Digital Technology for Halal Certification of Patented Drugs in Indonesia: A Panacea for the Pain?

Mas Rahmah^{a*}

^a Department of Business Law, Faculty of Law, Universitas Airlangga, Surabaya, Indonesis *Corresponding Author. Tel: (+61) 81230291789, E-mail: rahmah.arifin@gmail.com

Abstract

The rapid growth of the Muslim population in Indonesia has led to a corresponding increase in the demand for halal drugs and medication. To ensure the halal status of drugs, Indonesia has adopted a regulatory framework for halal certification and labeling for all products marketed in the country. The new framework makes halal certification mandatory for all food, beverage, drugs, cosmetics, chemicals (used for human consumption), sold in Indonesia by October 2019. However the implementation of the new framework faces complex challenges that call for innovative solutions. Apart from basic inconsistencies in the law, there are no clear regulations for implementation. More importantly, most drugs marketed in the country are patented imports. For halal certification, Indonesia will need well-regulated and transparent harmonized accreditation procedures that meet global standards that patent holders can comply with. Moreover, as a member of the WTO, Indonesia is bound by the Technical Barriers to Trade (TBT) Agreement that prohibit any trade barriers that might be presented by halal certification. Furthermore, 95% of Indonesian raw pharmaceutical ingredients are imported from different doubtful halal sources. This makes it difficult to audit the halal status of drugs even when patent holders manufacture the drugs in Indonesia. With only a few months left for the pharmaceutical industry to meet the October 2019 deadline, there is an urgent need for Indonesia to look at innovative ways to implement halal drugs certification effectively and efficiently. The paper critically evaluates the systemic challenges that face halal certification for patented drugs and recommends the use of digital technology as a remedy. The paper argues that the use of Online Single Submission and BlockChain technology may be the panacea for the pains of halal certification in Indonesia.

Keywords: halal certification, digital technology, patented drugs, Indonesia

INTRODUCTION

Halal pharmaceuticals industry has been an emerging industry in Indonesia and all over the world since the expanding Muslim population has increased the demand for halal drugs for their medication. Due to patented drugs account for the majority of the Indonesian pharmaceutical market, this study recognized that it is important to oversee the halal status of patented drugs to meet consumer demand and expectation on halal medicines. To ensure halal status on products including drugs, Indonesia actually has constructed regulation framework on halal certification and labeling for all products marketed in Indonesia under the Product Halal Guarantee (Halal Law No. 33/2014). According to the law, Halal certification is mandatory for all food, beverage, drugs, cosmetics, chemicals (used for human consumption), organic and genetically modified products sold in Indonesia as well as for the machinery and equipment involved in processing these products. However, this paper is carefully aware that halal certification in Indonesia emerges crucial issues and complex problems because the deadline to comply with requirements will very quickly approach soon in October 2019. At regulatory level, there are problems about contradicting provisions in Indonesian the Halal Law, the absence of mandated further regulations to implement the Law, and enforcement distress. In addition, it is a need of a well regulated and harmonized accreditation and halal management

system that is globally accepted. Moreover, as member of the World Trade Organization (WTO), the Indonesia is bound by the Technical Barrier to Trade (TBT) Agreement and shall not create any trade barrier regulation such as Halal certification which bans non-halal drugs enter to Indonesian market. At practical level, the halal certification for drugs will simply be unworkable in practice 95 percent of Indonesian raw pharmaceutical ingredients are imported, coming from different doubtful halal sources, thus making it difficult to audit the halal status of products.

The application of halal labels will disrupt the domestic medication distribution system caused with disease prevention programs since almost all active ingredients of imported medicines currently in circulation do not have halal certification. Only one percent of 930 active ingredients come from Indonesia. The investigations into the manufacturing process and ingredients of medication will be more complex and time consuming, leading to higher costs. Moreover, since full operation of the law is in this year, companies will have short time only to be compliant to this law. The certification body (BPJPH) will also only have short time to issue halal certificates for all goods and services. How will the agency be able to examine so many products in such a brief time?. Thid paper tries to overcome the problems by the utilizing digital technology as a strategic alternative such as Online Single Submission, utilization of block chain technology and Digital halal certification as means of very easy to investigate, screen, and track authenticity and validity of halal label.

Halal Patented Drugs

The Muslim population is about 2.18 billion people across the world and estimations of one out of three people being Muslim in 2030 according to the statistics. The Halal market is estimated to grow from US 666.25 billion in 2016 to over US R857.45 billion by 2022. Islamic Finance accounts for 43% of the halal industry, while the halal food market accounts for 36% (Alan Straton, 2016). According to 2018 reports, the halal market is expected to reach US\$739.59bn by 2025, and the halal market overall – encompassing travel, entertainment, food, finance and other services is expected to reach US\$12.14trn. Islamic finance counts for 43% of the total industry (Straton, 2016).

Halal products are consumable products such as food, beverages, drugs, cosmetics, chemical products, biological products, genetically engineered products, or any goods that can be use and applied by humans in accordance with Islamic principles. The subject matter of Halal Products is the raw materials and manufacturing processes for such products. Raw materials derived from certain animals are considered haram (opposite to halal) including corpses, blood, and pork (Article 18: 1). Halal manufacturing processes require that the location, facilities, equipment, processing, storage, packaging, distribution, and sale of Halal Products be strictly separated from non-halal products. Additionally, Halal Products manufacturing facilities must be kept clean and hygienic, free from impurities (najis), and free from non-halal materials.

Drug products with halal certification are confidently accepted by consumers especially Muslims as well as those of other religions. Patented drugs account for the majority of the Indonesian pharmaceutical market (Drug development, 2018). However, there are several challenges for this emerging niche industry, foremost of which is the need to establish a proper, well regulated, and harmonized accreditation and halal management system.

The Need Halal Certification for Patented Drugs

With a population of 262 million, Indonesia is the fourth most populous country in the world (Census.gov, 2018) and the world's largest Muslim population, with 82.7% of people identifying as Muslim (BBC, 2018). The position of Muslim majority is triggering a big demand for halal products, including pharmaceutical products. Global Islamic Economy Indicator 2017 announced that Indonesia is in the top 10 countries of the largest halal industrial consumers in the world. Indonesia also ranks number one in the world in halal food consumption. In the halal tourism sector, Indonesia is ranked number five in the world. In halal medicine and cosmetics as well as Islamic finance, Indonesia is ranked sixth and tenth in the world. In the future projection, the government wants Indonesia to be categorized as the world's top 10 producers of halal products (Halal Focus, 2017).

One rationale for the sweeping changes in certification rules is to position Indonesia as the benchmark for halal certification. Muslim consumer spending is expected to reach US\$2.6 trillion by the end of the decade from roughly US\$1.9 trillion in 2014. Indonesia's 204 million people consume about US\$138 billion of food every year, according to the Economic Research Institute for ASEAN and East Asia (Hutton, 2017)

Halal Law seemingly protects the constitutional rights of Muslims to carry out their religious obligations. The government will do this by giving a guarantee that every product is halal, or permissible. To meet the consumer demand and expectation on halal products, Indonesia has constructed regulation framework on halal certification and labeling for products marketed in Indonesia under the Law No. 33/2014 on The Guarrantee of Halal Products. Law No. 33/2014 obliges that all products marketed in Indonesia are certified as halal from October 17, 2019. According to the Law No. 33/2014, Halal certification is mandatory in Indonesia for all food, beverage, drugs, cosmetics, chemicals (used for human consumption), organic and genetically modified products sold in Indonesia as well as for the machinery and equipment involved in processing these products.

To oversee the process and provide ongoing certification for products, the Halal Products Certification Agency (BPJH-Badan Penyelenggara Jaminan Halal) has been formed under the Law. BPJPH will take over MUI's role, which was previously the sole institution that issued halal certificates. The law No. 33/2014 mandates the establishment of BPJPH that was created in 2017. Although halal certificates will be issued by the BPJPH, the process of verifying whether or not a product is halal will be carried out by a different party, namely the Halal Inspection Institution (Lembaga Pemeriksa Halal or "LPH"). In general, LPH will check and verify whether or not the raw materials and manufacturing process are halal. These activities may be carried out inside or outside the manufacturing facility.LPH may be established by the government and public institutions such as universities. To run its operations, LPH must be accredited by BPJPH, employ at least 3 inspectors, and has its own laboratory or cooperate with another party that has a laboratory.

To achieve halal certification, pharmaceutical company must ensure that the end products, equipment and raw materials (processed ingredients, additives and processing aids) used during production are complied under Shari'ah (Islamic) Law. In addition, if the companies produce non halal drugs, they must have two different plants at two different locations because the Law No. 33/2014 requires that the companies must separate production locations for halal and non-halal food. For imported products, pharmaceutical companies are not obliged to go through the certification process, and are only required to register their 'foreign' halal certification to (BPJH) before the products are marketed and distributed in Indonesia.

Based on the Halal Law No. 33/2014, after certifying as halal drug, the companies must post the Indonesian halal logo on their product pack. It means that drugs marketed in Indonesia is approved to use Indonesian halal logo only and the logo must be displayed in front of pack or the main part of product package. Before using the logo, the companies including the importers must obtain an approval from the National Agency for Drug and Food Control (NADFC), based on Head of NADFC Regulation No. 27/2017 on processed food registration.

The Halal Law No. 33/2014 introduces criminal sanctions imposed for non-compliance with halal related rules, as previously under the MUI regulation criminal sanctions were not possible due to the nature of its status of being an Islamic non-profit organization. Companies holding halal certificates and also on LPH. Holders of halal certificates that fail to maintain the halal quality of their products may be subject to 5 year imprisonments or IDR 2 billion in fines. LPH, on the other hand, may be subject to 2 years imprisonment or IDR 2 billion in fines for failing to safeguard trade secrets in the form of the formula of products that they evaluate.

Challenges of Halal Product Legislation Regulatory Challenges The Halal Law No. 33/2014 has fundamental flaws that will cause major regulatory problems for the public. Although National Law 33/2014 becomes the legal framework for halal certification and labeling for products in Indonesia, the regulation consists of contradicting provisions such as there is also ambiguity in articles 4 and 26 of the law. Article 4 of the Law stipulates that "Products that entered, distributed, and traded in Indonesia **must** be certified as halal". Article 4 can be interpreted that "all products in Indonesia must be certified halal". In legal context, "must" means "obligatory and necessary with legal consequence" (Efendi, 2018). The obligation in Article 4 it can be interpreted that non-halal products may not enter or be traded in Indonesia. This obligation will result a restriction of non-halal drugs in Indonesia because drug producers who do not obtain halal certification cannot enter and trade in Indonesia. However, conversely Article 26 of the Halal Law provides an opportunity for entry and distribution of non-halal products provided that they bear non-halal information on their label. This ambiguous provisions will precisely cause confusion to drug producers/companies who market their products in Indonesia. This ambiguity will make drugs producers confused and difficult to market their products in the territory of Indonesia and regarded as trade restriction.

In addition, there is challenge on further regulations. The Halal Law No. 33/2014 regulates that, within two years of enactment of law (in 2016), regulations on halal certification shall be further enforced by the government regulation. However, the Indonesian government has not published the Government Regulation yet, although the draft of government regulation has been final. Since 2019 is public election in Indonesia, the government regulation will be possibly hold up, and the draft will be probably changed by new government regime, further delaying the enactment of regulation process. The absence of implementing regulations such as the Presidential Regulation (PP) and the Regulation of the Ministry of Religious Affairs (PMA) affects to a legal uncertainty.

Another challenges related to the compliance to international agreement. As member of WTO, the Indonesian government is bound by the Technical Barrier to Trade (TBT) Agreement of WTO and should not create unnecessary trade barrier in any regulation which contradicts with the TBT Agreement. Taking this into account, it is most likely that the government will eventually permit the importation of non-halal drugs as long as it is clearly labelled as non-halal drugs. It is expected that the government to publish the enforcement Regulation in line with the WTO Agreement by permitting the importation of non-halal products provided they are clearly labelled as non-halal food.

As faced many obstacles in its efforts to realize the full target of halal certification, the introduction of mandatory halal certification provides consumers with assurance on the halal status of a product, contradictions within the Halal Law No. 33/2014 and delays to further regulations with its enforcement are causing confusion and other challenges for drugs or pharmaceutical products.

Practical Challenges

The enactment of Halal Law and the ensuing government regulations are bound to create myriad practical challenges. The practical challenges are very complex because halal certification will deal with industry players who mostly do not be eager for halal certification. The halal law is considered burdensome for pharmaceutical businesses because it is difficult to apply. Association of Pharmaceutical Companies urge not to apply halal certification to drugs. Drugs are sold in the market is made of materials that its halalness is doubtful and even some are forbidden. So that if certified automatically the drug manufacturers will have difficulty to produce their medicine (Halal Focus, 2017).

In addition, since government has task to give a guarantee that every product is halal, or permissible, through the Halal Products Certification Agency (BPJPH), it seems that the agency is the only body with the right to issue halal certificates. The certification body (BPJPH) will only have short time to issue halal certificates for all goods and services marketed in Indonesia. There is a big question about how the agency can examine massive products in such a brief time. It will be very difficult for the agency to be able to examine so many products in such a brief time. As comparison, at the previous voluntary halal regime, which was overseen by the Indonesian Ulema Council, a semi governmental body of Muslim clerics, doled out 35,000 halal certificates over five years. The food and beverage segment has more than 1.6 million companies and tens of millions of products that will need to be inspected (Hutton, 2017). If it is established

this year, the BPJPH will only have short time to issue halal certificates for all products and services. It is not impossible that in order to meet this target, the agency will simply work as quickly as possible and become nothing more than a rubber-stamp body.

In addition, number and capacity of certification agency would be need to be continually enhanced to meet the anticipated increase in applications for halal drug approvals.

A lot number of experts in specific production processes and drug development are needed as the different types of production process within the pharmaceutical production chain. As the different types of production process within the pharmaceutical production chain seek certification, different types of question peculiar to each niche process are bound to crop up. Therefore, experts in specific production processes and drug development are needed to answer these questions. Other steps to strengthen the certification process may include introducing tests for DNA and protein sources, and publishing the list of halal pharmaceutical sources based on the available pharmacopoeia, to name but a few (Norazmi & Lim, 2015).

Furthermore, pharmaceutical industry groups worry about compliance costs which may reach as much as S\$4.4 billion. Businesses face headaches from everything from reprinting labels, which can cost S\$7,000 per product as well as how to dispose of finished goods that can have a shelf life of three years. The companies will bear the brunt. They will be obliged to add halal labels to all products. The burden on companies will be even heavier because these certificates will have to be regularly renewed. Companies unable to afford the cost of certification will go out of business.

There will be another major inconvenience that the high compliant cost will arise price that causing a drop in sales, given that people's purchasing power continues to decline is still elusive. In addition, every product without a halal label will have to be withdrawn from the market. Companies who fail to do this, face two-year jail terms or fines of two billion rupiah, according to articles 56 and 57 of the law. Even companies whose products have halal labels will have to withdraw them so new labels can be attached.

There is still a lack of understanding on the halal concept that will deter the process. There will be another major inconvenience that every product without a halal label will have to be withdrawn from Indonesian market. There is still a lack of understanding on the halal concept that, with most of the community tend to associate halal with the religious matter.

More crucial is the issue of halal certification for medicine. The investigations into the manufacturing process and ingredients of medication will be far more complex and time consuming, leading to higher costs. Since the obligation of halal certification on pharmaceutical products is submitted to BPJPH, it means that the BPJPH will have to supervise the halalness each stage of production of any product, distribution and how it is served to consumers. The requirement for halal certification adds one more regulatory layer for pharmaceutical companies looking at the market. Products not only have to move through more traditional regulatory pathways, complete with various clinical trials, but also meet halal requirements that often ban the use of porcine products. Aside from rising high production costs, this will certainly make it difficult for the halal certificate institutions to verify. As a result, pharmaceutical industry would be vulnerable to sanctions and will affect the uncertainty of the pharmaceutical business that will ultimately disrupt the supply of drugs to the public.

The greater challenge related to the distribution, the application of halal labels will disrupt the domestic medication distribution system. Almost all active ingredients of imported medicines currently in circulation do not have halal certification. Only one percent of 930 active ingredients come from this country. If all medication containing non halal-certified ingredients is banned, it can be imagined that the disruption caused with disease prevention programs. Patients who find it difficult to obtain medication will suffer greatly as a result of this regulation.

Moreover, the Halal Law may also potentially disrupt the investment climate in Indonesia, which would potentially work against the government's efforts of trying to achieve an investment-friendly environment at the global level.

Digital Halal Certification As Panace

1. General Initiatives

Indonesia needs to set the efficient standard but still uphold the International Standards and Halal regulations itself need to align with other collective standards from Organization of Islamic Countries (OIC) and Muslim-majority countries worldwide. More specifically, government should adhere to halal standards regulated in Codex Alimentarius as part of Indonesia's commitment to the TBT Committee in the WTO. WTO allows each country to apply halal standards to protect Muslim consumers in accordance with GATT Article XX (general exception), that each WTO member country for the benefit of the consumer may apply its own technical regulation. However, the halal standard must be established and implemented in accordance with the Technical Barrier to Trade (TBT) Agreement, in order to gain international trade benefits. Government should observe the provisions of the TBT Agreement in implementing halal standards in measuring the consistency of the Halal Law with WTO law. This would also reduce trade restrictions for foreign producers who market their products in the territory of Indonesia.

Trade restriction should be eliminated by providing additional rules or explanatory in the application of articles 4 and 26 of the law. The rules should also describe procedures relating to 'non-halal products', so it is interpreted vary and non-halal products can enter the territory of Indonesia.

In global context, the BPJPH should be able to cooperate with halal certification bodies in some exporting countries in order to recognize halal certification of the countries concerned. This will reduce discriminatory treatment between imported products and domestic products that have halal certificate.

The establishment of halal assurance standard should be efficient by simplifying the processes and procedures for obtaining halal certificates, whether those processes are related to additional tests or procedures in obtaining halal certificates. Simple processes and efficient procedures will cost the production much cheaper. Efficiency can also be a fairly short time limit in obtaining a halal certificate. One-stop shopping is required for the process and procedures for obtaining halal certification.

2. Initiatives in digital area

The Halal certification is a process whereby the features and quality of products are according to the rules established by the Islamic Council, which further allows the Halal marking (Straton, 2016). Certifications have become a complex task right from the very beginning, and what makes it even more difficult is the trustability of it. In the case of halal certification, strict guidelines need to be maintained given that the Muslim population is dependent on it. Halal certification in Indonesia become emerge and crucial issue because the 2019 deadline to comply with requirements has approached soon in October. Since full operation of the law is this year (2019), companies will have short time only to be compliant to this law before all new Halal certifying and auditing agencies under the auspices of the Ministry of Religious Affairs are fully up and running.

Digital halal certification becomes a means of very easy to track authenticity of halal certification, validation before making a purchase decisions. The authenticity and validation of halal certification is important because there have been many instances of halal certificates being wrongly justified. For example in 2011, Orion a Cold Storage in Cape Town, South Africa was accused of using halal labels on disapproved meat. Orion labelled halal on Kangaroo meat from Australia and Water Buffalo meat from India even though they were not approved by South Africa's Muslim Judicial Council (MJC) (Straton, 2017).

United World Halal Development (2017), the digital halal certification may secure the stakeholders from vulnerability of the fraudster and help in bridging the gaps between industry and consumers by clearing:

- a. The genuine certificate is an essential part of the Halal Authenticity
- b. Certificates are added with patented 2D encrypted QR codes with Track & Trace to make sure secured
- c. Ensures reliability of Halal Certificate Issuing Authority / Body
- d. Halal certificate security is essential as several references are made prior to issuance to a vendor
- e. The Security levels must be both Physical, Virtual and machine readable in easier terms

f. The security offered must be not breached

Some digital halal certification have been launched to create efficient halal certification system. One instance id HalalChain launched in Dubai developed by HLC Technologies to allow consumers to trace and track halal products, helping them overcome regulatory uncertainty and any doubts about accreditation. HalalChain resolves these issues by offering a public permanent ledger for Halal related transactions across the value chain. As a public blockchain that serves as an open, distributed ledger that can record transactions between two parties efficiently, in a verifiable and permanent method, HalalChain can track and verify Halal food, pharmaceuticals and cosmetics through all stages of production, processing and distribution across the entire supply chain. The system will revolutionize the integrity of Halal compliance through real-time monitoring, comprehensive Halal standards application, as well as in ensuring Halal certification integrity. HalalChain is a comprehensive ecosystem where the Islamic economy and the digital economy complement each other. However, the use of HalalChain is not only limited to the Halal industry, it can be used to bring transparency to food label claims such as organic, non-GMO, and gluten-free (Halal Focus, 2018). HalalChain also provides comprehensive solutions to instant e-payment, e-commerce and other industry applications powered by blockchain and internet of things.

Similarly, UK-based Halal Trail tracks livestock and fresh food from the farm throughout the supply chain, ensuring verification is legitimate. HalalGuide, meanwhile, is an existing global platform used by 1.5 million Muslims worldwide on a peer-to-peer network, helping them connect with various halal resources. It recently unveiled a partnership with blockchain developer Apla. In addition, POCertify is a new decentralised application which uses blockchain and smart contracts technology to publish Halal certificates. These show that recently digital halal certification uses two new decentralized applications: blockchain and smart contracts technology

Blockchain technology, together with Islamic principles, will digitally encrypt the Halal Certificate in its PDF format, and verify the Halal Certificate on the blockchain. Blockchain technology has been widely hailed by enthusiasts as revolutionary because it is entirely decentralised. This means storage is not in one central point, removing the need for powerful central authorities and putting control in the hands of individual users instead (Fin24, 2018). Blockchain technology is a perfect fit for the needs and demands of Halal food traceability. Blockchain solves halal compliance global challenges, including the lack of a globally recognized Halal certification system, inaccurate and unauthentic data on Halal products, poor regulation of raw materials for Halal products, and the difficulty of managing a centralized regulatory system for Halal food. The condition and status of the product can be updated to the Blockchain in real-time and easily accessed by people seeking knowledge about it. The end-consumer benefits from a more holistic understanding of Halal product information, and can be assured that the items he is consuming are purely Halal. End-consumers will use the WhatsHalal app, which leverages the Blockchain, to procure tertiary services like food delivery and restaurant reservation. They also contribute to the eco-system by making product enquiries and providing feedback, which in turn can be relayed to producers who can provide more information and/or further refine their processes as necessary.

Smart Contract aims to expedite the application for Halal Certification, while also bringing transperancy and traceability to the process, as the information will be publically veriable, and immutably recorded on BlockChain. All of the information, such as the results of Halal Testing Lab, Venue inspection, Evaluation of the Equipment and Supplies of producers and the analysis result of the component ingredient list will be recorded on BlockChain. The certifying bodies are able to instantly and quickly review the information from BlockChain and come to decision. Therefore it can save more time and money.

By developing digital halal certification, it will be very easy to track authenticity of halal certification, validation, and more importantly it may help the possibility of Indonesia to be a champion of the global halal standard by leading the harmonization of the standard that would be applicable for business to navigate, and support simple, transparent and straightforward procedures.

In conclusion, logically, the Halal Law No. 33/2016 can support Indonesia in international trade since many countries have opened the opportunity for the entry of halal certified products. Thus, Indonesia shall facilitate the trade by consistent and conducive halal assurance. The halal regulations itself need to align with collective standards both Islamic and international standards.

Digital halal certification becomes a means of very easy to track authenticity of halal certification, validation before making a purchase decisions, and more importantly it may help the possibility of Indonesia to be a champion of the global halal standard by leading the harmonization of the standard that would be applicable for business to navigate, and support simple, transparent and straightforward procedures. The domestic business and investment environment will be highly developed, and the notion to increase Indonesia's share to global trade and commitments to WTO.

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