegakan Hukum Terhadap Peredaran Roti yang Mengandung Zat Berbahaya. *Jatiswara*, *40*(1), 1–11. https://doi.org/10.29303/jtsw.v40i1.1202

Nainggolan, I. (2018). Tanggung Jawab Pidana bagi Pelaku Usaha yang Menggunakan Bahan Tambahan Pangan (BTP) Berbahaya pada Produk Pangan. *EduTech: Jurnal Ilmu Pendidikan Dan Ilmu Sosial*, *4*(2), Article 2. https://doi.org/10.30596/edutech.v4i2.2429

Negara, A. A. G. P., & Satria, I. N. K. P. (2021). Upaya Perlindungan Konsumen terhadap Maraknya Penjualan Pakaian Merek Tiruan. *Ganesha Civic Education Journal*, *3*(2), Article 2. https://doi.org/10.23887/gancej.v3i2.439

Ngabito, R. I. P. (2025). Analisis Pertanggungjawaban Hukum Terhadap Pengedaran Produk Skincare yang Terbukti Overclaim. *Law, Development and Justice Review*, *7*(3), 284–301. https://doi.org/10.14710/ldjr.7.2024.284-301

Putra, R. F. L. (2024). Perlindungan Hukum Konsumen terhadap Penjualan Produk Hasil Industri Rumah Tangga Pangan (PIRT) yang Tidak Mencantumkan Tanggal Kadaluarsa pada Kemasan Dihubungkan dengan UU No. 8 Tahun 1999 tentang Perlindungan Konsumen. *Justitiable; Jurnal Hukum*, *6*(2), Article 2. https://doi.org/10.56071/justitiable.v6i2.844

Putri, S. A. (2022). Administrative Enforcement of Food Safety Regulation in Indonesia: Loopholes and Recommendations. *Law Reform*, *18*(2), 282–297. https://doi.org/10.14710/lr.v18i2.47415

Saptono, S., Hadiyanto, A., & Ciptono, C. (2024). Analisis Yuridis Perkembangan Tindak Pidana Pencucian Uang Saat Ini sebagai Upaya Pencegahannya di Indonesia. *Jurnal USM Law Review*, *7*(2), Article 2. https://doi.org/10.26623/julr.v7i2.8899

Sembiring, S. (2023). Perlindungan Hukum Konsumen Sebagai Korban Produk Berbahaya Dalam Perspektif Hukum Perdata. *RIO Law Jurnal*, *4*(1), Article 1. https://doi.org/10.36355/rlj.v4i1.1023

Sinduningrum, A., & Marlyna, H. (2023). Penerapan Strict Liability dalam Hukum Pelindungan Konsumen di Indonesia: Perbandingan Negara Lain. *UNES Law Review*, *6*(2), Article 2. https://doi.org/10.31933/unesrev.v6i2.1321

Sodikin, S. (2022). Perkembangan Konsep Strict Liability sebagai Pertanggungjawaban Perdata dalam Sengketa Lingkungan di Era Globalisasi. *Al-Qisth Law Review*, *5*(2), Article 2. https://doi.org/10.24853/al-qisth.5.2.261-298

Wardana, M. N. E., & Suhartini, D. (2023). Analisis Aspek Akuntabilitas Pengelolaan Dana Haji Melalui Aplikasi SISKOHAT. *Jurnal Ilmiah Universitas Batanghari Jambi*, *23*(1), Article 1. https://doi.org/10.33087/jiubj.v23i1.2580

Wiyono, T. S. (2020). Perlindungan Hukum Konsumen terhadap Produk Pangan yang Mengandung Bahan Berbahaya. *Alethea; Jurnal Ilmu Hukum*, *4*(1), Article 1. https://doi.org/10.24246/alethea.vol4.no1.p21-40

Wulandari, F., & Sayidin, B. A. (2022). Peredaran Obat Sirup yang Mengandung Bahan Berbahaya Cemaran Etilen Glikol dan Dietilen Glikol dalam Perspektif Hukum Perlindungan Konsumen. *Prosiding Sinantias: Seminar Nasional Hasil Penelitian Dan Pengabdian Kepada Masyarakat*, *3*(1), Article 1.

Yuliska, E. (2023). Larangan Pelaku Usaha terhadap Iklan Produk yang Menyesatkan Konsumen. *Normative Jurnal Ilmiah Hukum*, *11*(1 April), Article 1 April. https://doi.org/10.31317/normative

Yusuf, M., Putri, N. D., Dharmayanti, S., & Saragih, G. M. (2022). Pertanggungjawaban Hukum Bagi Produsen Obat Sirup Mengandung Etilen Glikol (EG) Dan Dietilen Glikol (DEG) Penyebab Ginjal Akut Progresif Atipikal (GgGAPA) Pada Anak. *JPDK; Jurnal Pendidikan Dan Konseling*, *5*(1), Article 1. https://doi.org/10.31004/jpdk.v5i1.10870

Zafitriani, D. A., & Khasanah, K. (2024). Kepastian Hukum dalam Pelaksanaan Pengawasan Produk-Produk yang Telah Bersertifikat Halal di Indonesia. *El-Hisbah*, *4*(1), Article 1. https://doi.org/10.28918/elhisbah.v4i1.7551