

The ethical aspects of *halal* certification of medical devices in Malaysia

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Abstract

The medical devices industry is one of the fastest growing sectors of healthcare industry with a large market, a wide variety of products and growing applications. In Malaysia, this industry is a major contributor to the economy and government initiatives support its growth to position Malaysia as a medical device manufacturing hub in the Asia-Pacific region. There are more than 180 manufacturers of medical devices in Malaysia involved in the production of sophisticated devices such as orthopedic products, surgical instruments and dialysis machines. Local companies are moving towards complying with internationally recognized quality standards such as ISO 13485 as an attempt to penetrate the global market. However, there is a religious need to provide medical devices that are certified *halal* in order to cater to the needs of Muslim consumers who make up 64.3% of the Malaysian population. It is an advantage that Malaysia *halal* certification industry is well-developed and recognized as a model all around the world. Malaysia shows a strong industrial manufacturing potential for a wide range of *halal* products. The availability of supporting industries thus provides Malaysia with the ideal conditions to develop into a medical device hub in Asia as well as to establish a global acceptance model for *halal* medical devices. This paper will discuss the ethical aspects of developing *halal* medical devices for the needs of Muslims in Malaysia and other Islamic nations.

Introduction

The issue of *halal* authenticity is a major concern for many Muslims today. In Islam, an important factor for Muslim consumers is whether a product is *halal* (lawful) or haram (unlawful) (Ramin Jorfi et al. 2012). Malaysia is heading towards becoming a main player in the world *halal* market.

Demands for products with *halal* certification are escalating, in line with the growth of population (Ahmad Nizam Abdullah 2006). Extensive literature often debate on the determination of *halal* authentication of food products, cosmetics and pharmaceuticals (Mohammad Aizat Jamaludin et al. 2011). However, up to the best knowledge of the authors, there is still no specific study on *halal* medical devices. Hence, there is a religious need to provide medical devices that are certified *halal* in order to cater to the needs of Muslim consumers who make up 64.3% of the Malaysian population.

The total value of Malaysia medical device export was RM 15.35 billion (USD 4.76 billion) in 2013 representing a 7% increase over RM 14.35 billion in 2012 (AMMI, 2014). In the medical device industry, there are a number of stakeholders who need to have their voices heard throughout the process. Each stakeholder has diverse and unique needs relating to the medical device; the needs of one may highly affect the needs of another, and the relationships between stakeholders may be tenuous (de Ana, Umstead, Phillips & Conner 2013).

This study however, differs from the others as the aim is to identify two distinct types of stakeholders involved in developing *halal* certification of medical devices in Malaysia; either direct stakeholders or indirect stakeholders. This paper demonstrates how there are attribute differences for two distinct categories of stakeholders. This study would be useful for all players in this industry as the findings would help to develop strategies to promote *halal* certification of medical devices in Malaysia.

Methodology

The framework proposed in this study is based on two types of data collection; interview and electronic reference. Preliminary interviews were conducted with the local sutures manufacturers. It took about an hour to cover semi-structured questions. The manufacturer was asked about the process of catgut production in order to determine the *halal* built-in through the production chain and also the procedure to comply with the international standard as well as the *shariah*.

Interviews were also conducted with the Medical Device Authority (MDA) in order to have the details on acts and standards related to medical devices to follow as a guideline to start the *halal* certification for the medical devices in the market.

Discussion

Malaysia is fully committed to strengthening the *halal* industry and achieving the vision of making Malaysia a global *halal* hub. *Halal* is part of *Shariah* principle and is mentioned in the Holy Quran. *Shariah* is the code of conduct for the Muslims to follow and apply in every activity (Ab Talib & Mohd Johan 2012). The definition of *halal* is permitted, permissible and lawful. *Haram* (non-*halal*) is the opposite of *halal*, which means forbidden and unlawful in the context of Islamic law. Currently, *halal* issue has become a concern in the production and application of various products, for example meat products, cosmetics products, pharmaceuticals products, services such as banking and finance and tourism. Unfortunately, *halal* certification for medical devices has not being discussed intensely in the literature.

From a strategic perspective, stakeholder management urges corporations to consider the impact of their action and decision making on various stakeholders. Stakeholder management, with its underlying business ethics component, focuses on the fair treatment, by the 'firm', of its various groups of stakeholders, especially of suture manufacturers, doctors, and patients. However, besides these primary stakeholders, there are also important indirect stakeholders such as civil society and pressure groups who defend the interest of specific stakeholder groups. There are also regulators such as law, official institutions and control organisations; and finally the press and other media. The stakeholder approach also has to focus on the need for corporations to inform transparently and through dialogue, especially in its approach to pressure groups.

According to Freeman et al. (2004), stakeholder theory primarily focuses on corporate responsibility towards a firm's stakeholders. The literature suggests many classifications of stakeholders using various criteria (Vasi & King 2012). The classical categorisation, based on priority, refers to primary versus secondary stakeholders (Donaldson, et al. 1995) or normative versus derivative stakeholders (Phillips 2003).

Stakeholders are those groups or individuals with whom the organization interacts or has interdependencies and any individual or group who can affect or is affected by the actions, decisions, policies, practices or goals of the organization. Primary stakeholders are those who have a formal, official, or contractual relationship, and all others are classified as secondary stakeholders (Gibson 2000). Primary stakeholders enjoy a direct and contractually determined relationship with the organization whereas secondary stakeholders are at the boundaries of the organization who may be affected by its actions but lack any contractual connection (Fassin 2012). Secondary stakeholders are capable of influencing whether the operation is effective (Gibson 2000). The implication is that a stakeholder is any individual or group with the power to be a threat or benefit. Secondary stakeholders include nongovernmental organizations (NGOs), civil society groups, activist groups, outsiders or social movements (de Bakker & den Hond 2008).

Normative stakeholders are those stakeholders to whom the organization has a moral obligation (Phillips 2003). However, derivative stakeholders are those to whom the organization has no direct moral obligation as stakeholders. These groups cover the competitors, activists and the media (Phillips 2003). They can affect the organization even with no legitimate relationship with it as groups or individuals who can either harm or benefit the organization

According to the perspective of promoting *halal* certification for medical devices in Malaysia, this attempt involves ethics responsibility. Ethically, this duty should be a concern for large groups of stakeholders. In order to promote *halal* medical devices, there is a need to build a platform for a discussion between both direct and indirect stakeholders for *halal* medical device standardization (Idamazura 2014).

Primary stakeholders who should directly be involved in the application of *halal* medical devices are manufacturers (local or international), doctors, nurses, and patients. Basically, the manufacturer is responsible to ensure that the manufactured medical devices meet or exceed the required standards of safety and performance (Norshakira Ramli 2014).

The major users of medical devices include the doctors and nurses who employ the medical device only for intended indications. They also ensure the proper use of medical device by being a competent user (having appropriate qualification, training and experience). Besides that, doctors and nurses are encouraged to share the experience gained of using medical devices with others (users, distributors and manufacturers) by reporting any incidents to a coordinating centre from which warnings can be issued (Norshakira Ramli 2014). The users also need to ensure proper maintenance of medical devices during active use and safe disposal of obsolete medical devices (Medical Device Authority (MDA) 2013).

Patients and healthcare providers embody the engagement of religion with modern medicine on a daily basis. Patients' salient health beliefs and healthcare choices are often informed by religious values and understandings. Religion also influences the practice patterns of healthcare professionals in both visible and unconscious ways (Curlin 2008).

However, secondary stakeholders cover the responsibility carried by the policy maker; they include Medical Device Authority (MDA), Department of Islamic Development Malaysia (JAKIM), consumer association, and researchers. MDA serves to address issues of health and safety of people associated with the medical device (Jabatan Perdana Menteri 2012). Generally, MDA is responsible in establishing and implementing policies and regulations to control medical devices to ensure safe and effective medical devices sold or made available in the country (Nor Idamazura 2014).

JAKIM is the authority responsible for *halal* certification in Malaysia. There is a high potential in promoting *halal* medical devices in Malaysia since Malaysia's *halal* certification issued by JAKIM is globally recognised for its stringent criteria and is regarded as having a strong industrial and commercial set up to produce and market *halal* products as well as having strong relationships with the major trading nations of the world, and strong government support (Badrudin et al. 2012). The process of awarding *halal* certificates involves not only an official site inspection of production plants but also the examination on the *halal* status of raw materials (Badrudin et al. 2012). In order for us to promote *halal* certification of medical devices in Malaysia, this attempt has to take into account the needs of its various stakeholders and balance their divergent interests (Frooman 1999).

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