Journal of Social Research and Innovation
Volome 1, Issue 1, November, 2025, 24-31
e-ISSN : xxxx-xxxx, p-ISSN: xxxx-xxxx
https://ejournal.natacendekia.org/index.php/JoSRI/index

Harmonizing Regulatory Frameworks: An Evaluation of Divergent Technical Responsible Person Requirements and Their Impact on Indonesia's Cosmetic Import Notification Efficiency

Sri Anggraini[1], Ajeng I. Rosalina[2*]
[1,2]*Balai Besar Pengawas Obat dan Makanan di Jakarta*
Jl. Assyafiiyah no.133, Cilangkap, Jakarta
ajengrosalyne.air@gmail.com[2*]

Article Info

Article history:

Received: November 30, 2025
Revised: January 9, 2026
Accepted: January 9, 2026

Keywords:

Cosmetic Notification
Cosmetic importer
Distributor

Abstract

This study analyses the disparities in technical competence requirement for responsible person regarding cosmetic notification applicants in Indonesia specified in Regulation No. 12 of 2023 by the Indonesian National Agency of Drug and Food Control (BPOM) and Regulation No. 17 of 2024 by the Ministry of Health of the Republic of Indonesia. Regulation BPOM No. 12 of 2023 stipulates that the technical supervisor for cosmetic importers must possess a bachelor's degree in medicine, biology, or chemistry, whereas Regulation of the Ministry of Health No. 17 of 2024 necessitates that the technical supervisor holds relevant qualifications as a chemist. The study seeks to assess the influence of these varying restrictions on the volume of re-application submissions by enterprises, namely within the Cosmetic Wholesale Trade for Humans (cosmetic importers). The data employed consists of notification application records from the Jakarta BPOM Main Office for the years 2022 and 2023. The results demonstrate that these inconsistencies have resulted in a rise in re-applications, with around 35.75% of total submissions being re-applications due to problems such as the non-issuance of standard certificates through the Online Single Submission (OSS) RBA system, consequently hindering further processing. As a result, this circumstance has generated regulatory ambiguities for cosmetic importers and extended the registration timeline for cosmetic items. In light of these findings, it is advisable to undertake a reevaluation of Regulation BPOM No. 12 of 2023 to alleviate conflicts with other pertinent regulations.

To cite this article: Anggraini, Sri & Rosalina, AJeng I. (2026). Harmonizing Regulatory Frameworks: An Evaluation of Divergent Technical Responsible Person Requirements and Their Impact on Indonesia's Cosmetic Import Notification Efficiency. *Journal of Social Research and Innovation, 1*(1), 24-31

INTRODUCTION

Cosmetics are substances or formulations designed for application to the exterior surfaces of the human body for the purposes of cleansing, enhancing aesthetics, or ameliorating body odor (Susanti et al., 2024). They may manifest in multiple forms, such as solids, powders, semi-solids, creams, gels, pastes, liquids, viscous liquids, suspensions, or aerosols (Maqbool et al., 2018). Cosmetics must undergo a notification process for registration prior to distribution in Indonesia. A notification is an authorization issued by the Head of the National Agency of Drug and Food Control (BPOM) to business entities, permitting the commercialization of cosmetic products. This is acquired after the business entity meets the criteria for submitting a cosmetic distribution permit application (BPOM, 2022). The entity submitting the notification is designated as the notification number holder, classified into three categories: Cosmetic Manufacturers, Importers, and Individual Businesses/Entities engaged in contract production within Indonesia.

An importer is an individual, organization, or commercial entity involved in the acquisition of goods from foreign countries into a nation's customs jurisdiction. An importer is the entity accountable for bringing goods from abroad (Ruiz, 2018). Per applicable legislation, an importer is designated as a Wholesale Trader of Cosmetics for Humans. To receive notification as an importer, many prerequisites must be fulfilled, including securing a recommendation from the Head of the local Technical Implementation Unit of BPOM (UPT BPOM). The recommendation application is filed via the Online Single Submission Risk-Based Approach (OSS RBA) system, and the issue of the recommendation is

*Corresponding Author
Ajeng I. Rosalina, Balai Besar Pengawas Obat dan Makanan di Jakarta, Indonesia ✉ ajengrosalyne.air@gmail.com

also performed through this method. A crucial prerequisite is the designation of a Technical Responsible Person (Penanggung Jawab Teknis) possessing expertise in the pertinent domain (BPOM, 2022). Meeting this requirement is essential to guarantee the safety, quality, and legality of imported cosmetic items while facilitating oversight by the appropriate authorities.

The educational qualifications for the Technical Responsible Person for cosmetic importers are outlined in two government rules. According to BPOM Regulation (PerBPOM) Number 12 of 2023, the Technical Responsible Person designated by a cosmetic importer must possess at least a bachelor's degree (S1) in Pharmaceutical Science, Medical Science, Biological Science, or Chemical Science (BPOM, 2023). According to Regulation of the Minister of Health of the Republic of Indonesia (Permenkes RI) Number 17 of 2024, wholesale cosmetic traders, particularly importers, must employ a Technical Responsible Person with at least a Pharmacist qualification (Kemenkes RI, 2024). This provision seeks to ensure technical proficiency and professionalism in the oversight and administration of imported cosmetic products to uphold the quality and safety of market-available items.

The primary distinction between these two regulations is to the educational qualifications mandated for the Technical Responsible Person in the wholesale trade of cosmetics for humans (cosmetic importers). PerBPOM No. 12 of 2023 permits anyone with a bachelor's degree in Pharmacy, Medicine, Biology, or Chemistry to assume the role of Technical Responsible Person, whereas Permenkes No. 17 of 2024 stipulates that the Technical Responsible Person must possess at least a Pharmacist degree. As a result, graduates in Medical Science, Biological Science, or Chemical Science are ineligible to serve as the Technical Responsible Person for cosmetic imports according to the Ministry of Health Regulation.

The discord between PerBPOM No. 12 of 2023 and Permenkes RI No. 17 of 2024 has resulted in considerable operational repercussions. Cosmetic importers adhering to PerBPOM, by employing a Technical Responsible Person with an S1 degree in Medicine, Biology, or Chemistry, encounter automatic rejection in obtaining the standard certificate via the OSS RBA system, since Permenkes mandates that only a Pharmacist can serve as the Technical Responsible Person. Consequently, commercial entities are compelled to refile their recommendation applications by substituting the Technical Responsible Person, despite the facilities and products remaining unchanged. This strategy extends the notice procedure, elevates the administrative cost for enterprises and regulatory bodies, and engenders legal uncertainty that may destabilize the investment climate. If uncoordinated, this regulation overlap poses a danger of hindering the control of imported cosmetics in Indonesia.

This paper examines a research gap due to the absence of previous empirical analysis on the operational effects of regulatory discord over the Technical Responsible Person for cosmetic importers in Indonesia. Despite numerous rules overseeing the sector, no research has assessed how the direct conflict between PerBPOM No. 12 of 2023 and Permenkes No. 17 of 2024 engenders procedural bottlenecks, escalates administrative burdens, and delays market entry. This research is novel due to its quantitative evaluation of administrative data from the BPOM notification system, which accurately quantifies the application burden—indicating that 35.75% of submissions were re-applications resulting from regulatory conflict—and its development of a systematic, phased strategy for harmonization. This technique encompasses rapid stakeholder engagement, medium-term regulatory assessment, and the creation of a long-term institutional framework for proactive policy alignment, providing a reproducible model for addressing analogous discrepancies in other regulated industries.

This paper examines a research gap due to the absence of previous empirical analysis on the operational effects of regulatory discord over the Technical Responsible Person for cosmetic importers in Indonesia. Despite numerous rules overseeing the sector, no research has assessed how the direct conflict between PerBPOM No. 12 of 2023 and Permenkes No. 17 of 2024 engenders procedural bottlenecks, escalates administrative burdens, and delays market entry. This research is novel due to its quantitative evaluation of administrative data from the BPOM notification system, which accurately quantifies the application burden—indicating that 35.75% of submissions were re-applications resulting from regulatory conflict—and its development of a systematic, phased strategy for harmonization. This technique encompasses rapid stakeholder engagement, medium-term regulatory assessment, and the creation of a long-term institutional framework for proactive policy alignment, providing a reproducible model for addressing analogous discrepancies in other regulated industries.

This research was undertaken to examine the proportion of re-applications for cosmetic notification applicant recommendations by Wholesale Traders of Cosmetics for Humans (importers) due to the discrepancy between BPOM Regulation No. 12 of 2023 and Ministry of Health Regulation No. 17 of 2024 concerning the educational qualifications of the Technical Responsible Person. The results are

anticipated to offer strategic recommendations to BPOM and other institutions for regulatory harmonization, aimed at mitigating legal uncertainty and inefficiencies in the notification process.

METHOD

This study employed a descriptive analytical methodology grounded in quantitative policy analysis and administrative data research approaches. The methodological framework is supported by the theory of Regulatory Impact Analysis (RIA), which systematically examines the effects of regulatory policies on administrative processes, business compliance, and operational efficiency (Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt, 2010). By utilizing secondary administrative data, this research aligns with the ex post evaluation strand of RIA, which assesses real-world outcomes after policy implementation (Carrigan & Coglianese, 2011). Furthermore, the study applied principles of quantitative descriptive analysis, which is appropriate for summarizing, organizing, and interpreting numerical data to identify patterns, frequencies, and percentages related to regulatory compliance behaviors (Grimmer et al., 2022)

Data Acquisition on Recommendation Applications for Cosmetic Notification Applicants
Data collection was conducted by retrieving records from the recommendation certification monitoring spreadsheet kept by the Jakarta Main Center of BPOM. The data included all application requests for cosmetic notification recommendations submitted within the Jakarta jurisdiction between the years 2022 and 2023.

Data Acquisition on Recommendations for Applicants as Wholesale Cosmetics Traders for Humans
Data were filtered from the aforementioned monitoring spreadsheet for applications submitted by organizations designated as Wholesale Traders of Cosmetics for Humans (cosmetic importers) for the years 2022 and 2023. The dataset was later categorized into two groups depending on the educational qualifications of the designated Technical Responsible Person: Pharmacy background (Apoteker or S1 Pharmacy) and Non-Pharmacy background (S1 Medicine, S1 Biology, S1 Chemistry).

Data Acquisition on Re-applications Submitted by Wholesale Cosmetics Traders for Human Use
Further extraction was conducted from the dataset of cosmetic importer applications to identify applications that were re-submitted by the same corporate entity. The re-applications throughout the 2022-2023 period were notably associated with instances where the initial application was succeeded by another due to a modification in the Technical Responsible Person, presumably resulting from non-compliance with existing regulations.

Data Processing and Analysis
All gathered data were processed and evaluated with Microsoft Excel. The analysis concentrated on quantifying:

- The percentage distribution of applications according to the educational background of the Technical Responsible Person (Pharmacy versus Non-Pharmacy).
- The proportion of re-applications due to the alteration of the Technical Responsible Person in relation to the total number of recommendations granted for importers.

This analytical process enabled an evaluation of the operational implications resulting from the disparity in educational qualifications for the Technical Responsible Person as outlined in BPOM Regulation No. 12 of 2023 compared to Ministry of Health Regulation No. 17 of 2024 for Wholesale Traders of Cosmetics for Humans (importers).

RESULTS AND DISCUSSION

Quantity of Recommendation Applications for Cosmetic Notification Applicants

A notification is an authorization issued by the Head of BPOM for company operators to distribute cosmetics. It is acquired upon the business entity meeting the criteria for submitting a cosmetic distribution permit application (BPOM, 2022). A recommendation from the Head of the local BPOM Technical Implementation Unit (UPT) is a prerequisite for importers to secure a notification. The application is filed through the Online Single Submission Risk-Based Approach (OSS RBA) system, and the recommendation is also delivered via the same channel.

According to the statistics on recommendation applications for cosmetic notification applicants, 292 applications were received in 2022, while 260 were received in 2023 (Table 1). In 2022, the Jakarta Main Center of BPOM gave 262 recommendations, whereas in 2023, it issued 234.

Table 1. Number of Recommendation Applications for Cosmetic Notification Applicants

Tahun	Jumlah Permohonan	Jumlah Rekomendasi diterbitkan
2022	292	262
2023	260	234

Quantity of Recommendations for Applicants as Wholesale Cosmetics Traders for Humans

According to the data, the quantity of recommendations granted to applicants as Wholesale Traders of Cosmetics for Humans (cosmetic importers) was 219 in 2022 and 240 in 2023. Out of the 219 recommendations made in 2022, 97 pertained to importers whose Technical Responsible Person has a non-Pharmacy educational background. In 2023, of the 240 recommendations, 67 importers employed a Technical Responsible Person lacking a Pharmacy background (Table 2).

The study indicates a rise of 21 facilities (about 9.58%) in suggestions for cosmetic importers in 2023 relative to 2022, propelled by the burgeoning trend and utilization of innovative cosmetics in Indonesia.

Table 2. Recommendations Issued to Importers Based on the Educational Background of the Technical Responsible Individual

Year	Recommendations Issued for Cosmetic Importers	Educational Background	
		Pharmacy Background (Pharmacist & S1 Pharmacy)	Non-Pharmacy Background (S1 Medicine, S1 Chemistry, S1 Biology)
2022	219	122	97
2023	240	173	67

Frequency of Re-applications by Wholesale Cosmetic Traders

Wholesale Traders of Cosmetics are categorized as a medium-high risk enterprise under current legislation, necessitating a company Identification Number (NIB) and a standard certificate as components of their company documentation (Pemerintah Republik Indonesia, 2021). A fundamental prerequisite for the issuance of the standard certificate is that the Technical Responsible Person must, at a minimum, possess the qualifications of a Pharmacist (Apoteker), as mandated by the pertinent Ministry of Health regulation.

The inconsistency in the educational qualification criteria for the Technical Responsible Person, as stipulated by Ministry of Health Regulation No. 17 of 2024 (which requires a Pharmacist) and BPOM Regulation No. 12 of 2023 (which permits S1 graduates in Medicine, Biology, or Chemistry), has resulted in operational challenges. When a corporate entity submits an application with a non-Pharmacist Technical Responsible Person, the standard certificate cannot be generated using the OSS RBA system.

This regulatory discrepancy has resulted in a considerable number of re-applications. Of the 459 recommendations granted to importers in 2022 and 2023, 164 importers (about 35.75%) re-applied for the same business facility, mostly to alter the designated Technical Responsible Person (Table 3).

Table 3. Re-applications by Wholesale Traders of Cosmetics (2022-2023)

Total Recommendations for Importers (2022 & 2023)	Number of Facilities Submitting Re-applications	Percentage of Facilities Submitting Re-applications
459	164	35.75%

This study reveals that the varying educational qualifications mandated for the Technical Responsible Person in PerBPOM No. 12 of 2023 and Permenkes No. 17 of 2024 have led to an increase in applications at the Jakarta Main Center of BPOM, attributable to re-submissions by the same business entities. The re-applications arise because the standard certificate cannot be issued through OSS RBA, rendering the first issued recommendation ineffective for subsequent phases of product registration. This scenario is aggravated by the continued reliance of several business entities on the previous provisions of BPOM Regulation No. 12 of 2023.

Discussion

The detected issue underscores a regulatory discrepancy between PerBPOM No. 12 of 2023 and Permenkes No. 17 of 2024. A SWOT analysis of the current scenario is provided below:



Figure 1. SWOT Analysis

Strengths:

- **Existing Regulations:** The presence of both BPOM and Ministry of Health regulations demonstrates government commitment to ensuring product quality.
- **Infrastructure:** A system for issuing recommendations is already in place.

Weaknesses:

- **Divergent Regulatory Requirements:** The difference in qualification requirements creates confusion and difficulties for business actors, especially importers.
- **Complex Application Process:** The multi-step process with complex procedures hinders efficiency and prolongs the time to obtain permits.

Opportunities:

- **Market Expectations:** The growing number of cosmetic importers presents an opportunity for product innovation to meet diverse consumer needs.

- **Improved Coordination with MoH:** Effective coordination with the Ministry of Health can facilitate resolving the gap in qualification requirements.

Threats:

- **Business Actors' Understanding:** Low comprehension among business actors regarding application requirements persists.
- **Regulatory Uncertainty:** Uncertainty due to changing government regulations can negatively impact all related parties.

Recommendations for improvement can be structured into three phases

To address the identified regulatory misalignment, a phased improvement strategy is recommended. In the short term, the National Agency of Drug and Food Control (BPOM) should prioritize disseminating the current regulations to all business actors operating as Wholesale Traders of Cosmetics for Humans. Concurrently, systematic data collection on the specific operational hurdles caused by the discrepant qualification requirements should be initiated at the Jakarta Main Center and extended through coordination with other Regional BPOM Technical Implementation Units (UPTs) to determine the nationwide scope of the issue. Furthermore, internal coordination with relevant directorates within BPOM, such as the Directorate of Cosmetic Supervision, is essential to formulate a cohesive administrative response.

The medium-term strategy necessitates a formal review and revision of BPOM Regulation No. 12 of 2023 concerning the educational qualifications of the Technical Responsible Person for cosmetic importers. The current discrepancy signifies legal uncertainty, which is known to hinder product registration processes and deter investment (Purba et al., 2025; Fabrizio, 2013). Therefore, a structured review following established regulatory impact assessment protocols is critical. This process should involve comprehensive data gathering, in-depth analysis, drafting of amendments, inter-departmental consultations, and public feedback before final enactment (Pečarič, 2019; Staronova, 2010). The revised regulation must then be submitted to the Ministry of Law and Human Rights for harmonization (Jaelani et al., 2020). Additionally, technical collaboration between BPOM's Data and Information Center and the Investment Coordinating Board is required to modify the OSS UMKU system. This update should accommodate a mechanism for revoking previously issued recommendations, thereby preventing the overlap of conflicting approvals.

For a sustainable long-term solution, the establishment of a proactive and continuous regulatory review mechanism is paramount. This institutionalized process should ensure that whenever a higher-level regulation (such as a Ministry of Health decree) is amended, all related subordinate regulations are automatically reviewed for consistency. The fundamental principle must be that lower-tier regulations consistently align with higher-tier laws to prevent future regulatory fragmentation and operational bottlenecks (Review, 2019). This approach is supported by contemporary governance studies emphasizing the need for dynamic regulatory alignment. For instance, research on regulatory coherence in multi-level governance systems highlights that automated review triggers can significantly reduce compliance costs and legal uncertainty (Ateş et al., 2024; Tamtik & Colorado, 2022). Similarly, a study on Southeast Asian regulatory frameworks found that institutionalized harmonization mechanisms are critical to preventing bureaucratic bottlenecks and fostering a stable business environment (Rajagukguk, 2012).

CONCLUSION

This study quantifies the significant operational impact arising from the regulatory disharmony between BPOM Regulation No. 12 of 2023 and Ministry of Health Regulation No. 17 of 2024 concerning the educational qualification of the Technical Responsible Person for cosmetic importers in Indonesia. The analysis of administrative data from the Jakarta Main Center of BPOM reveals that, of the 459 recommendations issued to Wholesale Traders of Cosmetics for Humans (cosmetic importers) in 2022 and 2023, a substantial portion—35.75% or 164 applications—were re-submissions by the same business entities. This high rate of re-application is directly attributed to the conflicting stipulations, where a Technical Responsible Person with a bachelor's degree in Medicine, Biology, or Chemistry (permitted under BPOM Regulation No. 12 of 2023) fails to meet the mandatory Pharmacist requirement (stipulated by Ministry of Health Regulation No. 17 of 2024) for issuing the standard certificate via the OSS RBA system.

Consequently, this regulatory misalignment creates a dual burden. For business actors, it prolongs the product notification timeline, fosters legal uncertainty, and increases administrative costs. For the regulatory authority, it leads to inefficiencies, consuming additional time and audit resources to process duplicate applications. The findings underscore that such inconsistency acts as a non-tariff barrier, hindering market entry and potentially affecting the investment climate within the sector. Therefore, immediate and structured harmonization of these regulations is not merely an administrative formality but a crucial step towards enhancing regulatory predictability, streamlining business processes, and strengthening the overall oversight framework for cosmetic products in Indonesia. The phased recommendations—encompassing immediate socialization, a formal medium-term regulatory review, and the establishment of a long-term mechanism for continuous regulatory alignment—provide a concrete pathway to resolve this impediment.

REFERENCES

Ateş, A., Rogge, K. S., & Lovell, K. (2024). Governance in multi-system transitions: A new methodological approach for actor involvement in policy making processes. *Energy Policy*, *195*.

BPOM. (2022). Peraturan BPOM No 21 tentang Tata Cara Pengajuan Notifikasi Kosmetik. In *BPOM* (21/2022; pp. 1–63). https://www.pom.go.id/new/view/more/berita/76/Keracunan-yang-Disebabkan-Gas-Karbon-Monoksida.html

BPOM. (2023). PerBPOM 12 th 2023 Pengawasan Pembuatan Dan Peredaran Kosmetik. In *Bpom Ri* (pp. 1–18). https://www.pom.go.id/new/view/more/berita/76/Keracunan-yang-Disebabkan-Gas-Karbon-Monoksida.html

Carrigan, C., & Coglianese, C. (2011). The Politics of Regulation: From New Institutionalism to New Governance. *Annual Review of Political Science*, *14*, 107–129.

Fabrizio, K. R. (2013). The Effect of Regulatory Uncertainty on Investment: Evidence from Renewable Energy Generation. *Journal of Law, Economics, and Organization*, *29*(4), 765–798. https://doi.org/10.1093/jleo/ews007

Grimmer, J., Roberts, M. E., & Stewart, B. M. (2022). *Grimmer , J ., Roberts , M . E ., & Stewart , B . M . (2022). Text as Data : A New Framework for Machine Learning and the Social Sciences . Princeton University Press*.

Jaelani, J., Studi, P., & Hukum, I. (2020). *Kewenangan Kementerian Hukum Dan Hak Asasi Manusia Dalam Proses Harmonisasi Rancangan Peraturan Daerah*.

Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt, P. H. S. (2010). *The Reality of Precaution Comparing Risk Regulation in the United States and Europe*. Routledge. https://doi.org/10.1080/13669877.2013.788821

Kemenkes RI. (2024). No TitleΕΛΕΝΗ. In *Kementrian Kesehatan Republik Indonesia* (Vol. 15, Issue 1, pp. 37–48).

Maqbool, M. A., Mishra, M. K., Pathak, S., Kesharwani, A., & Kesharwani, A. (2018). *Semisolid dosage forms manufacturing: Tools, critical process parameters, strategies, optimization and recent advances*. *February*. https://www.researchgate.net/publication/322925854_Semisolid_dosage_forms_manufacturing_Tools_critical_process_parameters_strategies_optimization_and_recent_advances

Pečarič, M. (2019). The Centre of Government as the Coordination Point for the Implementation of General Legal Rules. *Danube*, *10*(3), 241–265. https://doi.org/10.2478/danb-2019-0013

Pemerintah Republik Indonesia. (2021). *Peraturan Pemerintah no 5 tentang Penyelenggaraan Perizinan Berusaha Berbasis Risiko*.

Purba, H. Y. M., Natasya Sirait, N., Siregar, M., & Harianto, D. (2025). Unequal regulation in partnerships between MSMEs and large enterprises in Indonesia. *Problems and Perspectives in Management*, *23*(1), 424–436. https://doi.org/10.21511/ppm.23(1).2025.32

Rajagukguk, E. (2012). *Harmonization of Law in ASEAN Countries towards Economic Integration*. *9*(4). https://doi.org/10.17304/ijil.vol9.4.358

Review, S. I. (2019). *The centre of government as the coordination point for the implementation of general legal rules*. https://doi.org/10.2478/danb-2019-0013

Ruiz, M. (2018). Chinese Customs Regulations on Cross-Border E-Commerce: A Growth Opportunity for Foreign Enterprises and Chinese Commercial Platforms. *Sinología Hispánica. China Studies*

Review, *6*(1), 133–156. https://doi.org/10.18002/sin.v6i1.5492

Staronova, K. (2010). Regulatory Impact Assessment: Formal Institutionalization and Practice. *Journal of Public Policy*, *30*(1), 117–136. https://doi.org/10.1017/S0143814X09990201

Susanti, S. ., Puspitasari, C. . dan, & Ridwan, S. (2024). Pengaruh Edukasi Terhadap Pengetahuan Terkait Penggunaan Kosmetika Pada Remaja Di Pondok Khusus Putri Al- Halimy Lombok Barat. *Jurnal Inovasi Penelitian*, *4*(9), 1483–1488.

Tamtik, M., & Colorado, C. (2022). Multi-level governance framework and its applicability to education policy research - the Canadian perspective. *Research in Education*, *114*(1). https://doi.org/10.1177/003452372211401