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Legal Liability of Pharmaceutical Industry In Consumer Class Action Lawsuits: Analysis of Court Decision Number 771/Pdt.G/2022/Pn Jkt.Pst

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Abstract: The case of atypical progressive acute kidney injury in children caused by contaminated syrup medicines containing ethylene glycol and diethylene glycol raises legal issues concerning the liability of the pharmaceutical industry. This study analyzes the legal responsibility of pharmaceutical producers and the application of class action mechanisms in Central Jakarta District Court Decision Number 771/Pdt.G/2022/PN Jkt.Pst. The research employs a normative juridical method with statutory and case approaches, using secondary data from legislation, court decisions, and legal literature. The findings show that pharmaceutical industries are obliged to guarantee product safety and quality under Indonesian law, and their negligence gives rise to civil liability enforced through compensation. The class action mechanism proved effective in securing access to justice, procedural efficiency, and legal certainty. This study highlights the need for strict compliance with production standards and the strengthening of class action procedures to enhance consumer protection in Indonesia.

Keyword: Consumer Protection, Pharmaceutical Industry, Legal Liability, Class Action.

INTRODUCTION

Indonesia upholds human rights and ensures legal certainty for consumers through Law No. 8 of 1999 on Consumer Protection (UUPK), which came into effect on 20 April 2000. This statute establishes the rights and obligations of both consumers and business actors, reflecting the State's commitment to balancing economic activity with consumer protection (Karinda, 2020). Pursuant to Article 1 points 2 and 3 of the UUPK, a consumer is defined as any individual who uses goods or services for personal purposes or for the benefit of others without a commercial objective, while a business actor encompasses both individuals and business entities, whether incorporated or not, conducting business activities within the jurisdiction of Indonesia.

Within the framework of consumer protection law, business actors, including the pharmaceutical industry as producers of medicines, bear a legal duty to ensure product safety in accordance with Article 7 letter d of the UUPK, which mandates that products must meet

applicable quality standards. This duty corresponds to the rights of consumers as stipulated in Article 4 letter a of the UUPK, namely the right to safety, comfort, and security in the use of goods and/or services. There exists legal certainty that consumers are entitled to obtain the benefits of the products they use, as well as a guarantee that such products do not pose any threat to their safety, security, or property (Truwulandari, 2022). Accordingly, the rights and obligations between consumers and business actors are reciprocal in nature (Fahreza & Kongres, 2023).

However, this principle of balance was tested in 2022 when Indonesia confronted a public health crisis due to a surge in cases of Acute Kidney Injury (AKI) among children. As of February 2023, data from the Ministry of Health recorded 326 cases across 27 provinces, with a peak increase occurring in September-October 2022 (Lubis & Tarina, 2023). The Indonesian Pediatric Society (IDAI) likewise reported a sharp escalation of cases during September and the early weeks of October 2022. The majority of the affected patients were children between one and five years of age, constituting the most vulnerable group to exposure from hazardous substances contained in pharmaceutical products (Lubis & Tarina, 2023).

The Ministry of Health determined that the principal cause of AKI was contamination by toxic chemical compounds, specifically ethylene glycol (EG) and diethylene glycol (DEG), which were detected in a number of syrup-based medicines consumed by the affected children. Laboratory examinations revealed that the levels of these substances far exceeded the permissible safety limits established for pharmaceutical formulations (Tharif & Wiyanti, 2024). This discovery generated considerable public concern and ultimately prompted the families of victims to pursue legal remedies by filing a class action lawsuit. The purpose of this action was to hold the responsible parties legally accountable for the losses suffered, to secure compensation and remediation, and to ensure preventive measures against the recurrence of similar incidents in the future, thereby embodying a form of collective justice for the victims and their families.

A number of scholarly works have previously addressed issues comparable to those raised in the AKI case. The first study, conducted by Achmad Raihansyah Lubis and Dwi Desi Yayi Tarina (2023), emphasized the dual significance of preventive and repressive forms of legal protection for consumers. The second study, authored by Adelia Fairuz Wirawan and Sulastri (2023), underscored the institutional shortcomings of the National Agency of Drug and Food Control (BPOM), arguing that the agency failed to uphold consumers' rights to safety, comfort, and security. According to their analysis, this failure was closely linked to the agency's inability to optimally perform its supervisory functions as mandated under Presidential Regulation Number 80 of 2017. The third study, prepared by Raihan Muhammad Tharif and Diana Wiyanti (2024), adopted a more juridical approach by examining the legal basis for the liability of pharmaceutical producers under the UUPK.

This study differs from previous research by specifically examining the legal liability of the pharmaceutical industry for consumer losses through a class action mechanism. Using the Central Jakarta District Court Decision Number 771/Pdt.G/2022/PN Jkt.Pst as a case study, it focuses on how the Panel of Judges considered the accountability of pharmaceutical industries, thereby providing a basis for evaluating the role of business actors in ensuring the safety of pharmaceutical products in Indonesia.

METHOD

This research employs a normative juridical legal research method, which is a research approach that emphasizes the examination and analysis of legal norms contained in legislation and relevant legal literature (Firmanto, Sufiarina, Reumi, & Saleh, 2024). The sources of data used in this research are secondary data, consisting of primary legal materials in the form of UUPK, BPOM Regulation Number 7 of 2024, Supreme Court Regulation (PERMA) Number

1 of 2002 on Class Action Procedures, and Court Decision Number 771/Pdt.G/2022/PN Jkt.Pst. Secondary sources include academic journals, scientific articles, research reports, and scholarly papers presented at seminars and workshops. In addition, tertiary sources comprise legal dictionaries, Indonesian and English language dictionaries, encyclopedia, and other references that clarify terminology and support legal interpretation (Ahmad, Fachrurrazy, Hartati, Amalia, & Fauzi, 2024).

The research applies two main approaches, namely the statutory approach and the case approach. The statutory approach is carried out by examining the provisions of the UUPK and other relevant regulations as the normative foundation for determining the obligations of pharmaceutical industries in ensuring product safety. Meanwhile, the case approach is implemented through an in-depth study of Court Decision Number 771/Pdt.G/2022/PN Jkt.Pst., particularly regarding the court's interpretation of legal liability and its alignment with consumer protection principles. The results of this research are analyzed qualitatively using descriptive-analytical methods, involving the description, interpretation, and evaluation of relevant legal documents, followed by conclusions drawn through systematic legal reasoning (Manggala & Nugroho, 2025).

RESULTS AND DISCUSSION

The Legal Liability of The Pharmaceutical Industry for Consumer Losses Within The Framework of a Class Action Lawsuit in the Acute Kidney Injury (AKI) Case in Chilren

The pharmaceutical industry, as a specialized branch of the manufacturing sector, occupies a vital position in safeguarding public health through the large-scale and highly regulated production of medicines (Ubaydillah & Faqihuddin, 2022). As a business actor, the pharmaceutical industry carries a primary legal duty to guarantee that every product released to the market meets rigorous safety and quality standards. This obligation is not merely an ethical or commercial consideration but is explicitly mandated under Article 7 letter d of the UUPK, that business actors are legally responsible for ensuring that the goods they produce are safe for consumption and do not endanger consumer interests.

The legal duty of pharmaceutical producers is further elaborated in Article 7 letter b of the UUPK, which emphasizes consumers' rights to receive correct, clear, and honest information about the conditions and guarantees of goods and/or services. This provision means that pharmaceutical industries must fully disclose all relevant details to consumers, including composition, usage instructions, potential side effects, and foreseeable risks. Together, Articles 7 letter b dan d create a dual obligation: to ensure product quality and safety on the one hand, and to uphold transparency and information disclosure on the other.

This broad legal obligation is further implemented through compliance with Good Manufacturing Practice (GMP) standards, which establish detailed technical requirements and procedural guidelines for the production of pharmaceuticals. The importance of GMP compliance is reinforced under the recent regulatory framework, namely the BPOM Regulation No. 7 of 2024 on GMP. Compliance with these quality standards is evidenced by the possession of a Good Manufacturing Practice Certificate, which is explicitly required under Article 1 point 5 of BPOM Regulation No. 7 of 2024. Furthermore, Article 2 paragraph (1) letter a emphasizes that GMP standards serve as a mandatory reference for all pharmaceutical manufacturing activities, in order to ensure the safety, quality, and efficacy of products circulating in society. The regulation provides that GMP principles constitute binding guidelines that must be observed at every stage of pharmaceutical production, including the procurement of Active Pharmaceutical Ingredients (APIs), manufacturing processes, packaging, labeling, and distribution.

The urgency of these obligations became starkly evident in the case of contamination involving 101 pharmaceutical products from six companies; PT Yarindo Farmatama (6

products), PT Universal Pharmaceutical Industries (10 products), PT Afi Farma (39 products), PT Ciubros Farma (6 products), PT Samco Farma (8 products), and PT Rama Emerald Multi Sukses (32 products) excessive EG levels were detected in both APIs and finished goods. Laboratory tests revealed EG content in Propylene Glycol (PG) ranging from 4.69% to 99.09%, and in sorbitol solvents containing EG and DEG levels between 0.003% and 1.34% (Fikri & Firmansyah, 2023).

EG and DEG are hygroscopic liquids that are colorless, odorless, and possess a sweet taste. Both are soluble in water and organic solvents, and are commonly employed as humectants, solvents, sweetening agents, and antifreeze agents. Despite their industrial functions, these compounds are classified as toxic alcohols that may cause death and have significantly contributed to the high incidence of AKI (Ramdani, 2024). These levels far exceeded the permissible contamination threshold of 0.1% (Aryawati & Ubaidillah, 2024), as well as the tolerable daily intake (TDI) limit of 0.5 mg/kg body weight/day set by national regulations and the Pharmacopoeia (Aisya, Iswanto, Sulistyaningsih, Dakum, & Heniyatun, 2024). The presence of contaminants at such high levels represented a grave violation of consumer safety and directly contravened the quality requirements mandated under Article 7 letter d of the UUPK.

In response to these breaches, BPOM imposed administrative sanctions in the form of revoking the GMP certificates and marketing authorizations for liquid syrup medicines from six pharmaceutical companies. It further ordered the cessation of production and distribution, the return of marketing licenses, the withdrawal of all products from circulation, the destruction of existing stock under BPOM supervision, and the submission of reports on the implementation of these measures to BPOM (Wirawan & Sulastri, 2023). These enforcement actions align with Article 60 paragraphs (1) and (2) of the UUPK, which authorize the Consumer Dispute Settlement Baord (BPSK) to impose sanctions and order compensation up to Rp200.000.000,00. The compensatory dimension of UUPK obligations is equally significant. Article 19 stipulates that business actors are obliged to provide compensation to consumers for losses caused by their products, either through refunds, replacement with equivalent goods or services, or monetary damages, to be fulfilled within seven days of the transaction. In circumstances where producers fail to voluntarily fulfill these obligations, consumers are entitled to pursue legal remedies, including litigation or alternative dispute resolution, either individually, collectively, or through consumer protection organizations (Rahman, 2020). This framework ensures that consumers have broad access to justice and that business actors cannot evade accountability for harm caused by defective products (Novita & Santoso, 2021).

In the AKI case arising from contaminated syrup drugs represents a concrete illustration of these legal principles in practice. Parents of child victims, acting collectively, filed a class action lawsuit against PT Afi Farma as the producer and CV Samudera Chemical as the supplier of APIs. The Central Jakarta District Court, in its ruling, held both parties jointly liable and ordered compensation payments of Rp50,000,000 to the heirs of deceased victims and Rp60,000,000 to survivors undergoing treatment or rehabilitation. Importantly, the scope of compensation was limited to those plaintiffs who were able to substantiate their claims in court. This judgment demonstrates the practical application of UUPK provisions on business actor liability, compensation rights, and consumer dispute resolution. It also highlights how corporate accountability can be judicially enforced in cases where negligence or regulatory non-compliance results in consumer harm.

The Judicial Consideration in Decision Number 771/Pdt.G/2022/PN Jkt.Pst Concerning The Application of Pharmaceutical Industry in The Context of a Consumer Class Action

The legal dispute over the AKI tragedy in children was brought before the Central Jakarta District Court through a class action, registered as Case Number 771/Pdt.G/2022/PN Jkt.Pst., highlighting its significance as a matter of public interest. In Indonesian law, a class action allows one or more representative plaintiffs who have suffered losses to litigate on behalf of a larger group with similar facts and legal claims (Marbun, 2024). This mechanism not only consolidates similar lawsuits to reduce time and costs but also enhances access to justice for victims with limited resources and serves a deterrent function against future misconduct (Adhim, 2018).

The procedural basis for class actions in Indonesia is governed by Supreme Court Regulation (PERMA) Number 1 of 2002 on Class Action Procedures. This regulation establishes key admissibility criteria, including that the class must be sufficiently large to make individual lawsuits impractical and that representative plaintiffs must share substantial similarity in facts and legal claims with class members. Representatives are further obliged to act in good faith, prioritizing collective over personal interests (Marbun, 2024). Article 3 of PERMA Number 1 of 2002 outlines the formal requirements of a class action claim, such as the complete identity of representatives, a clear class definition, and notification to members regarding case progress. The statement of claim must specify subgroups, if any, and detail the relief sought, including the type and amount of compensation. It must also propose a concrete distribution mechanism, such as a supervisory team or panel to guarantee fairness, transparency, and accountability in the enforcement of court decisions.

The lawsuit was initiated by a representative group of plaintiffs, namely parents of children affected by the tragic cases of Acute Kidney Injury (AKI). The defendants comprised pharmaceutical companies alleged to have manufactured or distributed drug products containing hazardous substances, alongside government agencies accused of neglecting their regulatory and supervisory obligations to safeguard public health and consumer safety. The named defendants were; PT Afi Farma (Defendant I); PT Universal Pharmaceutical Industries (Defendant II, later released from the suit following a settlement); CV Samudera Chemical (Defendant III); PT Tirta Buana Kemindo (Defendant IV, also released after settlement); CV Mega Integra (Defendant V, released after settlement); PT Logicom Solution (Defendant VI, released after settlement); CV Budiarta (Defendant VII, released after settlement); PT Mega Setia Agung Kimia (Defendant VIII, released after settlement); BPOM (Defendant IX); the Ministry of Health (Defendant X); and the Ministry of Finance (Co-Defendant).

The class action was advanced on behalf of three groups of plaintiffs, each representing families directly harmed by allegedly contaminated or improperly manufactured pharmaceutical products. Group I consisted of eighteen families whose children died after consuming syrup medicine produced by Defendant I. Group II comprised six families whose children suffered serious illness after ingesting products of Defendant I. Group III included one family whose child died after consuming syrup medicine produced by Defendant II; however, this group was subsequently excluded from the litigation following a settlement with the defendant. The plaintiffs were legally represented by the Tim Advokasi untuk Kemanusiaan (TANDUK), a humanitarian legal advocacy team.

In this case, the Panel of Judges relied on Article 163 of the *Herziene Indonesisch Reglement* (HIR), Article 283 of the *Rechtsreglement voor de Buitengewesten* (RBg), and Article 1865 of the Indonesian Civil Code as the legal basis for allocating the burden of proof. These provisions affirm the principle that in civil proceedings, the party asserting a claim bears the responsibility of substantiating it (Aulia, Ramadhan, Fauzi, Doorson, Diaz, & Siswajanthy, 2024). This principle is consistent with the concept of *passive rechter* within the Indonesian civil procedural law system, in which judges remain passive and adjudicate solely on the basis

of the claims and evidence submitted by the parties during the proceedings. Unlike in criminal cases, judges do not play an active role in seeking or uncovering evidence. Consequently, judges are bound by the statements of claim and the evidence presented, and may not render a decision beyond the relief sought in the petitum (Rifai, 2020).

Within the AKI class action, the plaintiffs sought a judicial declaration that the defendants had committed an unlawful act. Pursuant to Article 1365 of the Indonesian Civil Code, an unlawful act is defined as conduct that contravenes juridical norms and causes harm to others, thereby giving rise to an obligation to provide compensation. The establishment of liability under this provision requires proof of four essential elements; (1) the existence of an act, whether through action or omission; (2) the act's contravention of statutory provisions or established norms; (3) the occurrence of material or immaterial loss; and (4) a causal connection between the act and the injury suffered (Halipah, Purnama, Pratama, Suryadi, & Hidayat, 2023).

In the AKI case, the remaining defendants were Defendant I, Defendant III, Defendant IX, and Defendant X. The court held that only Defendant I and Defendant III had committed unlawful acts. Defendant I liability was supported by a prior criminal judgment against its directors and managers under the Health Law, which established the company's role in producing and distributing contaminated medicines. Defendant III was likewise held responsible for supplying contaminated Propylene Glycol to Defendant I. The combination of civil evidence and criminal findings reinforced the conclusion that both companies bore civil liability for damages. By contrast, claims against Defendant IX and Defendant X were dismissed. The court reasoned that the plaintiffs' reliance on Article 46 paragraph (1) of the UUPK was misplaced, as the UUPK applies solely to business actors engaged in commercial activities, not to state institutions performing regulatory or supervisory functions.

In addition to the application for unlawful acts, the plaintiffs also submitted an application for compensation for both material and immaterial losses. Under Indonesian law, material losses refer to compensation claims for pecuniary losses that can be directly quantified in monetary terms, such as medical expenses, loss of income, or property damage. By contrast, immaterial losses denote requests for compensation arising from non-pecuniary harm, encompassing emotional distress, reputational damage, or the deprivation of life's enjoyment resulting from unlawful conduct (Monalisa, Hasan, & Yahya, 2025). Details of the material and immaterial losses experienced by the plaintiffs are as follows:

1. The material losses for the plaintiff whose child died include costs for components during pregnancy for approximately nine months amounting to IDR 25,500,000; costs for components for childbirth amounting to IDR 23,500,000; costs for components for the child during infancy (under five years old) amounting to IDR 250,000,000; and losses during the period of illness, treatment, and funeral process amounting to IDR 50,000,000.
2. The material losses for plaintiffs whose children were ill but did not die, material losses include loss of income due to being unable to work for nearly three months, amounting to IDR 30,000,000; medical and transportation costs for approximately three months, amounting to IDR 10,000,000; and costs during the child's hospitalization for three months, amounting to IDR 45,000,000.
3. The immaterial losses for plaintiffs whose children died include loss of potential income calculated from the age of 23 to 60 years (37 years) with a minimum monthly wage of IDR 3,500,000, for a total of IDR 1,554,000,000; loss of other potential income, including appreciation in property values over approximately 60 years, amounting to IDR 1,000,000,000; and psychological losses for the victim's family, estimated at IDR 500,000,000.
4. The immaterial losses for plaintiffs whose children are sick but do not die, immaterial losses include loss of potential income as a healthy person where the victim suffers from lifelong

internal and physical disabilities resulting in the loss of half of the wages that should have been earned until the age of 60, with a total loss of IDR 555,000,000; losses due to having to bear the cost of long-term treatment for organ damage and disabilities amounting to IDR 2,000,000 per month for the remainder of life until the age of 60 (55 years), with a total loss of IDR 1,320,000,000; as well as psychological losses for the victim's family which are assessed at IDR 250,000,000.

In granting the class action for compensation, the Panel of Judges was required to determine the amount of compensation, the beneficiaries, the distribution mechanism, and the procedural steps to be carried out by the class representatives (Parlina, 2021). In its reasoning, the court referred to Article 19 of the UUPK and to Minister of Social Affairs Decree No. 185/HUK/2023, which had established compensation of IDR 50,000,000 for the heirs of deceased child victims and IDR 60,000,000 for surviving victims undergoing treatment. In its legal reasoning, the Panel of Judges considered that the amount of compensation stipulated in the Decree of the Minister of Social Affairs was appropriate to serve as a reference in granting part of the Plaintiffs' claim for damages. Accordingly, the Panel of Judges held that Defendant I and Defendant III were jointly and severally liable to pay compensation in the form of financial relief to the Plaintiffs, in an amount equivalent to that determined by the Government.

The granting of such compensation was limited only to the Plaintiffs who were proven to have legal capacity as the parents of the child victims of GGAPA, in accordance with the evidence submitted during the proceedings, namely Group I and Group II, comprising a total of 24 victim families. The court emphasized that PERMA Number 1 of 2002 only recognizes an *opt-out* mechanism, which allows class members to withdraw from the case, but does not provide a mechanism for joining after judgment (Widiarty, 2015). To ensure effective enforcement, the Panel of Judges approved detailed procedures for compensation distribution, delegating responsibility to the Plaintiffs' Team, composed of legal counsel and class representatives, to oversee implementation. Payments were to be disbursed through the plaintiffs' legal representatives or duly authorized agents, a safeguard designed to protect victims' interests and guarantee orderly execution of the court's ruling.

CONCLUSION

The case of Acute Kidney Injury (AKI) in children, triggered by contamination of syrup-based medicines with ethylene glycol (EG) and diethylene glycol (DEG), demonstrates that the pharmaceutical industry bears a strict legal responsibility to guarantee product safety in accordance with the Consumer Protection Law (UUPK) and the National Agency of Drug and Food Control (BPOM) Regulation No. 7 of 2024 on Good Manufacturing Practice. The failure of pharmaceutical industry to comply with these standards caused severe consumer losses and legally confirmed the principle of producer liability, both through the obligation to compensate victims and to comply with mandatory production standards.

At the same time, the class action mechanism proved to be an effective instrument in pursuing consumer rights in this case. Based on Supreme Court Regulation (PERMA) No. 1 of 2002, the representative lawsuit enabled victims with identical legal interests to consolidate their claims, thereby improving procedural efficiency and access to justice. The judicial reasoning in this case emphasized the application of the unlawful act principle as the foundation of liability, while clarifying the limits of responsibility for state institutions that cannot be equated with business actors. Furthermore, the adoption of a collective compensation mechanism through class representatives ensured fairness, transparency, and effective enforcement of the court's decision.

Accordingly, this study concludes that consumer protection in the pharmaceutical sector requires strict compliance with production standards by the industry, and that the legal system

must be prepared to enforce producer liability through the class action mechanism as a means of ensuring collective and tangible remedies for victims.

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