Multidisciplinary Output Research For Actual and International Issue (MORFAI Journal) ISSN (e): 2808-6635
Volume 6 No. 5 (2026)

LEGAL PROTECTION FOR CONSUMERS AGAINST MEDICINAL PRODUCTS THAT POSE HEALTH RISKS: OPTIMIZING THE SUPERVISORY ROLE OF THE INDONESIAN FOOD AND DRUG AUTHORITY (BPOM) FROM THE PERSPECTIVE OF THE RULE OF LAW

Aulia Jasmine Ayu Malika[1], Himawan Sugiharto[2], Soesi Idayanti[3]
[1,2,3]Universitas Pancasakti Tegal
E-mail: jasmine.ayumaaaa@gmail.com[1*], himawan_sugiharto@upstegal.ac.id[2], soesi_idayanti@upstegal.ac.id[3]

Received : 10 June 2026 Accepted : 04 July 2026
Revised : 22 June 2026 Published : 20 July 2026

Abstract

"As a rule of law state that embraces the welfare state concept, Indonesia has an affirmative obligation to safeguard the safety of its citizens through the supervision of high-risk pharmaceutical products. The 2022 outbreak of Atypical Progressive Acute Kidney Injury (APAKI), caused by contamination with Ethylene Glycol (EG) and Diethylene Glycol (DEG) in syrup-based medicinal products, which resulted in the deaths of 324 children, underscores the urgent need to reconstruct the pharmaceutical regulatory oversight system. This study employs a normative juridical research method using statutory, case, and conceptual approaches. The findings indicate that the pre-market and post-market supervisory functions carried out by the Indonesian Food and Drug Authority (BPOM) have not been implemented optimally due to structural constraints, limited resources, and insufficient responsiveness to the evolving risks associated with modern pharmaceutical preparations. Grounded in the Responsive Law Theory and the concept of law as a tool of social engineering, the optimization of preventive and repressive legal protection for consumers must be achieved through the transformation of risk-based supervision, strengthening the accountability of state liability, digitalization of the pharmaceutical supply chain, and the integration of inter-institutional regulatory oversight.

Keywords: Consumer Protection, Indonesian Food and Drug Authority (BPOM), Optimization of Regulatory Oversight, Rule of Law, High-Risk Medicinal Products.

INTRODUCTION

Indonesia explicitly declares itself to be a rule of law state (rechtstaat), as stipulated in Article 1 paragraph (3) of the 1945 Constitution of the Republic of Indonesia. This manifestation of the modern rule of law concept, which is oriented toward the welfare state, imposes an affirmative obligation upon the State to provide public services in order to guarantee every citizen's right to health and the protection of life as fundamental human rights. Within the health sector, this state intervention is entrusted to the Indonesian Food and Drug Authority (BPOM) under Presidential Regulation Number 80 of 2017, which authorizes the Agency to conduct the standardization, certification, and supervision of pharmaceutical products both prior to their distribution (pre-market control) and after they have entered the market (post-market control).

However, this commitment to substantive legal protection experienced a functional decline following the emergence of the unprecedented humanitarian tragedy involving the 2022 outbreak of Atypical Progressive Acute Kidney Injury (APAKI). A total of 324 children died after consuming syrup-based medicinal products contaminated with the hazardous chemical substances Ethylene Glycol (EG) and Diethylene Glycol (DEG), the concentrations of which exceeded the permissible safety threshold. The occurrence of this fatal incident, further aggravated by the discovery of similar cases in early 2023 involving the circulation of Praxion syrup, underscores the existence of critical deficiencies in the early detection mechanism and internal audit processes within BPOM's pharmaceutical regulatory oversight system.

From the perspective of the sociology of law, this failure of legal protection reflects an imbalance in bargaining power between consumers of pharmaceutical products, who possess limited access to information, and large pharmaceutical corporations that command substantial capital and technological resources. To examine this issue, Roscoe Pound's Theory of Law as a Tool of Social Engineering is employed as the principal analytical framework to assess the extent to which administrative law is capable of regulating and directing the conduct of

pharmaceutical industry actors in the interest of public welfare. Furthermore, the Responsive Law Theory developed by Philippe Nonet and Philip Selznick is utilized to evaluate BPOM's institutional capacity to evolve from a conventional, reactive, and bureaucratic model of administrative oversight toward a predictive and preventive risk-based supervision (risk management) framework. Based on these juridical and empirical dynamics, this article comprehensively examines the principal duties and supervisory functions of BPOM, as well as the formulation for optimizing its institutional oversight in order to uphold the legal protection rights of consumers of pharmaceutical products in Indonesia.

METHOD

This study employs a normative legal research method, which examines the law through library materials or secondary data as the primary sources of information. This approach focuses on analyzing legal norms embodied in statutory regulations, legal doctrines, and judicial decisions to examine the regulatory framework governing drug supervision by the Indonesian Food and Drug Authority (BPOM) and its implementation in providing legal protection for consumers against the circulation of medicines that may pose risks to public health. Normative legal research views law as a prescriptive system of norms and therefore aims to identify the legal rules, principles, and doctrines relevant to addressing the research problem (Marzuki, 2021).

This study also examines the effectiveness of the implementation of legal norms in practice, particularly regarding BPOM's supervision of pharmaceutical products, which in several cases continues to exhibit various shortcomings. Accordingly, the research adopts a descriptive-analytical design that systematically describes the legal facts concerning BPOM's supervisory system and subsequently analyzes the legal issues arising from the suboptimal implementation of its supervisory functions, thereby generating conclusions that are consistent with the objectives of the study (Marzuki, 2021).

In addition to its descriptive-analytical nature, this study is also prescriptive, as it not only identifies legal issues but also proposes recommendations to optimize BPOM's supervisory role in strengthening legal protection for consumers. These recommendations are formulated through the application of the IRAC approach (Issue, Rule, Application, and Conclusion), ensuring that the proposed solutions are supported by systematic legal reasoning and are directly relevant to the legal issues examined in this study (Marzuki, 2021).

RESULTS AND DISCUSSION

The Indonesian Food and Drug Authority (BPOM) is a non-ministerial government agency whose principal mandate is to supervise the safety, efficacy, and quality of medicinal products and food circulating in Indonesia. BPOM was established pursuant to Presidential Regulation Number 80 of 2017 and is directly accountable to the President. The Agency plays a strategic role in ensuring that products consumed by the public comply with the prescribed standards of safety and quality. Broadly speaking, the implementation of BPOM's administrative supervisory authority is divided into two principal pillars, namely Pre-Market Control and Post-Market Control.

BPOM performs a wide range of functions, including monitoring products circulating in the market, establishing regulatory standards and safety requirements, and educating the public regarding safe and legally authorized products. In addition, BPOM possesses the authority to impose administrative sanctions, including the revocation of marketing authorizations and the withdrawal of products that fail to satisfy regulatory requirements. One of its principal functions is pre-market control, which constitutes a concrete manifestation of the preventive function of law within the framework of state administrative law. At this stage, BPOM acts as a gatekeeper by assessing whether pharmaceutical products satisfy the requirements of quality, safety, and efficacy before granting a Marketing Authorization Number (Nomor Izin Edar—NIE). Such evaluation is conducted through the examination of registration dossiers, verification of compliance with Good Manufacturing Practices (Cara Pembuatan Obat yang Baik—CPOB), and laboratory toxicity testing.

However, the Ethylene Glycol (EG) and Diethylene Glycol (DEG) contamination incident involving syrup-based medicinal products in 2022 revealed the existence of a critical structural deficiency. To date, pre-market supervision has frequently been confined to administrative formalities through documentary review, while failing to undertake comprehensive direct testing of the import supply chain for pharmaceutical excipients, such as sorbitol, glycerin, and propylene glycol, which are vulnerable to contamination by industrial impurities. The limited availability of liquid chromatography technology and the lack of direct audits of chemical importers' warehouses have become major weaknesses within this preventive line of defense.

Post-market control is founded upon the principle of continuous control, under which the State is obligated to ensure that the quality of pharmaceutical products remains consistent and safe throughout their use by the general public. Its scope encompasses periodic product sampling, inspection of distribution facilities, and the implementation of pharmacovigilance systems for monitoring adverse drug reactions. The mass fatalities of children resulting from acute kidney injury exposed the fact that the existing post-market surveillance subsystem was highly reactive and bureaucratic in nature. There has been a persistent phenomenon of under-reporting, whereby reports of medical anomalies or adverse drug reactions submitted by healthcare facilities are frequently responded to belatedly or fail to be adequately integrated into BPOM's central database. Consequently, the recall of hazardous products and the revocation of marketing authorizations for pharmaceutical companies violating regulatory requirements were significantly delayed. From the perspective of the Responsive Law Theory, the supervisory institution has demonstrated insufficient sensitivity and adaptability in detecting latent public health threats, despite the law explicitly guaranteeing consumers' absolute rights to comfort, safety, and security.

The systemic failure to detect at an early stage the circulation of pharmaceutical products contaminated with hazardous chemical substances constitutes tangible evidence of the fragility of consumer legal protection in Indonesia. In fulfilling the right to health and safety, the Indonesian Food and Drug Authority (BPOM) possesses absolute administrative authority and bears primary responsibility as the State's regulatory authority, vested with both preventive and repressive functions pursuant to Presidential Regulation Number 80 of 2017. Nevertheless, the empirical reality of the mass outbreak of Atypical Progressive Acute Kidney Injury (APAKI), which claimed the lives of hundreds of children across various regions, reveals a profound and contradictory gap between law in books and law in action. In carrying out its post-market surveillance function, BPOM has demonstrably remained confined to a rigid supervisory model characterized by paper-based inspections and slow responses to reports of medical anomalies, thereby failing to detect at an early stage the entry of hazardous imported pharmaceutical excipients supplied by pharmaceutical corporations. This systemic ineffectiveness has resulted in widespread violations of Article 4 of Law Number 8 of 1999 concerning Consumer Protection, which expressly guarantees consumers the absolute right to comfort, security, and safety in consuming goods and/or services.

Consumers occupy an extremely vulnerable bargaining position due to the asymmetry of information concerning the biochemical composition of liquid pharmaceutical preparations. Consequently, they are compelled to place complete reliance upon governmental supervision and the ethical integrity of the pharmaceutical industry, which, unfortunately, is frequently subordinated to motives of economic profit maximization. This imbalance is further aggravated by a bureaucratic administrative sanctioning process that tends to be overly accommodative, whereby decisive measures such as product recalls and the suspension of Good Manufacturing Practices (CPOB) certification are often implemented only after the number of fatalities has escalated into a national public health emergency. Such circumstances demonstrate that the early detection subsystem has failed to operate in a responsive manner.

A more comprehensive examination reveals that the fragility of this legal protection originates from the inadequate performance of the State's first line of defense during the initial stage of the product life cycle. Pre-market control constitutes the cornerstone of BPOM's pharmaceutical regulatory oversight system because it is at this stage that the State, through its administrative authority, determines whether a pharmaceutical product is suitable for public distribution or should instead be rejected due to potential health risks. From the perspective of state administrative law, this stage embodies the preventive function of a rule of law state, whereby the State acts not merely after harm has occurred but proactively seeks to prevent potential dangers through rigorous screening mechanisms before medicinal products enter the market.

From a doctrinal standpoint, pre-market control is conducted through a drug registration process involving comprehensive evaluations of multiple aspects, ranging from raw materials and manufacturing processes to clinical trial results demonstrating the product's safety and effectiveness. It is at this stage that BPOM exercises its authority to conduct thorough assessments of quality, safety, and efficacy documentation, which constitute internationally recognized standards within pharmaceutical regulatory systems. Ideally, such evaluations should not merely consist of formal administrative document reviews but should also be scientific in nature, involving rigorous laboratory analyses and toxicological assessments.

However, the contaminated syrup-based medicinal product case demonstrates that this scientific preventive function has undergone severe bureaucratic simplification. BPOM has frequently granted marketing authorizations solely on the basis of documentary verification of compliance, including certificates of analysis, based upon the assumption that manufacturers have independently conducted the required testing, without undertaking random confirmatory laboratory analyses to verify the authenticity of solvents such as glycerin, sorbitol, or propylene

glycol submitted by chemical importers. Once the registration process is reduced to a mere administrative formality for obtaining a marketing authorization, the very essence of pre-market control as an expression of the State's preventive sovereignty is fundamentally undermined, resulting in the toleration of risks that are potentially catastrophic for the public.

Considering the extensive loss of children's lives resulting from failures at both the upstream and downstream levels of regulatory oversight, legal accountability can no longer be imposed exclusively upon business actors under the doctrine of product liability. Rather, it must also encompass the principle of state liability, grounded in the General Principles of Good Governance (algemene beginselen van behoorlijk bestuur). Where maladministration arises in the form of institutional negligence in detecting industrial toxic substances such as Ethylene Glycol (EG) and Diethylene Glycol (DEG) exceeding the permissible limits established under pharmacopoeial standards, the State may, from a juridical perspective, be held liable for both material and immaterial damages on the basis of unlawful acts committed by public authorities (onrechtmatige overheidsdaad), as provided under Article 1365 of the Indonesian Civil Code (Kitab Undang-Undang Hukum Perdata—KUHPerdata). At the same time, law enforcement against pharmaceutical corporations that intentionally or negligently violate Good Manufacturing Practices (CPOB) standards must be strengthened through the application of the doctrine of strict liability, whereby victims are no longer required to establish fault, thereby shortening complex judicial proceedings and relieving consumers of an evidentiary burden that is scientifically beyond their capacity to discharge.

This failure of consumer protection further indicates that the bureaucratic character of pharmaceutical regulatory oversight in Indonesia remains situated within the rigid paradigm of autonomous law. Consequently, optimizing BPOM's institutional performance requires a fundamental transformation toward a responsive law model that rejects rigid legal formalism and prioritizes the protection of human life over administrative procedures. A closer examination reveals that the fragility of legal protection originates from the inadequate performance of the State's first line of defense. Pre-market control constitutes the primary foundation of BPOM's pharmaceutical regulatory oversight system because it is at this stage that the State, through its administrative authority, determines whether a pharmaceutical product is suitable for public distribution or should instead be rejected because it poses potential health risks. From the perspective of state administrative law, this stage embodies the preventive function of the rule of law, whereby the State acts proactively to prevent potential harm through stringent screening mechanisms before medicinal products enter the market. Doctrinally, pre-market supervision is implemented through a drug registration process involving comprehensive evaluations of raw materials, manufacturing processes, and clinical trial results demonstrating the product's safety and effectiveness. At this stage, BPOM exercises its authority to conduct comprehensive assessments of quality, safety, and efficacy documentation, which constitute internationally recognized standards within pharmaceutical regulatory systems. Such evaluations should ideally extend beyond formal administrative review by incorporating rigorous laboratory analyses and toxicological assessments.

The contaminated syrup-based medicinal product case demonstrates that this scientific preventive function has been reduced through bureaucratic simplification. BPOM has frequently granted marketing authorizations solely on the basis of documentary verification of compliance—assuming that manufacturers have independently conducted the required testing—without performing random confirmatory laboratory analyses to verify the authenticity of solvent substances submitted by importers. Once the registration process is reduced to a mere administrative formality for obtaining a marketing authorization, the essence of pre-market control as the embodiment of the State's preventive sovereignty is fundamentally undermined. Therefore, future legal reform must mandate the reconstruction of the registration system by requiring the submission of specific toxicological analysis certificates for every pharmaceutical excipient supply chain before a Marketing Authorization Number (Nomor Izin Edar—NIE) is issued.

CONCLUSION

Based on the findings and discussion comprehensively presented in the preceding sections, several fundamental conclusions may be drawn in response to the principal issue concerning the effectiveness of legal protection for consumers in relation to the circulation of pharmaceutical products in Indonesia. First, legal protection for consumers of pharmaceutical products in Indonesia is currently experiencing a profound crisis of legitimacy and functionality. The ineffectiveness of the Indonesian Food and Drug Authority (BPOM) in carrying out its supervisory functions, both at the pre-market and post-market stages, has been empirically demonstrated by the tragedy of Gangguan Ginjal Akut Progresif Atipikal (GGAPA), which claimed the lives of hundreds of

children. This study concludes that such failure was not merely the result of a medical incident or operational negligence, but rather stemmed from a systemic failure to integrate the welfare state paradigm into the governance of pharmaceutical regulatory oversight. BPOM has remained confined within an autonomous-legalistic bureaucratic model in which supervisory efforts are predominantly focused on compliance with formal administrative requirements, while the substantive safety of pharmaceutical products—characterized by dynamic and complex biochemical considerations—has been neglected. The weakness of the early detection system for contamination by Ethylene Glycol (EG) and Diethylene Glycol (DEG) in syrup-based medicinal products demonstrates that the pre-market control mechanism, which should serve as the primary safeguard of preventive legal protection, has deteriorated into a merely procedural licensing process.

Second, from a doctrinal perspective, this failure of legal protection is rooted in the inability of the supervisory institution to transform itself into a responsive legal institution. According to the Responsive Law Theory advanced by Nonet and Selznick, an ideal pharmaceutical regulatory authority should possess a high degree of sensitivity to social needs and public safety, be capable of rapidly adapting to evolving health threats, and be willing to undertake progressive intervention beyond the rigidity of administrative procedures. In reality, BPOM remains entrenched within the characteristics of autonomous law, exhibiting delayed responses to anomalies identified in the field and tending to act only after fatalities have escalated, rather than adopting a predictive approach. This reflects a substantial gap between das Sollen (what the law ought to be) and das Sein (what actually occurs in practice), ultimately negating consumers' fundamental right to security and safety in the consumption of goods and services as guaranteed under Article 4 of Law Number 8 of 1999 concerning Consumer Protection.

Third, this study concludes that the existing legal accountability framework has yet to provide substantive justice for victims. The doctrine of product liability, which primarily attributes liability to business actors, is often insufficient to restore justice, particularly where the State—through its supervisory authority has demonstrably committed maladministration in fulfilling its duty of care. Accordingly, the principle of state liability, based upon unlawful acts committed by public authorities (onrechtmatige overheidsdaad), becomes relevant to ensure that the State also bears legal responsibility for public losses arising from failures within the regulatory oversight system. Likewise, the application of the doctrine of strict liability to the pharmaceutical industry constitutes an essential legal necessity, as it eliminates the burden of proving fault that has traditionally disadvantaged consumers as the more vulnerable party from both economic and technical-biochemical perspectives. Consequently, the reconstruction of pharmaceutical regulatory oversight should be regarded as an integral instrument of social engineering, whereby law functions not merely as a collection of static legal provisions but as a dynamic instrument (law as a tool of social engineering) for compelling the establishment of a pharmaceutical industry that places the protection of human life above the pursuit of profit.

REFERENCES

I. BOOKS

Asshiddiqie, J. (2021). *Konstitusi dan Konstitusionalisme Indonesia*. Jakarta: Sinar Grafika.
Hadjon, P. M., & Djatmiati, T. S. (2020). *Argumentasi Hukum*. Yogyakarta: Gadjah Mada University Press.
Ibrahim, J. (2019). *Teori dan Metodologi Penelitian Hukum Normatif*. Malang: Bayumedia.
Luhmann, Niklas. *Social Systems*. Stanford: Stanford University Press, 2021.
Marzuki, P. M. (2021). *Penelitian Hukum*. Jakarta: Kencana.
Nonet, Philippe, & Philip Selznick. (2017). *Hukum Responsif*. Terjemahan Rafael Edy Bosch. Jakarta: Nusa Media.
Pound, Roscoe. *An Introduction to the Philosophy of Law*. New Haven: Yale University Press, 2020.
Rini, I., & Idayanti, S. (2025). Strategi Penelitian Hukum: Teori, praktik, dan Inovasi. K-Media.
Soekanto, S., & Mamudji, S. (2021). *Penelitian Hukum Normatif*. Jakarta: RajaGrafindo Persada.
Stahl, Friedrich Julius. *Philosophy of Law*. Oxford: Oxford University Press, 2004.
Sunggono, B. (2020). *Metodologi Penelitian Hukum*. Jakarta: RajaGrafindo Persada.
Widiyastuti. *Asas-Asas Pertanggungjawaban Perdata*. Jakarta: (Penerbit), 2020.
Widjaja, G., Santoso, B., & Hidayat, M. (2022). *Manajemen Risiko dalam Pengawasan Produk Farmasi*. Jakarta: Prenada Media.

II. JOURNAL ARTICLES / SCHOLARLY WORKS

Agusta, M. "Pengaturan Mutu Produk Pangan." *DATIN Law Journal* 1, no. 1 (2020)

Amalia, R. A., & Mulyanti, A. S. (2024). Peranan Badan Pengawas Obat dan Makanan (BPOM) dalam Mengawasi Peredaran Obat Tradisional yang Mengandung Bahan Kimia Obat. *ALADALAH: Jurnal Politik, Sosial, Hukum dan Humaniora*, *2*(4).

Ardianti, L.. "Analisis Persepsi Orang Tua Terhadap Obat Sirup dan GGAPA." *Jurnal Kesehatan* 3, no. 3 (2023)

Ardianti, R., Prasetyo, B., & Kurniawan, D. (2023). *Risk-Based Supervision dalam Pengawasan Obat di Indonesia*. Jurnal Hukum Kesehatan.

Aryawati, K. A. "Tanggung Gugat Farmasi Akibat Obat Sirup EG/DEG." *Indonesian Journal of Legal Justice* 1, no. 4 (2024): 18–25. Bahmid, B. "Peranan BPOM dalam Perlindungan Konsumen." *De Lega Lata* 5, no. 2 (2020)

Bahmid, A., Panjaitan, B., & Siregar, R. (2020). *Peran BPOM dalam Sistem Perlindungan Konsumen di Indonesia*. Jurnal Hukum dan Regulasi.

Bahmid, B., Martua, J., & Arbiah, A. (2020). Peranan Badan Pengawas Obat Dan Makanan Dalam Memberikan Perlindungan Studi Di Kantor Cabang Badan Pengawas Obat Dan Makanan Badan Pengawas Obat Makanan (BPOM) Tanjungbalai. *De Lega Lata: Jurnal Ilmu Hukum*, *5*(2).

Lubis, Achmad Raihansyah, & Dwi Desi Yayi Tarina. (2023). Perlindungan hukum terhadap konsumen akibat mengkonsumsi obat sirup yang merusak kesehatan. *Jurnal USM Law Review*, 6(3)

Tampubolon, W. S. (2018). Peranan dan Tanggung Jawab Badan Pengawas Obat dan Makanan (BPOM) Terkait Kasus Albothyl Menurut Undang Undang Perlindungan Konsumen. *Jurnal Ilmiah Advokasi*, *6*(1).

Umami, Allan Mustafa, et al. (2023). Tanggung gugat keperdataan Badan Pengawas Obat dan Makanan (BPOM) Indonesia dalam peredaran obat-obatan yang menyebabkan gagal ginjal akut pada anak. *Jurnal Risalah Kenotariatan*, 4(1).

Simanjuntak, H. (2024). *Reformasi Kelembagaan BPOM dalam Meningkatkan Pengawasan Obat*. Jurnal Kebijakan Publik.

Widjaja, G. "Pengawasan serta Pemberian Izin Edar Vaksin COVID-19." *ZAHRA Journal* 2, no. 4 (2022)

Widodo, S. (2023). *Negara Hukum dan Perlindungan Hak atas Kesehatan*. Jurnal Konstitusi dan HAM.

Wirawan, A. F. "Tanggung Jawab BPOM Berdasarkan UU 17/2023." *Innovative Journal* 4, no. 3 (2024)

Zein, Syafira. (2023). Aspek hukum perlindungan konsumen produk obat-obatan berdasarkan BPOM (Kasus obat sirup tercemar EG/DEG). *Unnes Law Review*, 6(2)

II. LEGISLATION

International Covenant on Economic, Social and Cultural Rights (ICESCR), 2022.

Kitab Undang-Undang Hukum Perdata (Burgelijk Wetboek).

Peraturan BPOM Nomor 21 Tahun 2020 tentang Organisasi dan Tata Kerja BPOM.

Peraturan Presiden Nomor 80 Tahun 2017 tentang Badan Pengawas Obat dan Makanan.

Undang-Undang Dasar Negara Republik Indonesia Tahun 1945.

Undang-Undang Nomor 8 Tahun 1999 tentang Perlindungan Konsumen.

Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan.

III. INTERNET SOURCES

Asatunews. "Panggil BPOM atas Kelalaian Mengawasi Obat Sirup." 2022.

BBC Indonesia. "Gagal Ginjal Akut: Skandal Obat Sirop Belum Berakhir." 2023.

BPOM. *Laporan Pengawasan Obat dan Makanan 2021*. Jakarta: BPOM, 2021.

BBC News Indonesia. (2024). *Gagal Ginjal Akut: Skandal obat sirup belum berakhir*. Diperoleh dari https://www.bbc.com/indonesia/articles/cx9v2z98ze8o

Salsabila, Rindi. (2024). *Obat sirup berbahaya: 324 anak meninggal, BPOM digugat*. CNBC Indonesia. Diperoleh dari https://www.cnbcindonesia.com/lifestyle/20221226174054-33-400254-meninggal-bpom-digugat

CNBC Indonesia. Salsabilla, R. "Obat Sirup Berbahaya: 324 Anak Meninggal." 2022.

CNBC Indonesia. Salsabilla, R. "Update Kasus Obat Sirup." 2022.

EMA – European Medicines Agency. *Pharmacovigilance Systems Overview*. 2021.

FDA – U.S. Food & Drug Administration. *Drug Safety Communication Guidelines*. 2020.

National Library of Medicine. "What Are Drug Substances?" 2024.

Ruff, K. "Global Pharmaceutical Supply Chains." *International Journal of Health Policy* (2020)