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Reconstructing the Legal Framework for Drug and Food Supervision by Indonesia's Food and Drug Supervisory Agency: A Conceptual and Practical Analysis

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ABSTRACT

Recent incidents involving unsafe drugs and food products in Indonesia highlight persistent challenges in regulatory oversight. Although the Food and Drug Supervisory Agency (BPOM) is the primary authority for public health protection, institutional overlap and legal limitations constrain its supervisory effectiveness. This study examines the legal framework governing BPOM's drug and food supervision and evaluates its institutional position within Indonesia's constitutional system to identify necessary legal reforms. Unlike previous studies focusing mainly on regulatory implementation, this research analyzes BPOM's authority from institutional and constitutional perspectives and proposes a reconstruction of its legal framework. A socio-legal approach was employed using statutory, conceptual, historical, and case approaches. Primary data were obtained through interviews with legal experts and practitioners, while secondary data comprised legislation, legal literature, and relevant judicial and policy documents. The findings show that fragmented institutional arrangements and overlapping governmental authority weaken BPOM's supervisory effectiveness. Existing legislation also provides insufficient support for institutional independence, particularly following the discontinuation of the Draft Law on Drug and Food Supervision. This study proposes reconstructing BPOM's legal and institutional framework to strengthen regulatory certainty, institutional independence, and public health protection.

INTRODUCTION

Health, a divine gift bestowed upon humankind, must be safeguarded. It enables individuals to conduct daily activities and fulfill their essential needs.¹ Normatively, health is understood as a state of physical, mental, and social well-being, rather than merely the absence of disease or infirmity, allowing individuals to live productive lives.² Under the objectives of healthcare administration, which include promoting healthy lifestyles and providing legal protection and certainty for patients, human resources, and the broader public,³ the government is responsible for planning, regulating, organizing, fostering, and supervising the delivery of quality, safe, efficient, equitable, and accessible healthcare services.⁴

¹ Takdir, Introduction to Health Law, 1st ed. (IAIN Palopo Campus Publishing Institution, 2018), 11.

² Article 1 Number 1 of Law Number 17 of 2003 concerning Health.

³ Article 3 of Law Number 17 of 2003 concerning Health.

⁴ Article 6 of Law Number 17 of 2003 concerning Health.

One key aspect of public health, namely, the supervision of drugs and food products, continues to encounter various challenges in Indonesia, as evidenced by numerous high-profile cases. For instance, the Acute Kidney Injury (AKI) outbreak among children in 2022, resulting from the consumption of fever-reducing syrup medications contaminated with hazardous levels of ethylene glycol (EG) and diethylene glycol (DEG), highlighted serious deficiencies. These chemical compounds, commonly used in textile dyeing, can metabolize into oxalic acid and form crystals in the kidneys, leading to renal failure.⁵ The incident raised widespread public concern and was perceived as a consequence of governmental negligence, particularly by the National Agency of Drug and Food Control (BPOM), the primary regulatory authority in this domain. According to the Indonesian Consumers Foundation (YLKI), the crisis reflected systemic regulatory and institutional failures. BPOM was viewed as a multi-agency body lacking singular authority due to its overlapping functions with institutions such as the Ministry of Health.⁶

Another notable issue involved the distribution of counterfeit drugs in Jakarta and West Java, where the Regional Police arrested ten suspects and seized approximately 430,000 tablets. Laboratory tests conducted by BPOM indicated that the drugs were counterfeit, illegally produced without authorization, and had expired.⁷ In 2023, additional concerns emerged regarding excessive or false claims (overclaims) in cosmetic product advertisements.⁸ These products were often marketed with exaggerated or misleading descriptions of their ingredients and efficacy, undermining safety, quality, and effectiveness merely to expedite sales and obtain distribution permits.

Institutional challenges persist, particularly regarding the effectiveness of BPOM's roles and responsibilities. In principle, policy formulation prior to and during product distribution, as well as the development of norms, standards, procedures, and criteria, and the implementation of evaluations and reporting in the realm of supervision, are comprehensively regulated under BPOM Regulation No. 21 of 2020 concerning the Organizational Structure and Working Procedures of BPOM. Both central and regional governments conduct health sector supervision and may involve community participation. In cases where violations occur, as exemplified by the aforementioned

⁵ Umami Allan Mustafa, et al., "Civil Liability of the Indonesian Food and Drug Supervisory Agency (BPOM) in the Circulation of Drugs Causing Acute Kidney Failure in Children.," *Journal of Notary Treatise* 4, no. 1 (2023): 377, <https://doi.org/https://doi.org/10.29303/risalahkenotariatan.v4i1.111>.

⁶ Nasional Kompas, "Cases of Acute Kidney Failure, Syrup Raw Materials Management, and the Authority of BPOM," <https://nasional.kompas.com/read/2022/11/12/06030091/kasus-gagal-ginjal-akut-oplosan-bahan-baku-obat-sirup-dan-kewenangan-bpom?page=all>, December 11, 2022.

⁷ Kompas, "Police Arrest Manufacturers of Hundreds of Thousands of Counterfeit and Illegal Drugs," <https://www.kompas.id/baca/metro/2023/01/27/sejumlah-430000-butir-obat-obatan-ilegal-telah-beredar-selama-satu-tahun>, January 27, 2023.

⁸ Rafyanka Ivana Putri Ngabito, "Analysis of Legal Liability for the Distribution of Skincare Products Proven to be Overclaimed," *Law, Development & Justice Review* 7, no. 3 (2024): 286, <https://doi.org/https://doi.org/10.14710/ldjr.7.2024.284-301>.

incidents, or where inspectors find initial indications of criminal offenses,⁹ post-market surveillance becomes imperative.

Institutionally, BPOM is authorized to appoint Civil Servant Investigators (PPNS) who function as law enforcement officers with specific investigatory powers under the applicable criminal procedural law and related legislation. Although these investigators hold *lex specialis* authority in drug and food regulation, successful prosecution often depends on collaboration with other law enforcement bodies. However, conflicts frequently arise between the Indonesian National Police (POLRI) and BPOM investigators, mainly due to divergent interpretations of investigatory findings, resulting in insufficient deterrence for offenders.¹⁰

Another institutional issue relates to BPOM's ambiguous hierarchical status. Under Presidential Decree No. 103 of 2001, BPOM is classified as a Non-Ministerial Government Institution (LPNK) directly responsible to the President. However, Article 1(2) of Presidential Regulation No. 80 of 2017 stipulates that BPOM reports to the President through the Minister of Health (MoH), thereby creating a perception that BPOM is subordinated to the MoH. This situation has fueled discussions of a potential merger between BPOM and the MoH. The MoH has criticized the agency for delays in licensing processes and has expressed an interest in assuming some of BPOM's responsibilities, arguing that bureaucratic red tape contributes to inflated drug and drug prices.¹¹

Modern state development necessitates government responsiveness to public concerns manifested through two primary dimensions: justice and legal legitimacy. Justice relates to the community's inherent need for fairness. Simultaneously, legality pertains to enforcing positive law, rules enacted by legitimate state authority and imposed with the force of law.¹² This conceptual framework is essential to achieving the fundamental goal of the state: the attainment of individual and social well-being.¹³ SF Marbun asserts that a just and well-ordered state must be founded upon sound and equitable law. Good laws are those that are democratic, grounded in the will and awareness of the people, while just laws are those that align with and fulfill the essential aims of all legal systems, including public health regulation.¹⁴

Prior studies have addressed overlapping themes relevant to this research. One study examined BPOM's regulatory framework and its interaction with the Ministry of Health, proposing

⁹ Article 111 of Law Number 18 of 2012 concerning Food.

¹⁰ Hukum Online, "PPNS Authority Overlaps with Police," <https://www.hukumonline.com/berita/a/kewenangan-ppns-tumpang-tindih-dengan-polri-hol16248/>, February 21, 2007.

¹¹ Detik News, "Review of the Plan to Merge BPOM into the Ministry of Health," <https://news.detik.com/kolom/d-4825789/meninjau-ulang-rencana-melebur-bpom-ke-kemenkes>, December 17, 2019.

¹² Edi Prabowo, *Law and Public Policy* (YPAPI, 2004), 30-31.

¹³ Juniarso Ridwan, *State Administration Law and Public Service Policy* (Nuansa Cendekia, 2009), 47.

¹⁴ SF Marbun, *Administrative Justice and Administrative Efforts in Indonesia* (Liberty, 1997), 8.

revisions through the draft Drug and Food Supervision (RUU POM).¹⁵ Another study explored the effectiveness of BPOM's supervisory role in handling the acute kidney injury outbreak in children, highlighting its function in consumer protection. Although thematically related, these works differ in focus, particularly their case-based approach to regulatory effectiveness.¹⁶ A further study emphasized that, normatively, BPOM should hold sole authority over the supervision of drugs and food products manufactured and distributed in Indonesia, with mandatory distribution permits based on product quality, efficacy, and safety. Despite sanctions, unauthorized products remain circulated, primarily due to misleading promotional content, particularly online.¹⁷

Given the outlined background, it is essential to explore the extent to which BPOM contributes to drug and food supervision in Indonesia, and whether it is necessary to redesign BPOM's institutional structure as a non-ministerial supervisory agency. While prior studies have discussed related regulatory and institutional issues, none have specifically examined BPOM's supervisory role as a formal legal procedure, nor have they assessed the urgency of institutional restructuring. To achieve the objectives of this study, the discussion is organized into three main parts. The first part examines the institutional status of BPOM as an auxiliary state organ within Indonesia's constitutional framework, with particular emphasis on its legal position and supervisory authority. The second part evaluates the implementation of drug and food supervision by BPOM, highlighting practical challenges and institutional issues identified through legal analysis and empirical findings. The final part proposes measures to strengthen BPOM's institutional framework by addressing regulatory gaps, clarifying institutional authority, and enhancing the effectiveness of drug and food supervision in Indonesia.

Despite the existence of an extensive regulatory framework, BPOM continues to face institutional and legal challenges arising from overlapping authority, ambiguous institutional status, and fragmented regulatory governance. These conditions raise fundamental questions regarding whether the current legal framework adequately supports BPOM's supervisory functions and whether institutional reconstruction is required. Accordingly, this study addresses two research questions: (1) how is BPOM's supervisory authority positioned as a legal procedure within Indonesia's regulatory framework; and (2) how should BPOM's institutional framework be reconstructed to strengthen the effectiveness of drug and food supervision?

¹⁵ Decky Firmansyah, "Three Strong Reasons for the Need to Strengthen the Functions and Authority of the POM Agency, Pharmaceutical Magazine, vol. 3, 2016, p. 1-4

¹⁶ Yuliana Kemalasari, et al., "The Effectiveness of BPOM RI Supervision on the Circulation of Fever, Flu and Cough Drugs That Cause Death from Acute Kidney Failure in Children."

¹⁷ Rafyanka Ivana Putri Ngabito, "Legal Liability Analysis..." *Op.cit.*, pp. 289–293.

Previous studies have primarily focused on BPOM's regulatory implementation and consumer protection functions. However, limited attention has been given to BPOM's institutional position and the adequacy of its legal framework in supporting effective supervision. This study addresses this gap by examining BPOM's supervisory authority from constitutional and administrative law perspectives and proposing institutional reforms to strengthen legal certainty, independence, and regulatory effectiveness.

METHODS

This study employed a qualitative socio-legal research method, design combining normative legal analysis with empirical inquiry to evaluate the legal framework governing drug and food supervision in Indonesia. Primary legal materials consisted of the 1945 Constitution, statutes, presidential regulations, and other regulations governing BPOM. Secondary legal materials included books, journal articles, legal commentaries, and previous studies, while tertiary legal materials comprised legal dictionaries and encyclopedias.

These included the statute approach, applied to examine the primary function of BPOM, namely its regulatory and supervisory authority; the conceptual approach, used to explore theoretical frameworks related to supervision and institutional structures; the case approach, employed due to the frequent occurrence of legal cases in the health sector discussed in this article; and the historical approach, utilized to trace the institutional development of BPOM as a Non-Ministerial Government Institution (LPNK) vested with supervisory authority over drugs and food.

Empirical data were collected through semi-structured interviews with key informants representing BPOM, the Ministry of Health, and legal scholars specializing in administrative and health law. Informants were selected through purposive sampling based on their institutional roles and expertise. Documentary data were collected through systematic review of legislation, judicial decisions, government reports, and academic literature.

Documentary data were collected through systematic review of legislation, judicial decisions, government reports, and academic literature.¹⁸ All collected data were subsequently organized in a structured and coherent format. This entailed systematically interrelating all the gathered data, which were subsequently analyzed qualitatively in accordance with the main research problems, ultimately forming an integrated and comprehensive analysis.¹⁹

Legal materials were analyzed using qualitative legal analysis by interpreting statutory provisions through conceptual, historical, statutory, and case approaches. Interview data were

¹⁸ Muhaimin. 2020. *Legal Research Methods*, 1st ed. Mataram: Mataram University Press, p. 65.

¹⁹ Ronny Hanitidjo Soemitro. 1990. *Legal Research Methodology and Jurimetry*. Jakarta: Ghalia Indonesia, p. 12.

analyzed using thematic analysis and triangulated with documentary evidence to identify institutional inconsistencies, regulatory gaps, and opportunities for reconstructing BPOM's legal framework.

DISCUSSION

The Status of BPOM as an Auxiliary State Organ within the Indonesian Constitutional Framework

Supervising drugs and food plays a strategically vital role in safeguarding public welfare and enhancing the quality of life. Given its critical importance, a specialized agency, categorized as a state auxiliary organ, has been established to ensure effective drug and food oversight implementation. Establishing such auxiliary institutions is also driven by the evolving structure of state administration, which has led to institutional experimentation.²⁰ The BPOM was initially formed as a Non-Departmental Government Institution specializing in the supervision of drugs and food, under Presidential Decree No. 166 of 2000. This agency is directly responsible to the President and coordinates with the Ministry of Health and Social Welfare. This legal basis was subsequently refined through Presidential Decree No. 103 of 2001 on the Status, Duties, Functions, Authority, Organizational Structure, and Working Procedures of Non-Departmental Government Institutions. Article 3 of this decree lists 26 LPNDs, including BPOM.

Presidential Decree No. 103 of 2001 has been amended multiple times, through Presidential Decrees No. 3 of 2002, No. 46 of 2002, No. 30 of 2003, No. 9 of 2004, No. 11 of 2005, Presidential Regulations No. 64 of 2005, No. 3 of 2013, and No. 145 of 2015. However, none of these amendments specifically address substantive changes concerning BPOM. The change in nomenclature from LPND to Non-Ministerial Government Institution was introduced under Article 3 of Presidential Regulation No. 3 of 2013, which amended Presidential Decree No. 103 of 2001 for the seventh time.

It is important to note that prior to the enactment of Law No. 10 of 2004, the term commonly used for such regulations was Presidential Decree. This was formalized through the Provisional People's Consultative Assembly (MPRS) Decree No. XX/MPRS/1966, which abolished previously existing regulatory instruments such as Presidential Regulations and Presidential Determinations. According to the aforementioned MPRS Decree, the Presidential Decree was intended to implement the provisions of the 1945 Constitution and the MPRS/MPR Decrees in the executive sphere, or the form of Government Regulations.²¹ Consequently, the content of Keppres during this period varied, some functioned as regulations (*regelings*), while others were interpreted as administrative decisions

²⁰ Jimly Asshiddiqie, 2006. *Development and Consolidation of the State Post-Reformasi*, 2nd ed. (Jakarta: Sekretariat General and Clerkship of the Constitutional Court of the Republic of Indonesia, p.vii-viii.

²¹ Decree of the Provisional People's Consultative Assembly No. XX/MPRS/1066 part II of the Sequence of Laws and Regulations of the Republic of Indonesia according to the 1945 Constitution.

(*beschikkings*), intended for single-use or *einmalig* purposes. This mixture resulted in a lack of distinction between regulatory and administrative elements within the Presidential Decree.²²

Although auxiliary state institutions serve a functional and service-oriented role, their position and role at the national level are crucial for realizing the constitutional objectives articulated in the Preamble to the 1945 Constitution of the Republic of Indonesia, particularly in its fourth paragraph. The establishment of BPOM falls within this broader constitutional mandate. This institutional positioning can be illustrated as follows:

Table 1.
Institutional Positioning of Constitutional Organs and State Auxiliary Bodies in Indonesia

Established State Goals		Main State Organs		State Auxiliary Organs		Targeted State Goals
1. Protect the entire Indonesian nation and all Indonesian people	⇒	1. People's Consultative Assembly (MPR),	⇒	1. BPOM	⇒	1. Protection of citizens
2. Promote public welfare		2. House of Representatives (DPR),		2. KOMNAS HAM		2. Public welfare
3. Educate the life of the nation		3. Regional Representative Council (DPD),		3. OMBUDSMA N RI		3. Legal certainty
4. Participate in establishing a world order based on freedom, lasting peace, and social justice		4. President, Supreme Court (MA),				4. Public accountability
		5. Constitutional Court (MK),				5. Good governance
		6. Judicial Commission (KY),				6. Public health protection
		7. Audit Board of the Republic of Indonesia (BPK)				7. Consumer protection
						8. Food and drug safety

Sources: Developed by the author based on the Preamble to the 1945 Constitution of the Republic of Indonesia

The diagram clearly demonstrates that auxiliary state organs hold an equal status to primary constitutional organs. However, auxiliary institutions are characterized by their flexibility. They may be established, restructured, or dissolved in accordance with national governance needs and alignment with their foundational objectives.²³

Currently, BPOM is governed by Presidential Regulation Number 80 of 2017 concerning the National Agency of Drug and Food Control (Perpres on BPOM), which was established as a form of institutional reinforcement of BPOM's duties and functions. The issuance of this regulation was

²² Jimly Asshiddiqie, 2006. *Introduction to Constitutional Law*, Jakarta: Secretariat General and Clerk of the Constitutional Court of the Republic of Indonesia, p. 216-127.

²³ Taufik Sri Soemantri, *State Institutions and State Auxiliary Bodies in the Constitutional System According to the 1945 Constitution*, National Dialogue Forum in Legal and Non-Legal Fields, BPHN Ministry of Law and Human Rights of the Republic of Indonesia, 26-29 June 2007, p. 93-95

prompted by the fact that Presidential Regulation Number 4 of 2013, insofar as it regulated BPOM, was no longer aligned with developments in law and societal needs,²⁴ thereby necessitating its replacement. However, there is no further explanation regarding the transition from Presidential Regulation Number 145 of 2015 to Presidential Regulation Number 80 of 2017. Although the regulation does not explicitly mention the agency's independence, the oversight function inherently demands institutional independence. Despite being structurally placed under the government, BPOM should be evaluated based on the nature of its responsibilities and the level of professional integrity it upholds.²⁵ According to an expert interviewed for this study, BPOM possesses institutional characteristics that distinguish it from many other government agencies. As the authority responsible for supervising the safety, quality, and efficacy of drugs and food products distributed throughout Indonesia, BPOM is expected to exercise its regulatory authority independently and be protected from undue interference by other governmental institutions. Such independence is essential to ensure that its supervisory functions are carried out objectively, professionally, and effectively in the interest of public health. The interviewee further explained that BPOM's institutional design reflects this objective, as it is established by the President, operates separately from ministries and other government institutions, and is directly accountable to the President.

Article 3 of PR 80/2017 outlines eleven (11) core functions of BPOM, encompassing policy formulation, implementation, procedure development, supervision, coordination, guidance, enforcement, logistics management, oversight, and provision of substantive support in drug and food regulation.²⁶ One of the primary functions, "implementation of supervision," indicates that BPOM is tasked with conducting comprehensive full-spectrum oversight in the drug and food sectors, encompassing pre- and post-market controls.²⁷ This full-spectrum approach enables BPOM to identify risks early and take corrective actions when necessary. It also supports the agency's broader mandate to protect public health by ensuring that drugs and food products available on the market are safe, effective, and of high quality.

Full-spectrum supervision entails regulatory activities that begin with pre-market assessments, ensuring that products meet safety, efficacy, and quality standards²⁸ before being approved for circulation. This preventive function is designed to protect public health by ensuring that drug and

²⁴ The "Weighing" Part Letter C of Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency

²⁵ "Interview with Indra Perwira" Constitutional Law Expert, Faculty of Law, Padjadjaran University, by Farina Firda Eprilia, (Bandung, April 22, 2025).

²⁶ Imam Suyudi, et al., "Analysis of Post-Market Supervision of the Food and Drug Supervisory Agency on the Circulation of Dangerous Cosmetics," *Deviance Journal of Criminology* 6, no. 2 (December 2022), pp. 142–143.

²⁷ David Eko Prabowo and Dede Kurniawan, "Regulation of Supervision of the Food and Drug Supervisory Agency (BPOM) in Consumer Protection," *Journal of Projudice* 2, no. 2 (2021), p.7.

²⁸ Article 3 paragraph (2) of Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency.

food products are free from harmful substances.²⁹ Full-spectrum oversight also encompasses post-market supervision, which includes sample testing of distributed products³⁰ to verify compliance with the same standards and to enable legal enforcement when violations are identified.³¹ Therefore, drug and food oversight constitutes BPOM's primary mandate, positioning the agency as the frontline institution responsible for public protection and preventing hazardous product circulation.³²

The emergence of auxiliary state institutions such as BPOM reflects a broader constitutional evolution that introduces a so-called "Fourth Branch of Government." These institutions are characterized by their independent status and functional autonomy from the traditional branches of Government. Moreover, such institutions may perform legislative, executive, and judicial functions concurrently, thereby possessing quasi-legislative, quasi-executive, or quasi-judicial powers.³³ Consequently, by examining the duties, functions, and authorities of BPOM, alongside relevant theoretical perspectives, it can be concluded that BPOM is a state auxiliary institution performing an executive governmental function, specifically the implementation of national policy in the drug and food regulation domain.³⁴

Implementation of Drug and Food Supervision: A Reality Check

Fundamentally, all drug products manufactured and distributed within society must comply with safety, efficacy, and quality standards and/or requirements.³⁵ These products must undergo testing aligned with the current state of scientific and technological development and in accordance with Good Manufacturing Practices (GMPs).³⁶ Ideally, compliance should also be substantiated through scientific data and clinical trials, ensuring consistency between the final product and laboratory findings.³⁷ Although the duties and functions of the BPOM, including technical matters, are clearly delineated in relevant regulatory frameworks, violations and incidents in the drug and

²⁹ Allan Mustafa umami, *et al.*, p. 377.

³⁰ Arief Handoko Usman, "Optimizing Drug and Food Circulation Supervision in the Context of Public Health Protection," *Juristic* 4, no. 3 (December 2023), p. 343–344.

³¹ Article 3 paragraph (3) of Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency.

³² Salundik, "Law Enforcement by the Food and Drug Control Agency for Drugs Containing Ethylene Glycol," *Journal of Law Tambun Bungai Palangka Raya*, 7, no. 2 (2022), pp. 198–199.

³³ Refo Rivaldo Fransiscus Pangaribuan, *et.al.* "Sharing of power in the system of government in Indonesia." *Lex Administratum* 11, no. 5 (2023), pp. 7-9.

³⁴ Hilaire Barnett, 2002. *Constitutional and Administrative Law*, 4th ed, London: Great Britain, p. 107-108

³⁵ "The 'Considering' Section of the Food and Drug Control Agency Regulation Number 7 of 2024 concerning Standards for Good Drug Manufacturing.

³⁶ Marisca Gondokusumo and Nabbilah Amir, "The Role of Government Supervision and the Food and Drug Supervisory Agency (BPOM) in the Circulation of Counterfeit Drugs in the State of Indonesia (Reviewed from Law Number 36 of 2009 and Regulation of the Head of the Food and Drug Management Agency)," *Legal Perspective* 21, no. 2 (November 17, 2021), p. 275, <https://doi.org/10.30649/ph.v21i2.16>.

³⁷ CNBC Indonesia, "Many Skincare Overclaim Cases, Here's How to Choose Maklon to Be Safe," <https://www.cnbcindonesia.com/lifestyle/20250206175354-33-608594/ramai-kasus-overclaim-skincare-begini-cara-pilih-maklon-agar-aman>, February 6, 2025.

food safety domain continue to occur. One such case is the Acute Kidney Injury due to a Contaminated Drug incident, which underscored BPOM's negligence in fulfilling its supervisory role. This negligence is particularly concerning given BPOM's strategic mandate to oversee drug and food products and the drug industry as a whole. The Acute Kidney Injury case represents a systemic failure in the oversight mechanism, allowing drug products containing hazardous substances to circulate beyond safe thresholds. This failure was exacerbated by the absence of a standardized national benchmark for drug and food safety, resulting in the unauthorized circulation of products without a BPOM-issued Import Certificate.³⁸

The handling of acute kidney injury cases also drew attention to the involvement of the Ministry of Health and the Ombudsman, an independent body with the authority to monitor public service delivery by government agencies. The Ombudsman's findings serve as a crucial form of institutional accountability, validating whether government institutions with administrative authority are fulfilling their mandates appropriately.³⁹ In this instance, the Ombudsman concluded that the Ministry of Health had committed maladministration and demonstrated institutional incompetence in its supervisory responsibilities at the central, provincial, and district/city levels, contrary to the provisions outlined in Minister of Health Regulation No. 10 of 2018 concerning Health Supervision. A critical failure in this case was the Ministry's refusal to declare the Acute Kidney Injury outbreak as an Extraordinary Event, which prevented the deployment of proper emergency response protocols and health services.⁴⁰

Other recurring issues in the circulation of drug and food products further complicate the landscape of supervision. The proliferation of illegal drugs, such as counterfeit drugs, is largely attributed to the rapid growth of digital platforms and the increasing prevalence of online drug distribution. This has introduced significant complexities to regulatory oversight in the digital realm and has revealed resource limitations within BPOM's enforcement capacity. Violations are more commonly distributed through social media than through conventional means. Although BPOM is formally authorized to take enforcement action, implementation remains hampered by inadequate institutional capacity and limited resources.⁴¹

The suboptimal resolution of these cases is also partly due to insufficient inter-agency

³⁸Indira Ratna Wismaya and Husni Syam, "Legal Liability of BPOM and Business Actors for the Circulation of Toxins in Paracetamol Syrup Drugs Reviewed from the Regulation of the Food and Drug Control Agency," *Bandung Conference Series: Law Studies*, 2024, p. 573–574

³⁹ Project Group on Administrative Law, *"A Handbook: The Administration and You Principles of Administrative Law Concerning the Relations between Administrative Authorities and Private Persons"*, Council of Europe, 1996, p. 37.

⁴⁰ Afrilian Rizki Fahreza and Evi Kongres, "Supervision by the Ministry of Health and BPOM on the Circulation of Children's Syrup Drugs Causing Acute Kidney Failure" *Magna Opus Law Journal* 6, no. 2 (June 2023), p. 105–108

⁴¹ Dicky William, "Counterfeit Drug Circulation Reviewed from Health Law and Information Law and Electronic Transactions," *Bandung Conference Series: Law Study* 2, no. 1 (2022), pp. 288–289.

coordination. There are often overlaps and ambiguities in the division of authority and coordination mechanisms among relevant institutions. According to Lukas Doso Nugroho, these issues necessitate deeper inter-institutional discussions, particularly in light of Indonesia's decentralized governance system, which significantly influences supervisory functions at the local level. Further impediments emerge from sociological factors, including shifting public behavior patterns, wherein individuals increasingly favor convenience-oriented solutions due to pervasive technological advancement. In drugs and food, societal attitudes and cultural norms have yet to fully adapt to the need for safe, effective, and high-quality products.⁴² Ardini Raksanagara similarly observes that a major challenge lies in the disparity between the accelerating pace of technological innovation and the relatively slow growth in public knowledge and awareness.⁴³

Another pressing concern involves the widespread circulation of cosmetic and skincare products through conventional outlets and digital platforms. This phenomenon is largely driven by aggressive marketing strategies, advertising pressures, and business competition, which create opportunities for unethical practices among industry actors. One such malpractice is overclaiming, making exaggerated or scientifically unverified product claims. When consumers lack adequate knowledge, such overclaims can lead to significant harm. Therefore, there is an urgent need to protect consumers' rights, including by revoking the distribution permits of cosmetics and skincare products found to be making such claims. Administrative sanctions to address these issues are regulated under Articles 98 to 100 of BPOM Regulation No. 3 of 2022 on the Criteria and Procedures for the Registration of Health Supplements, which provides the legal basis for addressing violations.

The regulation of cosmetic advertising is governed by Articles 7 to 9 of BPOM Regulation No. 32 of 2021, which outline procedures for ensuring advertisements are accurate, not misleading, and comply with safety standards. The regulation prohibits the use of overclaims or exaggerated promotional language that may mislead consumers about the product's benefits or safety. BPOM holds the authority to monitor, assess, and take action against non-compliant advertisements, including the issuance of warnings or administrative sanctions. Effective regulation of advertising is essential, as misleading claims can influence consumer behaviour, result in inappropriate product use, and potentially harm public health. This is particularly relevant in the cosmetic industry, where marketing strategies often blur the line between aesthetic and therapeutic claims. Overclaims in skincare advertisements raise important legal and regulatory concerns regarding the accountability of brand owners and their compliance with advertising laws. Therefore, the government—through

⁴² Kurniasanti and Joko Setiyono, "The Urgency of Regulating Supervision and Law Enforcement by BPOM Against Illegal Drug and Food Trafficking," *Yuriska: Journal of Law* 12, no. 2 (June 2022), pp. 73–75, <https://doi.org/10.24903/yrs.v12i2.884>

⁴³ "Interview with Ardini Raksanagara" Public Health Science Expert, Faculty of Medicine, Padjadjaran University, by Farina Firda Eprilia, (Bandung, May 5, 2025).

BPOM—plays a critical role not only in ensuring product safety and quality but also in supervising advertising practices. This dual oversight helps prevent deceptive marketing, promotes responsible business practices, and protects consumers from health risks. Ultimately, these efforts reflect the state's commitment to upholding the right to health for all citizens.⁴⁴

Strengthening the Institutional Framework of BPOM to Enhance Supervisory Effectiveness

State institutions should not be narrowly defined as those traditionally recognized in the classical doctrine of state power. Instead, the definition must be expanded to encompass all institutions established by law to perform governmental functions, excluding civil society institutions and market institutions.⁴⁵ Contemporary developments in legal and political thought indicate that the classification of state institutions is no longer limited to the conventional triad, legislative, executive, and judicial, but now includes a broader array of institutions assigned with specific state functions.⁴⁶ According to Jimly Asshiddiqie, state institutions may be categorized based on their functions as primary constitutional or auxiliary state organs.⁴⁷ Hence, a state institution is understood as a body formed under the law to conduct either classical functions of the state or newly emerging public functions, in which such institutions form a cohesive process of state administration and governance through interrelated functions.⁴⁸ Having established BPOM as an auxiliary state organ, the next question is whether its current institutional framework adequately supports the effective exercise of its supervisory authority. This study argues that it does not, primarily because the existing regulatory framework fails to provide sufficient institutional independence and clear coordination mechanisms.

The establishment of BPOM reflects the principles of regulatory governance within the framework of administrative law. As the institution responsible for supervising drugs and food, BPOM exercises authority derived from legislation and presidential regulations in accordance with the principles of legality, accountability, transparency, and proportionality. Its regulatory functions involve administrative discretion and procedural mechanisms to ensure objective, lawful, and accountable decision-making. Through this framework, BPOM embodies the State's commitment to protecting public health through effective regulatory governance.

Additionally, its actions are guided by established *procedural frameworks*, which regulate how

⁴⁴ Sahda Saraswati Akbar, et al., "Legal Liability of Skincare Owners Related to Overclaims on Beauty Products," *Forschungsforum Law Journal* 2, no. 1 (2025), pp. 82–88. <https://doi.org/10.35586/flj.v2i1.9889>.

⁴⁵ Jimly Asshiddiqie. 2005. *Disputes of Authority Between State Institutions*, 1st ed. Jakarta: Constitution Press, p. Vii.

⁴⁶ Made Nurmawati, et.al. 2017. *State Institutional Law*. Denpasar: Faculty of Law, UNUD, p. 4-6.

⁴⁷ Jimly Asshiddiqie, *The Development and Consolidation of the State Post-Reform*, *ibid*, p. 113.

⁴⁸ Firmasyah Arifin, "State Institutions and Disputes of Authority Between State Institutions," in *Konsursium Reformasi Derecho Nasional (KRHN) in Collaboration with the Constitutional Court (MKRI)*, 2005, p. 31.

inspections, licensing, enforcement, and compliance measures are conducted. Through this structured approach, BPOM functions not only as an operational body but also as an institutional embodiment of the state's commitment to uphold administrative law and protect public health through accountable and transparent governance.⁴⁹ However, the existing legal framework has not fully operationalized these principles. In particular, overlapping institutional authority weakens accountability, while fragmented regulatory arrangements undermine legal certainty and the effective implementation of drug and food supervision.

In line with the Preamble "considering" clause of Presidential Regulation No. 80 of 2017, the formation of BPOM as a Non-Ministerial Government Institution is explicitly aimed at strengthening institutional capacity to improve the effectiveness of drug and food supervision. BPOM is designated as the governmental agency responsible for executing state functions in the drug and food regulation domain and is accountable directly to the President. Given this role, the agency should not be staffed merely with bureaucrats fulfilling general administrative duties. Instead, BPOM should be led and operated by individuals with proven professional expertise and specialized competencies. Furthermore, functional positions within the agency should ideally be independent of political and ministerial influence to ensure objectivity and scientific accountability. [Click or tap here to enter text.](#)

Normatively, Article 1(2) of Presidential Regulation No. 80/2017 states that BPOM is "accountable to the President through the minister responsible for health affairs." On the surface, this provision appears straightforward and has received limited critical examination in existing literature. However, this study draws attention to a significant institutional tension inherent in this arrangement. Although BPOM was established as an independent regulatory agency to ensure objective oversight of drugs and food safety, its formal accountability through the Ministry of Health introduces a dual reporting structure that may compromise its operational autonomy. This duality creates a potential conflict between independence and hierarchical oversight, raising important questions about the extent to which BPOM can exercise unbiased regulatory authority free from political or bureaucratic influence. Empirical data gathered during this study corroborates these concerns, revealing instances where ministerial oversight has influenced BPOM's decision-making processes. This institutional ambiguity highlights the need for a clearer delineation of authority and accountability mechanisms to safeguard the agency's independence and enhance its effectiveness in public health governance. Such institutional ambiguity creates legal uncertainty regarding regulatory responsibility and weakens the effectiveness of administrative accountability.

Although this chain of accountability may appear administratively routine, it creates an

⁴⁹ Philipus M Hadjon, 2012. *The Need for General Administrative Law, in Administrative Law and Good Governance*, Jakarta: Trisakti University, p. 22.

institutional tension regarding BPOM's independence. While BPOM is expected to function as an autonomous regulatory body, its obligation to report through the Ministry of Health establishes a structural relationship that may influence regulatory decision-making and blur the distinction between institutional independence and ministerial oversight. This ambiguity may affect the exercise of BPOM's supervisory authority and underscores the need to reassess its governance framework to ensure objective, effective, and accountable regulation.

These institutional challenges are reflected in BPOM's coordination with the Ministry of Health, particularly during the Acute Kidney Injury crisis. Divergent responses exposed weaknesses in communication, role delineation, and inter-agency decision-making, delaying regulatory action, creating public confusion, and weakening accountability. From an administrative law perspective, these shortcomings demonstrate that the existing governance framework lacks a sufficiently clear allocation of supervisory authority. Accordingly, strengthening drug and food supervision requires not only improved administrative coordination but also legal reform to clarify institutional responsibilities and establish a more coherent framework for inter-agency cooperation.

Ideally, collaboration among state institutions should reflect a cooperative relationship grounded in shared responsibility and mutual respect for each institution's legal authority and functional mandate.⁵⁰ From an administrative law perspective, these coordination failures demonstrate the absence of a clearly defined allocation of supervisory authority, resulting in fragmented regulatory governance and uncertainty regarding institutional accountability.

A significant regulatory issue tied to BPOM's institutional position concerns RUU POM's proposal. This legislative initiative was supported by various legal scholars and policy actors who viewed the bill as necessary to establish a comprehensive legal foundation for BPOM's mandate. The House of Representatives' Commission IX had advocated for the bill's inclusion in the National Legislative Program (Prolegnas) 2019-2024, with the objective of institutional strengthening and regulatory clarity for independent state agencies, particularly in drug and food supervision.⁵¹

While RUU POM was initially viewed as a “welcome development” for reinforcing the legal authority and operational efficacy of BPOM, it was later withdrawn from deliberation following a working meeting between DPD RI Committee III, the Ministry of Health, and BPOM. The Ministry of Health argued that the substantive elements of drug and food supervision listed in the bill's Problem Inventory List had already been comprehensively addressed in existing legislation, including The Health Law, which regulates drugs, medical devices, and related health matters; The Food Law, which

⁵⁰ UU Nurul Huda. 2020. *Law of State Institutions*, 1st ed. Bandung: PT Refika Aditama, p. 145-146.

⁵¹ Hukum Online, "Legal Experts to Professors Urge the Ratification of the POM Bill," <https://www.hukumonline.com/berita/a/pakar-hukum-hingga-guru-besar-desak-pengesahan-ruu-pom-lt6405bc41666ad/?page=2>, March 6, 2023.

governs the classification of processed foods, product information, distribution, and research; The Consumer Protection Law, which addresses producer liability in food and drug distribution; and The Omnibus Law on Job Creation, which regulates licensing, supervision, and administrative sanctions. On these grounds, the Government declined to continue deliberations. BPOM acknowledged that while its institutional authority is already sufficiently regulated, there is a pressing need for organizational and structural reinforcement.⁵² This distinction is critical, particularly considering that drug and food regulation involves cross-sectoral supervision, which demands effective collaborative mechanisms among state institutions. In addition to inter-agency collaboration, strong partnerships with research institutions and higher education entities are essential. Click or tap here to enter text.

Before these developments, the government issued Presidential Instruction No. 3 of 2017 on Enhancing the Effectiveness of Drug and Food Supervision.⁵³ However, the recurring obstacles faced in practice, particularly in the division of authority and coordination among institutions, suggest that further regulatory reform is necessary. Accordingly, this situation invites critical reflection and evaluation as to whether the Presidential Instruction, regarded as tangible evidence of the Government's commitment to strengthening supervisory performance to ensure the safety of drugs and food circulating in the public sphere, has been effectively implemented. This is particularly relevant given the cancellation of the deliberation on the Drug and Food Supervision Bill (RUU POM), whose substance was considered to have already been addressed in various other existing regulations. The foregoing analysis may also be synthesized into a SWOT table, as presented below.

Table 2.
SWOT Analysis of BPOM's Institutional Framework

Strengths	Weakness	Opportunities	Threats
Strong legal mandate for drug and food supervision.	Dual accountability through Ministry of Health limits institutional autonomy.	Legal reforms to reinforce independence and authority	Overlapping jurisdiction weakens regulatory responsiveness.
Professional and science-based regulatory capacity.	Vulnerable to political and bureaucratic influence.	Strengthened cross-sectoral and research collaboration	Crisis mismanagement risks erosion of public trust
Established and standardized regulatory procedures.	Coordination challenges with other health institutions.	Improving governance mechanisms for clearer accountability	Policy shifts may pressure regulatory objectivity.

Sources: Author's analysis based on Indonesian legislation and institutional documents discussed in this study

Based on the foregoing analysis, this study proposes four principal measures to strengthen BPOM's institutional framework. First, provide explicit statutory recognition of BPOM's institutional

⁵² DPD RI, "Committee III DPD RI Working Together with the Minister of Health and BPOM to Discuss the POM Bill," <https://www.dpd.go.id/daftar-berita/komitee-iii-dpd-ri-raker-bersama-menkes-dan-bpom-bahas-ruu-pom>, July 2, 2024.

⁵³ Hukum Online, "Minister of Health: The Material of the POM Bill Has Been Comprehensively Regulated by a Number of Laws and Implementing Regulations," <https://www.hukumonline.com/berita/a/menteri-kesehatan--materi-ruu-pom-sudah-komprehensif-ditatur-sejumlah-uu-dan-peraturan-pelaksana-lt6684b9362ddba/>, July 3, 2024.

independence. Second, clarify the allocation of supervisory authority between BPOM and the Ministry of Health. Third, establish a permanent inter-agency coordination mechanism. Fourth, strengthen scientific and professional autonomy in regulatory decision-making.

CONCLUSION

This study finds that although BPOM performs supervisory functions requiring objective and independent regulatory decision-making, the existing legal framework does not explicitly guarantee its institutional independence or clearly delineate supervisory authority among relevant government institutions. Consequently, overlapping authority and ineffective inter-agency coordination continue to undermine regulatory effectiveness. The recurring cases of unsafe drugs and food products, including the Acute Kidney Injury crisis, demonstrate that these weaknesses stem not only from regulatory implementation but also from deficiencies in BPOM's institutional design. The discontinuation of the Draft Law on Drug and Food Supervision (RUU POM) further left unresolved issues concerning institutional authority and coordination. Academically, this study contributes to administrative law and regulatory governance by showing that effective supervision depends not only on substantive regulation but also on the institutional design of the supervisory authority. Practically, it proposes reconstructing BPOM's legal framework through explicit recognition of institutional independence, clearer allocation of supervisory authority, and stronger inter-agency coordination to enhance legal certainty, regulatory effectiveness, and public health protection.

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