

Opportunities and Challenges for Developing Halal Pharmaceuticals Industry in Indonesia

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ABSTRACT

This study explores the opportunities and challenges of developing halal pharmaceutical industry in Indonesia following the issuance of the Halal Assurance Product Law (UU JPH) and Indonesia's Masterplan of Islamic Economics and Finance (MEKSI) 2019-2024. It employs a qualitative research approach with the content analysis method. It collected primary data through interviews and Focus Group Discussion with various stakeholders of the Indonesia's pharmaceutical industry, including regulators, industry players, Muslim scholars, and academics. The study identified five opportunities for the Indonesian halal pharmaceuticals industry, including the enormously growing global and local market, increasing awareness for halal products, more flexible timeline to adjust with the Indonesian Halal Products Assurance Law, involvement of cross-institutional regulators in maintaining the halal regulation, and abundance of pharmaceutical resources. Meanwhile, the challenges faced include a substantial proportion of imported raw materials for producing halal pharmaceutical products, a lack of technical guidance regarding the halal certification regulation, and a lack of qualified human resources. Two strategies are suggested to overcome the challenges: promoting domestically produced raw materials and encouraging halal certification among the global raw materials supplier. The findings and analyses also highlight the urgency for the government and industry to implement appropriate strategies in implementing the halal-related Law effectively and capture the opportunities.

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1. Introduction

By 2050, the global Muslim population will be approximately 2.76 billion, sharing almost 30% of the global population (Stonawski et al., 2015). This figure signifies the potential of a growing global market with one of the most visible consequences of increasing demand for halal products, among which is halal pharmaceutical products. Furthermore, the State of Global Islamic Economy Report asserted that the COVID-19 pandemic had raised the issue of the lack of halal-certified medicines and pharmaceutical ingredients in the market. The concern on the halal status of the newly developed COVID-19 vaccines that will be distributed to more than 1.9 billion Muslims globally seeks the importance of halal pharmaceuticals products in the market. It is estimated that global Muslim spending on pharmaceutical products will increase by 2.3% annually, reaching \$105 billion by 2024, urging the increasing demand for halal pharmaceutical products soon (Dinar

Standard, 2020). These raise the recognition of some emerging economies, such as Malaysia, South Korea, and Indonesia, in surging halal pharmaceutical production.

Indonesia is one of the largest Muslim countries worldwide, with around 87% of its 270.2 million population is Muslim (Statistics Indonesia, 2013). Data show that Indonesian Muslims are increasingly adherent to religious teaching, shown in higher religious awareness, higher demand for halal products, and more substantial government support to develop Islami economics and the halal industry (Bappenas, 2018; PEBS FEB UI, 2022). Regarding halal pharmaceuticals products, Indonesia is the fourth largest consumer, with total spending of \$5.4 Billion in 2020 (Dinar Standard, 2020). Whereas the COVID-19 supply chain disruptions signaled the importance of more localized drug manufacturing, Indonesia's global position in halal pharmaceuticals creates an exceptional opportunity to emphasize local halal pharmaceutical productions (Madjid, 2022; Kasri et al., 2021).

Aside from the growing Muslim market, the perceived awareness of halal pharmaceutical products is also expected to be driving the increasing future demand for halal pharmaceutical products. For instance, acceptance of vaccination among Indonesian Muslims is determined by their trust in the vaccine's safety and efficacy and the vaccine's halal status. Indeed, the vaccine's halal status was the second most important characteristic of vaccine acceptance among Muslims (Harapan et al., 2019). Thus, a halal-certified vaccine is among the essential strategic action plan to encourage vaccination among the Muslim population (Ahmed et al., 2018). A halal label is also one of the most critical factors in engaging prominent religious and community leaders to encourage community acceptance of vaccination (Padmawati et al., 2019). Therefore, there is a need for legal enforcement for the halal pharmaceutical industry to capture the potential demand (Aziz et al., 2014). These issues surge government concern about assuring the halal certification of pharmaceutical products.

In line with this, in 2013, the Indonesian Muslim Scholar Council (MUI or Majelis Ulama Indonesia) issued Fatwa (legal opinion) No. 30/2013 that encouraged Muslim consumers to consume only halal medicine (MUI, 2013). However, the fatwa also mentioned that the Muslims could temporarily consume non-halal products in certain critical conditions, including emergency (life and death) situations and inexistence of halal materials and medicines. The following year, the Indonesian government issued Law No.33/2014 regarding Halal Product Assurance (known as UU JPH). The Law stated that products that enter, circulate, and trade within Indonesia's territory must be halal certified to improve products' safety standards and strengthen consumer protections in the country. The scope of halal products regulated includes products that have been declared halal or following Islamic Law. Meanwhile, the halal product process scope includes providing materials, processing, storage, packaging, distribution, sale, and presentation of the products. The Law applies to all halal products, including food and pharmaceutical (medicine) products, as mentioned in the Law's technical regulation (Indonesian House of Representative, 2014). Notably, the exclusion mentioned in the MUI Fatwa is also stated in the technical regulation.

To accelerate the development of halal industry in Indonesia, the Indonesian government established the National Committee for Islamic Economy and Finance (KNEKS) in 2017 and launched the Indonesia Islamic Economic and Finance Masterplan (MEKSI) 2019-2024 in the following year. According to the Masterplan, with the vision to make Indonesia the center of the global Islamic economy, establishing the halal industry and value chain is one of the main strategies besides strengthening the Islamic financial system, small and medium enterprises (SMEs), and digital economy (Bappenas, 2018). In addition to halal pharmaceutical and cosmetics, five other halal industry sectors are targeted: food & beverages, tourism, fashion, media & recreation, and renewable energy.

MEKSI received very good reception and high expectations from the public. Indeed, since its launch, Indonesia has seen a rapid increase in its ranking in the Global Islamic Economy Indicator: rising from the tenth position in 2018 to the fourth in 2021. Indonesia also ranks among the top ten in most halal economy sectors, including halal pharmaceuticals and cosmetics (see Table 1). Indonesia's domestic spending across halal economy products and services is at \$184 billion in

2020 and is projected to increase by 14.96% CAGR to reach \$281.6 billion by 2025 (Indonesia Halal Lifestyle Center et al., 2021).

Table 1. Indonesia's Halal Industry Market Value and Position

	Value	Rank
Halal Food Consumer Markets	\$144 billion	1
Outbound Travel Muslim Countries	\$11.2 billion	5
Modest Fashion Consumer Markets	\$16 billion	5
Halal Pharmaceuticals Consumer Markets	\$5.4 billion	4
Halal Cosmetics Consumer Markets	\$4 billion	2
Muslim Media & Recreation Consumer Markets	\$22 billion	3

Source: State of Global Islamic Economy Report (SGIE) 2021/2022 (DinarStandard, 2021)

Furthermore, according to the Ministry of Industry, the chemical, pharmaceutical, and traditional medicine industries are the top two contributors to the national GDP in the second quarter of 2021 (Kementerian Perindustrian, 2021). As such, these subsectors' development is needed, especially with the rising demand for pharmaceuticals product. The pharmaceutical industry is also included in the list of the mainstay industry sectors of the Ministry of Industry.

Table 2. Muslim Spending, Covid-19 Impact, and Growth

Muslim Spend Parameters on Pharmaceuticals Product			
2020 (US \$ billion)	2025 (US \$ billion)	2019-20 (COVID-19 Impact)	5 Years CAGR% (2020-25)
\$5.13	\$6.81	-4.29%	5.83%

Source: Indonesia Halal Market Report 2021/2022 (Indonesia Halal Lifestyle Center et al., 2021)

In the halal pharmaceutical and cosmetics sectors, Indonesia is ranked at fourth place globally. It is also estimated that in 2023 the pharmaceutical market will increase by 7% to US\$ 131 million, and the cosmetic market will increase by 6.9% to USD 90 million (in KNEKS, 2019). Furthermore, the halal pharmaceuticals sector is also included as one of the strategic sectors in the Indonesia Islamic Economic and Finance Masterplan 2019-2024 developed by KNEKS. Muslim spending on pharmaceutical products due to covid-19 went down by 4.29% in 2020, or around US\$5.13 billion. However, the number is expected to reach pre-pandemic levels and increase by 5.83% or US\$6.81 in 2025 (see Table 2). It is also notable, as shown in Figure 1, that Indonesia is still a net importer of pharmaceutical and cosmetic products, with net imports of \$0.56 billion and \$0.35 billion, respectively.

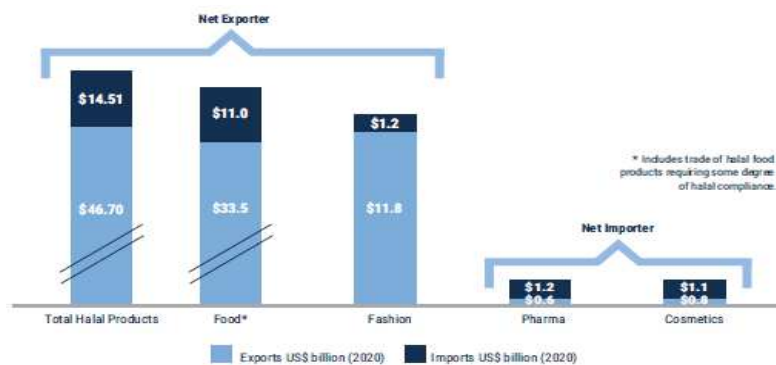


Fig.1. Indonesia's Trade by Halal Economy Sector, 2020 (US\$ billion)

Source: Indonesia Halal Market Report 2021/2022 (Indonesia Halal Lifestyle Center et al., 2021)

Amidst the high demand, however, there is a perception that the pharmaceutical industry in Indonesia is not ready to develop halal pharmacies and capture the opportunities. Whereas, as the Law mandates, the industry should be ready for this by 2024 (Majalah Farmasetika, 2018). However, the later regulation at governmental and ministerial levels offered the pharmaceutical industry a more flexible timeline following the halal certification process. Furthermore, while regulation is in place, the challenges and opportunities still need to be discussed. Previous studies explored halal pharmaceutical challenges and opportunities at the global level, in which one of the findings concerns legal and regulatory frameworks (Norazmi&Lim, 2015; Zehra&Naqvi, 2017). While Indonesia has the necessary legal and regulatory enforcements, only some empirical studies explored the halal pharmaceutical industry's opportunities and challenges in Indonesia.

With these perspectives, this study aims to explore opportunities and challenges faced by the pharmaceutical industry and the main stakeholders in developing halal products in Indonesia. The study employs a qualitative research method to explore the opportunities and challenges of developing the halal pharmaceuticals industry in the world's largest Muslim country. The primary data was collected through interviews and a Focus Group Discussion (FGD) with various pharmaceutical industry stakeholders. Content analysis was subsequently conducted to analyze the primary data obtained.

To proceed, this research is structured as follows. Section 2 explains the research methodology, Section 3 provides the study's results and discussion, whereas Section 4 provides conclusions of the study.

2. Methodology

This study employs a qualitative research method with content analysis to explore the opportunities and challenges of developing the halal pharmaceuticals industry in Indonesia. According to Bryman (2016), qualitative studies are appropriate for exploratory studies. Thus, it is appropriate to achieve the research objective, primarily due to the current study's explorative nature, which explores the potential and challenges of developing the halal pharmaceutical industry in Indonesia. It is also well-suited for providing factual and descriptive information (Johnson & Christensen, 2012), which is needed in this research.

In a qualitative study, research instruments commonly used are in-depth interviews and focus group discussions (FGD). Both interview and FGD explore an issue or topic for specific and targeted respondents. While the interview intensively investigates a respondent, FGD is commonly conducted for several respondents, ideally 6-12 persons (Folch-Lyon & Trost, 1981; Adam & Cox, 2008). The primary advantage of in-depth interviews is that they provide much more detailed information than other instruments, such as surveys. While, for FGD, alongside the advantage of conducting intensive communication like in-depth interviews, this instrument also provides direct argumentation and response between respondents (Bryman, 2016). Moreover, these two instruments also allow the researcher to elaborate on an issue and interesting topics found during the investigation or discussion (Boyce & Neale, 2006; Adam & Cox, 2008).

The advantages of employing the research instruments are the encouragement of this study to employ in-depth interviews and FGD as data collection methods. It is believed that these techniques are very relevant to elaborate on the halal industry development in Indonesia from the perspective of several related institutions. In addition, it allows this study to elaborate on the case with high flexibility to control the topic scale and intensify some exciting points that probably appeared during the discussion.

Therefore, the primary data was collected through interviews and a Focus Group Discussion (FGD) with various pharmaceutical industry stakeholders. The first interview was conducted in 2020 with a resource person who is the Manufacturing Director of the largest pharmaceutical company in Indonesia and serves as a member of the Indonesia Pharmaceutical Industry Association (known as GP Farmasi). Additional interview was conducted in 2021 with a Strategic Analyst of the KNEKS's Halal Industry Unit. The issues discussed include, among others, current conditions of the pharmaceutical industry in Indonesia, opportunities/prospects, and challenges in developing the

halal pharmaceutical industry in the Muslim country. Meanwhile, the FGD was conducted in 2020 and attended by the representatives of 12 institutions or around 20 resource persons, including from government/regulators and industry players.¹

The qualitative data were subsequently analyzed using content analysis. Content analysis is considered suitable because it is useful in interpreting communication materials and documents to analyze values, intentions, attitudes, and cognitions in management studies (Bryman, 2016). In this study, the content analysis was conducted by initially transcribing the results of interviews and FGD. All of the stakeholders' perspectives and concerns regarding halal pharmaceutical industries are taken into account and classified into opportunities and challenges of halal pharmaceutical industries in Indonesia. The results and analyses, enriched with relevant data and references, are discussed below.

3. Results and Discussions

3.1. Results

3.1.1. The Opportunities for Halal Pharmaceutical Industry in Indonesia

Based on the interviews and FGD conducted, at least five key opportunities for the halal pharmaceutical industry in Indonesia is identified, namely (a) the potential from an enormously growing global and local market, (b) the increasing awareness and demand for halal products, (c) the more flexible timeline for pharmaceutical products to adjust with the Halal Products Assurance Law (UU JPH), (d) the involvement of cross-institutional regulators in maintaining the halal regulation, and (e) the abundance of pharmaceutical resources (raw materials) in Indonesia.

The first opportunity for the Indonesian halal pharmaceutical industry is the enormous potential market. As the world's largest Muslim country, accounting for around 10% of the global Muslim population, Indonesia has a vast potential market for halal pharmaceutical products. The Indonesian population, of which around 87% are Muslims, is predicted to continuously grow by around 8% for the next decade or jump from 270 million to 294 million in 2030 (Statistics Indonesia, 2013). This number shows the country's enormous potential demand for halal pharmaceutical products. Besides, the potential demand comes from its demographic and future economic prospects. Currently, Indonesia is experiencing a demographic dividend in which demographic composition is in the phase to peak at the optimum point of productivity (Gardner&Gardner, 2017). Therefore, pharmaceutical product demand is expected to increase, especially for health supplements and dietary products, due to their necessity for supporting productive workers/individuals (Euromonitor, 2020). Moreover, the Indonesian economy is expected to be the seventh largest economy by 2030 (Oberman et al., 2012), shifting consumers' behaviour and lifestyle to demand more secondary and tertiary products like halal pharmaceutical products. All these will increase the purchasing power of Indonesian consumers for halal pharmaceutical products.

The potentially increasing demand for halal pharmaceutical products is also recognized globally. With the growing global Muslim population, capturing the global market would be a prominent opportunity for halal pharmaceutical products. Even in Muslim minority countries, Muslim purchasing power is still considered high. Hence, this is an opportunity for global market leaders of halal pharmaceutical products (Noazmi&Lim, 2015). Indonesia, among others, has the advantage of legal enforcement with the current Halal Products Assurance Law. The conditions should serve

¹ The participants from government/regulator includes National Committee for Islamic Economy and Finance (KNEKS); Ministry of Health (MoH); Halal Product Assurance Organizing Agency (BPJPH); The Institute for Assessment of Foods; Drugs and Cosmetics Indonesian Council of Religious Scholars (LPPOM MUI); Indonesian National Agency of Drug and Food Control (BPPOM); Capital Investment Coordinating Board (BPKM); Bank Indonesia (Central Bank of Indonesia); the participants from the Industry includes The National Association of Local Pharmaceutical Manufacturer Companies (GP Farmasi); Indonesian Pharmacy Association (GP ASAP); Indonesian Herbal and Drug Entrepreneurs Association (GP Jamu); while the other participant is a Public policy observer who is also a member of the Indonesian Public Health Association (IPHA/IAKMI).

as a strength in competition with global market leaders. Therefore, the Halal Products Assurance Law should encourage Indonesian halal pharmaceutical products to capture opportunities in both local and global markets. This opportunity was highlighted by the KNEKS representative during the FGD conducted.

One of the strategies to develop the halal industry in Indonesia is [push it to be] a global [halal] hub, which intends to collaborate with global industry, integrate the halal supply chain, and strengthen the legitimization of Indonesia's halal certification. (KNEKS)

The second opportunity for the Indonesian halal pharmaceutical industry is increasing halal awareness among the population. This opportunity was clearly expressed by the KNEKS representative, who said, "Overall, the public awareness towards halal lifestyle is increasing, in line with the increasing government's concern on the halal industry." Indeed, the current Halal Products Assurance regulation captured this public awareness and should ideally serve as a bridge between the consumer demands for halal products and the halal pharmaceutical industry. However, some pharmaceutical industry representatives did not seem to be aware of this increasing religious awareness, albeit they revealed a higher demand for halal-labeled pharmaceutical products in the past few years.

Furthermore, based on the information revealed by one of the market leaders of the drugstore in Indonesia during the interview, halal medicine is believed to increase sales growth significantly. Considering that only a small percentage of drugs have been halal-certified, certifying more products will predictably increase the sales growth to be substantially higher than the current figure. This view is echoed by the representative of KNEKS interviewed afterwards. More specifically, as mentioned by the public policy observer during the FGD, it is notable that Daewoong Infion, a joint venture between Daewoong Pharmaceutical and an Indonesian company called Infineon, has obtained the benefits of having halal-certified products.² Additionally, increasing demand comes from the hospital, particularly halal-labeled hospitals. One of the respondents from GP Farmasi highlighted this situation: "Specifically, for a halal pharmaceutical product, the increasing demand also comes from the related institution such as the hospital." The increasing demand for halal pharmaceutical products following increasing halal awareness is also in line with the previous studies findings, which suggested that halal status is among the critical determinant of vaccines, an example, halal pharmaceutical products, acceptance among Muslims (Ahmed et al., 2018).

The third opportunity appears related to a more flexible halal pharmaceutical product timeline adjusting to the mandatory halal certification regulation. Indonesia's current market opportunity is supported by the positive shift of regulation to concern more regarding halal pharmaceutical products certification. Aside from food and beverage products, the main priority for halal-certified products, the government has extended the halal products regulation coverage to include the pharmaceutical products such as medicine, vaccine, and medical devices. Following the Law mandate, all of these products should be certified before entering the market. The timelines to be fully halal-certified are different among different categories of products. According to the Ministry of Religious Affairs Regulation, as mentioned by a representative from BPPOM during the FGD, halal pharmaceutical products are entitled to a longer registration period than other products, such as food and beverages. The timeline among halal pharmaceutical products also varies based on the complexity of its manufacturing process. This flexibility is an opportunity as the pharmaceutical industry obtains a more flexible time to adjust to the Law's implementation. This point was also mentioned by the representative from the Ministry of Health (MoH)

² Six months after obtaining the halal label for its product, Epodion, in 2017, it achieved 40% of market shares for Indonesia's EPO (the joint venture's Erythropoietin) market, jumping from the third to the first rank. Following the success of Epodion, Daewoong Infion certifies all of its products to capture both the Indonesian market and enter the global halal pharmaceutical markets.

Based on the Ministry of Religious Affairs regulation, the halal products assurance law implementation varies among different sectors, whereby the pharmaceutical sector is provided with the most prolonged implementation deadline. This timeline is expected to give sufficient time for this sector to settle with the implementation. (Ministry of Health)

The fourth opportunity is cross-institutional management in promoting the implementation of the Halal Assurance Law and developing the halal pharmaceuticals industry in Indonesia. The implementation of the Halal Products Assurance Law engages various multidisciplinary regulators. Following the mandate in Government Regulation No. 31/2019, the Halal Products Assurance Law comes under the authority of the ministry of religious affairs and involves several inter-ministerial administrations (i.e., the Ministry of Industry, Ministry of Trade, Ministry of Health, Ministry of Agricultural, Ministry of Cooperative and SMEs, Ministry of Foreign Affairs, Bank Indonesia, and other related ministries). Consequently, there will be various programs run by government institutions to enforce the implementation of the Law. This issue was highlighted by Bank Indonesia's representative during the FGD, "*The growing concern on halal industry development also involved other regulators and institutions, such as Central Bank, which have launched various programs to support the halal industry.*" However, as emphasized during the interview with KNEKS representative, KNEKS will lead and serve as the coordinator for the ministries/institutions involved in developing the halal pharmaceuticals industry. Given the track record of KNEKS, which has successfully led the transformation of Indonesia's Islamic economy marked by the significant improvement of global ranking, i.e., from the 10th place in 2018 to 4th place in 2021, it is believed that it could also do the same for the halal pharmaceuticals industry. As such, the cross-institutional management in developing the halal pharmaceuticals industry is seen as an opportunity for this sector.

It is further revealed that there are three critical regulators for the implementation of the Law, namely (1) the Halal Product Assurance Organizing Agency (BPJPH), which holds the highest responsibility for the supervision of Halal Products Assurance Law implementation; (2) the Indonesian Council of Religious Scholars (MUI), mainly through its Institute for Assessment of Foods, Drugs, and Cosmetics (LPPOM MUI); and (3) the Indonesian National Agency of Drug and Food Control (BPM). Before BPJPH conducts the halal certification process, a product should pass the safety, quality, and efficacy process from BPPOM. Meanwhile, in determining the halal aspects of a product, BPJPH also needs to conform with the MUI as the highest Islamic Law authority in Indonesia. The involvement of various regulators in assuring the halal certification process is believed to promote the halal product's reputation in terms of product quality and *fiqh/sharia* compliance, as suggested from the following notes during the FGD.

In the near future, BPPOM will make an MOU regarding the halal and safety assurance system with Halal Product Assurance Organizing Agency (BPJPH). This step will be beneficial to prepare for the technical implementation of the halal assurance system. In this context, BPPOM ensures that the product is halal (lawful) and tayyib (good). (BPPOM)

The fifth notable opportunity is the abundance of natural resources or raw materials for producing pharmaceutical products in Indonesia. Despite the issue of a large proportion of imported raw chemical materials for producing pharmaceutical products faced by the country, as will be elaborated in the next section, the abundance of natural resources is believed to provide the industry with a competitive advantage in raw materials availability. During the FGD, this opportunity was emphasized by GP Jamu, affiliated with herbal and drug companies in Indonesia, and supported by LPPOM MUI. LPPOM UI also reported that the number of herbal medicines has already been certified is significantly bigger than other medicine types. Most herbal medicine components are also categorized as a positive list that only requires simple or even excluded from the halal certification process.

Furthermore, the Indonesia Science Institution (known as LIPI) suggested that over 80% of world medicinal plants are found in Indonesia. Indeed, currently 1,845 out of 28,000 species in Indonesia

have been identified as medical plants (Lembaga Ilmu Pengetahuan Indonesia, 2020). Indonesia also has a vast potential for marine biodiversity in Indonesia that has yet to be optimally utilized and identified. This underutilized and unrecognized opportunity helps accelerate the halal products certification process and improve Indonesia's current halal pharmaceutical products supply chain.

3.1.2. The Challenges for Halal Pharmaceutical Industry in Indonesia

We identify at least three critical challenges for the halal pharmaceutical industry following the implementation of the Halal Products Assurance Law and MEKSI, namely (a) the large proportion of imported raw materials with unclear halal status, (b) the lack of technical guidance on the halal certification regulation, and (c) lack of qualified human resources for conducting a halal audit or halal certification process.

The first challenge is related to the imported raw materials. The current market structure of the Indonesian pharmaceutical industry is relatively complex. Around 90% of the raw materials for producing pharmaceutical products are imported, and their halal status cannot be guaranteed. The fact was revealed during the interview with the Pharmaceutical Company Director, who said that one of the bottlenecks in the halal products assurance implementation for halal pharmaceutical products is the large percentage of imported raw materials. The raw materials are dominated by chemical raw materials helpful in making medicine. Although the amount imported by each pharmaceutical company was not very large, the variations (i.e., the types of chemical raw materials) were high. These facts make it difficult to ensure the raw materials' halal status since requiring each raw material to be halal-certified by the suppliers takes much work. Notably, this issue has also been a global concern. It is deemed difficult to ensure the medicines' source's halal status and the raw materials used in the development of the medicines (Thomson Reuters, 2017; Annabi&Wada, 2016). This situation implies that the halal certification will relate to the global supply chain and manufacturing process beyond Indonesian regulation coverage.

Producing raw materials is another related challenge facing the industry. The current pharmaceutical industry lacks adequate technology to produce raw materials. This condition was highlighted during the FDG by the public policy observer having experience in visiting the pharmaceutical company in Indonesia, Singapore, and India. He said that "*.....I have visited the pharmaceutical raw materials industry in India and Singapore several times. They have amazing technology as well as supportive instrument. While in Indonesia, the industry is still a secondary producer and dominantly taking part in the packaging process.....*". This condition raises the difficulty in the halal certification process and developing competitive halal pharmaceutical products. This situation implies the importance of investment in research and development (R&D) for the halal pharmaceutical industry to develop competitive halal pharmaceutical products with reliable supply chain processes – from the raw materials to the end products. This finding is in line with Mohezar et al. (2016), which emphasized the importance of the supply chain in tapping into the global halal pharmaceutical market. It is also notable that the process in the pharmaceutical industry is far more complex than other FMCG products, whereby raw materials and needed products need to undergo a long process of validation and qualification. With Indonesia currently still relying on imported raw materials for the pharmaceutical industry, the industry representatives strongly believe that this creates a big challenge for implementing halal product assurance in the pharmaceutical industry.

The second challenge is the halal products assurance regulation's technical aspects. The industry perceives that the current regulation lacks technical guidance, as the regulation has not yet been followed by a straightforward technical procedure that could be easily accessed and understood by stakeholders in the pharmaceutical industry. The guidance expected is about the process of certifying the products and understanding the halal concept itself, which is crucial since the character of pharmaceutical industry manufacturing is more complex than others. Since most raw materials are imported, such guidance will require more effort to deliver the idea of halal beyond domestic businesses. This issue was emphasized by the representative of the Association of Indonesian Pharmaceutical Industry (GP Farmasi).

As some business practitioners suggested, the halal assurance system's clear technical guidance that the government still needs to provide remains a challenge for implementation. (GP Farmasi)

The implementation of the Law is also seen as having a lack of enforcement on stakeholder collaborations. A strategic collaboration across key stakeholders involving academicians, businesses, government, and the community should be essential to the regulation implementation. The collaboration, on one side, can serve as a literacy channel for implementing the halal regulation and, on another side, can be a way to improve the regulation. When comparing the experience of India dan Malaysia in developing their pharmaceutical industry, the public policy observer concurred that collaboration among academics, government, business, and community (ABGC) is needed. Such collaboration is believed to encourage effective regulation, efficient financing, research development, and faster adaptation to develop Indonesia's halal pharmaceutical industry.

The third challenge is the lack of qualified human resources. It is understood that providing professional human resources with sufficient knowledge of halal and high-quality pharmaceutical products is difficult. Currently, the number of such trained human resources is deficient in the country. This problem is suggested by the KNEKS representative, who said that "... *the government has recognized that one of the challenges in developing this halal assurance system in Indonesia is the lack of capacity of the human resources in this area*". Furthermore, the government stated that the Halal Authority (BPJPH) needs at least 5000 institutions to perform the halal audit. However, only 71 institutions can perform the task (Coordinating Ministry for Human Development and Cultural Affairs, 2019; BPJPH, 2020; Bisnis.com, 2019). This challenge is also recognized in other countries, where the current global halal pharmaceutical market lacks specialized human capital in the industry (Zehra&Naqvi, 2017). The legal enforcement for mandatory halal-certified products means that the government – together with the industry and the respective stakeholders – also needs to promote critical inputs in halal pharmaceutical product production. Therefore, the current Halal Products Assurance Law shall be seen as a justification for the industry to demand support from the government and related educational institutions to provide sufficient human resources input.

3.2. Discussion

As an inherited part of capturing the opportunity, overcoming the determined challenges would be the key to accelerating the halal pharmaceutical industry development and implementing the Halal Products Assurance Law mandate effectively. There are several recommendations to overcome the challenges explained earlier in this situation.

Firstly, it is vital to promote domestically produced raw materials to overcome the challenge due to the large proportion of imported raw materials for producing halal pharmaceutical products. This effort is essential to reduce dependency on imported raw materials and unleash the potential of abundant natural resources, which could provide the pharmaceutical industry with a competitive advantage in the future. Furthermore, this would help improve the current halal pharmaceutical products supply chain and accelerate Indonesia's halal products certification process. This approach needs to be complemented by massive investment in R&D and technological development, as suggested during the FGD.³

Related to this, it is realized that the Indonesian pharmaceuticals industry also suffered from the economics of scale problem since it has yet to be able to reach the efficient amount of the minimum production of halal products. In this respect, product quantity competitiveness would be the key to

³ The importance of this strategy was highlighted by the KNEKS representative during the FGD, "*The national strategy to develop halal industry in term of research and regulation is already recognized by KNEKS. A systematic research program has not supported the potential of resources. Currently, KNEKS in the process of creating a research tree in the area of halal industry.*"

meeting domestic and global market demands. However, this option needs to be supported by a robust industrial foundation of halal pharmaceutical production in Indonesia. Despite that, it is notable that the Indonesian pharmaceutical industry is currently dominated by the 'assembling industry,' in which only a small number of producers produce their raw materials. Therefore, to encourage domestic raw materials production, the government might apply tariff or non-tariff barriers for imported pharmaceutical products raw materials. Furthermore, tax or other applicable fiscal and non-fiscal incentives will be necessary to support those investments.

Implementing tax incentives is possible under regulations in Indonesia. During the FGD, the BKPM's representative mentioned two tax incentives for the pharmaceutical industry: *tax holiday* for new business investment (or business extensification, which usually involves vaccine and biotechnology products) and *tax allowance* for human pharmaceutical and Phyto pharmacy products. The incentives are regulated under Presidential Regulation No. 6/2016 regarding the Acceleration of Pharmaceutical and Medical Instrument Industry Development, which makes the pharmaceutical industry one of the most prioritized sectors. Furthermore, from an investment perspective, as stipulated in the BKPM regulation No. 6/2019, pharmaceutical industries producing raw materials for medicine and vaccines based on biotechnology are listed as sectors obtaining the tax holiday for the pioneer company. Besides, based on government regulation No. 78/2019, tax allowance is also given for pharmaceutical materials, traditional medicine, and phytopharmacology industries. The extensification of the two tax incentives will ease the halal certification process's transition as it helps the industry lower its production costs. Moreover, this incentive should not be limited to halal pharmaceutical products and other industries mentioned in Halal Products Assurance Law. Despite being a more costly and time-consuming alternative, this option is considerably lucrative to develop a promising path for the future Indonesian halal pharmaceutical industry in the long run.

Whereas developing domestic production seems impossible to be realized soon, the other option is strengthening Indonesian demand's bargaining position with the global producer. This idea needs full governmental support as well as strong industrial lobbies. The government and the industry must convince the global supplier that halal-certified products will mutually benefit the supplier and the pharmaceutical industry. By offering high-quality halal-certified products in the market, the supplier will be recognized by the other halal manufacturing industry – suggesting a competitive advantage of having halal-labeled products. This way, it is also expected that the supplier will be willing to invest more R&D in halal product development. This option must be supported by comprehensive guidance of the halal certification process and concept, which is the second biggest challenge in developing halal pharmaceutical products.

Second, it is crucial to have good standard and technical guidances to implement the halal product certification and halal pharmaceuticals industry in general. The guidance will provide the same or equivalent understanding between regulators and the industry. It is also essential to guide pharmaceutical companies in developing the product and adjusting the manufacturing process. In this case, as pointed out during the FGD, Malaysia provides good guidance on the standard for the halal pharmaceutical industry. Under the Malaysian Standard on Halal Pharmaceutical MS 2424: 2012, there are guidelines for Pharmaceutical Inspection Co-operation Scheme (PIC/s) GMP Guidelines, Manual Procedure for Malaysia Halal Certification, and Guidelines for Halal Assurance Management System of Malaysia Halal Certification. Provision of the standards providing specific guidance for each of the industry mentioned in Halal Products Assurance with the involvement of related institutions is an essential strategy that Indonesia could adopt.

Furthermore, since some institutions are involved in the halal management system in Indonesia, strengthening the system coordination will be needed to simplify the bureaucracy and optimize the halal certification process. Moreover, engaging a broader set of key stakeholders, especially for the aspects of R&D that could involve academicians, the industry, government, and the community, will be an essential part of accelerating the process. A harmonized and unified regulatory framework at the global level will also be considered necessary in developing the global supply chain for halal pharmaceutical products.

Finally, it is urgent to prepare the human resources needed to conduct halal audits or halal assurance processes. At the moment, the availability of such human resources is very limited whereas the tasks that must be done are innumerable. With appropriate number and quality human resources, it is possible to accelerate the halal pharmaceutical industry's development in Indonesia. This effort would also require synergy between various stakeholders, particularly government, academic institutions, and industry.

4. Conclusion

Following the Halal Product Assurance Law in Indonesia, some opportunities arise while some challenges appear. This study identifies five key opportunities for the halal pharmaceutical industry in the world's largest Muslim country, namely the growing global and local market, the increasing awareness for halal products among Muslims, the more flexible timeline for pharmaceutical products following the Halal Products Assurance law, the various regulators' involvement, and the abundance of resources in Indonesia. Furthermore, three challenges identified in the study include the local industry's dependence on imported raw materials, the lack of technical guidance on the halal certification regulation, and the need for more availability of qualified human resources.

As the most significant obstacle is the industry's dependence on imported raw materials, there are two strategies that could be pursued to overcome the challenge. Firstly, promoting domestically produced raw materials through appropriate tax incentives (i.e., tax holidays and tax allowances), substantial investment in R&D, human resource development, and strong pharmaceutical raw materials industry. Secondly, encourage halal certification among global raw materials suppliers. This option should be followed with governmental support, strong industrial lobbies, comprehensive technical guidance of the regulation, cross-stakeholder collaboration, and harmonized and unified regulatory frameworks at the global level.

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