

AN ESCALATING TRANSITION TOWARDS HALAL VACCINE CERTIFICATION IN MALAYSIA

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ABSTRACT

In Malaysia, there is a need to provide halal certification for vaccine products. The Department of Islamic Development Malaysia (JAKIM) together with other relevant government agencies and the pharmaceutical industry have improved and expanded the scope and standards of Malaysian Standard MS 2424 Halal Pharmaceuticals-General Requirements (Malaysian Standard MS 2424) in 2019, which serves as general requirements references for the halal pharmaceutical including vaccine products. It is a positive movement. Currently, Malaysia only relies on vaccine products that are not halal or whose halal status is unknown. Although the development of this standard will be able to create a halal vaccine product certification system, however, the actual implementation of the standard by the Malaysian halal certification body (JAKIM) and the vaccine industry needs to

be scrutinized, because it is a new standard revision. Therefore, the study on halal vaccines based on Malaysian Standard MS 2424 as a progressive transition towards halal vaccine products certification implementation in Malaysia is very important, especially to see how the implementation can be carried out. In general, the objective of this study is to analyze the regulations, provisions, applications, issues, and challenges of standards. To achieve these objectives, qualitative method approaches have been used in this research, data were collected through document analysis and semi-structured interviews conducted with relevant informants who are directly involved in the halal vaccines sector in Malaysia. The findings of this study show that, in implementing halal vaccine certification based on Malaysian Standard MS 2424, some several obstacles and challenges had to be faced by the stakeholders. At the end of the study, several recommendations were prepared to strengthen and facilitate the certification implementation of halal vaccine products.

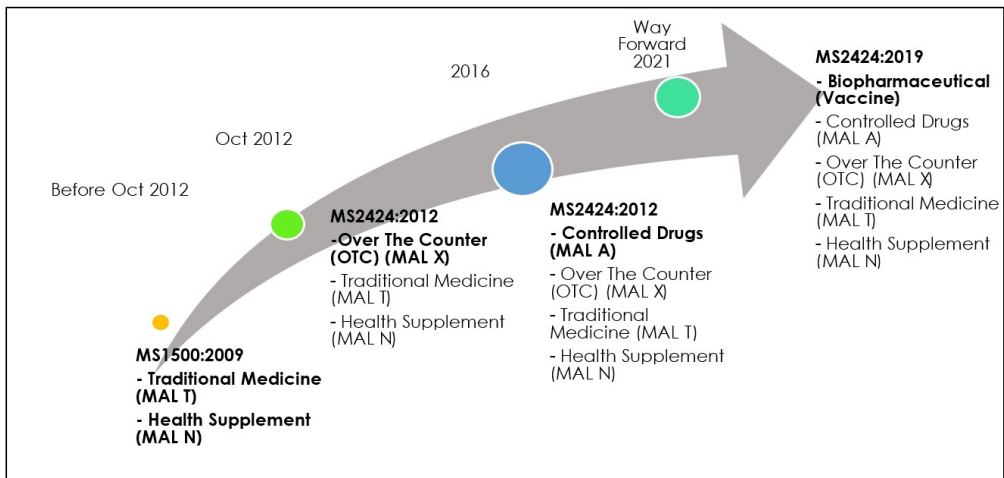
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INTRODUCTION

The Malaysian Standard for Halal Pharmaceuticals, also known as Malaysian Standard MS 2424, is the first Halal pharmaceuticals standard ever created. Incorporating general guidelines or requirements for halal pharmaceuticals, this national standard aims to serve as a basic document of reference for production purposes. This will help address the Halal integrity aspects in the manufacturing and servicing chain of medications and health supplements. Malaysia is also the first Organization of the Islamic Conference (OIC) nation to join the Pharmaceutical Inspection Cooperation Scheme (PIC/S). The launch of Malaysian Standard MS 2424 provides the Malaysian pharmaceutical industry with a reliable foundation to utilize other halal markets, particularly those in other OIC nations, in a competitive manner. Malaysia is well recognized as one of the pioneers in halal pharmaceuticals on a global scale. This can be attributed to the country's introduction of the first halal pharmaceutical standard in the world, Malaysian Standard MS 2424 in 2012, the standard underwent its first modification in 2019. Once in the while, the evolution of halal certification for pharmaceutical products changed, starting with traditional medicine, health supplements, Over the Counter (OTC) in 2012, and eventually moving on to controlled drug items in 2016, and expanding to biopharmaceutical and vaccines in 2021. Today, halal certification of vaccine products is a necessary

requirement to be implemented, however, the implementation process needs to be examined and research needs to be carried out, this is to ensure that the implementation can be done with perfection. Figure 1.1 illustrates the stages of halal certification for products in the pharmaceutical category including a vaccine.

Figure 1.1 The Halal Certification Stages of Pharmaceutical Category Products



Source: JAKIM, 2018

HALAL VACCINE DEFINITION

Halal vaccines mean, vaccines with ingredients that are allowed by *Shariah* law and *fatwa* including those that are safe and effective for human use according to the prescribed dosage, quality, and hygiene; do not contain *najs* according to *Shariah* law and *fatwa*, and are not prepared, processed, or manufactured using equipment that is not halal or that is not slaughtered according to *Shariah* law and *fatwa*. The halal vaccine products are physically separated from any other vaccine products that do not meet the requirements stated above, or any other items that have been deemed non-halal and *najs* by *Shariah* law and *fatwa*, during the preparation, processing, handling, packaging, storage, and distribution.¹

¹ Department of Standards Malaysia, Malaysian Standard MS 2424:2019 Halal Pharmaceuticals-General Requirements, (Selangor: Department of Standards Malaysia, 2019), 1-22.

DEVELOPMENT OF MALAYSIAN STANDARD MS 2424

On November 1st, 2008, Malaysian Standard MS 2424 was developed. The Halal Industry Development Corporation (HDC) first put forward the idea in response to requests and nudges from various parties, including those in the public, private, and business sectors, in order to provide direction for the implementation of halal certification for pharmaceutical products (Johari Ab Latiff, 2015: 47). The first part of this standard's development known as Malaysian Standard MS 2424: 2010 Halal Pharmaceuticals-General Guidelines (P),² was drafted in 2010. However, the standard is not complete enough to be considered a standard in its entirety. This is due to the fact that the standard was not developed through a procedure known as "Issue for Public Comment" or with soliciting public comment as a requirement (Johari Ab Latiff, 2015: 46-47). A complete standard must pass through eight stages of development: first, there must be a demand or request for new standards; second, National Standard Committee (NSC) approval; third, funding and prioritization; fourth, drafting of Malaysian Standard (MS); fifth, public comment and proofreading; sixth, acceptance draft by NSC; seventh, verification by standard Malaysia; and eighth, Minister approval. All approved MS will be declared on the Standard Malaysia website.

The second phase of the development of Malaysian Standard MS 2424 is on 6 January 2012. After going through all eight steps processes, then the Malaysian Standard MS 2424 drafted was confirmed by the Department of Standards Malaysia and approved by the Minister of the Ministry of Science, Technology, and Innovation (MOSTI) at that time. Malaysian Standard MS 2424 was developed through the Technical Committee on Halal Food and Islamic Consumer Goods (Working Group of Technical Committee on Halal Food and Islamic Consumer Goods) chaired by the Director-General of the JAKIM. It was then presented to the Industry Standards Committee on Halal Standards (ISC I). There are many parties involved in the development of this standard, including government organizations, the corporate sector, NGOs, and so forth. The Malaysian Standard MS 2424 developed is the result of the cooperation of various parties. Its development is guided by the MS development process based on ISO methodologies, incorporating all Islamic religious requirements for halal (*Ibid.*).

² Provisional Standard Specification means a standard specification which has not undergone the normal procedures of technical committees deliberation and public comment and: (a) which in the opinion of the Council is urgently needed; or (b) in respect of which the Minister considers that trial use thereof is necessary before it can be finalized.

In the early stages of the halal certification procedure for medicinal products, products categorized as pharmaceutical products such as controlled drugs by the Ministry of Health Malaysia (MOH) is not allowed to apply for halal certification applications except for health supplement and traditional medicine products. According to a study, one of the main reasons why the JAKIM and the MOH did not issue halal certificates for pharmaceutical products at that time is to avoid scenarios where patients may refuse to accept non-halal pharmaceuticals or drugs even though there is no alternative or other drugs that can be used to treat their disease (Abd. Rahman, 2012: 217). Basically, for pharmaceutical products that contain non-halal materials, they need to meet certain conditions that require their use such as the absence or difficulty of obtaining halal materials to treat serious diseases and their use also needs to be under the direction and advice of a medical officer, whereas using drugs derived from non-halal substances should only be done when it necessary.

Following the establishment of Malaysian Standard MS 2424, JAKIM then developed a halal certification scheme. This is the result of a strategic collaboration with the concept of the “Blue Ocean Strategy” with the Working Group and other agencies such as NPRA, the Pharmacy Division of the Ministry of Defense Malaysia (MINDEF), and the University of Malaya Medical Center (UMMC). Although Malaysian Standard MS 2424 was developed in 2010, the implementation of the halal certification for pharmaceutical products application only began starting on 11 October 2012. This is due to a review of other related documents that are used in the halal certification implementation process such as the Manual Procedure for Malaysia Halal Certification (MPHC) and so on, so that it is in line with the requirements as stated in Malaysian Standards. Apart from that, the coordination of the standards also needs to be done at the JAKIM, JAIN/MAIN, relevant agencies, and also the pharmaceutical industry level. So, the implementation of this halal certification will be able to be implemented effectively. Following the effective implementation of halal certification on pharmaceutical products, in 2017 an amendment to the Malaysian Standard MS 2424 was made by providing an extension to the application of the standard on products in the biopharmaceutical category including vaccine products. Malaysian Standard MS 2424 then completed its revision process in 2019, and its implementation phase is in 2021, when the newly revised standard focuses on pharmaceutical products for the biopharmaceutical and vaccine categories.³

³ Department of Standards Malaysia, Malaysian Standard MS 2424:2019 Halal Pharmaceuticals-General Requirements, 1-22.

ISLAMIC VIEWS ON THE USE OF VACCINES IN DISEASE PREVENTION

Islam has established a clear code of ethics for the ethical development of medicinal products for the benefit of the populace. Medicine is a substance that is administered to patients in order to treat, care for, or prevent illness in humans as well as to raise their level of hygiene. It can be administered to the skin in the form of a cream or ointment, injected under the skin, implanted under the skin, or taken orally as well as through the anus or any other orifices. Some of the diseases can be prevented by using early preventive treatment methods such as vaccines. Such diseases are also known as vaccine-preventive diseases, among which are smallpox, measles, pertussis, poliomyelitis, Haemophilus influenza, tuberculosis, and others (Azizi Ayob, 2017: 11).

All humans are required by the Holy Al-Qur'an and hadith to make every effort to stay healthy and to seek treatment if they already have a sickness. Muslims must abide by the supreme divine law in order to practice Islam. The holy verses of the al-Quran mean:

“Therefore, (O Believers) eat of the lawful and good things that Allah has provided for you, and be grateful for His favors, if it is true that you only worship Him. Indeed, Allah has forbidden you that which dies of itself, blood, and the flesh of swine; also, any flesh consecrated to something other than in the name of Allah. But whoever is compelled by necessity (to eat any of this) not intending to sin or transgress (regarding the quantity eaten), will find Allah Most Forgiving, Most Merciful”. (Q.S. An-Nahl 16:114-115).

In general, all halal substances are required for medicinal use, while impurities are banned for use as medicines such as porcine-based materials and substances that are defective. This is clearly mentioned in many of the hadith of the Prophet Muhammad (PBUH), one of which is being narrated by Abu Darda' in the following hadith meaning:

“Allah has sent down both the disease and the cure, and He has appointed a cure for every disease, so treat yourselves medically, but use nothing unlawful.”⁴

In essence, the aforementioned passage serves as justification for why Muslims abstain from using non-halal products and from consuming pork or products made from them. It appears that the present *Fatwa* in Malaysia holds

⁴ Abu Dawud, *Sunan Abi Dawud*, (Beirut: Dar al-Kitab al-Ilmiyah, 2005), 610.

the belief that vaccinations made from sources of porcine origin are forbidden. Instead, unless there is an immediate necessity to utilize such products, the use of vaccinations free from porcine derivatives is given priority.

VACCINE REGULATION IN MALAYSIA

Vaccine products are highly regulated. Companies in this industry are subject to a variety of laws and regulations relating to their products such as the Research & Development (R&D) activities, testing methods, manufacturing processes, marketing, sales, and distribution. The processing is strictly governed by International Standards of Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Storage Practice (GSP), and Good Engineering Practice (GEP) (Khairun Nain Nor Aripin, 2021: 7).

In Malaysia, Drug Control Authority (DCA) is the regulatory body. The operations of drug registration, cosmetic notification, monitoring, and surveillance activities are delegated to The National Pharmaceutical Regulatory Agency (NPRA), which is the secretariat of DCA. NPRA is a regulatory body in Malaysia which responsible for guaranteeing the vaccines registered are safe, have been properly evaluated, and meet other applicable WHO quality and safety standards. Any drug in a pharmaceutical dosage form intended to be used, or capable of being purported or claimed to be capable of being used on humans or any animals, whether internally or externally, for a medicinal purpose is required to be registered with the DCA. Medicinal purpose means any of the following purposes (*Ibid.*):

- a) alleviating, treating, curing, or preventing a disease or a pathological condition, or symptoms of a disease; meaning any therapeutic drug such as painkillers, anti-asthmatics, anti-cholesterol drugs;
- b) diagnosing a disease or ascertaining the existence, degree, or extent of a physiological or pathological condition; meaning drugs used in diagnosis such as injectable dye used in radiological procedures;
- c) contraception; meaning oral contraceptive pills or injections;
- d) inducing anesthesia; meaning drugs used prior to surgery such as propofol and vecuronium;
- e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
- f) controlling body weight; for example sibutramine; and

g) general maintenance or promotion of health or well-being.

Based on that description, the vaccine products registration product will be processed through NPRA by taking into account the evaluation on the dossier and lab test to comply with quality, safety, efficacy, and labeling requirements. DCA will approve after all the requirements have been met. The operation of DCA is based on the regulation of The Control of Drugs and Cosmetic Regulations 1984. The DCA will then mark that the product had been reviewed for safety, quality, and efficacy, according to the Drug Registration Guidance Document (DRGD), under Regulation 29, Control of Drugs and Cosmetics Regulations 1984 before the product can apply for halal certification (Khoo et al., 2020: 530-538).

PRE-CLINICAL, CLINICAL STUDIES, REGISTRATION, AND POST-MARKETING STUDIES

Basic research and pre-clinical studies for vaccines are longer but more frequently conducted and financed by governments (Tabassum Khan, 2014: 44). Basic research and pre-clinical studies involved antigens identification and testing for a vaccine-induced immune response, development of techniques for producing and isolating's antigens, animal testing (pharmacology, toxicology, teratology, and oncology), and normally conducted and funded by universities, research centers, small biotech, and large pharmaceutical companies, and it usually will take a duration from 2-5 years. While for the clinical studies implementation will be divided into 3 phases:

- a) Phase 1, (safety control on 20 to 100 subjects), duration (< 1 year);
- b) Phase 2 a: (safety and immunogenicity data validation, b (dose-response efficacy and safety test on hundreds of subjects), (1-3 years); and
- c) Phase 3, randomized double-blind, placebo-controlled studies enrolling thousands of participants, (3-5 years).
- d) Vaccine Registration.
- e) Phase 4 trials also known as Post Marketing Studies. Additional safety trials may be required by DCA, drug agencies for a certain country, or initiated by companies to examine the effect of the use on extended populations.

Registration applications for approval and regulatory review will be carried out by Drug Control Agencies in certain countries such as DCA in Malaysia, Food Drug Administration (FDA) in US, and European Medicines Agency (EMA) (*Ibid.*). The manufacturer or distributor must provide details about

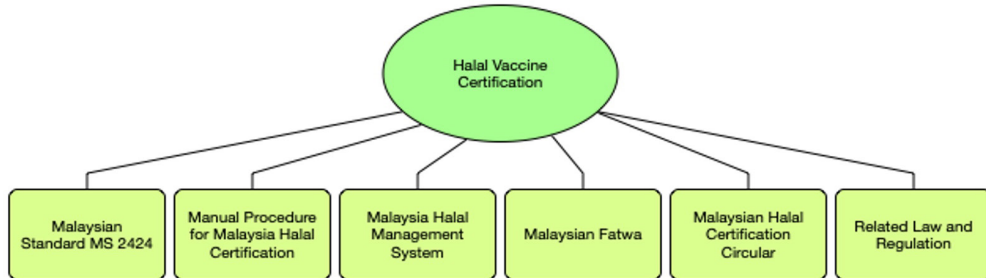
the product's quality and its ingredients as part of the registration process (Kausar Ahmad, 2015: 112).

ANALYSIS ON HALAL VACCINE CERTIFICATION IMPLEMENTATION

In order to inform Muslim patients or Muslim customers that the product is delivered in accordance with halal standards and practices, the halal vaccination products certification scheme is essential. Halal products can be identified by the adoption of halal certification, and halal labeling regulations defend the rights of consumers or patients.⁵ A Halal Certificate is an official document issued by halal-competent authority that certifies a product or service as being halal under the Malaysian halal certification process. Food/beverage/ additional food items, food premises, consumer goods, cosmetics and personal care, logistics (transportation, warehousing, and retail), slaughterhouses, and pharmaceutical including vaccines are among the applicants who are qualified to submit an application for a halal certificate. For both domestic and foreign production, online applications for a halal pharmaceuticals certificate should be filed through the JAKIM portal (*Ibid.*). Applications for halal vaccine certification can be made through the pharmaceutical product scheme because vaccines are one of the components of the pharmaceutical category (*Ibid.*). Due to the fact that vaccine product is highly regulated and has a distinct production process than other products, the adoption of halal certification for it needs to be reviewed and debated in more detail. In implementing halal vaccine certification, based on the findings of this study, six components are the backbone of its implementation such as Malaysian Standard MS 2424, MPHC, Malaysia Halal Management System (MHMS), Malaysia Fatwa, circular on halal vaccine certification implementation by Halal Competent Authority, and related law and regulation. Without these six components, then the implementation of halal certification of vaccine products will not be able to be implemented. Figure 1.2 portrays the NVivo 12 visual representation of the framework for the implementation of halal certification of vaccine products in Malaysia.

⁵ <https://www.halal.gov.my/v4/images/pdf/MPPHM2014BI.pdf>

Figure 1.2 Framework for the Halal Vaccine Certification Implementation



Malaysian Standard MS 2424

The main reference for establishing halal certification of vaccine products is Malaysian Standard MS 2424. Halal vaccine certification is not achievable without implementing all of the provisions and elements in the applicable standard. In order to develop and implement a halal certification scheme for the industry in Malaysia, a standard must first be established. Without a standard, the halal competent authority will not be able to offer a halal certification scheme. MS are created through a consensus-building process by committees made up of a fair representation of producers, users, consumers, and other interested parties, depending on the topic at hand. Malaysian Standards are adopted from or, to the maximum extent practicable, harmonized with international standards. The Standards of Malaysia Act 1996 [Act 549] governs the approval of a standard to become a Malaysian Standard. Malaysian Standards are often reviewed. Except where they are made required by regulatory bodies through regulations, municipal by-laws, or other similar mechanisms, the usage of Malaysian Standards is optional.⁶

The major purpose of Standards Malaysia is to cultivate and promote standards, standardization, and accreditation as a method of advancing the national economy, encouraging efficiency and industrial growth, benefiting public health and safety, protecting consumers, facilitating domestic and international trade, and advancing international cooperation in connection to standards and standardization (*Ibid.*). While Malaysian Standard MS 2424 is one of the standards that need to be given the main focus because the

⁶ Department of Standards Malaysia, *Malaysian Standard MS 2424:2019 Halal Pharmaceuticals-General Requirements* (Selangor: Department of Standards Malaysia, 2019), 1-22.

Malaysian Standard MS 2424 is the main reference in the implementation of halal certification of vaccine products. The criteria and provisions contained in the standard should be used as an initial reference before a specific reference is made to other documents. The general specifications in the production and management of halal pharmaceuticals including vaccines are laid out in this Malaysian Standard. All halal vaccines, it acts as a fundamental pre-requisite.

Manual Procedure for Malaysia Halal Certification (MPHC)

A reference guide for halal certification, the Manual Procedure for MPHC, is used in conjunction with the halal Malaysia Standards. In addition to outlining the conditions and specifications for certification, MPHC provides details on the halal certification application process, certification procedures, fee structures, and other matters.⁷ For simple study and reference by the inspection officers and the industry, the requirements and conditions for certification in the MPHC have been updated and reformed. In addition, the MPHC amendment is created in accordance with the MHMS. JAKIM, JAIN/MAIS Inspection Officers should adhere to the rules outlined in this MPHC in order to properly manage the Malaysia Halal Certification. When maintaining the Malaysia Halal Certification, this document should be studied in conjunction with the standards, Fatwa rulings, and relevant legislation that are currently in effect.

Malaysia Halal Management System (MHMS)

JAKIM published Guidelines for Halal Assurance Management System of Malaysia Halal Certification in 2011, which marked the beginning of the MHMS, also known as Halal Assurance System (HAS). Later, the Guidelines for Halal Assurance Management System Malaysia were replaced by this MHMS in 2020. It offers information on how to use the HAS for the multinational company (MNC) and medium-sized industries and the Internal Halal Control System (IHCS) for small and micro businesses.⁸ This MHMS recommendation encourages the industry to adhere to halal laws, rules, guidelines, and requirements in the application of halal certification by using the system in creating, implementing, and increasing the effectiveness of the

⁷ Department of Islamic Development Malaysia, Manual Procedure for Malaysia Halal Certification (Third Revision), (Kuala Lumpur: Department of Islamic Development Malaysia, 2014), 1- 62.

⁸ Jabatan Kemajuan Islam Malaysia, Malaysia Halal Management System (MHMS), (Putrajaya: Jabatan Kemajuan Islam Malaysia, 2020), 1.

halal assurance system. Concerning that, the context of the implementation of halal certification of vaccine products, it is the responsibility of the vaccine industry to develop, implement and maintain this system as one of the prerequisites for halal certification. Without implementing MHMS, a halal certification application will not be processed by the halal certification body in Malaysia. In terms of its implementation, the MPHC the halal standards, the *fatwa*, and other pertinent regulators, rules, and circulars enforced in the halal certification procedures must all be reviewed in conjunction with the MHMS to fully understand its content and requirements.

Malaysian *Fatwa*

In Islam, formulating religious judgments (*ifta*) is essential, particularly in the fields of pharmaceuticals or vaccines. Its significance is undeniable since it involves the interpretation and justification of divine statutes, and new problems or challenges frequently require legal clarification. Islamic laws frequently apply to the entire community, country, and world as well as to specific individuals. As a result, creating *fatwas*, or religious judgments necessitates a thorough understanding of the Islamic fundamentals of *Manhaj*, or legal process. Reliable circumstantial evidence is crucial in the process of formulating a *fatwa*.⁹ In some countries, a Mufti who has been nominated by the government is responsible for issuing *fatwas*; however, in other countries, in the absence of a Mufti who has been appointed, some Islamic organizations have the responsibility to do so (*Ibid.*). A final *qawl* based on the Mazhab Shafi'i will typically be issued in Malaysia as part of the process of passing legislation or issuing a *fatwa*. The final *qawl* of the Mazhab Hanafi, Maliki, and Hanbali, or any other mazhab or school of thought whose legal framework is akin to this stream, may be referred to if the last *qawl* of the Mazhab Shafi'i clashes with the common interest. The Fatwa Committee will apply its jurisprudence if there is a conflict of interest with the general public when referring to the most recent *qawl* (*Ibid.*).

In implementing halal certification of vaccine products, the decision of a *fatwa* issued by an authoritative body in Malaysia is mandatory and very important, this is because the reference to a *fatwa* is necessary to guarantee the smoothness of a halal certification implementation, especially for vaccine products, which begins for every production process up to its use it is subject to the provisions and decisions of the *fatwa* to be referred to. Apart from that,

⁹ Department of Islamic Development Malaysia, Monograf Al-Ifta (First Edition), (Putrajaya: Department of Islamic Development Malaysia, 2010), 12-13.

the importance of the *fatwa* to the halal vaccine certification is due to the use of ingredients that are questionable in terms of *Shariah* law or non-halal such as antigens, membrane separation, and purification units, host cells for virus production, growth media for host-cell consumption, proteolytic enzymes - trypsin, proteolytic enzymes - trypsin and stabilizers, all the components mentioned above are commonly used in the vaccine manufacturing process (A Halim Basari, 2022). With that, a legal view based on the *fatwa* is necessary for making an assessment of the use of these components. Without a clear legal opinion or *fatwa* in the use of the components or materials, the implementation of halal certification of vaccine products will not be able to be implemented. Concerning that, with the existence of a legal opinion or *fatwa*, then its implementation is more feasible.

Malaysian Halal Certification Circular

A circular is a formal communication regarding a subject that is disseminated for informational purposes or to guide the behaviour of specific parties.¹⁰ While Malaysia halal certificate is an official document stating the halal status of products and/ or services according to the Malaysia halal certification scheme issued by the competent authority.¹¹ Any alert or instruction for action about the implementation of halal certification, whether for vaccine or non-vaccine products, must be made through this circular; otherwise, an alert or instruction for action will not be feasible. For instance, despite the fact that the Malaysian Standard MS 2424, MPHC, and the MHMS have all been established, their implementation is still reliant on the implementation instruction circular issued by the halal competent authority because it is also related to the effective date that has been set and determined by the halal certification body based on the circular. Once it has been issued, the notification will bind all related parties, which have agreed to give a commitment to applying for halal certification and comply with all the conditions and requirements that have been set for it. Starting from 2014 until now, fourteen Malaysian halal certification circulars have been issued by the halal competent authority in Malaysia, which include various practice instructions related to the implementation of halal certification in Malaysia.¹² Concerning that, in the context of the implementation of

¹⁰ <https://prpm.dbp.gov.my/Cari1?keyword=pekeliling&d=175768&-%20rujukan%20penuh%20laman%20web%20ini>.

¹¹ Department of Islamic Development Malaysia, Manual Procedure for Malaysia Halal Certification (Third Revision), 6.

¹² <https://www.halal.gov.my/v4/index.php?data=bW9kdWxlcY9wZWtlbGlsaW5nOzs7OW>

halal certification of vaccine products, it is necessary to notify the practice instructions through a circular which will later provide clear guidance on any issues that arise, especially when it involves the effective date of the halal authority starting to open applications for halal certification to this vaccine product, the vaccine industry cannot apply for halal certification until after notification has been made.

Related Law and Regulation

One of the primary sources for halal certification implementation references is Malaysia's halal-related law regulation. Regulations and laws governing other organizations, such as the Ministry of Domestic Trade and Consumer Affairs, are also relevant to the implementation of halal certification. According to the Trade Description Act and Trade Description Order 2011, these rules and regulations govern the appointment of a halal competent authority, and any activity related to halal certification. While in the context of reference to regulations and legislation on vaccine products this is through the NPRA, DCA based on the Control of Drugs and Cosmetics Regulations 1984. Medicines Act (Advertisement and Sale) 1956 revised 1983, Poisons Act 1952 (Revised 1989), Sale of Drug Act 1952 (Revised 1989), Registration of Pharmacists Act 1951 (rev. 1989) & Its Regulations, Dangerous Drugs Act 1952 (rev. 1980), Wild Life Protection Act 1972, and Patent Act 1983. All these rules and regulations must be coordinated together during the implementation of the halal certification of this vaccine product. Any violation and contradiction to these rules and regulations will result in the process of implementing the halal certification of this vaccine product being subject to action or not being able to be implemented.

CONCLUSION

In order to administer the halal vaccine certification in Malaysia, as a pre-requisite condition before the halal certification application can be made, the vaccine must first be registered with the NPRA and have a valid manufacturer's license from NPRA, and has gone through the process of a pre-clinical and clinical study and so on, in order to guarantee the items' safety, quality and efficacy, at the same time to make sure only products that meet certain criteria can enter the market. Meanwhile, in the context of the implementation of halal certification, six main components determine success in the implementation of halal certification of vaccine products as discussed, which needs to be emphasized in the context of effective implementation for Malaysian Standard

MS 2424, MPHIC, MHMS, Malaysian halal certification circular, Malaysian *Fatwa*, and related law and regulation. Due to this, the government must streamline the processes and procedures for the implementation and issuance of halal certificates to reliable industries without jeopardizing the integrity of halal while also encouraging the vaccine or pharmaceutical industry to adhere to all requirements.

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