



SUPERVISION OF HALAL CERTIFICATION IN THE PHARMACEUTICAL INDUSTRY IN INDONESIA

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ABSTRACT

The supervision of halal certification in the pharmaceutical industry in Indonesia aims to ensure that pharmaceutical products comply with halal standards for the country's Muslim majority. This research utilizes a normative juridical approach to analyze regulations and the implementation of supervision in halal certification. The findings indicate that halal certification supervision in Indonesia's pharmaceutical industry is governed by Law No. 33 of 2014, Law No. 6 of 2023, Law No. 17 of 2023, and Government Regulation No. 42 of 2024. Although these regulations cover various essential aspects, their implementation faces challenges due to the lack of clarity in supervision mechanisms and coordination between institutions. BPJPH, in collaboration with LPH, MUI, and BPOM, oversees the process through periodic inspections and technological tools such as Online Single Submission (OSS) and Continuous Auditing Continuous Monitoring (CACM). BPOM plays a crucial role in ensuring the halal status of pharmaceutical products through pre-market and post-market audits to guarantee their safety, efficacy, and quality. The main challenges include limited access to halal raw materials and the need to enhance the expertise of relevant authorities. This study suggests the necessity of additional regulations and strengthened inter-agency coordination to improve the effectiveness of supervision and ensure that pharmaceutical products meet halal standards

Keywords: Supervision, Pharmaceutical Industry, Halal Certification

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INTRODUCTION

Halal certification has become a crucial issue because the majority of Indonesians are Muslim. Oversight of halal certification has expanded to include pharmaceutical products. Since Law No. 33 of 2014 on Halal Product Guarantees was enacted, halal certification has become mandatory for all products. Therefore, every product marketed in Indonesia must clearly indicate its halal status (Malau & Svinarky, 2020).

Supervision is conducted by the Halal Product Assurance Agency (BPJPH), in collaboration with halal inspection agencies and the Indonesian Ulema Council (MUI). These institutions ensure that the halal certification process adheres to relevant regulations. In the pharmaceutical industry, supervision is particularly stringent due to the extensive use of chemicals and complex manufacturing processes, including active pharmaceutical ingredients, capsule coatings, and other additives. Each pharmaceutical product must undergo detailed auditing to verify both the halal status of its ingredients and compliance with established halal standards during the manufacturing process (Khairuddin & Zaki, 2021).

Despite ongoing challenges in supervising the halal pharmaceutical industry in Indonesia, including insufficient socialisation, limited access to halal raw materials, and resource constraints, Indonesia possesses significant potential to become a global hub for the halal pharmaceutical sector. The substantial demand for halal products, combined with comprehensive government regulations, creates considerable opportunities for growth. The Indonesian Ulema Council (MUI), the National Halal Product Assurance Agency (BPJPH), and the Halal Inspection Agency (LPH) are instrumental in certifying pharmaceutical products as halal in accordance with internationally recognised standards. Indonesian halal certification is recognized by 41 institutions across various countries, including

Canada, the United Kingdom, Japan, and ASEAN member states. This recognition is further supported by ratifying the Mutual Recognition Agreement (MRA) with 37 foreign halal institutions. To enhance international competitiveness, it is essential to improve regulatory oversight, foster institutional collaboration, and increase access to halal raw materials, thereby enabling Indonesia to establish itself as a leading centre for the global halal pharmaceutical industry (Hamka et al., 2024).

Law No. 33 of 2014 authorizes BPJPH to supervise halal products, including monitoring the validity of certificates, ensuring proper halal labeling, and classifying them accordingly. BPJPH collaborates with the Ministry of Health and BPOM to oversee pharmaceutical products' production, distribution, and certification, ensuring compliance with domestic and imported goods, and bolstering global competitiveness.

Law No. 17 of 2023 concerning Health provides the regulatory framework for supervising halal pharmaceutical products. This law mandates that pharmaceutical preparations, medical devices, and household health supplies (PKRT) comply with safety, efficacy, quality, and halal assurance standards. Additionally, Government Regulation No. 39 of 2021 reinforces the role of BPJPH in collaborating with the Ministry of Health and BPOM to oversee halal certification and revocation, particularly for pharmaceutical, cosmetic, and processed food products.

Several previous studies have discussed the development of the halal industry, particularly in the pharmaceutical sector. Fathurohman et al. (2024) highlight the challenges that arise related to the limited availability of halal-certified pharmaceutical products in Indonesia. From an Islamic and Muhammadiyah perspective, this study emphasizes the significance of halal certification in ensuring that pharmaceutical products are safe for use in accordance with Sharia principles.

Furthermore, research by Hakim and Anggraeni (2023) identifies several challenges in implementing halal standards within the pharmaceutical industry. Key obstacles include reliance on imported raw materials with uncertain halal status and the complexity of the certification process. Their study also emphasises the significance of implementing the Halal Assurance System (HAS) 23000 to verify the halal status of pharmaceutical products, despite persistent implementation challenges. Collectively, these studies offer valuable insights into the challenges and opportunities associated with halal certification in the pharmaceutical sector.

This study specifically addresses the crucial issue of supervision within Indonesia's halal pharmaceutical industry, an area that has often been overlooked in past research. Unlike previous studies focused on Sharia perspectives or operational challenges, this analysis concentrates on the legal and regulatory supervision framework, reviewing relevant laws and examining BPJPH, BPOM, and LPH mechanisms. By exploring supervision mechanisms and the integration of technologies such as OSS and CACM, this study aims to clarify how effective supervision ensures that Indonesia's pharmaceutical products consistently meet established halal standards.

METHODOLOGY

A normative juridical method is employed, focusing on the analysis of written legal norms. Normative legal research seeks to examine legal provisions, juridical principles, and legal doctrines to provide solutions to emerging legal problems. Field research is not conducted, as the objects of study are legal materials. Consequently, this research is library-based, centering on the reading and analysis of primary and secondary legal materials (Muhammad, 2022).

The data sources consist of primary and secondary legal materials. Primary legal materials comprise legislation that establishes the legal basis for product certification and supervision. Secondary legal materials, including legal literature, scientific articles, legal theories, and discussions of other legal issues, are used to enrich the analysis.

Data collection methods include literature studies and document analysis, encompassing reviews of primary and secondary legal materials, official documents related to halal regulations, and reports from halal inspection agencies. A qualitative approach is applied to analyze data and identify challenges in halal certification oversight and regulation. The scope of the study encompasses halal certification oversight in the pharmaceutical industry, as well as a legal analysis of the oversight process and regulatory implementation.



RESULTS & DISCUSSIONS

Halal Certification Regulations and Supervision Schemes

Halal certification is a formal procedure that grants halal recognition through a series of defined stages. This process verifies that raw materials, production methods, and the Halal Assurance System (SJH) comply with standards established by the Indonesian Ulema Council's Food, Drug, and Cosmetics Assessment Agency (LPPOM MUI). The halal certificate, issued as a written fatwa by BPJPH based on a fatwa from MUI, affirms that a product is halal according to Islamic law. Possession of this certificate is a prerequisite for displaying the halal label, which assures Muslim consumers that the food, medicine, or cosmetic product is safe for consumption (Syamsuri, 2020).

The halal certification process includes LPH auditors who are specifically trained to identify ingredients that may be haram under Islamic law. Following their training, these auditors conduct on-site inspections at manufacturing facilities to examine raw materials and verify the accuracy of documentation. Ingredients deemed questionable are subjected to laboratory analysis, and if they fail to meet halal standards, auditors recommend their replacement. The audit findings are then submitted to the MUI Fatwa Commission, which issues a halal fatwa and, if all criteria are satisfied, grants a Halal Certificate. This certification assures Muslim consumers of the product's halal status (Taufik, 2024).

Although regulations concerning JPH have been established to cover aspects of halal assurance, regulations on the supervision of halal certification are still limited and scattered across only a few specific articles, without a comprehensive law specifically regulating this supervision scheme. Currently, halal certification supervision has been incorporated into several articles of the aforementioned law; however, the regulations do not provide a detailed description of the supervision mechanism. Based on this background, the first discussion in this study will review the existing regulations and the current implementation of the halal certification supervision scheme.

1. Law Number 33 of 2014 on Halal Product Guarantee

The Halal Product Guarantee Law (JPH Law) regulates the implementation of halal certification, which is managed by BPJPH to ensure comfort, safety, and certainty for Muslims in consuming and using halal products. The law includes provisions on Halal Product Guarantees (PPH) to ensure the availability of halal products for the public. These products encompass materials derived from animals, plants, microbes, or those processed chemically, biologically, or through genetic engineering, provided they have been verified as halal (Fatima et al., 2023).

The law assigns BPJPH overall responsibility for supervising the Halal Product Guarantee (JPH). This supervision encompasses various aspects, including LPH, certificate validity periods, product halal status, and the inclusion of halal and non-halal labels on products. The law also mandates the separation of locations, equipment, and processes between products and requires the presence of halal supervisors at each stage of production. BPJPH may collaborate with relevant ministries and agencies, as permitted by applicable laws. Technical rules for supervision are to be further detailed in government regulations.

The law also facilitates public participation in JPH supervision through socialization and monitoring activities. The public is entitled to report products that do not comply with JPH standards. BPJPH is authorized to recognize individuals who make active contributions. Additionally, the law prescribes legal sanctions for business owners who violate its provisions (Wulansari & Anggraini, 2018).

2. Law No. 6 of 2023 Ratifying Government Regulation instead of Law No. 2 of 2022 on Job Creation

Law No. 6 of 2023 ratifies Perppu No. 2 of 2022 on Job Creation, amending several articles. The law introduces more detailed definitions and adds specific regulations, particularly regarding supervision and certification for business actors. Key changes include new definitions related to halal products, clarification of the roles of BPJPH, MUI, and LPH, as well as provisions concerning business actors. Article 4a requires micro and small businesses to obtain halal certificates in accordance with BPJPH standards. The law also strengthens BPJPH's role, including collaboration with MUI and educational institutions in developing halal assurance.

Additional amendments address the establishment of LPH (Article 13), the appointment of halal auditors (Article 14), and requirements for both LPH and halal auditors, which are further detailed in the Government Regulation. BPJPH is granted expanded authority to accredit and



appoint LPH for halal product inspections and to process halal certification requests from business operators.

Article 50 regulates JPH supervision by granting BPJPH and related agencies the authority to ensure business actors comply with halal certification requirements. The public is also permitted to participate actively in supervising halal products in the market by reporting to BPJPH (Article 53). Administrative sanctions are imposed on business operators who fail to meet halal status requirements, including fines for certification costs (Article 44) and penalties for failing to register products (Article 48).

3. Government Regulation No. 42 of 2024 concerning the Implementation of Halal Product Guarantee

Government Regulation No. 42 of 2024 concerning the Implementation of Halal Product Guarantee regulates various aspects of implementing and supervising Halal Product Guarantee in Indonesia. In the context of Halal Product Guarantee supervision, BPJPH is responsible for conducting comprehensive monitoring of several important aspects. This supervision includes LPH, ensuring halal certification in products, and maintaining separation of locations and equipment between halal and non-halal products throughout production, distribution, and presentation. In addition to BPJPH, local governments, relevant ministries, and various other government agencies are also required to cooperate in supervising JPH (Faridah, 2019).

This regulation also governs the involvement of third parties in supervision, whereby BPJPH, together with relevant ministries and agencies, may involve other parties in providing input or support for the implementation of JPH supervision. This supervision is carried out by official supervisors appointed by the competent authorities in each relevant institution. Every JPH supervisor must meet specific requirements, including being a Muslim, a civil servant (ASN), possessing a minimum of a bachelor's degree, understanding the concept of halal in Islamic law, and completing special training as a JPH supervisor. Supervisors are required to maintain the confidentiality of the results of supervision to protect the integrity of the process.

In terms of supervisor training, BPJPH is also responsible for organizing special training for JPH supervisors, in collaboration with relevant ministries and institutions. This training covers understanding the halal status of products according to Islamic law and the technical aspects of JPH supervision. The training curriculum is developed by BPJPH, which then coordinates with relevant agencies to provide instructors and training materials (Sukri, 2021).

JPH supervision is carried out periodically and incidentally. Periodic supervision is carried out every six months, while incidental supervision is carried out at any time if there are indications of violations of JPH provisions. To ensure effectiveness, JPH supervision is integrated with a risk-based licensing system through the Online Single Submission (OSS) platform, which enables a more efficient and coordinated licensing and monitoring process. Further provisions regarding the supervision mechanism and its integration with the OSS system are regulated through a Ministerial Regulation.

The current regulations address multiple aspects of supervision; however, they lack clarity and specificity regarding supervisory mechanisms. Furthermore, these regulations do not provide comprehensive oversight procedures, especially concerning routine inspections and inter-agency coordination to ensure business compliance. This situation underscores the necessity for more targeted and comprehensive legislation to establish an effective oversight framework, particularly to minimize loopholes that non-compliant businesses might exploit.

Difanti and Karimatul (2024) found that regulations governing the supervision of halal-certified products in Indonesia remain unclear and lack detailed implementation guidelines. This shortcoming is particularly evident in the absence of technical regulations that address periodic supervision and monitoring mechanisms in practice. As a result, legal uncertainty persists and the effectiveness of supervision is potentially diminished, since there are no operational guidelines to ensure that products maintain their halal status after certification. These findings indicate that, while existing regulations include provisions for supervision, their practical implementation remains limited. Consequently, more specific regulations are required to strengthen the halal supervision framework, thereby enhancing legal certainty and public confidence in the halal status of products in Indonesia (Zafitriani, 2024).

Despite existing areas for improvement, the government has undertaken several initiatives to enhance the effectiveness of halal-certified product supervision. The implementation of the Online



Single Submission (OSS) system aims to streamline the licensing process, including halal certification, and is expected to improve efficiency and transparency in coordination among ministries and related institutions. Additionally, the government has introduced a Continuous Auditing and Continuous Monitoring (CACM) system to reinforce the integration of halal supervision across agencies. Although a specific law governing comprehensive supervision mechanisms is not yet in place, the current framework demonstrates potential for further development to strengthen the halal product supervision system in Indonesia. The following outlines the implemented supervision scheme:

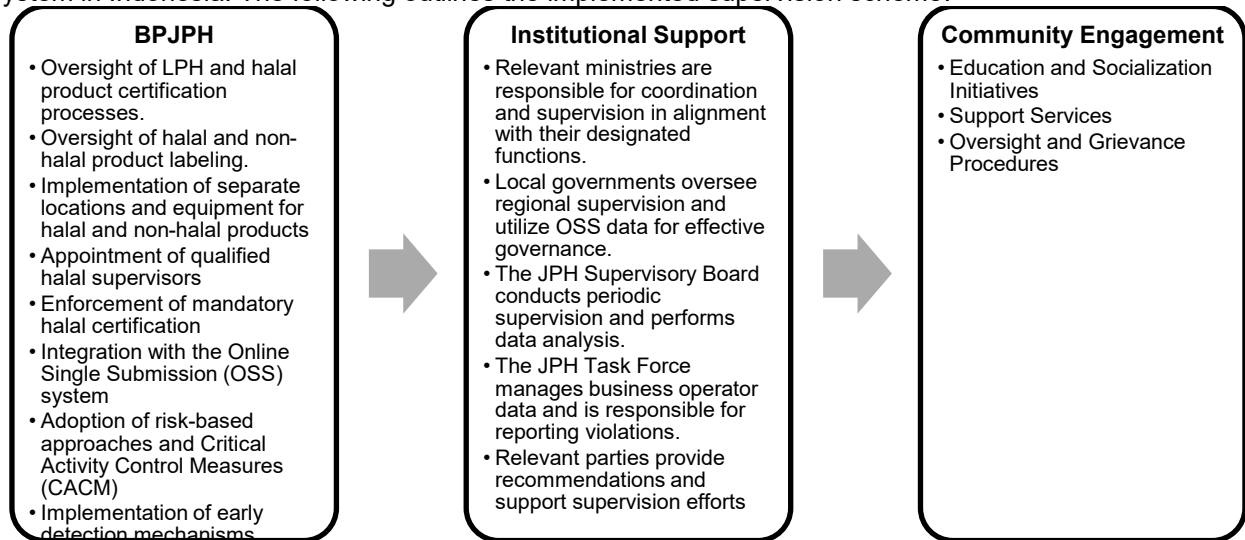


Figure 1. Halal Certification Supervision Scheme in Indonesia (Source: Compiled by Author)

Figure 1 illustrates that the supervision of halal certification is primarily the responsibility of BPJPH, which serves as the main supervisory authority. BPJPH employs OSS technology for data-driven supervision and implements the CACM initiative for ongoing monitoring. Additionally, inter-agency coordination is conducted with support from ministries, local governments, the JPH Task Force, and other relevant stakeholders. The following section discusses the halal certification supervision scheme in Indonesia:

1. Halal Product Assurance Agency (BPJPH)

The BPJPH serves as the primary institution authorized to supervise Halal Product Assurance (JPH) in Indonesia, as mandated by Law Number 6 of 2023 concerning Job Creation and Government Regulation Number 42 of 2024. The agency's six principal functions include supervising Halal Inspection Agencies (LPH), ensuring the halal status of products, overseeing the labeling of halal and non-halal products, managing the separation of facilities for halal and non-halal products, ensuring the presence of halal supervisors, and implementing halal certification obligations according to a predetermined schedule.

Both regulations mandate the use of an integrated electronic system for JPH services. Law No. 6 of 2023 concerning Job Creation requires that JPH services connect BPJPH, LPH, the Indonesian Ulema Council (MUI), and other relevant institutions. This system, managed directly by BPJPH, facilitates the halal certification process and supports related services, including public oversight and complaint management. Government Regulation No. 42 of 2024 further stipulates that JPH supervision must be integrated with the Online Single Submission (OSS) system as part of risk-based licensing supervision, thereby enhancing inter-agency coordination and the effectiveness of halal supervision.

The implementation of JPH supervision comprises two types: periodic supervision, conducted every six months, and ad hoc supervision based on indications of violations. This supervision is carried out individually or jointly by the government with the support of the community. The community has the right to participate by reporting violations to the BPJPH, and these reports can be forwarded in the form of complaints or direct reports to the BPJPH for follow-up. In addition, funding for the implementation of JPH, which comes from the State Revenue and

Expenditure Budget (APBN), Regional Revenue and Expenditure Budget (APBD), and other legitimate sources, provides a strong financial foundation to ensure the sustainable implementation of this supervision. The role of the BPJPH, which is strengthened in both regulations as the main authority in JPH supervision, is expected to increase legal clarity and certainty regarding the halal status of products marketed in Indonesia, as well as ensure the effectiveness of the certification and supervision process through a more modern and collaborative system integration

2. Online Single Submission (OSS)

Government Regulation No. 42 of 2024 concerning the Implementation of the JPH Sector mandates that supervision be conducted in a coordinated and integrated manner through an electronic system connected to the Online Single Submission (OSS). The OSS platform provides flexible access to business license registration and forms a component of E-Governance, addressing challenges associated with previous manual licensing processes. Before the implementation of OSS, business license registration involved lengthy and complex procedures. The adoption of OSS has streamlined and accelerated the licensing process for business actors (Rahmadani et al., 2024).

OSS is a technology platform that facilitates data integration between BPJPH and related agencies, ensuring efficient risk-based supervision. The platform centrally records and monitors licensing data and business actor compliance. Real-time access to data and supervision processes enables coordinated oversight by relevant agencies. Through OSS, BPJPH, and other agencies can optimize the supervision process by:

- 1) Integration of Supervision and Compliance Data: The OSS functions as a licensing data center, storing profiles, compliance statuses, and supervision results for each business operator. These data provide essential guidelines for BPJPH and relevant authorities in supervision and decision-making.
- 2) Risk-Based Supervision: OSS enables supervision based on the risk profiles of business operators. Businesses identified as higher risk are subject to more frequent supervision, whereas those demonstrating compliance may experience reduced supervision intensity.
- 3) Business Operator Compliance Profile: OSS maintains regularly updated records of supervision and inspection results. These profiles inform the determination of future supervision frequency and intensity, enabling more efficient and targeted oversight.

3. Continuous Auditing and Continuous Monitoring (CACM)

Continuous Auditing and Continuous Monitoring (CACM) are monitoring methods implemented by independent entities, such as the Inspectorate, to ensure effective internal controls and provide early warnings of potential issues. Under CACM, audits are performed in real-time by analyzing complete datasets, rather than relying solely on samples, which enables the timely and accurate identification and mitigation of significant findings or risks. This method enhances the quality of internal controls, enabling organizations to respond to risks with greater efficiency (Mudeng & Monoarfa, 2024).

The Inspectorate General of the Ministry of Religious Affairs supports CACM to promote more transparent, structured, and data-driven supervision. Through CACM, BPJPH can continuously monitor issues, thereby enhancing the quality of JPH supervision. The primary features of the CACM initiative are as follows:

- 1) Continuous Monitoring of Issues: BPJPH continuously monitors issues arising at each stage of JPH supervision until resolution is achieved.
- 2) Data-Based and Transparent Supervision: CACM uses data from OSS to create evidence-based supervision, so that supervisory actions are more accurate and reduce the possibility of unfounded supervision.
- 3) Early Problem Detection: With CACM, BPJPH can detect problems early on and take corrective action before they become more serious. This supports the Ministry of Religious Affairs' goal of digital transformation, aiming to improve public services using information technology.

The CACM initiative seeks to enhance visibility and transparency in BPJPH's supervision of halal products. This program is structured to improve the assessment of BPJPH's performance, ensuring transparency across all supervisory activities. CACM also enables ongoing monitoring



of issues, with the Ministry of Religious Affairs emphasizing that all issues at BPJPH will be tracked until fully resolved. This approach aims to detect potential problems early and prevent escalation. Through CACM, BPJPH adopts a proactive and impactful supervisory strategy, consistent with the Ministry's digital transformation agenda, which prioritizes improved public services through a data-driven management information system.

Apart from the monitoring aspect, the CACM initiative also supports the achievement of halal certification service targets. This program can motivate BPJPH to continue to optimally improve halal certification services. This aligns with the Ministry of Religious Affairs' vision to become a service-oriented bureaucracy. With the implementation of CACM, BPJPH's supervision has become more systemic, structured, and data-driven, thereby supporting the implementation of JPH in Indonesia (Kementerian Agama Republik Indonesia, 2024).

4. JPH Field Supervision and Inspection

JPH supervision in Indonesia is conducted by BPJPH in collaboration with the JPH Supervisory Board and relevant institutions. All products marketed in Indonesia are required to comply with halal standards as stipulated by regulations. Supervision is implemented through an integrated system that utilizes the Online Single Submission (OSS) platform to enhance efficiency and comprehensiveness, in addition to regular and ad hoc field inspections.

Ministries are responsible for supervising products and facilities within their respective sectors, working in coordination with BPJPH to ensure adherence to halal standards. Local governments play a crucial role in implementing this supervision, particularly for medium and large businesses that are mandated to obtain halal certification. By accessing data through the OSS platform, local governments can independently identify and monitor businesses within their jurisdictions, thereby supporting the enforcement of Regional Regulations (Perda) on halal in accordance with the JPH Law. These efforts align with JPH's objectives to provide comfort, safety, and protection for the public when consuming halal products, as well as to ensure sustainable legal certainty for business actors in fulfilling halal certification requirements (Arifin, 2021).

Beyond the roles of ministries and local governments, JPH supervision is further supported by the JPH Supervisory Board, which is responsible for overseeing and advising on the management of Public Service Agencies (BLU). The Supervisory Board's duties include participating in meetings, providing recommendations on regulatory compliance, and suggesting governance improvements to BLU management officials. Additionally, the Board monitors the implementation of business strategic and budget plans and offers input on periodic reports, including financial and performance reports. The Board also develops an annual supervision work program, which is submitted to the Minister or relevant institutional authorities, and undertakes other assigned duties in accordance with applicable regulations. JPH supervisors are designated officers appointed by BPJPH, ministries, or local governments to conduct field inspections.

Supervision by the Supervisory Board is carried out both periodically and incidentally in accordance with the risk profile recorded in the OSS. Periodic supervision is conducted every six months to ensure the continued compliance of business actors with medium to high risk. Meanwhile, ad hoc or incidental supervision is carried out without notice if there are indications of violations. All inspection data is recorded in the OSS and updates the business operator's risk profile, thereby influencing the intensity of future supervision.

To support supervision at the local level, the JPH Service Task Force (Satgas) in provinces, districts, or cities plays an active role. The task force assists in collecting and reporting data on business operators who have not met halal certification requirements, with a primary focus on medium and large businesses. Its responsibilities include gathering data on business operators and supervised entities, such as slaughterhouses, restaurants, hotels, and packaged food products in both modern and traditional markets. The Task Force is also tasked with reporting field violations to BPJPH for further action. Additionally, BPJPH collaborates with various relevant parties possessing specialized expertise or information to enhance JPH supervision. These collaborations provide critical input and supplementary data, enabling BPJPH to determine appropriate supervisory actions. Such partnerships contribute to a more systematic and comprehensive approach to JPH supervision.

5. Community Involvement



Community involvement in supervision is essential for protecting consumers from potential losses resulting from products available in the market. This responsibility extends beyond the government to include direct participation by the community and the Independent Consumer Protection Agency (LPKSM). According to Article 30 of Law Number 8 of 1999 concerning Consumer Protection, community supervision and LPKSM encompass monitoring the implementation of consumer protection, ensuring compliance with relevant regulations, and overseeing goods and services in the market through mechanisms such as research, testing, and surveys (Dewi, 2019).

Beyond monitoring the availability of accurate information about product risks, the community is responsible for verifying labels, monitoring advertisements, and ensuring that information provided by business actors complies with relevant regulations. For instance, products with inherent risks must include labels that clearly explain these risks, enabling consumers to make informed decisions. LPKSM collaborates with the community to promote awareness of consumer rights and to assist consumers who experience losses or identify discrepancies in the products they use.

Community supervision also includes participation in oversight activities conducted by BPJPH to ensure that products in the market comply with halal standards. This role involves disseminating information about JPH and halal product labeling to consumers, thereby increasing public awareness and understanding of halal products. Furthermore, the community is encouraged to actively submit complaints or reports when discrepancies are identified in market products, particularly when products fail to meet halal requirements or other applicable standards (Syafrida, 2020).

Public oversight conducted by the public and relevant institutions promotes transparency and builds consumer confidence in market products. It also involves evaluating the accuracy of information provided by business actors, including verifying that product packaging and advertising are not misleading or deceptive. Meanwhile, the government is responsible for responding to public reports and complaints to ensure that sanctions for violations endangering consumers are enforced according to applicable regulations.

Oversight of Halal Certification in the Pharmaceutical Industry

The halal pharmaceutical sector has experienced substantial growth, marked by a rapid increase in the supply of products that comply with Islamic principles. The State of the Global Islamic Economy Report 2023/24 indicates that Muslim spending on halal pharmaceuticals reached \$108 billion in 2022 and is projected to rise to \$142 billion by 2027, with an annual growth rate of 5.7%. This trend highlights significant potential for meeting the demand for halal pharmaceutical products, particularly in Muslim-majority countries such as Indonesia. Nevertheless, a major challenge remains the reliance on imported pharmaceutical raw materials from non-OIC countries, including Germany, the United States, and India (Gateway, 2023).

In Indonesia, products, including medicines, must obtain halal certification as mandated by Article 2 of Government Regulation No. 39 of 2021 concerning JPH. Government Regulation No. 6 of 2023 further specifies the types of medicines requiring halal certification, encompassing medicinal ingredients, over-the-counter medicines, restricted over-the-counter medicines, prescription medicines, traditional medicines, health supplements, and quasi-medicines. The pharmaceutical and herbal industries are deemed compliant with halal standards if they meet several key criteria:

- 1) Raw materials and production processes must adhere to Islamic principles.
- 2) Products must contain only halal ingredients and be free from haram or Najis elements.
- 3) Products must be protected from contamination or mixing with haram or Najis ingredients.
- 4) During production, storage, transportation, distribution, and presentation, products must remain protected from contamination or mixing with haram or impure ingredients.

Before the implementation of the JPH Law, collaboration among the government, industry stakeholders, and the community was essential in preparing for halal product certification. The JPH system, formerly known as the Halal Assurance System (SJH), has become a fundamental requirement for halal certification of products, including medicines and herbal medicines, with LPPOM MUI serving as the supervisory agency. The SJPH is a management system that regulates raw materials, production



processes, products, personnel, and procedures to ensure compliance with halal standards (Shalahuddin et al., 2024).

Companies are required to appoint internal auditors to monitor the implementation of the SJPH and report to the Halal Inspection Agency (LPH); one example is LPPOM MUI. As an LPH institution, LPPOM MUI also conducts inspections, and if any non-compliance is found, the company must rectify it so that halal certification can continue. In addition, companies must document the procedures for selecting new ingredients and developing new products or facilities. Before discussing further the increasingly stringent halal supervision and certification mechanisms with the enactment of the JPH Law, it is important to first understand the supervision scheme applied in halal certification in the pharmaceutical industry:

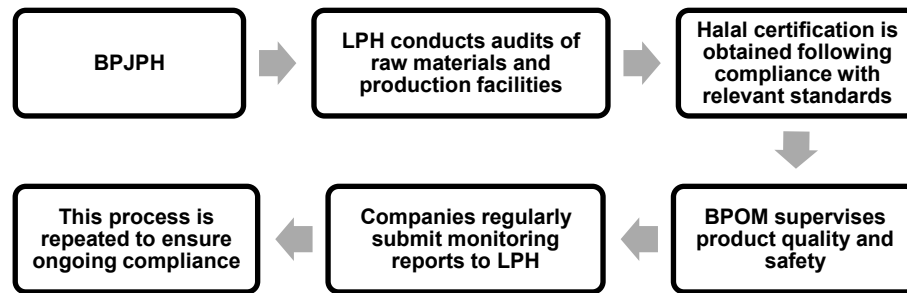


Figure 2. Oversight of Halal Certification Processes in the Pharmaceutical Industry (Source: Compiled by Author)

The enactment of the JPH Law has led to a more stringent and structured halal certification process and enhanced oversight mechanisms. The LPH is responsible for conducting inspections, while ISO certification bodies audit companies in the pharmaceutical and herbal medicine sectors. In the event of a change in halal status, the LPH initiates appropriate actions. Companies are required to submit reports every six months to facilitate monitoring of SJPH implementation. The BPOM oversees quality control, whereas the BPJPH, supported by the LPH, monitors halal compliance. BPOM supervision encompasses both pre-market activities, including ingredient procurement, production, and labeling, as well as post-market activities, such as laboratory sample testing. Products that fail to meet established standards, such as herbal medicines containing non-standard chemicals, must be rectified.

Figure 3 illustrates that the BPOM drug and food surveillance system comprises several key stages. The first stage is centralised standardisation, which establishes consistent standards and regulations nationwide. The second stage involves pre-market evaluation to assess products prior to the granting of marketing authorisation, applicable across Indonesia. The third stage is post-market surveillance, which ensures product safety and quality through sampling, facility inspections, label monitoring, and advertising surveillance. The fourth stage involves laboratory testing to verify compliance with established standards. The final stage involves law enforcement action against non-compliant products, including sanctions such as the withdrawal of marketing authorization and product destruction.

BPOM supervises both pre-distribution and distribution phases of drugs and food products to ensure safety, efficacy, and quality. This supervision encompasses the formulation of facility and product standards, the evaluation of registered products for the issuance of a Marketing Authorisation Number (NIE), and oversight of labels and advertising. Additionally, BPOM conducts quality testing through sampling, inspects production and distribution facilities, monitors for illegal or counterfeit products, and investigates and imposes sanctions on entities that violate regulations governing product production, distribution, or circulation (Badan Pengawas Obat dan Makanan, 2023).

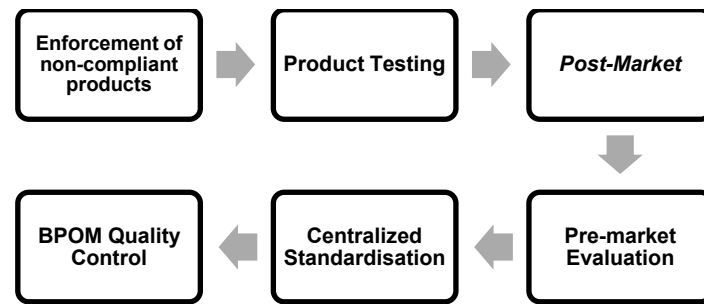


Figure 3. Halal Certification Supervision of the Pharmaceutical Industry (Source: BPOM Annual Report 2023)

The monitoring of the safety of marketed medicines includes pharmacovigilance, as outlined in BPOM Regulation No. 15 of 2022. Pharmacovigilance involves official inspections by the BPOM to ensure compliance with regulations by the pharmaceutical industry, through the review of existing documents, facilities, and resources. The main objective is to ensure that the industry has adequate systems, personnel, and facilities to support pharmacovigilance, as well as to identify non-compliance that poses a risk to public health. In 2023, BPOM conducted inspections of 28 pharmaceutical companies. In addition, BPOM participates in the ASEAN Post Market Alert System (PMAS), an ASEAN Pharmaceutical Product Working Group programme that enables the rapid exchange of information on the safety and quality of traditional medicines, health supplements, and cosmetics between ASEAN countries, especially for products that need to be immediately withdrawn from circulation (BPOM, 2021).

The LPH conducts audits by verifying the raw materials for medicines and comparing them with the list available on-site. In addition, supervision also encompasses production infrastructure, including areas for weighing, mixing, and liquid filling. This process also involves examining various important documents, including the Halal Quality Manual, Raw Material and Finished Product Analysis Certificates, Operational Procedures, Manufacturing Batch Books, Halal Policies, and internal and external halal training records. Other documents examined include halal ingredient certificates, product flow charts, and lists of approved halal ingredients. If all supervision and audit procedures are in order, the LPH will complete the halal certification process for the product (Mubarok, 2019).

The BPOM 2023 Annual Report outlines the agency's efforts in halal supervision within the pharmaceutical industry. BPOM has expanded its supervisory capacity through 76 Technical Implementation Units (UPT) across Indonesia, including Central and POM Offices in various regions. A significant challenge remains the shortage of human resources required for consistent supervision, particularly given the rise of illegal products in online markets. BPOM has actively enforced regulations by targeting violations, including the sale of illegal products and those containing hazardous ingredients. These enforcement actions have reduced the circulation of illegal products, though monitoring products on digital platforms remains challenging. For instance, BPOM addressed a case involving illegal cosmetic products valued at Rp7.7 billion. Such law enforcement efforts have improved industry compliance, despite ongoing difficulties in overseeing products in the rapidly evolving online market.

The effectiveness of JPH's legal policy is measured by the achievement of its objectives, specifically the assurance of halal products through certification. Halal Product Assurance (HPA) has demonstrated notable progress, with the number of halal-certified pharmaceutical products rising from 1,891 in 2019 to 2,586 in 2022. Although regulations concerning JPH and certification supervision exist in several laws, these provisions remain limited and do not establish a comprehensive framework for supervision. BPJPH, responsible for overseeing halal certification, holds authority over halal inspection institutions, certificate validity periods, and product halal status. Nevertheless, this supervisory function lacks full coordination and detail.

Regulations such as the Job Creation Perppu strengthen the role of BPJPH and further regulate the supervision of business actors, but there are still gaps in the implementation of effective supervision in the field. Although several areas need improvement, the government has made various efforts to enhance the effectiveness of supervising halal-certified products. One of the steps taken by the government is the implementation of the OSS system, which aims to simplify the licensing process,

including halal certification. Through OSS, coordination between relevant ministries and agencies is expected to be more efficient and transparent. Additionally, the government initiated the CACM system to strengthen the integration of halal supervision across various agencies.

Research indicates that, despite the existence of regulations on halal supervision, their practical application remains ambiguous. There are currently no operational guidelines or regulations to ensure the halal status of products after certification. Consequently, more comprehensive regulations are required to enhance the effectiveness of supervision and bolster public confidence in the halal status of products in Indonesia. The halal certification process in the pharmaceutical industry faces several challenges, particularly regarding the lack of transparency in product supervision and the presence of production facilities that do not meet halal standards. Many pharmaceutical facilities lack the necessary infrastructure to produce halal medicines at scale, which impedes industry development (Fadliyah & Nurwahyuni, 2022).

BPOM has also observed that the supervision of halal products remains inefficient, with a need for stronger coordination among ministries and institutions. Furthermore, specialised training for religious institutions in halal science and technology is necessary, along with the development of scientific methods to support the certification and supervision of pharmaceutical products. Effective collaboration among government agencies, religious scholars, pharmaceutical manufacturers, and medical personnel is crucial to establishing an efficient surveillance system and facilitating the acceptance of halal products in the global market. Product quality continues to present challenges, as changes in drug formulation or retesting may impact quality (Alfath, 2023). A more holistic surveillance approach is required that integrates halal status, quality, and adherence to international standards.

CONCLUSIONS

Supervision of halal certification in Indonesia's pharmaceutical industry is governed by several regulations, including Law No. 33 of 2014, Law No. 6 of 2023, and Government Regulation No. 42 of 2024. The BPJPH serves as the primary authority, coordinating with the LPH for technical audits, the MUI for issuing halal fatwas, and the BPOM for ensuring product quality and safety through both pre-market and post-market audits. Supervision also involves relevant ministries and local governments, each operating within its respective jurisdiction, and is supported by the JPH Task Force at the regional level. Community participation is encouraged through socialization, assistance, and complaint mechanisms. The effectiveness of this supervision is enhanced by technologies such as the OSS and CACM systems, which facilitate integrated and continuous monitoring. Nevertheless, persistent challenges include inadequate inter-institutional coordination, limited availability of halal raw materials, and a shortage of certified supervisory personnel. Addressing these issues requires additional technical regulations and greater cross-sector collaboration to strengthen the overall halal supervision system.

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