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The Usage of the *Mashbooh* Ingredients in the Pharmaceutical Industry: A Review

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Abstract:

The global Halal pharmaceutical market, which accounted for 6.7% of the global pharmaceutical market two years ago is expected to reach US\$370 billion in size in 2021 by showing an average annual growth of 9.3%. Along with the advancement of science and technology, the raw materials or ingredients can be obtained from many different sources which the status can be Halal, Haram or Mashbooh. This is why Islam is very particular when it comes to the matter of raw materials or ingredients. However, study on the Mashbooh ingredients seems scanty to be found. The objective of this study is to understand the dilemma of the usage of the Mashbooh ingredients in the pharmaceutical industry. It will discuss about the common Mashbooh ingredients used in the pharmaceutical industry along with Islamic perspectives related to Mashbooh ingredients. The primary source will be used in this study is library research through reviewed literatures and documents pertaining to the objective. Hence, this study signifies the importance of understanding the usage of the Mashbooh ingredients in the pharmaceutical industry.

Keywords: *Pharmaceutical, Mashbooh, Halal, ingredient, Islamic perspective*

1. Introduction

Throughout history and to this date in a continuously globalized world, Halal industry keep on growing and expanding in gaining people's attention and awareness in every aspects of life. Hence, Malaysia is one of the leading countries in Halal industry and the only country which have certification body right under the government known as Jabatan Kemajuan Islam Malaysia (JAKIM). It is the agency responsible for the Islamic affairs including halal certification in Malaysia. Since Malaysia is a country that has a majority Muslim population, Halal matters become one of the important and integral part of religious observance for all Muslims. Halal constitutes a universal standard for a Muslim to practice in their daily lives. By definition, Halal foods are free from any component that are prohibited for Muslims consumption. According to the Quran, all good and clean foods are Halal. In non-Arabic-speaking countries, the term is most commonly used in a narrower context of Muslim dietary laws only, especially when meat and poultry are concerned. However it also refers to a number of other consumer and industry related products like pharmaceuticals, biological products and fertilizers (Afifi et al., 2014). Pharmaceutical products were not part of Halal debates previously. Nevertheless this scenario had changed when consumers are made aware of the genuine concept of Halal in all aspects of life. This paper is thus attempt at creating awareness among the people about Mashbooh ingredient used in pharmaceutical industry along with Islamic perspectives related to it.

2. Overview of the Global Halal Pharmaceutical Industry

In recent years, Muslim consumers around the world have become more discerning about Halal issues. Halal applies not only to food products but to all aspects of life. Muslims are aware about the prohibition from using alcohol, pork and any other related items as much as they aware about the Halalness of transactions, premises, logistics, managements and operations in the industry. (Ahlam Nuwairah Ahmad, Azmawani Abd Rahman, & Suhaimi Ab Rahman, 2015). Moreover, Halal has made headway into cosmetics and pharmaceuticals industry too (Salama, 2016).

According to Mun-hee (2017), the size of the global Halal market reached US\$1.89 trillion in 2015 and is estimated to grow to US\$3 trillion within four years. The global Halal pharmaceutical market, which accounted for 6.7% of the global pharmaceutical market two years ago, is expected to reach US\$370 billion in size in 2021 by showing an average annual growth of 9.3%. As the pharmaceutical industry grows bigger, many companies all around the world are lurking into this business and do joint ventures with other companies as well. For example in the Iranian pharmaceutical market, which has a population of approximately 79.1 million, is one of the biggest in the Middle East. The market is expected to grow from US\$1.93 billion to US\$3.59 billion between 2015 and 2025. The Iranian government is planning to boost the ratio of domestically-produced biopharmaceutical products to at least 75% within five years (Mun-hee, 2017).

Besides, there is a company from Korea, Ildong Pharmaceutical's digestive Biovita obtained the first Halal certificate in the South Korean pharmaceutical industry from the Korea Muslim Federation (KMF) in which KMF is one of the certification bodies recognized by JAKIM. In April last year, Ildong Pharmaceutical signed a business agreement with MS Pharma, a pharmaceutical company headquartered in Jordan, to supply the country with its antibiotics, hyaluronic acid-based products, etc. (Mun-hee, 2017). It shows that the pharmaceutical industry could make a business across the region and would be in more advantages if the pharmaceutical products have the Halal certificate from the recognized certification bodies.

Furthermore, Brunei Darussalam which is a Muslim majority country has their own set of guidelines and standards for the manufacture of Halal pharmaceutical and food products. It would put Brunei in the forefront as the Sultanate could become among the earlier nations to have guidelines for Halal pharmaceuticals. Their Minister of Industry and Primary Resources, Pehin Orang Kaya Seri Utama Dato Seri Setia Hj Yahya Begawan Mudim Dato Paduka Hj Bakar said that the publication of the guidelines marked another milestone in Brunei's halal initiative and the universality of the halal industry, particularly for those who are involved in the sector. The guidelines named "The Brunei Darussalam Guidelines for Manufacturing and Handling of Halal Medicinal Products, Traditional Medicines and Health Supplements" were formulated to provide a standard framework for producing and handling medicinal products, traditional medicines and health supplements that are halal which covered the entire supply chain from the acquisition of raw materials, production, packaging, transportation and storage of medicinal products, traditional medicine and health supplements (Hamid, 2010).

3. The Development of Halal Pharmaceutical in Malaysia

The pharmaceutical sector has grown by an average annual rate of 8% over the last decade, reaching RM8.6 billion or 16.5% of total healthcare expenditure (RM52 billion) in 2016. Imported medicines at RM5.4 billion still account for the largest part (63%) of the RM8.6 billion pharmaceutical market, while exports are only RM0.7 billion. Generic medicines now account for 55% of the controlled (prescription) medicines market by value ((MyCC), 2017).

The market structure of Malaysia's pharmaceutical sector:

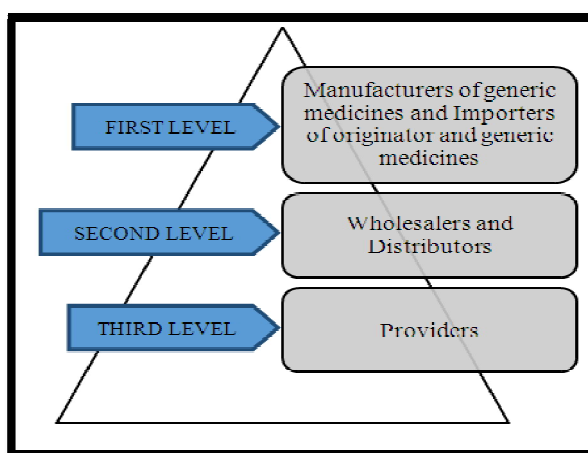


Figure 1

Based on the figure above, it shows the three levels of supply chain in the market structure of Malaysia's pharmaceutical sector. For the first level, there are 28 companies manufacturing controlled medicines in Malaysia, 23 are locally owned and 5 are foreign-owned, with none from high-income countries. The total sales revenue of this market was RM1.7 billion in 2014/15. As for the importers of originator and generic medicines, out of 54 importers, there are 35 are foreign-owned, accounting for RM3.9 billion or 87% of market share, with 19 locally owned companies taking 13% of market share. Importers are dominated by subsidiaries of multinational corporations (MNCs) from high-income countries that import patented (originator) medicines from their parent companies. However, the importers have the power on the market for the products but the decisions on the price still lie with their parent companies ((MyCC), 2017).

At the second level of the supply chain, out of 709 companies holding wholesale licenses issued by the National Pharmaceutical Regulatory Agency (NPRA) to distribute controlled medicines. Four categories of wholesalers and distributors were identified: large independent distributors, Bumiputera agents, wholesalers and distributors that are subsidiaries of manufacturers, and retail pharmacies that also do wholesaling. In fact, the wholesaler holds zero power over the price as they do not own the products they distribute.

The third level is the providers, it consist of general practitioners' and specialists' clinics (individual and group clinics), private hospitals (individual and group hospitals), retail pharmacies (single outlet and chain pharmacies) and public hospitals and clinics.

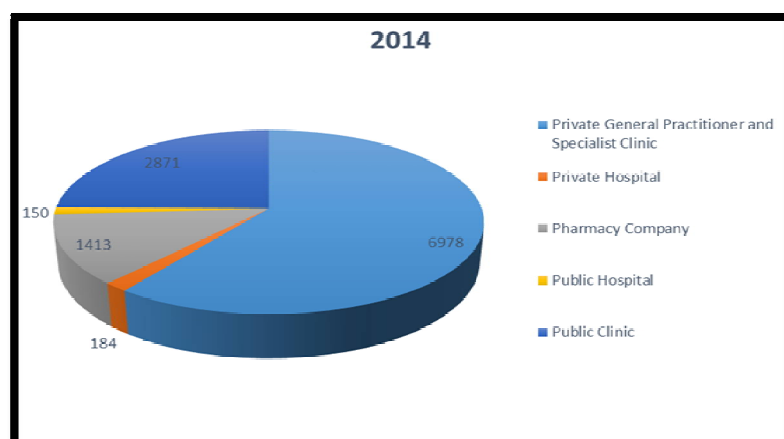


Figure 2

The chart above showed the providers who provide medicines to patients and end users in 2014, there were 6,978 private General Practitioners and specialist clinics, 184 private hospitals, 1,413 pharmacy companies with 2,098 outlets, 150 public hospitals and 2,871 public clinics.

4. Pharmaceutical from Islamic Perspectives

Malaysian Standard becomes a main referral to the Halal pharmaceutical industry in Malaysia. In the standard mentions that pharmaceutical products in finished dosage forms and include both prescription medicinal products for human use are registered with the Drug Control Authority, Ministry of Health Malaysia (MS2424). The standard further added that Halal pharmaceutical are products that contain ingredients permitted under the Shariah law and fulfill the conditions in the standard. According to the majority of scholars, the use of forbidden substances or mixing with the najis for medical purposes is prohibited (Ab Halim, Mohd Kashim, Mohd Salleh, Nordin, & Muhammad Husni, 2015). However, the manufacturers' lists of ingredients on medicine packets tend not to be comprehensive. In order to be in accordance with Sharia law, all non-Halal animal derived ingredients should be replaced with Halal ingredients (Amani & Mustapha, 2016). These sources are the components that make the final products Halal or haram. Moreover, the use of alcoholic products as sources for medicines is still doubtful for producing Halal medicines (Nasaruddin, Mel, & Hamid, 2011). There are two ways of producing alcohol which is fermentation and chemical substances. Fermentation is the main process to produce liquor while to produce alcohol from petroleum is through chemical substances process (Ab Halim et al., 2015). According to the consensus of the scholars (Hanafi, Maliki, Shafie and Hanbali), alcohol that comes from liquor is najis because it intoxicates but the late Pehin Dato Dr Haji Ismail bin Umar Abdul Aziz (former Mufti of Brunei) expressed that treating diseases with the original liquor (najis) is also forbidden unless it is mixed with other things (Fatwa Series 34/70). Yet, alcohol is believed to be more harmful than useful in Islam. It is mention in the Sahih Muslim, Hadith 15, book 36 by the Prophet Muhammad (PBUH), "Khamr (Alcohol) is not a medicine, but a disease". The Prophet Muhammad shed more light on the statement, saying, "Allah has sent down the disease and the cure, and for every disease, there is a cure. So take medicine, but do not use anything haram as medicine" (taken from Al-Qaradawi, 1999). Although in a later version of this scholar's works it was suggested that haram products are potentially permissible if certain conditions exist (Amani & Mustapha, 2016).

This rule applies to all unlawful ingredients used to produce the medicine. There is another controversial pharmaceutical ingredients such as gelatin have raised religious concerns due to its possible derivation either from plants (Halal) which has no problem or from animals (Haram). But, the haram source is used more frequently because it is less expensive than plant-based gelatin (Shah & Yusof, 2014). There is a study done by the Ministry of Science, Technology and

Innovation stated that out of 15 samples of pharmaceutical products taken randomly, 3 are wrapped with gelatins from pig DNA (Ab Halim et al., 2015). According to the Shariah law, there are two conditions if the gelatin comes from animals, if it is from Halal animals, the animals must be slaughtered according to the Shariah law while the other condition is if the gelatin comes from Halal animals but not slaughtered according to the Shariah law or comes from Haram animals such as pig, then automatically it is forbidden to be used and known as najis (unclean) (Ab Halim et al., 2015). This is how Islam play its role in pharmaceutical industry to overlook the risks involved in producing a certifiable Halal product which involve strict monitoring of the entire process from the beginning of production to the point that the customer receives the product hand-in-hand (Amani & Mustapha, 2016).

5. The Understanding of Mashbooh in Pharmaceutical

Apart from Halal and Haram, there is another term which are nor less important to be concerned by the Muslim communities around the globe in their daily lives including pharmaceutical and medications. The term is categorised as Mashbooh (questionable or doubtful). Mashbooh refers to products or items which are not amenable to straightforward

categorization of Halal or Haram. It represents a category of ambiguous products that are neither Halal nor Haram. Naturally, when people get sick or having illnesses, they will seek for remedies in any kind of ways they could along with the technological advancement in the field of medicine which can be from the traditional use of plants and natural resources to produce potions, mixtures, ointments and so on to the modern scientific exploitation of chemicals and drugs to produce medicines in various forms known (Mohd Zarif, Abd Murad, & Mdyusof, 2013). Though, there are numbers of arising issues on the ingredient used in the pharmaceutical which should be taken seriously by the Muslims. This is in lined with the verses in the Quran that call Muslims to seek for 'halalan and toyyiban' in their life and avoid any food or medication that originates from doubtful sources (Abd. Aziz et al., 2014).

The most common substance categorized as Mashbooh was magnesium stearate, followed by gelatin and glycerol particularly in the formulation of respiratory medications (Sarriff & Abdul Razzaq, 2013). According to Ibnu Ruslan (Shafie School of Thought) in Sunan Abu Daud, the use of medicine mixed with najis besides alcohol in emergency situations is permissible (Ab Halim et al., 2015) which najis could be from Haram or Mashbooh sources. Based on the chapter 2, verse 173 from the Quran, 'Haram' or 'Mashbooh' substances are allowed in moderate amount if there is no other alternative and in emergency or as a last resort to save from death if for example the person are left with no choice between death and taken the medicine to survive (Ab Halim et al., 2015; Abd. Aziz et al., 2014).

He hath only forbidden you dead meat, and blood, and the flesh of swine, and that on which any other name hath been invoked besides that of Allah. But if one is forced by necessity, without wilful disobedience, nor transgressing due limits- then is he guiltless. For Allah is Oft-forgiving Most Merciful (2:173).

In spite of that, when it comes to the matter of darurah where a person does not have any Halal food or drink that can be consumed and the only available to him is Haram which can make him survive and shunned from greater danger and death, the concept of darurah is mostly agreed upon by the jurists of all school of thought in general. Hence, by all of unnecessary means, the use of unlawful substances or intoxicants could never be tolerate. This stance is based on an authentic tradition of the Prophet when asked about using intoxicants for medical purposes, then he replied, "it is not medicine, but an ailment". It show an absolute no to the use of any unlawful materials for medicinal purposes in that ultimatum without mentioning any exception to any particular situation (Mohd Zarif et al., 2013).

6. Issues on Ingredient in Pharmaceutical Products

Along with the advancement of science and technology, the raw materials or ingredients can be obtained from many different sources (Pandagel, Waranuch, & Plianbangchang, 2013). It explains for the products which are in need of raw materials or ingredients in the formulation. This is why Islam is very particular when it comes to the matter of raw materials or ingredients. However, Halal is not only about foods or beverages but also a big matters to the pharmaceuticals which supposed to come from Halal, clean and healthy sources because they are something people eat or consume (Afifi et al., 2014).

Nowadays, many medicines have issues on the ingredients which it could made out of Haram or unknown sources as the advancement of time and science, various innovative discoveries were made to increase the quality of human life through various methods in genetics and medical biotechnological engineering. This includes the use of any material, including the forbidden ones for the Muslims, in critical diseases and treatment of thrombosis, heart surgery, hemodialysis as well as critical medicinal products particularly in the forms vaccines, antibiotics, health supplements and so on (Mohd Zarif et al., 2013). Furthermore, there are certain medicinal products which are both porcine and bovine-based used in certain medical treatment. Porcine-based medicine is derived from Haram material for the Muslims whereas the bovine derived medicine is permissible for their use. Although products can contain ingredients derived from animals (except non-Halal animals), these have to be prepared according to Shariah law which have its own procedures for slaughtering and preparing animals (Sarriff & Abdul Razzaq, 2013).

While many additives and ingredients can be clearly identified to be Halal or Haram, there are others which are not so clear. Substances of this kind are questionable and doubtful, and more information may be needed to categorize them as either Halal, Haram or Makruh (Kamali, 2013). Shabana (2013) stated that sources of ingredients like heparin, gelatin, ethanol, glycerin, glycerol and the enzyme trypsin are mostly non-Halal derived. Other ingredients like stearates, (magnesium, calcium and stearic acid) are generally sourced from lard or fatty acids from pigs' stomachs and are used as lubricants and binders, although they can also be derived from vegetables. Thus, aforementioned sources of ingredients are amongst the common Mashbooh ingredients used in pharmaceutical products.

7. Conclusion

In a nutshell, there are various kinds of ingredients found on the labels of products at the market places in Malaysia. However, as Muslims we should know if the ingredients we see on the label are Halal, since they are possibilities of obtaining it from either animal, plant, microbial, or synthetic sources. There are conditions to be adhered as stated in the Shariah guidelines in order to ensure the permissibility of medicine or pharmaceutical products which are mixed with alcohol and gelatin in treating disease during emergency cases. Therefore, it is important to Muslim consumers to have knowledge about the common Mashbooh ingredients used in pharmaceutical industry in order to assist them in choosing the Halal and safe medicines and pharmaceutical products without any hesitation.

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