ISSUES AND CHALLENGES IN IMPLEMENTATION OF *HALAL* MEDICAL DEVICE CERTIFICATION IN MALAYSIA

Johari Ab Latiff
Senior Assistant Director, Malaysia *Halal* Council Secretariat,
Department of Islamic Development Malaysia (JAKIM).

Khairunnisa Che Omar
Assistant Director, *Halal* Management Division,
Department of Islamic Development Malaysia (JAKIM).

Abstract

This article discusses on halal issues and challenges in the medical device that has yet to be included in halal certification scheme. This new halal scheme will be focused on the application of reclassified pharmaceutical product to the medical device, products containing any parts of animals or products of animals and manufacturers who are interested in their products to be certified halal. This paper will discuss halal authentication method for medical device application. Hence, this study attempts to identify issues on the application of the medical device that contributes to the requirements of developing a halal medical device ecosystem. From the study, there are few essential aspects such as sources, processes, industrial revenues and inventories that shall be taken into consideration in developing halal medical devices guidelines for halal certification.

Keywords: Medical Devices, Halal, Scheme, Issue and Challenges

1. Introduction

The *halal* industry is growing very fast with continuous demand and support by government, industry, academician and consumers. Malaysia is a pioneer and a first mover in developing the *halal* industry and has expanded globally for the huge market for both Muslim and non-Muslim countries. There is a wide range of products and services that can be certified *halal* including food and beverage, food premises and hotel's kitchen, consumer goods, cosmetic and personal care, abattoir, pharmaceutical and logistic (Jabatan Kemajuan Islam Malaysia, 2014). To remain competitive, *halal* certification must be emphasised according to current needs. *Halal* is perhaps expanding towards a new scheme which is the medical device since there are high demands and requests for *halal* certification from the industry and importing countries. It is subsequent with the establishment of Medical Device Authority under the Ministry of Health (MOH) and *Medical Device Act 2012 (Act 737)* in November 2011 and fully enforced in July 2013. In conjunction with that, some pharmaceutical products that had been reclassified and registered under the medical device could not be certified *halal* since there was no standard reference for the medical device. It was burdensome for the affected industry when the mandatory phase took place. Apart from that, The Malaysian Standard relating to *halal* has been developed to meet the challenges. The framework and strategic plan have been outlined and initial steps have been taken in terms of competency, manpower and commitment of the certifying bodies (Johari Ab Latiff, 2018).

2. Terms and definitions

The term 'medical device' refers to any product used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excluding drugs. The Medical Device Act 2012 (Act 737) define 'Medical device' as any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

i. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
iii. investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;
iv. providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;
v. and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Medical devices are classified as Class A (low risk), Class B (low to moderate risk), Class C (moderate to high risk) and Class D (highest risk), similar to the classification scheme used in the European Union.

Halal Medical Device means a medical device in which the ingredients, materials and/or components are permitted under the Shariah law and *fatwa* which (Johari Ab Latiff, 2018):

a) do not contain any parts or products of animals that are non-*halal* or any parts or products of animals which are not slaughtered according to Shariah law and *fatwa*;
b) do not contain najs according to Shariah law and *fatwa*;
c) are safe and efficacious for human use according to the prescribed dosage, of quality and hygienic;
d) are not prepared, processed or manufactured using equipment contaminated with najs according to Shariah law and *fatwa*;
e) do not contain any human parts or its derivatives that are not permitted by Shariah law and *fatwa*;
f) during the preparation, processing, handling, packaging, storage and distribution, and the *halal* medical device is physically segregated from any other medical device that does not meet the requirements stated in items a), b), c), d) or e) or any other items that have been decreed as non-*halal* and najs by Shariah law and *fatwa*; and
g) certified by *halal* competent authority Medical Device

3. Issues and challenges toward medical device's *halal* certification

3.1 Medical Device's *Halal* Certification Mandatory or Voluntary Basis

The *halal* issue of medical devices has attracted the attention of many, not only in Malaysia but also from abroad. The industry faces issues on the status of *halal* certification whether the application of *halal* certification is a must for all medical device products. Some of the industry and association such as the Association of Malaysian Medical Industries (AMMI), Asia Pacific Medical Technology Association (APACMed) dan Advanced Medical Technology Association (AdvaMed) (Johari Ab Latiff, 2018) have found that *halal* certification can affect the business expansion. As referred to the Standards of Malaysia Act 1996 (Act 549), "standard" means a document established by consensus and approved by a recognised body, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context, with which compliance and not mandatory (Ahmad Hidayat Buang & Zulzaidi Mahmod, 2012). In the legal context in Malaysia, there has been no mandatory requirement of *halal* certification since there is no enforcement by any laws and regulations. Therefore, the *halal* medical device is a voluntary basis parallel with other schemes.

3.2 No Clear Scope for *Halal* Medical Device

The other issue is medical device scope that can be *halal*-certified since the range of medical devices is immense such as pacemakers, cardiovascular stents, respiratory ventilators, surgical trays, breast implants, diagnostic tests (e.g., pregnancy tests, blood glucose tests, *etc*.) or relatively simple devices such as tongue depressors, patient scales, and elastic bandages. There is still no endorsement on *halal* certification scope for the medical device (Johari Ab Latiff, 2018). According to the Manual Procedure for Malaysia *Halal* Certification 2014 (Jabatan Kemajuan Islam Malaysia, 2014), products which do not referenced standard or guideline is not eligible for *halal* application unless fulfils the criteria such as having direct contact with food, there is uncertainty on the sources of the manufacturing materials or ingredients may be from *halal* or non-*halal* sources, use as processing aids in food manufacturing and does not raise confusion if it is certified. With reference to that, the criteria mentioned are very general and the scope needs to be determined. Therefore, a certification scheme for *halal* application needs to be developed.

3.3 Manufacturing of Medical Device is Different from Non-Medical Device

Halal represents a substantial global business sector. Recognising this need, the industry has taken advantage of business opportunities in the *halal* industry to generate income. The concern in the industry is to fulfil the *halal* requirements in terms of the processing method. The industry should ensure *halal* integrity throughout the processes wherein raw materials are transformed into final products. Besides that, raw materials including ingredients, processing aids, packaging and equipment must also meet the regulatory requirement (Nur Farhani Zarmani *et al*. 2015). During the preparation, handling, processing, packaging or transporting of product, the product must be clean and free from any non-*halal* ingredient. Since the manufacturing process of the medical device is different compared to the non-medical device process, the industry needs to bear the cost, time and other difficulties as to ensure every requirement is fulfilled.

3.4 Difficulties in Getting *Halal* Raw Materials

The main *halal* issues regarding the medical device are the common raw materials used. The industry must ensure the sources of each raw material are *halal* and deal with suppliers who supply *halal* materials or the suppliers are *halal*-certified certificate holders. Raw materials without *halal* certification should be accompanied with the complete certification such as the certificate of origin, flow chart and product specification. For the medical device industry, the raw materials and the components are very wide which include mechanical, fabric, fibres which may come from animal and synthetic sources (Nur Farhani Zarmani *et al*., 2015). These are the dilemmas that exist in the industry, especially for the raw materials and components that are imported from other countries.

4. Islamic Law Perspective Relating to Medical Device

Islamic law highlights the use of prohibited substances in treatment is forbidden. Abu Darda reported: The Messenger of Allah (Peace and blessing be upon him; PBUH) said:

"*Surely Allah has sent down sickness and medicine, and made for every such illness, then repent and do not repent of the forbidden*" (Abu Da'ud, 3874).

The use of prohibited substances in treatment is categorised into *al-daruriyyah* and *al-hajiyyah*. *Al-daruriyyah* is defined as the preservation of the basic survival necessities of humanity needs which are religion (*deen*), life (*nafs*), intellect (*akl*), progeny (*nasb*) and wealth (*ma'al*). The preservation of the above-mentioned elements can be made possible through two types of essential elements. These necessities serve the basis for the establishment of welfare in this world and the hereafter. If they are ignored, the coherence and order cannot be established. Therefore, any medicine containing *haram* substance is permissible only under certain conditions such as if there is entirely no *halal* alternative or substitute medication available, if the patient's life is in danger if the medicine is not taken and if the medication is prescribed by a Muslim physician who is both knowledgeable and God-conscious. As mentioned in the Holy al-Quran:

"*Only He has forbidden to you the dead animals, and (the) blood, and flesh, (of) swine, and what has been dedicated [with it] to other than Allah. So, whoever (is) forced by necessity without (being) disobedient and not transgressor, then no sin on him. Indeed, Allah (is) Oft-Forgiving, Most Merciful*." (al-Quran, 2:173)

Some Bedouin from 'Uraynah came to the Prophet of Allah (PBUH) and accepted Islam, but the climate of Al-Madinah did not suit them; their skin turned yellow and their bellies became swollen. The Prophet of Allah sent them to some milk camels of his and told them to drink their milk and urine until they recovered. In this regard, narrated Anas (May Allah be pleased with him, RA), Imam Bukhari reported the hadith of the Prophet (PBUH) as:

"*The climate of Medina did not suit some people, so the Prophet (PBUH) ordered them to follow his shepherd, i.e. his camels, and drink their milk and urine (as a medicine). So, they followed the shepherd that is the camels and drank their milk and urine till their bodies became healthy*." (Muslim, 1671)

Jurists differ over some of the forbidden food substances that can be used as medicine. Some do not classify medicine as a compelling necessity like food. Others consider the need for medicine equal to that of food, for both are necessary for preserving life. As narrated by 'Izz Ibn 'Abd al-Salam, the priority of life is more vital compared to prevent from najs. At some points, some of the difficulties put in a situation of *darurah* or necessity ('Abd al-Karim Zaydan, 1986).

5. Recommendation

Obtaining *halal* certification is seen as a value-added element. There are some systematic approaches to the implementation of the *halal* medical device. It is suggested that those stakeholders such as JAKIM and the industry should play a big role to ensure the process can succeed. The recommendations are as follow:

5.1 Development of *Halal* Certification Scheme for Medical Device

Halal certification Scheme is a systematic plan for a course of action. To enable the action on medical device scheme to be taken, the development of the scheme including the scope, specific condition and requirements and guideline needs to be executed with the aim to clarify the requirements to be complied with in managing Malaysia's *halal* certification. For each scheme, there is a specialist team overseeing the certification process and they will collaborate with industries. JAKIM should make a concerted effort to partner with agencies, industry, academicians and consumers so as to form a working group in developing a new scheme for the medical device so that *halal* certification is applicable for JAKIM and industry players.

5.2 Development of MYe*HALAL* system of medical device

To ease the application for *halal* medical device products, the online application process should be introduced. This is attested to the fact that most organizations have now either completely or partially embraced the use of online application system. The system built should be user-friendly to ensure the process is smooth. Based on the study, the level of satisfaction for existing MYe*HALAL* system used for other schemes is low and said to be less user-friendly especially for less-skilled customers in information technology (ICT) (Johari Ab Latiff, 2015). MYe*HALAL* system needs to be upgraded and updated parallel with the current condition. Despite the existing system of MYe*HALAL*, the MYe*HALAL* system should also be developed specifically for medical device products so that it is more practical to the manufacturers of medical device products. Therefore, further discussions with the Medical Devices Authority (MDA) should be held to share views on the product registration system used by the Medical Devices Authority. Additionally, the views of the medical device industry are also taken into account in the development of this system to facilitate the certification process of both parties.

5.3 Scope and Requirements

Medical device products to be certified *halal* should be registered in advance with the Medical Devices Authority (MDA) before the Malaysia *halal* certification application is made to ensure that the product is effective, safe and efficient. Furthermore, the manufacturer must also comply with the ISO 13485 (Quality Management Certification for Medical

Device) for the production of medical device products. The scope of the medical device product should be determined clearly since the product has a wide range of specifications and categories. The proposed certification scope to be given priority in *halal* certification is as follows (Johari Ab Latiff, 2018):

i. there is a doubt about the potential source of ingredients or potions from a *halal* or non *halal* source;
ii. touching/directly with humans;
iii. products that have been or are still certified *halal* by *halal* authorities under the pharmaceutical product schemes or goods product schemes are as follow:
    a) Dental floss
    b) Dialysis solution
    c) Haemodialysis solution
    d) Water for irrigation
    e) Suture
    f) Humidifier
    g) Wound wash
    h) Eye lubricant
    i) Surgical mesh; and
    j) Bone graft

iv. subject to the approval of the competent authority.

5.4 Comprehensive Training

Currently, *Halal* Medical Device Certification is a new scheme to be launched by JAKIM. Hence, comprehensive training should be conducted in collaboration with the Medical Devices Authority (MDA), related agencies and other medical device industries. A well-planned training should consist of a series of modules including the classification of medical device products, the introduction of new terminology, ingredients involved and familiarisation of associated processing methods. The enhancement of knowledge and skills especially for comprehensive *halal* medical devices is of paramount importance. This is because the provision of competent officers and an efficient *halal* certification system is capable of providing the best service to the development of medical device product certification in Malaysia. Even issues involving the *halal* application of *halal* certification and its enforcement can be better dealt with by the exercise.

Medical device industry is also an important target for *halal* education. They work to provide products that meet *halal* standards or Malaysian Standards (MS). With increased understanding and awareness through continuous training among *halal* medical device industry operators, issues involving the preparation of premises, *halal* products and services can be effectively addressed. *Halal* medical device industry operators should be prepared to meet the requirements before, during and after the *halal* certification. Similarly, *halal* medical device industry players need to develop *Halal* Assurance System (HAS) in the company so that *halal* certification requirements can be done optimally. In fact, the willingness to appoint the Internal *Halal* Committee (IHC) or *Halal* Executives (EH) helps to smoothen the process of *halal* certification of Malaysian companies. Hence, integrity as a *halal* medical device manufacturer is more assured.

6. Conclusion

The article discusses on halal issues and challenges in the medical device in Malaysia. The conclusions of this article found several issues and challenges have been identified in regards to the implementation of *halal* certification for *halal* medical device schemes, such as whether the application of *halal* certification is a must for all medical device products, no clear scope for *halal* medical device, manufacturing of medical device is different from non-medical device and difficulties in getting *halal* raw materials. Some systematic approaches to the implementation of the *halal* medical device is suggested. The recommendations are as development of *halal* certification scheme for medical device, development of MYe*HALAL* system for medical device, the scope of the medical device product should be determined clearly since the product has a wide range of specifications and categories and lastly comprehensive training should be conducted in collaboration with the Medical Devices Authority (MDA), related agencies and other medical device industries. It is also suggested that those stakeholders such as JAKIM, Medical Devices Authority (MDA) and the medical device industry should play a big role to ensure the implementation of *halal* medical device certification can be succeed. The ongoing efforts of all parties in the search for solutions have to be taken to overcome the problems raised, so that, the implementation of *halal* certification of medical device products can be fully implemented in Malaysia.

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