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From Farm to Hospital Bedside: Recommendations for Halal Medical Device Development

Nur Farhani Zarmani, Mohd Anuar Ramli
and Shafik Mohd Saifudddeen Shaikh Mohd Salleh

1 Introduction

The reality of the potential of halal label on medicinal products is evident when Malaysia continues its strategy for targeting to export medical products to the Organisation of Islamic Cooperation (OIC) countries. This is in line with the requirements in these countries that their healthcare industry must be in line with halal standards. While concern for healthcare halal products is still relatively new compared to food products and consumables, Malaysia has become the first country in the world to lead the halal certification in the field of pharmaceuticals through the halal standard MS2424:2012 Halal Pharmaceuticals. This standard helps to improve competitiveness and penetrate the international market due to the strength of the Halal logo that is highly respected and well received by Muslim countries. Halal certification system also gives confidence to the businesses, customers, suppliers and other stakeholders that pharmaceutical products are halal and Shariah compliant (Latiff and Zakaria 2016).

However, in the complex healthcare ecosystem, there is another sector that plays an important role in the healthcare industry but has not yet discussed in the halal aspect seriously, namely medical devices. Medical device is any type of medical equipment available at hospitals which covers a wide range of medical equipment.
available at the hospital from a simple tool such as plaster to a complex machine such as CT scanners. Although pharmaceutical products and medical devices are used to provide treatment, both have different types of reaction. The mode of action of a medical device on the human body does not involve the reaction of metabolic, immunological and pharmacological, which is in contrast with pharmaceuticals.

Based on the Medical Device Act (Akta Peranti Perubatan (Akta 737) 2012), medical device refers to any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, or related intended by the manufacturer to be used alone or in combination in humans for the purpose of

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation or compensation of an injury;
iii. investigation, replacement or modification, or support of the anatomy or a physiological process;
iv. supporting or sustaining life;
v. controlling conception;
vi. disinfecting medical devices; and
vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body.

The medical device industry has a complex ecosystem with a wide variety of medical devices such as implantable medical devices, invasive medical devices and contraceptive devices. Generally, all types of medical devices are categorized into four classes, namely Class A, Class B, Class C and Class D depending on the levels of risk incurred towards the users. The classification considers several aspects, such as degree of invasiveness, duration of the device implanted in the body and biological effect of the devices towards human body (Medical Device Control Division).

In 2013, there was a demand for halal certification from the medical device industry which includes four classes of medical devices (Taboola 2014). For example, there is a need for halal certification from the manufacturers of surgical sutures, gloves and haemodialysis solution. Unfortunately, without the existence of halal standards and guidelines that are specific to medical device products, it is impossible to implement halal certification for medical devices. Therefore, this study aims to identify halal critical points in the medical device supply chain, consequently suggesting a number of components for the development of halal medical device guideline through a comprehensive study on one of the most frequent implanted medical devices in the human body, namely surgical sutures.

2 Methods

To achieve the objectives of this study, the method used in this study is based on library research and field study, which involve in-depth interview methods. Preliminary interviews were conducted using different semi-structured questions which were given to the interviewees of this study which include representatives
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from the Department of Islamic Development Malaysia (JAKIM), Selangor Islamic Religious Department (JAIS) and religious scholars to determine halal aspects of medical devices, as well as the Medical Device Authority (MDA) of Ministry of Health to clarify the regulation of medical device safety.

The scope of this study focuses on the processing and use of surgical sutures, which is one of the most frequent implanted medical devices in the human body. Consequently, study on halal critical points of the suture can be indirectly adapted to suggest the guidelines for halal medical devices in general (Idris 2016).

3 Results and Discussions

This study identified several components of halal critical points along the supply chain of the suture which can be taken into considerations in the development of halal medical devices guidelines. Every element and processing involved in producing the suture starting from retrieving raw material at farm to the used at hospital bedside are recognized. At present, medical device regulatory framework is intended to protect health and safety aspects of the public. The regulatory framework monitors safety and performance of medical devices throughout its life cycle which consists of pre-market, market and post-market (Fig. 1).

Basically, before placing a medical device in the market, conformity assessment should be conducted objectively to provide evidence of the safety, performance, benefits and risks of the device to attain confidence of the consumers. Conformity assessment is a technical term that refers to the process of evaluation and approval of a medical device. In the context of medical device regulatory system, it acts as an evidence resulting from a systematic inspection and procedures implemented by the manufacturer, according to the requirement imposed by the authorities to ensure that the medical devices are safe and perform as intended by the manufacturer (Idris 2016).

![Fig. 1 Three stages of regulatory control through life cycle of a medical device (Source World Health Organization)](image-url)
Through this study, we adapted and harmonized the safety aspects of medical devices and determined critical issues in producing not only safety and quality but also halal medical devices such as sources and processes, of a device. These guidelines combine elements of halal with device safety.

3.1 Definition of Halal Medical Device

This study suggests that halal medical device refers to a medical device that is permissible to use and should meet the following Shariah requirements:

i. Does not contain any parts or products from animals that are non-halal or from animals not slaughtered according to Islamic law;
ii. Does not contain filth or najis;
iii. Safe for human consumption; and
iv. Non-toxic or harmful or dangerous to human health.

3.2 Halal Critical Points and Halal Guidelines for Medical Devices

Regulation of halal aspects of medical device still encompasses on the processes that is taking place along the supply chain of medical devices. Hence, based on the regulatory framework of medical devices developed by the MDA, halal critical points are identified besides monitoring the aspect of safety and performance of the devices. This is because, the halal certification on a product including medical device provides a benchmark to ensure that the products are compliant with Islamic principles, that is, halal and tayyiba, clean, safe and good quality. Therefore, monitoring the halal critical points through production of surgical sutures acts as an aid to fill the gaps and support the existing medical device regulatory framework which already cover the safety aspects (Fig. 2).

At present, there is still no act, policy or guideline adopted by the MDA in respect of medical devices that touch on the halal aspects of medical devices. However, based on this study, we found that there are a few critical points that should be regulated by authorized body such as JAKIM, in order to produce medical device products that are not only safe but also halal. For the MDA, their emphasis is on product safety, since there are acts and various standards developed on safety and quality aspects (Idris 2016).

Halal critical points are identified in two phases of a medical device production, namely pre-market and market, and consequently adapted and used as fundamental requirements that significantly relevant to develop guidelines for halal medical devices. In this part, elements of halal critical points in the production and application of medical devices through the study on surgical suture will be discussed as follows.
3.3 Halal Sources of Medical Devices

Basically, the source of raw material has been positioned as a general requirement for halal certification in the Manual of Procedure for Halal Certification. In the production of surgical sutures, in order to determine its halal status based on the raw material is somewhat challenging. This is because, various materials including animal-based and plant-based sources are used to make organic sutures sources, while a wide variety of polymeric materials are used to produce synthetic sutures (Zarmani et al. 2016). Therefore, in order to produce halal medical devices, a manufacturer should implement the following requirements:

i. Sources of raw materials are halal and safe (Maryakon 2015);
ii. Animal-based raw materials are certified halal;
iii. Approval of JAKIM and the Department of Veterinary Services (DVS) for imported animals (Aziz 2015); and
iv. Storage of raw materials that are halal is physically separated from others that are not fulfilling the requirement (Omar 2015).

3.4 Halal Slaughter of Animal-Based Suture

Halal status of suture made of plants and polymer elements is not complicated to be determined compared to those with animal elements. For example, one of the contemporary sutures named catgut sutures is taken from the intestines of ruminant animals such as goat, sheep or cattle. Although these animals are classified as halal animals, it is necessary to comply the procedure of halal slaughtering method. Management of a good and halal slaughter commences from pre-slaughter phase (farm) to a slaughterhouse and continuously to be monitored along the line of production of medical devices like sutures.

For example, catgut sutures that are made of the intestines of ruminant animals are either from local abattoirs or from abroad. Therefore, some critical aspects for
halal slaughtering need to be identified to produce halal sutures are as follows (Rahman 2012):

i. Receiving of animals;
ii. Handling of animals;
iii. Stunning of animals;
iv. Using sharp tools;
v. Muslim butcher;
vi. Bleeding;
vii. Thoracic sticking; and

3.5 Halal Processing of Suture

Medical device processing chain also consists of a few critical points that should be strictly monitored for producing halal products. The surgical sutures development process and medical device safety rules such as regulation stated in ISO 13485 are also applicable to produce halal products. Furthermore, the concept of halalan tayyibah in a product including medical device not only encompasses halal itself but also cover safety, performance and quality of the device (Zamani et al. 2015). This study found a few halal critical points involved in the processing of sutures, namely

i. Cleaning procedure (Ezanda 2015);
ii. Status of chemicals (Shakirah 2014); and
iii. Sterilization procedure (Izan 2015).

3.6 Halal Logistics of Suture

Halal logistics management has been defined as the process of acquisition, movement, storage and handling of materials, livestock, semi-finished or finished products, information and documentation flows through the supply chain comply with the general principles of Shariah. Elements that must be followed to ensure the halal logistics of medical devices are as follows:

i. Basically, the logistics system of the medical devices must comply with the requirement of safety and performance that has been mentioned in the document of Good Distribution Practice for Medical Devices (GDPMD) (Idris 2016);
ii. Storage of raw materials and stocks of medical devices should be physically separated from any raw materials and stocks of medical devices that are not complied with the requirement or considered unclean by Islam;
iii. During storage, there is no mixing of raw materials and stocks of medical devices halal and non-halal on a pallet or carrier;
iv. Transportation of raw materials and products of medical devices that are halal must use dedicated transport and transportation of raw materials and products of medical devices that are not halal or material considered unclean by Islam.

v. To prevent mixing and contamination of medical devices that are clean and unclean, raw materials and stocks of medical devices should be categorized, clearly labelled and separated.

vi. Transport and storage must be washed according to Islamic guidelines and in accordance with hygiene standards, if it has been used previously to transfer haram material.

### 3.7 Halal in Suture Usage

This study also recommends that it is also necessary to include the usage of sutures at the point of consumers as halal critical point. At the phase of post-market, requirement of halal usage of sutures must ensure the safety and performance of the sutures on patients. There can be situations where, even if the product is halal, it is still unsafe and harmful for patients because of their medical history. General requirement of safety and performance of medical devices has been stated in Medical Devices—Quality Management System—Requirements for Regulatory Purposes (ISO 13485). Therefore, the application of sutures must implement the following requirements:

i. Sutures have to comply with the quality standards for medical devices, for example, ISO13485.

ii. Sutures have been tested for its safety and effectiveness.

iii. Use of sutures must consider historical background of patients.

### 4 Conclusions

This study found that there are several components such as sources and processes of a device which can be taken into considerations in the development of halal medical devices guidelines. These guidelines combine elements of halal with that of device safety. With the establishment of these guidelines, the medical device industry can be incorporated into the halal industry. This can be a catalyst to spur the halal industry further.

Apart from the point of retrieving raw material, processing and logistics, proper training should be included as halal critical point in medical device production. Although training appeared to be unrelated to the raw materials, this element is stated clearly in Halal Certification Manual (Jabatan Kemajuan Islam Malaysia (JAKIM) 2015). Training element will reflect on the understanding of the personnel in handling raw materials and monitoring the halal aspects along the supply chain of medical devices (Maryakon 2015).

The resulting guidelines refer to the regulatory framework which is monitored by the Medical Device Authority (MDA) that only oversees the safety and effectiveness of
medical devices. Therefore, the vacuum that is addressed in this study is the halal-haram aspect which is identified along the supply chain of medical devices.

In order to ensure that the production of medical devices is handled according to Shariah requirement, this industry should be explored in detail by the government and all stakeholders in both halal and safety perspectives of a medical device (Aziz 2015). The urge to initiate halal medical device industry should also be explored using adequate number of relevant samples for a clear understanding, so that it can be discussed using the same language among diverse stakeholders (Maryakon 2015).

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References

Akta Peranti Perubatan (Akta 737) (Percetakan Nasional Berhad 2012).

Interviewees

Aziz, S. (Assistant Director of Halal Division, Department of Islamic Development Malaysia, JAKIM) (2015, December 9). Personal Interview.
Maryakon, S. (Senior Assistant Director, Halal Management Division, Selangor Islamic Religious Department, Jais) (2015, November 5). Personal Interview.