

WAR 38 HALAL STEM CELL RESEARCH AND THERAPY: THE MALAYSIAN PERSPECTIVE

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ABSTRACT

Issues of Halal products and services have been a major focus in Malaysia for years. In line with the Malaysia's plan to become a global halal hub, this paper therefore examines the emergence of stem cell research and therapy services in Malaysia from the medico-legal, ethical and Halal perspectives. Building on the fact that stem cells research and therapy are already available in Malaysia, this paper examines the Halal status and how the Malaysian's approach in ensuring the Halal status in order to dominate the national and international halal market. As Muslims are now acknowledged as a unique group of consumers and there are evidently demarcated markets for halal medical services, this paper therefore will also examine whether there have been attempts to develop a common halal standard nationally and internationally to harmonize the whole stages from research until the products meet the consumers.

Keywords: stem cells; stem cells research and therapy; halal; halal research governance.

INTRODUCTION

There is a rising call for Halal therapy and medicine among Muslim patients. Research based on stem cells based therapy and therapeutics products so far have not been part of *Halal* debates despite their availability in Malaysia. The matters pertaining to *Halal* and *Haram* should always be considered by every Muslim including the choice of treatments. The term "*Halal* therapeutics" should be inclusive of therapeutics products free from the forbidden (*Haram*) substances and also *Tayyib* (products that meet the standard of quality). The following tradition of the Prophet, peace be upon him has explained:

"What is Halal is clear and what is Haram is clear. Midway between them there are things which many people do not know whether they are Halal or Haram. He who keeps away from them will protect his religion and will be saved. He who approaches them will be very near to Haram, like a herdsman wandering near Hima (the place set by the king to be used by his cattle only), who could soon fall into this protected area. Surely for every king there is such a protected area and God's is what He declared forbidden". (Muhammad Bin Ismail al-Bukhari, 2000)

The term *Tayyib* refers to a particular good or product that is clean, pure and produced based on standard processes and procedures (Azmi Sarriff and Hadeer Akram Abdul Razzaq, 2013). Thus, a therapeutic product must not only be Halal but also clean according to Shariah. The

presence of the element of *Tayyib* further strengthen the Halal concept itself which means good and pure as a manifestation of the principles of *Ihsan* (Competent) and *Itqan* (Orderly Manner). For this reason, the quality or estimated value of the lawfulness or the unlawfulness (halal or haram) of a matter cannot be judged in isolation but it must take into account the process of production, manners and ways of consumption and its' effect. (Anas Bin Mohd Yunus, Wan Mohd Yusof Bin Wan Chik and Mahani Binti Mohamad, December 2010). Therefore, Muslims are responsible for ensuring that the products are Halal and *Tayyib* during the whole manufacturing, distributing, dispensing, and prescribing process (Anas Bin Mohd Yunus, Wan Mohd Yusof Bin Wan Chik and Mahani Binti Mohamad, December 2010).

THE STATUS OF STEM CELLS BASED THERAPY

Issues related to Halal foods and medicines have been greatly debated. According to Mustafa Afifi Ab. Halim et al., (2014), all pure and clean foods and pharmaceuticals are permitted for Muslim consumption except for the following categories: any products derived from or contaminated with carrion of dead animals; flowing or congealed blood; swine and all its by-products; animals slaughtered not in the name of God; animals killed in a manner that prevents their blood from being fully drained from their bodies; animals slaughtered in the name of other than God; intoxicants of all types including alcohols and drugs; carnivorous animals with fangs such as lions, dogs, wolves, or tigers; birds with sharp claws (birds of prey) such as falcons, eagles, owls, or vultures; land animals such as frogs and snakes (Lokman, 2001).

However, given the unique characteristics and nature of stem cells based therapy, it must be carefully determined whether the existing rules of Halal may be also be applicable on stem cells therapy. Unlike pharmaceutical products, many stem-cell-based products may originate in academic laboratories where researchers are unfamiliar with the applicable regulations. (Dina Gould Halme and David A. Kessler, 2006). Being a class of therapeutic agents, stem-cell-based products meet the definitions of several different kinds of regulated products, namely biologic products, drugs, devices, xenotransplantation products, and human cells, tissues, and cellular and tissue-based products, the last category i.e. human cells, tissues, and cellular and tissue-based products is defined as “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.” By definition, any therapies that are considered to be stem-cell-based products fall into this category and thus are subject to the regulations that govern these products. (Dina Gould Halme and David A. Kessler, 2006).

In considering Halal drugs, it means that they must not contain anything that originated from pigs or dogs, or from any animal that was not slaughtered in accordance with the requirements set out in Islamic law (Takeshi Kumon, 2014). The Malaysian Standard of Halal Pharmaceutical – General Guidelines defines pharmaceutical products as “finished dosage forms, and include both prescription medicinal products for human use like biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products, which are registered with the Drug Control Authority, Ministry of Health Malaysia (Malaysian Standard, 2010). The Standard is silent on the status of products based on human biomaterial such as tissues and cells. Stem cells do not fall within the definition of medicine or pharmaceutical products hence a higher standard shall be applicable. One of the issues that must be determined is whether stem cells based therapy fall under the definition of drugs hence the similar standard applicable?

The Malaysian Standard, 2010 has listed Halal pharmaceuticals as products that contain ingredients permitted under the Shari'ah law and fulfil the following conditions:

- a) does not contain any parts or products or animals that are non-halal by Shari'ah law or any parts or products of animals which are not slaughtered according to Shari'ah law;
- b) does not contain najis according to Shari'ah law;
- c) safe for consumption, non-poisonous, non-intoxicating or non-hazardous to health;
- d) not prepared, processed or manufactured using equipment contaminated with najis according to Shari'ah law;
- e) does not contain any human parts or derivatives that are not permitted by Shari'ah law; and
- f) during its preparation, processing, handling, packaging and distribution, the food is physically separated from any other food that does not meet the requirements stated in items a), b), c), d),
- g) or any other things that have been decreed as najis by Shari'ah law.

The term impure (Najis) according to Shari'ah law are a) dogs, pigs, their descendants and derivatives; b) halal pharmaceuticals that are contaminated with items which are non-halal; c) halal pharmaceuticals that come into direct contact with items that are non-halal; d) any liquid and objects discharged from the orifices of human beings or animals such as urine, blood, vomit, pus, placenta, excrement, and sperm and ova of pigs and dogs except sperm and ova of other animals. (Milk, sperm and ova of human and animals, except dog and pig, are not najis); e) Maitah or carrion or halal animals that are not slaughtered according to Shari'ah law and; Khumar and food or drink which contains or mixed with khumar (Malaysian Standard, 2010).

ISSUES AND CHALLENGES IN HALAL STEM CELLS THERAPY IN MALAYSIA

Halal is defined as “anything that is free from any component that Muslims are prohibited from consuming” and the modern concept of Halal can no longer be restricted to simply meaning ‘pork free’ in its physical existence (Zalina Zakaria, 2008). Notwithstanding the fact that Malaysia is a multi-religious and multiracial country, Malaysia has become the most advanced country as a world class Halal hub. In fact, Malaysia is the first country in the world to have created a halal ecosystem called Malaysian Standard MS 2424:2012 Halal Pharmaceuticals-General Guidelines. (Noriah Ramli, Faqihah Salleh and Saiful Mohammad Nizam Azmi, August 2012). As there is no specific laws existed with regard to stem cells based therapy, the pharmaceutical related standards and guidelines may be adhered to whenever deemed suitable. As for the production and storage of halal pharmaceutical products, the Standards provide that: “they shall be provided with dedicated and self-contained facilities to prevent the risk of product contaminated and thus becoming a non-halal product.

When conducting quality control activities in the production area, the operations for control laboratories shall consider precaution steps as to prevent contamination on production line which also may lead to be non-halal product (MS 2424:2010 (P), 2010b). The requirement on manufacturing purpose materials in this standard covers all materials used in manufacturing of halal pharmaceuticals including starting and packaging materials. The materials may be from synthetically- or naturally-derived sources (MS 2424:2010 (P), 2010b). The track of material source and design for packaging is also a requirement as to obey the halal pharmaceuticals standard. The consumable and non-consumable packaging and printed materials shall be from any origin that is decreed as halal according to shariah. While the packaging design, sign, symbol, logo, name and picture shall not be misleading and contravening the principles of Shariah (MS 2424:2010 (P), 2010b). The following issues are relevant in considering Halal stem cells research and therapy:

1.1 Manual Procedure of Halal Certificate

The Manual Procedure of Halal Certificate was introduced by JAKIM in collaboration with various government ministries, all State Islamic Religious Departments and State Islamic Religious Council. However, the Manual covers only the procedure for food which is not inclusive of pharmaceutical, medicinal or therapeutic products. The Manual was prepared with the aim to provide understanding and clarification to all inspection officers, manufacturers and consumers on halal aspects according to Shariah Laws and Malaysian Laws. (Norazlina Abdul Aziz, Irini Ibrahim and Nurazlina Abdul Raof, 2014).

1.2 Lack of Uniformed Law

The global halal industry tends to be fragmented with numerous standards and sometimes competing with each other. In order to support the development of a reliable Halal pharmaceutical supply chain, effective laws and administrative regulation have to step in, where the scattered and non-uniform definition of Halal has become a barrier to the suppliers and exporters (Norazlina Abdul Aziz, Siti Sarah Sulaiman, 2014). The latest Trade Description Act 2011 has repealed the Trade Description Act 1972 and replaced the Trade Description (Use of Halal Expression) Order 1975 and the Trade Descriptions (Halal Labelling) Order 1975. However, the Trade Description Act 2011 is not the main Act governing halal matters. Other subsidiary laws have been designed following the introduction of the new Act namely the Trade Description (Definition of Halal) Order 2011, Trade Description (Certification and Marking of Halal) Order 2011 and the Trade Descriptions (Certification and Marking of Halal Fees) Regulations 2011 (Norazlina Abdul Aziz, Irini Ibrahim and Nurazlina Abdul Raof, 2014).

The amendment was made under the previous Trade Description Act 1972 that provides JAKIM enforcement officers are given the power as “assistant controller” where they can take action against the offender. However, neither the said amendment nor the latest Trade Description Act 2011 has granted powers to JAKIM officers to prosecute individuals or companies in violation of the Act. The Act does not make it an require for the products to be marked as Halal but only specifies that once the products is marked as Halal, then the manufacturer of the products shall be responsible to ensure that the product is accordingly ‘Halal’ (Zalina Zakaria, 2008). Section 3 of the Trade Descriptions (Use of Halal Expression) Order 1975, which comes under the Trade Descriptions Act, is regarded as the first attempt to define Halal: 1) Neither is nor consists of or contains any part or matter of any animal that a

Muslim is prohibited by *hukm syarak* to consume or that has not been slaughtered in accordance with *hukm syarak*. (Zalina Zakaria, 2008).

1.3 The Limited Applicability of Shariah Enactments

There are various state enactments that provides for the prohibition of displaying or indicating any prohibited foods as Halal as committing an offence, for instance Section 42 of Syariah Criminal Offences (Federal Territories) Act 1997 on abuse of Halal sign that stipulates: “Any person who displays, on or in respect of any food or drink which is not halal, any sign which indicates that such food or drink is halal, shall be guilty of an offence and shall on conviction be liable to a fine not exceeding five thousand ringgit or to imprisonment for a term not exceeding three years or to both. The similar offence is also charged under the Trade Descriptions (Definition of Halal) Order 2011 with fine not exceeding five million ringgit and for a second or subsequent offence, the fine does not exceed ten million ringgit. However, none of these provisions may be applicable on medical, pharmaceutical and therapeutic products as the provisions are restricted to food related products only.

1.4 Ensuring the Safety, Quality and Efficacy

The requirement for Good Laboratory Practise (GLP) to ensure the safety, quality and efficacy of any production is part of the Halal requirement. Likewise, it is also the global requirement for the pharmaceutical industries. The same rule therefore shall be extended to matters pertaining to stem cells based therapy. Under the Food and Drugs Administration rule, the applicant for an investigational new drug application for a stem-cell-based product, should be able to address the following questions: Does the donor pose a risk of transmitting infectious or genetic diseases? Does cell or tissue processing pose a risk of contamination or damage? What are the types of cells, and what are the purity and potency of cells in the final product? Will the product be safe and effective in vivo? (Dina Gould Halme and David A. Kessler, 2006).

1.5 Informed Consent

One of the most important issues that must be considered within the Halal therapeutic industry relates to the issue of informed consent. Muslim patients who have not been adequately informed on the presence of non Halal substances in the drugs would have consented to undergo a therapy that involved non-Halal substance.

WIDENING THE HALAL SPECTRUM

Issues relating to Halal are now must be widened to cover the domain of public health, the economic impact and international trade effectiveness. The word “Halal” often comes up in the context of food and drink, but the concept also applies to drugs given the fact that these substances goes into the human body too (Takeshi Kumon, 2014). The lack of consensus by the Muslim world and fragmentation of Halal standards makes Halal not only difficult to be understood by the most important suppliers of Halal products to the Muslim world, namely the non-Muslim countries, but also gives room for the non-Muslim countries to define what is Halal and able to choose and therefore define their own Halal standard (Marco Tieman, 2012).

CONCLUSION

The availability of stem cells based therapy which can be directly accessed by the public has increased the demand for the determination of Halal status of such products. However, given the unique nature of stem cells characteristics, the standard to determine the Halal status such services could be much more complex than expected. Thus, the existing Halal standard for food products and pharmaceuticals could be a good guidance and yet a specific standard should be established specifically for stem cells research and therapy. Therefore, it is now a challenge for the regulators to establish a proper, well-regulated, and harmonized accreditation and Halal management system for a Halal standard for therapies based on stem cells utilization.

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