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Abstract

Muslim consumers have special needs in medical treatment that differ from non-Muslim consumers. In particular, there is a growing demand among Muslim consumers for Halal medications. This descriptive exploratory study aims to determine the Halal status of selected cardiovascular, endocrine, and respiratory medications stored in an out-patient pharmacy in a Malaysian governmental hospital. Sources of active ingredients and excipients for each product were assessed for Halal status based on available information obtained from product leaflets, the Medical Information Management System (MIMS) website, or manufacturers. Halal status was based on the products' sources and categorized into Halal, Mushbooh, or Haram. The proportions of Halal, Mushbooh, and Haram products were at 19.1%, 57.1%, and 23.8%, respectively. The percentage of active ingredients for cardiovascular/endocrine products that were assessed as Haram was 5.3%; for respiratory medications, it was only 1.1%. For excipients, 1.7% and 4.8% fall under the category of Haram for cardiovascular/endocrine products and respiratory products, respectively. Ethanol and magnesium stearate were found to be the common substances that were categorized as Haram and Mushbooh.

Keywords: cardiovascular drugs, endocrine drugs, ethanol, halal, magnesium stearate respiratory drugs

Introduction

In Islam, the Holy Quran provides rules and regulations to guide its followers. A verse from the Quran states: "Let the human reflect on the food he eats (80:24)." This means that a Muslim who adheres to the Islamic religion is watchful and restrained in his behavior. Every Muslim should be careful with all of his/her actions, no matter how trivial. A Muslim must know what is permitted and what is not. In Islam, prohibitions are specified either by a verse of the Quran or an authentic and explicit Sunnah of Muhammad, peace be upon him (PBUH). These rules of Shariah (i.e., Islamic law) give Muslims the freedom to eat and drink anything they like as long as it is not *Haram* (prohibited).

Alcohol, for instance, can lead to addiction, misbehavior, and negative impacts on health; thus, it is judged *Haram* for the Muslim. Pigs or any animals that were not slaughtered based on Islamic rules, as well as anything unhealthy or which could cause disease or death, are also considered *Haram*. On the other hand, any substances including foodstuffs and medicines that are permissible and lawful to be consumed are classified as *Halal*. This also applies to other products including pharmaceuticals, cosmetics,

and personal care products. The term likewise, applies to personal behavior and interaction with the community. Other substances whose origins are questionable or doubtful, and that fall between the two extremes, are classified as *Mushbooh* (1–4). The term applies to situations wherein scholars' opinions differ on whether a product is Halal or Haram, or when there are undetermined ingredients in a particular product.

Halal Pharmaceuticals

The aspects of Halal and Haram should be a determining factor in every Muslim's actions and decisions to consume products, including medicines. The term 'Halal pharmaceutical' includes pharmaceutical products which may contain more than one active ingredient and various types of excipients. Halal pharmaceutical products should not only be free from Haram constituents, but they should also be *Tayyib*, a term given to goods and products which meet quality standards. The term *Tayyib* refers to a particular good or product that is clean, pure and produced based on standard processes and procedures. Thus, a pharmaceutical product should not only be Halal but should also be judged clean according to Shariah law.

Muslims who are directly engaged in

manufacturing, distributing, dispensing, and prescribing medications are responsible for ensuring that pharmaceutical products are Halal and Tayyib (5). This is an extremely challenging task in food production. It is possible that some people believe that medicines are vital and that Haram substances may be used in certain circumstances as they were permitted and tolerated in Islam. The lack of awareness and knowledge of Halal status of medications among Muslim consumers and patients could be the root of this complex issue related to the concept of Halal-Tayyib pharmaceuticals. Therefore, in-depth study and search for Halal and Tayyib pharmaceuticals is not only the responsibility of an individual (*fardhu ain*) but also the responsibility of the experts and the community (*fardhu kifayah*).

These days, increased attention is given to the Halal status of the food that Muslims consume. This is an important part of Islamic practices and faith. Similarly, Muslim consumers and patients are showing a growing interest in references concerning the Halal status of pharmaceuticals (6). Therefore, this study was undertaken in order to explore the Halal status of commonly used cardiovascular, respiratory, and endocrine categories of medications. The Halal status was determined for both the active ingredients and excipients contained in the dosage form of products that were assessed.

Materials and Methods

A descriptive and exploratory study was conducted from September 2009 to March 2010 at a government hospital in the Northern part of the Malaysian Peninsula. Pharmaceutical products in the categories of cardiovascular, respiratory, and endocrine medications that were available at the out-patient pharmacy at the time of this study were selected. Patients were not involved in the study as all data were collected from the evaluations of pharmaceutical dosage forms. The available product leaflets were sorted to list all the active ingredients and excipients. The official website of Medication Index for Malaysia and Singapore (MIMS) was referred to for additional information. The product's manufacturer was contacted if the necessary information was not found in the product's package insert and was not stated in MIMS.

The Halal status was categorized as Halal, Mushbooh or Haram. This was primarily based on information regarding the sources of the product's active ingredients and excipients. Similar to food products, the sources of all the ingredients—both

active ingredients and excipients—used in the formulation of a particular dosage form must be a Halal substance. The Halal status of all the ingredients used in the formulation of a particular dosage form was based on whether it is from animal source or whether it contains alcohol. Other aspects such as potential harmfulness and hygiene of the preparation processes were not taken into consideration.

Ethical approval was not required but permission was granted by the hospital authority for data collection from the product package inserts. The data were computed and analyzed using Statistical Package for the Social Sciences (SPSS) version 18 and descriptive analysis was conducted.

Results

Out of 221 pharmaceutical products in the categories of cardiovascular, respiratory and endocrine medications, only 63 were suitable for assessment of the Halal status. These products contained a total of 240 active ingredients and 570 excipients. Lack of information about the product's constituents was the main factor hindering the identification of the Halal status. Furthermore, majority of the manufacturers were not cooperative in providing detailed information about their products.

Injections and tablets comprised 49.2% and 28.6%, respectively, of the dosage forms. The assessment of the Halal status for the various types of dosage forms is shown in Table 1. The distribution of products categorized as Halal, Mushbooh and Haram is depicted in Figure 1. The distribution of Halal status for cardiovascular, endocrine and respiratory medications is presented in Figure 2.

The Halal status could not be assessed for 73 out of 240 active ingredients. This was due to the difficulty in obtaining accurate information related to their origins. The percentage of active ingredients categorized as Halal, Mushbooh and Haram was 83.8% (140), 13.2% (22), and 3% (5), respectively. The distribution of Halal status for the combination of cardiovascular and endocrine medications as well as for respiratory medications is presented in Figure 3.

Out of 570 excipients, 54 could not be evaluated due to lack of information. The distribution of Halal, Mushbooh and Haram was at 70% (361), 27.3% (141), and 2.7% (14), respectively. The distribution of Halal status for excipients contained in cardiovascular, endocrine and respiratory medications is presented in Figure 4.

Table 1: Distribution the Halal status of dosage forms

Dosage forms	Halal	Mushbooh	Haram	Total
Tablet	4	11	3	18
Injection	8	18	5	31
Capsule	-	2	-	2
Inhaler	-	1	5	6
Syrup	-	-	2	2
Nasal spray	-	2	-	2
Drop	-	1	-	1
Powder	-	1	-	1
Total	12	36	15	63

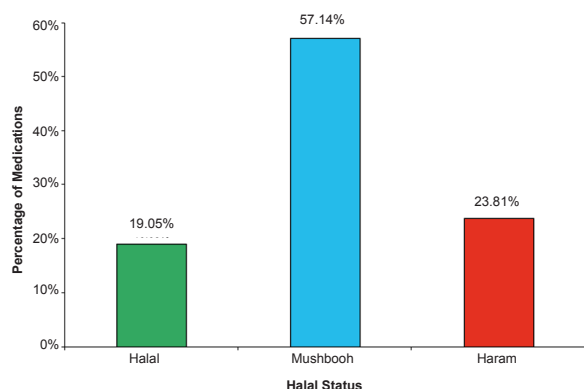


Figure 1: Evaluation of the Halal status of medications.

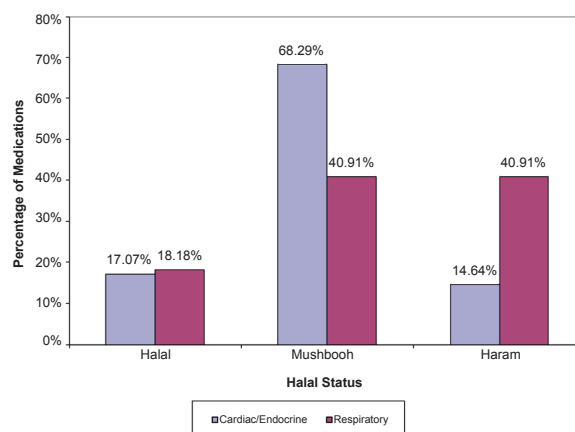


Figure 2: Evaluation of Halal status of the combination of cardiovascular and endocrine, and respiratory medications.

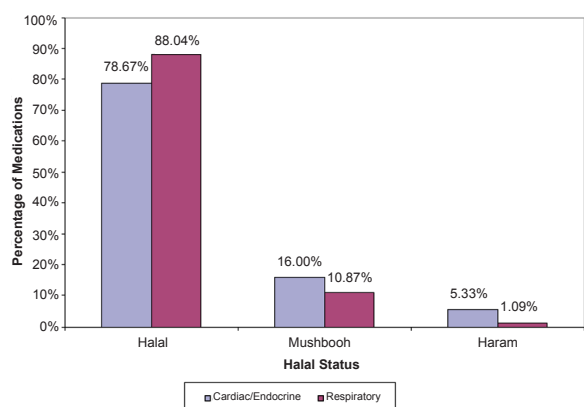


Figure 3: Evaluation of the Halal status of active ingredients found in the combination of cardiovascular and endocrine, and respiratory medications.

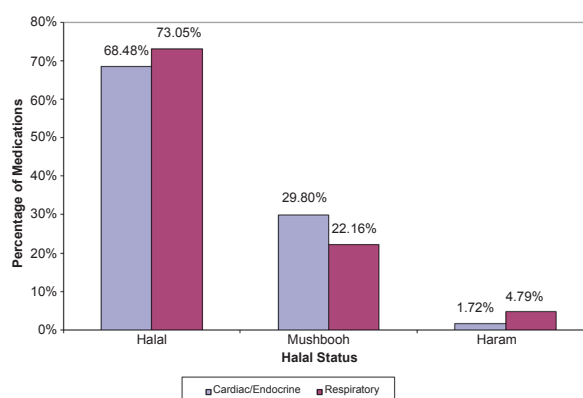


Figure 4: Evaluation of the Halal status of excipients found in the combination of cardiovascular and endocrine, and respiratory medications.

The most common types of ingredients that were categorized as Haram and Mushbooh are listed in Table 2. Most of the Haram substances had ethanol, which was used particularly in the formulation of respiratory medications. The most common substance categorized as Mushbooh was magnesium stearate, followed by gelatin and glycerol.

Discussion

Until recently, there were no specific guidelines available in the local context for patients and healthcare providers in understanding Halal medications. There are numbers of websites, documents and guidebooks dedicated for consumers to describe and explains issues

Table 2: Common non-Halal ingredients used in formulations

Mushbooh (n = 163)	Haram (n = 19)
Monobasic sodium phosphate (3)	Heparin sodium (5)
Polysorbate (9)	Ethanol (13)
Abciximab (1)	Beractant (1)
Magnesium stearate (30)	
Dibasic Calcium Diphosphat (3)	
Adrenaline (1)	
Lactose (5)	
Polyethylene glycol (4)	
Polyoxyl hydrogenated castor oil (4)	
Cholecalciferol (1)	
Amrinone lactate (1)	
Gelatin (12)	
Glycerol (11)	
Macrogol (4)	
Stearic acid (3)	
Triacetin (4)	
Dopamine (2)	
Metacresol (7)	
Disodium phosphate dehydrate (5)	
Nitroglycerin (2)	
Sodium starch glycolate (6)	
Indigo carmine (6)	
Sodium glutamate (5)	
Spirolactone (1)	
Thyroxine sodium (2)	
Beclomethasone dipropionate (8)	
Sorbitan trioleate (7)	
Propylparaben (5)	
Oleic acid (6)	
Dibasic sodium phosphate dehydrate (1)	
Aprotinin (1)	
Sodium biphosphate (3)	

related to Halal foods (7,8). This study, aimed to fill the gap in literature on Halal medications by highlighting the Halal status of medications used for the treatment of cardiovascular, respiratory, and endocrine problems.

It is important to note that the Halal status of the active ingredients and excipients of a particular dosage form was based on animal or alcohol source. Halal status is dependent on the nature of the product and how it was made, among others. Other aspects such as potential harmfulness and the hygiene of preparation processes were not taken into consideration. These aspects are normally addressed by competent authorities such as the Halal certification body and State Islamic Religious Department or Council. Competent certifying authorities examine all materials and processes used in the production of the pharmaceuticals. The safety and hygiene aspects of the manufacturing process need serious consideration as there are reports related to ethical issues pertaining to the use of dead materials (slaughtering and using of animals not based on Shariah law) in products (9). Some Islamic governments have even started asking pharmaceutical companies about the labelling of their products and the sources of their ingredients. The Competition Commission of Pakistan (CCP) has mandated that all pharmaceutical companies that supply the meningitis vaccine use only Halal materials (10).

In the last decade, awareness of Muslims on the use of Halal medications has improved (11–19). Several local studies on this issue have been published (20,21). Most recently, the Department of Standards Malaysia, in collaboration with religious authorities and university researchers, produced a final draft of the Malaysian Standard related to Halal Pharmaceuticals, known as MS 2424. This Malaysian Standard describes the general guidelines in the manufacturing and handling of Halal pharmaceuticals. It serves as a basic requirement for Halal pharmaceuticals in Malaysia (22). The MS 2424 can be considered as a starting point for the certification process of pharmaceutical products. However, the standard does not necessarily contain all the requirements for certification. Halal certification may be sought by fulfilling the requirements set by the competent Islamic authorities in Malaysia. The manufacturers have to furnish the authority with complete information on their products needed for Halal certification. Similarly, in the UK and in the US, pharmaceutical companies are mandated by their governments to provide full information about their products (23).

When it comes to religious matters related to medicines, especially Halal-Haram, there is a wide divergence of opinion which could be a recipe for controversy. Thus, some truths on the Halal status of pharmaceuticals need to be highlighted. For instance, majority of pharmaceutical products contain some constituents of ethanol and animal derivatives, which cannot be considered Halal. Although products can contain ingredients derived from animals (except non-halal animals), these have to be prepared according to Shariah Law which dictates procedures for slaughtering and preparing animals.

An example of an ingredient which is not Halal is dibasic sodium phosphate, which originates from several sources including animal bones or bone ash. Likewise, aprotinin is obtained from bovine lung, and the animal is most likely not slaughtered according to Islamic instructions. Similarly, other compounds such as beractant, sodium biphospahte and sodium phosphate dehydrate are of bovine origin and it is unsure whether the manufacturer complies with Shariah Law during the processing of these substances. Since there is no definite information and consensus on this matter, these substances are categorized as Mushbooh.

It was a challenge to convince the manufacturers to furnish detailed information regarding the sources of substances used in the formulation of pharmaceutical products. As shown in Table 1, some formulations in tablet form were categorized as Haram for this reason.

Conclusion

This exploratory study provides insight into the issue of Halal status of cardiovascular, respiratory, and endocrine medications. As highlighted earlier, 23.8% of products surveyed were categorized as Haram, while more than half (57.1%) were evaluated as Mushbooh. It adds to the existing research needed to meet the Halal requirements of the Muslim community in consuming Halal pharmaceutical products containing chemical substances. As there are few references on the topic, there is a need for further investigation and exploration for alternative products.

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