

Halal Certification Regulation on Health Products: A Global Comparative Study

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Abstract

The growing global demand for halal-certified healthcare products has brought renewed attention to the regulatory frameworks governing halal certification in the pharmaceutical and health sectors. This study aims to analyze and compare halal certification regulations across various countries, identifying best practices, structural challenges, and opportunities for harmonization. The research synthesizes data from industry reports, regulatory documents, and academic studies, complemented by case studies that illustrate the successes and failures of implementation in key halal markets such as Indonesia, Malaysia, the Gulf Cooperation Council (GCC) countries, and selected Western nations used a qualitative-comparative methodology. Findings reveal that while some countries have established robust institutional mechanisms and comprehensive halal assurance systems, others face systemic limitations, including inconsistent standards, high certification costs, and shortages of halal-compliant raw materials. The study highlights the fragmented nature of global halal certification and the resulting barriers to international trade and consumer trust. A thematic analysis further identifies recurring issues such as regulatory ambiguity, inadequate auditor capacity, and consumer sentiment surrounding certification speed and transparency. The research underscores the urgency of promoting regulatory convergence and cross-border cooperation to support the growth of a trusted and inclusive halal healthcare ecosystem.

Keywords: *Halal Certification, Healthcare Products, Regulatory Comparison, Global Standards, Pharmaceutical Industry.*

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A. INTRODUCTION

The discourse on the halal status of healthcare products has become increasingly urgent as awareness grows that halal principles encompass all aspects of life, including medical care and treatment. Adherence to Shariah for Muslim extends beyond food and beverages, encompassing health-related products such as pharmaceuticals, nutritional supplements, and medical devices used in treatment procedures. The need for clarity and assurance regarding the halal status of healthcare products represents a fundamental right of Muslim consumers to receive services aligned with their values (Ab Latiff et al., 2022; Sulaiman & Abdullah, 2022).

Rejection of products containing non-halal elements, such as gelatin derived from animals not slaughtered according to Islamic rites, is common among Muslim communities. Medical decisions are often influenced by the halal status of a product, even in emergency situations. Such realities highlight the critical importance of robust halal regulation and certification to provide legal certainty and peace of mind. Uncertainty about the origin of ingredients, production processes, and lack of transparency in supervision may trigger anxiety and hinder treatment compliance.

The global market has witnessed a significant surge in demand for halal-certified healthcare products. Reports on the global halal industry position the pharmaceutical and medical device sectors as key components of a growing halal ecosystem with strong economic potential. Amidst increasing globalization and cross-border healthcare integration, standardization and harmonization of halal regulations have become imperative (Al-Mahmood & Fraser, 2023; Ramli et al., 2018). Healthcare industries that can accommodate Muslim consumer needs are well-positioned to expand their market reach.

Healthcare products play a central role in maintaining the quality of life, including for the more than 1.9 billion Muslims worldwide. The need for safe, effective, and religiously acceptable treatment options renders healthcare products a vital component of inclusive medical services. Medicines containing animal-derived ingredients, supplements with non-transparent additives, or medical devices processed with non-halal materials often pose ethical dilemmas for Muslim patients. Reluctance to use products with questionable halal status may affect the continuity of medical therapy and patient safety. Providing healthcare products that are not only clinically safe but also spiritually acceptable is a fundamental necessity in a health system that respects diversity (Asa & Azmi, 2018; Masruroh & Mahendra, 2022).

This need becomes more pronounced when Muslim patients face long-term treatment or critical conditions that require the use of specific drugs and medical devices. When choices are available, preferences for halal-certified products tend to be stronger. In an ideal healthcare system, patient trust in the products and services provided is built not only through scientific evidence but also through respect for individual beliefs (Ab Latiff et al., 2021; Krisna & Yusuf, 2023; Salindal, 2019). Awareness of halal certification has now extended beyond the food and beverage industry. Cosmetic products, pharmaceuticals, personal care items, and even household chemical products are increasingly evaluated for their halal compliance by Muslim consumers. This growing demand is fueled by a broader understanding that halal values are not only rooted in religious law but are also closely linked to cleanliness, ethics, and sustainability. In the perception of the modern Muslim public, halal signifies cleanliness, transparency, and ethical processing.

The expansion of halal awareness into non-food sectors reflects a transformative shift in the consumption paradigm of the global Muslim community toward a more comprehensive approach. Amidst globalization and increased access to information, consumers are becoming more critical in tracing the origins and production processes of goods. In response, producers have begun to engage halal certification bodies to enhance the competitiveness of their products in international markets, and this shift presents both significant opportunities and challenges for the healthcare industry, which must now develop policies and production systems that comply not only with medical standards but also with Islamic principles.

The global halal industry is experiencing rapid and dynamic growth, driven by the rising Muslim population and increasing awareness of consumption aligned with sharia principles. The annual *State of the Global Islamic Economy (SGIE)* report

highlights that the halal sector has expanded beyond food and beverages to include other strategic areas such as pharmaceuticals, cosmetics, tourism, and finance. Within this trend, health products have emerged as a high-potential subsector, gaining increasing attention from both consumers and regulators across various countries (Abdul & Khokhar, 2023; Muneeza & Mustapha, 2021).

According to the SGIE 2023 Report, Muslim consumer spending on pharmaceuticals reached USD 116 billion in 2022 and is projected to grow to USD 181 billion by 2027, with an annual growth rate of approximately 9.2%. This data indicates that the halal pharmaceutical sector holds not only religious significance but also considerable strategic economic value. Countries such as Indonesia, Malaysia, and the United Arab Emirates have developed halal certification ecosystems that include the health sector as part of their national strategies to strengthen their positions in the global halal market.

One major issue is the controversy surrounding health products that lack guaranteed halal status. For instance, there has been debate over the use of meningitis and HPV vaccines that contain ingredients derived from non-halal sources or are processed using enzymes inconsistent with halal standards. Indonesia has concerns about the halal status of vaccines have led to public resistance against government vaccination programs (Al-Teinaz & Al-Mazeedi, 2020; Fibrianti et al., 2023; Krisharyanto et al., 2019). Similar resistance has occurred in other countries due to a lack of clear information about the ingredients and manufacturing processes, which has sparked mistrust among segments of the Muslim community.

Such instances underscore the critical need for transparency and precise regulation in halal certification, especially for health products that are widely used and essential. When religious principles and healthcare practices are not harmonized, public trust in the health system can be undermined. Countries with large Muslim populations are increasingly advocating for halal regulations that cover pharmaceuticals and medical devices as part of consumer protection and values-based healthcare services (Anggarkasih & Resma, 2022; Aziz et al., 2021; Othman et al., 2023). The following data further illustrates this trend:

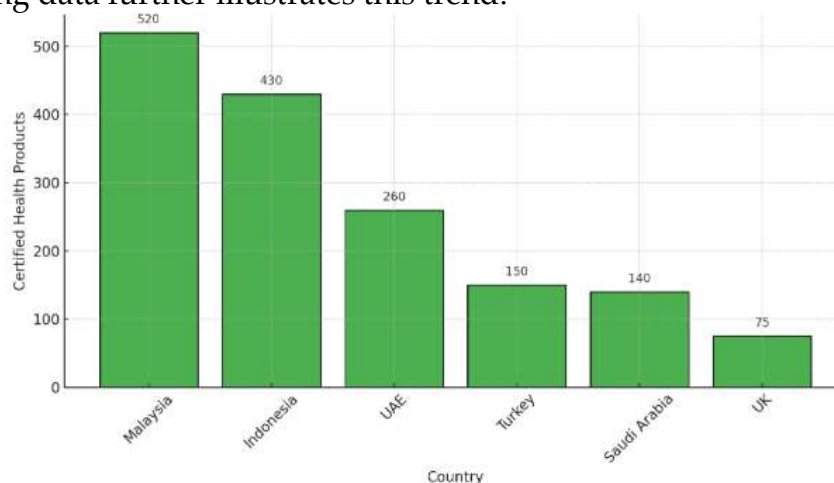


Figure 1. Number of Halal-Certified Health Products by Country

Source: State of the Global Islamic Economy Report (SGIE), 2023

Although awareness of the halal status of healthcare products continues to grow, efforts to implement halal certification in this sector face a number of complex challenges. One of the main difficulties lies in the complexity of the raw materials and production processes used in the pharmaceutical and medical device industries. Healthcare products often involve active ingredients, additives, solvents, and capsule coatings derived from various sources, including animals, plants, and synthetic chemical processes. Many of these components come from long and multilayered global supply chains, making it difficult to trace their origins (Latiff, 2020). Ingredients such as gelatin, magnesium stearate, or fermentation enzymes, for example, may be derived from animals that do not meet halal standards if not slaughtered according to Islamic law, or if the materials are contaminated with impure (*najis*) substances.

Table 1. Sector-wise Contribution to the Global Halal Industry

Sector	Contribution (%)	Description
Food	43%	The largest component of the halal industry, covering packaged food, meat, beverages, and food services that comply with Islamic dietary laws.
Clothing	23%	Includes modest fashion, Islamic garments, and accessories that adhere to religious dress codes.
Media	23%	Islamic media content, including TV, film, publishing, and digital platforms aligned with Muslim values and ethics.
Tourism	8%	Halal tourism ensures that accommodations, food, entertainment, and services are in line with Islamic principles (e.g., no alcohol, prayer facilities, halal food).
Pharmaceuticals	7%	Halal-certified drugs, vaccines, and supplements manufactured without non-permissible ingredients like alcohol or gelatin derived from non-halal sources.
Cosmetics	5%	Includes beauty and personal care products made without haram substances and not tested on animals.

Source: Halal Pharmaceuticals Market, 2022

The halal industry is emerging as one of the fastest-growing sectors globally, with its market value projected to exceed USD 3 trillion in the coming years. Among its various components, halal pharmaceuticals—currently representing a modest 7% share—are gaining significant traction. This growth is fueled by rising consumer awareness and a strong demand for healthcare products that align with ethical and religious standards. The momentum is especially pronounced in regions with

substantial Muslim populations, such as Southeast Asia, the Middle East, and South Asia, where favorable regulatory frameworks further accelerate the development and adoption of halal-certified products and services.

The manufacturing processes of pharmaceuticals and medical devices often involve technically complex stages and require high-quality standards, such as aseptic processing, the use of excipients, and clinical testing. This complexity makes halal auditing a multidisciplinary task, requiring collaboration among experts in chemistry, pharmacy, and Islamic jurisprudence. Without sufficient understanding of healthcare technologies, halal certification bodies may struggle to conduct accurate and comprehensive assessments (Draman et al., 2019; Safira et al., 2019).

Another challenge stems from the differences in regulatory policies and approaches between countries. Malaysia, through JAKIM, has developed a relatively mature halal standard that explicitly integrates the pharmaceutical sector into its certification scheme. Indonesia, through BPJPH and LPPOM MUI, has also established halal requirements for medicines and health products, although implementation remains gradual. The United Arab Emirates applies a strict approach based on GCC standards, while in Europe—particularly in countries like the UK and France—there is no official halal regulation specific to healthcare products, making certification largely voluntary and often initiated by industry actors or local Muslim communities. These differences create gaps in standards, cross-country recognition, and even trade barriers.

The lack of a unified global standard further complicates the effort to harmonize halal certification systems. No international consensus exists that comprehensively governs the halal certification mechanisms for healthcare products, whether in technical or legal terms. Although some efforts have been made by the Organization of Islamic Cooperation (OIC) and the Standards and Metrology Institute for Islamic Countries (SMIIC), implementation across countries remains can't be agreed. This fragmentation hinders industry players from marketing halal products across borders, as a product certified in one country may not be recognized in another. The absence of a global standard also affects the credibility and acceptability of the certification itself. In an increasingly competitive market, halal certification must ensure transparency, scientific validity, and cross-jurisdictional compatibility to truly protect consumers and strengthen market trust (Nurhayati et al., 2022; Ridwan, 2020).

This study aims to provide a comparative understanding of halal certification regulations for healthcare products in several key countries. The primary focus is on nations with significant influence in the global halal industry and those that have demonstrated initiatives in regulating halal healthcare products—such as Malaysia, Indonesia, the United Arab Emirates, and European countries. Implementation mechanisms, and the actors involved in the certification process, this research seeks to illustrate the diversity of approaches and their impact on both the industry and Muslim consumers by comparing policy frameworks.

The study aims to identify best practices that can serve as references for other countries in designing or improving their halal certification systems in the healthcare

sector. These best practices include aspects of legislation, auditing systems, the participation of religious and scientific authorities, and the involvement of industry stakeholders. The study will also highlight various implementation barriers—technical, regulatory, and social. By understanding these barriers, this research hopes to offer both conceptual and practical contributions to the global harmonization and strengthening of halal systems, especially in the healthcare sector, which plays a crucial role in public well-being.

B. METHOD

This research uses a comparative legal study approach to examine and compare halal certification policies for health products in five selected countries: Indonesia, Malaysia, the United Arab Emirates (UAE), Australia, and the United Kingdom. The selection of these countries is based on the variation in their legal systems and approaches to halal regulation, covering both Muslim-majority and non-Muslim countries with developing certification systems. Data collection techniques include documentation of national regulations and policies, literature review from journals and institutional reports, and semi-structured interviews with key informants, including officials from national halal certification bodies, such as BPJPH officials in Indonesia, practitioners in the pharmaceutical and hospital sectors, as well as academics and health law experts with a focus on halal regulation (Rahmah & Barizah, 2020). The interviews aim to gain direct perspectives on the implementation of policies, legal challenges, and the dynamics of halal certification practices in the field.

C. RESULT AND DISCUSSION

1. Each Country's Policy on Halal Certification Regulations for Health Products

Halal certification regulations for health products show significant differences in approaches between countries, reflecting the legal structure, culture, and the role of religious institutions in each region. Indonesia has a mandatory halal certification system as regulated in Law No. 33 of 2014 concerning Jaminan Produk Halal, with implementation focused through Badan Penyelenggara Jaminan Produk Halal (BPJPH). Its implementation covers medicines, medical devices, and biological products, although it is still being phased in. A BPJPH official explained:

"We are building a system that not only verifies the halal status of products but also builds public trust in Sharia-compliant healthcare services."

Malaysia has developed a well-established halal certification system through the Jabatan Kemajuan Islam Malaysia (JAKIM). Certification in the pharmaceutical sector is voluntary but widely adopted by the industry, given the power of the halal label in marketing strategies. The MS 2424:2012 standard is used as the technical reference for halal pharmaceutical products, including criteria for active ingredients and the production process. An expert from the pharmaceutical industry stated:

"Compliance with halal standards in Malaysia is more than just a religious requirement—it's part of the competitive advantage".

The United Arab Emirates (UAE) has strengthened halal regulations with support from the central government through the Emirates Authority for Standardization and Metrology (ESMA), which developed an integrated halal certification system and mandated that all imported pharmaceutical products obtain halal certification since 2016. This policy reflects the country's commitment to making Dubai a global halal industry hub. An academic from Sharjah emphasized:

"The UAE has shown that integrating halal principles into strategic sectors can be driven by state policy, not just market pressure".

Australia and the United Kingdom have a more liberal and market-based approach. Halal certification is conducted by private institutions recognized by the government, such as the Australian Halal Authority and Advisers (AHAA) and the Halal Monitoring Committee (HMC) in the UK. There is no legal obligation for halal certification of health products, but demand for halal products has increased with the growth of the Muslim population. Pharmaceutical producers in the UK mentioned:

"Demand from the Muslim community has encouraged us to develop a range of halal-certified products, even though it is not legally required".

The success of the halal certification system for health products cannot be solely measured by the existence of formal, legally binding regulations. While regulations are an important foundation, the effectiveness of their implementation is highly determined by several supporting factors that are institutional and social in nature. Institutional maturity is the key factor—certification bodies with authority, transparency, and adequate technical capacity are able to ensure that the certification process is accountable and trusted by both the public and industry players. In countries such as Malaysia and the UAE, institutional strength is reflected in consistent standardization, ongoing oversight, and an integrated accreditation system with national industrial policies.

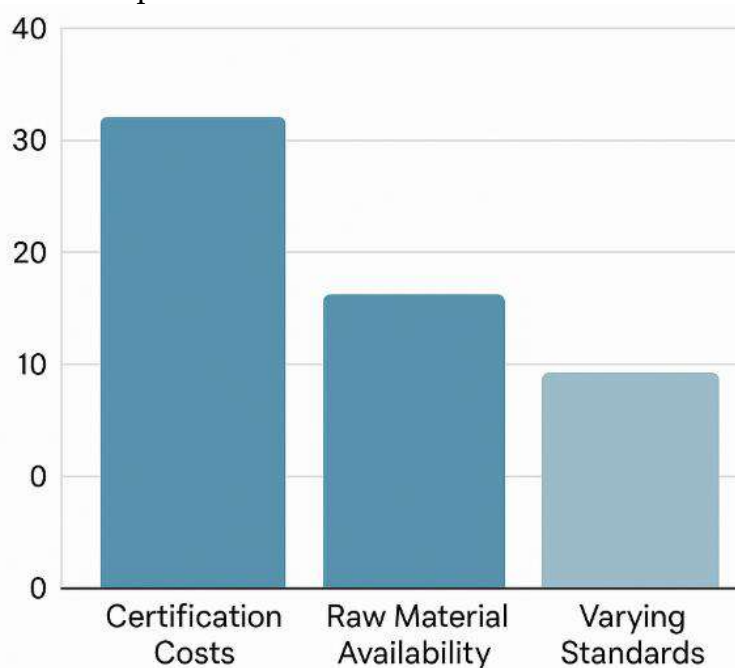


Figure 2. Frequency of Theme

Industry participation also plays a significant role, especially in the context of countries where halal certification is not legally required. When business actors voluntarily adopt halal standards, it shows that halal is no longer viewed solely as a religious obligation, but rather as an instrument for added value and market competitiveness. In the UK and Australia, pharmaceutical producers respond to the needs of the Muslim community by offering halal products as a form of commitment to inclusivity and market diversification.

Consumer awareness is another equally important aspect. The higher the knowledge and concern of the Muslim community regarding the halal status of the health products they consume, the greater the pressure on business actors and regulators to provide guarantees that align with Sharia principles (Asmuni et al., 2020; Radzi & Nordin, 2019). This awareness creates demand that is both ethical and spiritual, driving the transformation of the healthcare industry towards a system that is more adaptive to Islamic values. The combination of these three aspects—strong regulations, effective institutions, active industry participation, and consumer awareness—forms the prerequisites for creating a sustainable and globally competitive halal certification ecosystem.

2. Comparative Analysis

A comparative analysis between the five countries studied shows that there are common ground as well as fundamental differences in the regulation and implementation of halal certification for health products. One of the main similarities lies in the recognition of the importance of halal certification as a form of protection for Muslim consumers, although the implementation approaches vary. Both Muslim-majority countries such as Indonesia, Malaysia, and the United Arab Emirates, as well as non-Muslim countries such as Australia and the United Kingdom, show a tendency to increase attention to the halal aspect in the pharmaceutical and health sectors. All countries studied have involved certain institutions—both government and private—to carry out certification, audit, and compliance monitoring functions.

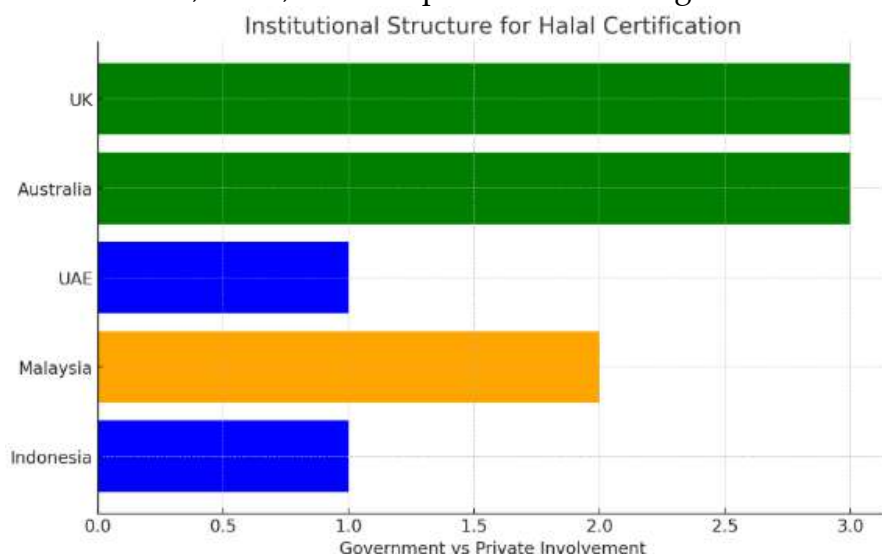


Figure 3. Institutional Structure for Halal Certification

The most prominent difference is seen in the legal obligation and institutional structure. Indonesia and the UAE implement mandatory policies for halal products, with a formal legal basis and direct supervision by government agencies. Indonesia views this obligation as comprehensively regulated through legislation, while in the UAE, the policy is strengthened by the active role of the state in making the halal industry a pillar of the national economy. In contrast, Malaysia applies a highly developed voluntary approach, where halal certification has become a strong industry norm thanks to the credibility of JAKIM and market trust.

The UK and Australia follow a non-interventionist legal approach, leaving halal certification to private authorities working based on accreditation and market recognition. National regulations do not explicitly govern the halal status of health products but still support the existence of certification bodies through general oversight mechanisms for pharmaceutical products (Bux et al., 2022; Yusuf et al., 2022). This data creates a more flexible system, but also opens the possibility of standard fragmentation. If simplified, the relationship between halal certification issues and the challenges faced by producers in different countries is as follows:

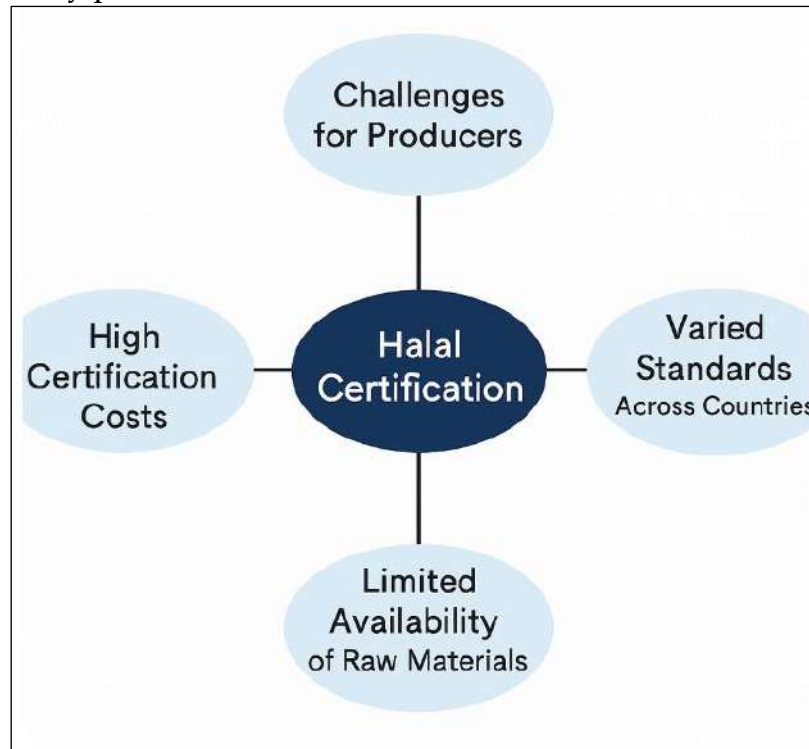


Figure 4. The Relationship Between Halal Certification Issues and the Challenges Faced by Producers

Differences also arise in terms of technical aspects of halal pharmaceutical standards, for example Malaysia which has its own national standard (MS 2424) which regulates in detail aspects of materials, production processes, to storage, the standard still refers to the general principles of halal, with adaptations that depend on the interpretation of certification bodies in other countries. Other differences are also apparent in the way each country responds to market pressures and consumer needs.

In Muslim-majority countries, this pressure actually comes more from normative orders and state policies, while in Muslim-minority countries, the pressure is more market-based, with producers responding to consumer demand as a form of economic opportunity. This comparison shows that the effectiveness of the halal certification system for health products is greatly influenced by the social, legal, and economic context of each country, as well as the ability to integrate religious values into the industrial system and public policy in a pragmatic but principled manner.

3. Case Study of Certification System Implementation and Failure

The implementation of the halal certification system for health products shows varied results across countries, reflecting both successes and challenges faced. Indonesia, through Badan Penyelenggara Jaminan Produk Halal (BPJPH) which issue Halal Certificate based on fatwas of Majelis Ulama Indonesia (MUI), ensures the halal status of health products. Although this system has been successful in providing high assurance to consumers, the main challenge lies in the certification process, which is often perceived as lengthy and complicated. Research by Irawan (2020) shows that small and medium-sized producers often struggle to meet the halal certification requirements, which affects their ability to access a broad market, despite the large demand for halal health products (Herdiana & Rusdiana, 2022; Hosen & Lathifah, 2020).

Malaysia has a more efficient and structured approach, with the Badan Pengawas Obat dan Makanan Malaysia (NPRA) playing a key role in the halal certification system. According to a study by (Ramli et al., 2018), Malaysia has successfully created a faster and more integrated certification system, allowing producers to meet market demand without compromising product quality and halal integrity, and this model highlights the importance of close cooperation between the government and producers in creating a system that facilitates market access while maintaining product integrity (Septiani & Ridlwan, 2020).

The global halal market was valued at \$2.3 trillion in 2020, with projections indicating it will reach \$3.2 trillion by 2024. This growth can be attributed to the uprising of Muslim population and increasing global preference for halal-certified products. In Indonesia, Badan Penyelenggara Jaminan Produk Halal (BPJPH) reported that by October 24, 2023, 2.9 million products had been halal certified, exceeding the target of one million for that year. This achievement underscores Indonesia's leadership in the global halal market and its strong commitment to upholding halal standards (Septiani & Ridlwan, 2020).

In countries that are developing halal regulations, greater challenges arise. In Turkey, for instance, despite the desire to implement a halal certification system, many producers and consumers are confused about consistent standards. Research by (Fibrianti et al., 2023) revealed that without internationally recognized certification bodies, many companies seek certification from lesser-known institutions, which undermines consumer trust in the halal status of these products.

The halal pharmaceuticals sector has also witnessed substantial growth. In 2022, Muslim consumer spending on pharmaceuticals reached \$108 billion, with projections suggesting it will increase to \$142 billion by 2027, reflecting a compound annual growth rate (CAGR) of 5.7%. This growth is fueled by rising awareness among Muslim consumers about the importance of halal-certified health products (Asa, 2019). Despite this expansion, the halal pharmaceuticals market faces significant challenges, notably the high costs associated with halal certification and compliance. The limited availability of halal-certified raw materials, such as gelatin and glycerin, which are often derived from non-halal sources, further complicates the certification process.

A study in Saudi Arabia also highlights the complexity of implementing a halal certification system. Although Saudi Arabia has a very stringent and globally recognized system, difficulties arise when attempting to align national regulations with international standards applicable to the global health industry. (Septiani & Ridlwan, 2020) noted that reliance on national institutions that are not fully integrated with the global health system can lead to failures in meeting international standards, especially for imported products. Data show that despite many countries attempting to implement effective halal certification systems, the main challenges remain regulatory differences between countries, bureaucratic barriers, and a lack of understanding among producers about global halal standards.

Despite impressive growth, the halal industry faces several challenges. One of the main issues is the lack of uniformity in halal certification standards across different countries and regions, which creates confusion among consumers and businesses. Products that are certified as halal in one country may not meet the same standards in another, complicating international trade and undermining consumer trust. The shortage of trained halal auditors and certifiers has led to a backlog of applications for certification. Efforts are underway to establish a harmonized global halal certification system to ensure consistency and transparency in the certification process, aiming to overcome these challenges and promote a more unified global market.

D. CONCLUSION

The comparative analysis of halal certification regulations in the healthcare sector across multiple countries reveals a complex landscape shaped by varying national standards, religious interpretations, and regulatory frameworks. Despite the rapid growth of the global halal market particularly in pharmaceuticals, nutraceuticals, and vaccines, producers continue to face significant challenges, including high certification costs, limited access to halal-compliant raw materials, and a lack of harmonization among international halal standards. These issues hinder both the efficiency of certification processes and the accessibility of halal healthcare products in global markets. Consumer demand for ethically produced, halal-certified health products continues to rise, indicating a strong need for international collaboration and standardized regulatory practices. Establishing a more unified, transparent, and inclusive halal certification system would not only enhance consumer trust but also facilitate global trade and innovation in the halal healthcare industry.

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