



HALAL PHARMACEUTICALS: LEGAL, SHARI'AH ISSUES AND FATWA OF DRUG, GELATINE AND ALCOHOL

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ABSTRACT

Halal products are fast gaining worldwide recognition as a new benchmark for safety and quality assurance. Products with halal certification are confidently accepted by consumers especially Muslims as well as those of other religions. Undoubtedly halal product industry has been an emerging industry in Malaysia and all over the world. Recognizing the new concept of halal industry presents an opportunity for manufacturers to make better strategies and innovations in producing their products toward halal certification. Today, halal products are not focused only on food but all products including pharmaceuticals. Since most of Malaysian population are Muslim, the Malaysian Standard on halal pharmaceuticals has been launched to ensure that manufacturers comply with the standard to produce them. The methodology of this study is by researching on legal, Shari'ah issues and the fatwa related to pharmaceuticals such as usage of drug, gelatine and alcohol in pharmaceutical products. Apart from that, this paper also looks into the Malaysian Standard of Halal Pharmaceutical - General Guidelines, 2010 and other policies and regulations which have been set by the government. The finding shows that there is an unresolved issue of Shari'ah for pharmaceutical products due to the different opinions of fuqaha'. However, there are also many policies and guidelines on halal pharmaceuticals in Malaysia which are good for Muslim consumers.

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Keywords: Halal, Halal pharmaceuticals, Shari'ah law, Regulation, Halal standard, Fatwa, Drug, Gelatine, Alcohol.

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Contribution/ Originality

This study is one of very few studies which have investigated the drug, gelatin and alcohol which has been used in Halal pharmaceutical from legal and Shari'ah perspective.

1. INTRODUCTION

Malaysia is a country that has a majority Muslim population. In spite of their geographic and ethnic diversity, Muslims follow their beliefs and the religion of Islam. Halal is a very important and integral part of religious observance for all Muslims. Hence, halal constitutes a universal standard for a Muslim to live by. However, the standard and halal certification used all around the world are different due to the disagreement over animal feed, slaughtering methods, packaging, logistics and other issues (Ab Halim and Mohd, 2012). This paper will study on the issue related to Halal pharmaceutical by looking at the legal, shari'ah issues and fatwa related to this issue.

By definition, halal foods are free from any component that Muslims are prohibited from consuming. 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 (Halal Group Industries PLC, 2011). Meanwhile haram means something that is prohibited in Islam. Consequently, almost all foods of plant and animal origin are considered halal except those that have been specifically prohibited by the Quran and the Sunnah (the life, actions, and teachings of the Prophet Muhammad). Using the same equipment and utensils as regular food, with a few exceptions or changes, can process halal food. Similar to halal food, halal pharmaceuticals are supposed to come from halal, clean, and healthy sources because they are something which are eaten or consumed. According to the Quran verse:

O ye who believe! Eat of the good things where with we have provided you, and render thanks to Allah, if it (indeed) He whom ye worship (Al-Quran, 2: 172).

Halal has been a long debated issue due to the reason of its complexity as a result of rapid expansion in innovation and technology (Ab Halim, 2013; Mohd Salleh and Ab Halim, 2013). Accordingly, 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) .

Several factors determine the halal or haram status of a particular product. This depends on its nature, how it is processed, and how it is obtained. Then we also must look at the ingredients, to ensure it does not contain any prohibited ingredients. Food and drink that are poisonous or intoxicating are obviously prohibited even in small quantities because they are harmful to health.

There is a staggering multi-billion dollar industry, which is currently untapped. The increasing number of Muslim around the world estimated around 1.8 billions in 2011 and the demand for halal product that is growing significantly make the halal market outstanding (Ab Halim and Ahmad, 2014) Outside of herbal and organic health food supplements, a majority of pharmaceuticals and medicines are not Halal-compliant (Halal Group Industries PLC, 2011).

Medicines containing alcohol would be considered Halal if there were no suitable alternatives available. It should be noted that only ethyl alcohol such as methylated spirits and ethanol, the alcohol found in alcoholic drinks, are intoxicating and are therefore haram. Other forms of alcohol (such as sterile) are not intoxicating. These types of alcohol will not be found in any food or drink due to the fact that they are generally poisonous, but it is a point worth bearing in mind when buying household goods containing these. Some medicines and supplements also use gelatine as part of their capsules. It is permissible to use these, if the gelatine is halal unless stated otherwise. If the medicine comes without label and the sickness is critical, the medicine can be used only if there are no suitable alternatives.

As a way to control use of non-halal elements in food and pharmaceuticals, Malaysia Standard provides to the food manufacturers HACCP and GMP with guidance in product processing in order to satisfy *Shari'ah* requirements. In other words, the Malaysian Standard provides the general guidelines on production, preparation, handling and storage of halal products that have been gazetted by the government, including for pharmaceutical products. The issue of certification is central to the global acceptability of halal products (Habibah *et al.*, 2008).

2. DEFINITION OF PHARMACEUTICALS AND DRUGS

Pharmaceutical is related to making and selling drugs and medicines (Oxford Advanced Learner's Dictionary, 1088). The study of drugs is known as pharmacology (Ishaq, 1997). It is about the study of manner in which the function of living tissues and organisms is modified by chemical substances (Ishaq, 1997). Pharmacology also related to study the effect of chemical agents on living process. Due to the latest technology, it is possible to use certain compounds from animal, for example worms in the making of pharmaceutical products due to its high protein and other minerals, which is benefited for the human being (Mohd Salleh and Ab Halim, 2013).

Drug is a word, which comes with certain aspects and purposes. It is known as something negative, dangerous and should be avoided. The word '*dadah*' is used only in Malaysia, while in Germany, Spain and France, drug is known as '*rauschmitter*', '*estupeciente*' and '*drogue*' respectively (Abdul Ghafar Taib, 1989).

2.1. Drug as Medicine

Generally drug means any substance that people use to cause the exchange of function and/or structure of organism physiology (Abdul Ghafar Taib, 1989). However, for the medical purpose the use the word '*dadah*' is not allowed but it is called as '*ubat*' (medicine) even though some of these substances for medical purposes are misused (Abdul Ghafar Taib, 1989).

2.2. Types of Drugs (Abdul Ghafar Taib, 1989)

There are four types of drugs:

- (a) Stimulant
- (b) Depressant
- (c) Hallucinogen
- (d) Narcotic (Opiate)

(a) Stimulant (Abdul Ghafar Taib, 1989)

Stimulant is a chemical substance that stimulates the nerve system which stimulates the brain. It makes someone eager to speak and happy (high). In addition, it also makes someone to sleep less and feel more confident. Usually, those who take this drug are mostly students. If someone takes an overdose of stimulant, they will lose consciousness or faint.

Among stimulant drugs are:

1. Natural: Cocaine, caffeine, Epinephrine (Adrenalin) and Ephedrine.
2. Synthetic: Amphetamines (Benedrine, Dexedrine, Methedrine) and Phenmetrazine (Preludin)

(b) Depressant (Abdul Ghafar Taib, 1989)

In medicine, this drug is used to treat insomnia patients. It causes drowsiness. Another effect of this drug is it makes people feel intense happiness and excitement (euphoria). However, it intoxicates if taken excessively.

Among depressant drugs are:

1. Natural: Cucare
2. Synthetic: Barbiturate, tranquilisers (Librium, valium) and methaqualone (mandrax)

(c) Hallucinogen (Abdul Ghafar Taib, 1989)

Hallucinogen is a drug or chemical substance that causes hallucination. Users of this drug see colours brighter than usual and hear music more intense and meaningful.

Among hallucinogen drugs are:

1. Natural: cannabis, peyote (Mescaline), hallucinogenic mushrooms (Psilocybin), Morning Glory seeds.
2. Synthetic: Lysergic Acid Diethyl amine (LSD), Diethyltryptamine (DET), Dimethyltryptamine (DMT), STP (Dom), and Phencyclidine.

(d) Narcotic (Opiate) (Abdul Ghafar Taib, 1989)

This type of drug is the most dangerous drug and known as opiate. There are a lot of abuses of these drugs. It is medically used to cure sickness and potentially a cause of addiction. Some narcotics like opium, heroin, morphine and codeine are obtained from poppy plants and available in the Middle Eastern and Asian countries. Meanwhile, methadone and pathidine are human-made synthetic narcotics.

Among the narcotics are:

1. Natural : Opium (*candu*), heroin, morphine, cocaine
2. Synthetic: Pathidine (mepuidine demerol), methadone (dolophine).

Generally, all medicine is risky when used. However, according to scientific evaluations, the risk outweighs the benefit obtained from the health aspect (Lokman, 2001). Abuse of the medicine arises when the medicine is used for purposes other than treatment.

So, drugs for medical purposes are called medicine, being a material used for treatment in order to relieve, nurse, cure or to prevent illness in human and to increase their hygienic level (Lokman, 2001). It can be used in many ways and forms. Not only can medicine be eaten or drunk but it can also be used in many ways such as through the anus (suppository), vagina, injection, implanted under the skin, or applied onto the skin as cream or ointment (Lokman, 2001).

Prophet Muhammad (p.b.u.h) said that every disease has its antidote. Base on the hadith (Jabatan Mufti Brunei Darussalam):

لكل داء دواء فإذا أصيب دواء الداء، برأ بإذن الله عز وجل

“Every illness has a cure, and when the proper cure is applied to the disease, it ends it, by the permission of Allah Azza wa Jalla”(Hadith narrated by Muslim)

Abu Dawud narrated from Usama Ibn Shareek who said; ‘I approached the Prophet (saw) and his companions, they appeared as if they had birds sitting on their heads, I extended my greetings and sat down, then many Bedouins came from here and there and asked: ‘O Messenger of Allah, should we seek medicine?’ He said:

”تَدَاوُوا فَإِنَّ اللَّهَ عَزَّ وَجَلَّ لَمْ يَخْلُقْ دَاءً إِلَّا وَضَعَ لَهُ دَوَاءً، غَيْرَ دَاءٍ وَاحِدٍ الْهَرَمُ، أَي «إِلَّا الْمَوْتَ»

“Yes, O slaves of Allah, seek medicine, for Allah has not created a disease except that he has also created its cure, except for one illness.’ They said, ‘And what is that?’ He said, ‘Al-Haram’ [death]” I.e. except for death (Hadith narrated by Abu Dawud)

3. THE *HUKUM* (ISLAMIC VERDICT) OF MEDICINAL USE OF DRUG

There are various *fatwas* with regards to this issue as outlined in the following:

3.1. Scholars

There is no *hukum* or rule in the Quran or Hadith which directly forbids or allows the use of drug. However, generally Islam prohibits its followers from doing something which can damage themselves. Some scholars agree that the *hukum* of drug is the same with that of liquor, which is forbidden to be used. They used the juristic reasoning by analogy (*qiyas*) using the verse in the Holy Quran, (Abdul Ghafar Taib, 1989).

يَا أَيُّهَا الَّذِينَ آمَنُوا إِنَّمَا الْخَمْرُ وَالْمَيْسِرُ وَالْأَنْصَابُ وَالْأَزْلَامُ رَجْسٌ مِنْ عَمَلِ الشَّيْطَانِ فَاجْتَنِبُوهُ لَعَلَّكُمْ تَفْلَحُونَ

“O ye who believe! Intoxicants and gambling, (dedication of) stones, and (divination by) arrows, are an abomination— of Satan's handiwork: eschew such (abomination), that ye may prosper” (Al-Quran, 5: 90. Translation by Yusuf Ali).

However, the four scholars Hanafi, Maliki, Shafie and Hanbali, did not mention any *hukum* related to drug use because it did not exist during their period and only appeared circa 106 or 107 A.H. from the commencement of the Government of Tartar (Abdul Ghafar Taib, 1989).

3.2. Fatwa in Egypt

According to a *fatwa* decided by the *Mufti Al-Diar Al-Masriah Al-Sabiq* (former *Mufti* of Egypt) and Al-Syeikh Hasanin Makhluf in his book '*Fatwa Al-Syari'ah*', page 184 said, drug is forbidden to be used, to be given, to be sold and to be traded. It is also agreed by the Hanafi and Shafie school of jurisprudence and Al-Syeikh Al-Islam Ibn Taimiyah from the Hanbali *mazhab* (Abdul Ghafar Taib, 1989).

3.3. Fatwa in Malaysia

The Council of Rulers in its 126th meeting held on 24 February 1983 approved the opinion of the Fatwa Committee, *Majlis Kebangsaan Bagi Hal Ehwal Agama Islam* (The National Council for Islamic Affairs), Malaysia on the drug problem, and decided the following (Abdul Ghafar Taib, 1989):

“Any misuse, including the abuse of drugs according to *Shari'ah* is forbidden and drugs can only be used for medical purposes approved by the *Shari'ah*.” However, prior to its use, an advice from experts like a doctor must be obtained, and its use must be based on the dosage approved by the doctor (Harmy, 2011). The use of drugs is permitted based on the following *fiqh* principles (Harmy, 2011):

1. الضرورات تبيح المحظورات

"Necessity knows no laws"

2. إذا تعارضت مفسدتان روعي أعظمها ضررا بارتكاب أخفهما.

When there is conflict between two things that can cause damage, the greatest damage has to be taken into account by committing the less damage

4. ISSUES REGARDING THE USE OF GELATINE AND ALCOHOL IN PHARMACEUTICAL PRODUCTS

To discuss on the gelatine issue, the authors will define the meaning of gelatine and the issues related to it.

4.1. What is Gelatine?

Nowadays, there is an issue of some pharmaceutical products containing gelatine. Gelatine is a clear substance used for making jellies (Longman Active Study Dictionary of English, 1991). It is derived from the collagen of tissues by boiling them in water. It swells up when put in cold water but dissolves in hot water (Ishaq, 1997). It has been used hypodermically as a haemostatic and to promote coagulation in certain cases of disorders (Ishaq, 1997). It has been stated that gelatine does not collapse at extreme temperatures, either the lowest degrees 0°C or at 100°C (Harmy, 2011). Gelatine consists of 84-90% original protein, 2% mineral and the balance is water (Harmy, 2011). It does not have cholesterol, preservatives, Arabic gum, or locus gum that consists of carbohydrate. Among its names are halal gelatine, bovine gelatine, gum base, emulsifier and E441 (Harmy, 2011). In the industry of pharmaceuticals, gelatine is used to make soft gel capsules,

tablets and serums and also used in injection (Harmy, 2011). There are two types of gelatine (Harmy, 2011):

1. Type A: Obtained from porcine animals or non-halal animals which are mainly pigs. This type of gelatine if processed and mixed with acid can produce a large amount and with good quality.
2. Type B: Obtained from bones and skins of cows and buffaloes which are processed in a mixture with alkali or lime water.

Muslims should find other alternatives for halal sources of gelatine like Vegicaps Soft which comes from plant sources for drug capsules (Harmy, 2011).

4.2. Gelatine Issue

Currently, Holista Colltech (Australia) Ltd., a biotechnology company owned by Malaysia, is trying to develop a method to commercialise a process of extracting collagen from skin of *tilapia* as a halal source of gelatine (Suffian, 2011).

According to the Chief Executive of Holista Colltech, Dato' Rajen M (Suffian, 2011):

“The fish is suitable to make gelatine, however because of that chemical bond is not as strong as the pig's chemical bond, so they have to make a research and development on that source. He said that their scientists are working hard to make the chemical bond of that gelatine to be as strong as pig gelatine chemical bond”.

“He also said that, the global market of gelatine is AS\$ 2.2 billion with an average 400,000 tonnes of gelatine produced per year. From that sum, 46% is made of pig and only 0.7 % is made of halal gelatine. So, Holista Colltech is now trying to find local investors to set up facilities for extracting the world's first halal collagen in Malaysia.” Besides that, a study done by the Ministry of Science, Technology and Innovation showed that out of 15 samples of pharmaceutical products taken randomly, three are wrapped with gelatines which are tested positive for pig DNA (Sakina, 2011). The DNA was tested by using a diagnosis kit, produced by a local multinational company in an effort to develop halal standard products in Malaysia through a pioneer project with the Ministry (Sakina, 2011).

According to the Minister in Prime Minister Department, Dato' Seri Jamil Khir Baharom, there are many manufacturers of health products which do not apply for halal certificate from JAKIM or JAIN and only 20 supplement product manufacturers and 14 traditional medicine manufacturers obtained halal certificate from JAKIM (Sakina, 2011).

5. FATWA REGARDING THE USE OF GELATINE AND ALCOHOL IN PHARMACEUTICAL PRODUCTS

There are various *fatwas* related to the use of gelatine and alcohol in pharmaceutical products.

5.1 National Fatwa Committee of Malaysia

The National Fatwa Committee in its 8th meeting in Kota Kinabalu, Sabah on 24 & 25 September 1984 discussed the issue of gelatine in medicines and decided as following (Jabatan Kemajuan Islam Malaysia, 2010):

“The use of gelatine in medicine currently is permissible because of emergency. If there is any halal element which can replace the use of gelatine then is forbidden to use gelatine in the medicine.” The skin of pigs, cows, and the bone of animals are the main elements to produce gelatine. According to the Raymond and Donald (1960), most of Type A gelatine (acid process) produced by the United States are made from pig skins. Meanwhile in Europe, the skins and the bones of cows are used to make the gelatine.

According to the majority of the scholars, the use of forbidden substances or mixing with the *najs* for medical purposes is prohibited. However, the use of medicine mixed with *najs* besides alcohol in emergency situations is permissible according to Ibnu Ruslan (Shafie *mazhab*) in *Sunan Abu Daud*, based on the *Hadith al-Urniyyin* narrated by Imam Bukhari and Muslim, whereby Prophet Muhammad (p.b.u.h) asked his companion to drink the urine of camel. It showed that generally the urine is haram. However it is permissible during emergency period.

وقد فصل لكم ما حرم عليكم الا ما اضطررتم اليه

“He has explained to you in detail what is forbidden to you — except under compulsion of necessity” (Al-Quran, 6:119 , Translated by Yusuf Ali)

5.2 Fatwa of Brunei

Based on the *fatwa* of The State of Brunei, it was discussed about the mixing of medicine with alcohol and gelatine as follows (*Jabatan Mufti Brunei Darussalam*):

According to *Ensiklopedia Malaysiana (5/77)* and *Encyclopaedia Britannica (G.165)*, gelatine is used widely in the food industry and as the foundation of gelatinous food like jelly. It also functions as sweetener and used in the making of ice cream. A lecturer from the Faculty of Science, University of Brunei Darussalam said that originally gelatine comes from animals. However, *Ensiklopedia Malaysiana* states that plant gelatines are the same as animal gelatine in their function and they come from wheat gluten or other wheat (5/77). So it can be said that gelatine also comes from plants. If the gelatine comes from animals, then we must look at the condition of those animals. If it is halal like cow, we must ensure that it is slaughtered according to the *Shari'ah* law. However if it comes from pig, automatically it is forbidden to be used and known as *najs* (unclean).

If the gelatine comes from haram sources such as pig, or it is not slaughtered the halal animals according to *Shari'ah* law, the product is forbidden and *najs*. If it is mixed in medicines, the medicine becomes *najs* and is forbidden to use. Meanwhile, alcohol is a colourless liquid produced by two ways of processing. Firstly, it can be produced by fermentation, the main process to produce liquor and secondly by chemical substances, which is a process to produce alcohol from petroleum.

The product produced by this process is known as ethanol or ethyl alcohol. In the medical field, alcohol is used as an antiseptic and solvent. Methanol which is known as methyl alcohol or wood alcohol is poisonous (*Malaysiana: 1/277*). All scholars (Hanafi, Maliki, Shafie, and Hanbali) agreed that alcohol that comes from liquor is *najs* because it intoxicates, according to the Quran verse:

يا أيها الذين ءامنوا إنما الخمر والميسر والأصاب والأزلام رجس من عمل الشيطان فاجتنبوه لعلكم تفلحون

“O ye who believe! Intoxicants and gambling, (dedication of) stones, and (divination by) arrows, are an abomination— of Satan's handiwork: eschew such (abomination), that ye may prosper” (Al-Quran, 5: 90. Translation by Yusuf Ali).

In the *hadith* related by Abu Tsa'labah, he said:

انا نجاور أهل الكتاب زهم يطبخون في قدورهم الخنزير ويشربون في انبيتهم الخمر، فقال رسول الله صلى الله عليه وسلم : ان وجدتم غيرها فكلوا فيها واشربوا وان لم تجدوا غيرها فارحضوها بالماء وكلوا واشربوا

"We adjoin the people of the book while they cook pork in their pots and drink Khamr from their vessels." The Messenger of Allah صلى الله عليه وسلم said: "If you find others than drink and eat from them. If you do not find others, then rinse them with water and eat and drink." (Hadith narrated by Abu Daud) (Abu Daud Sulayman ibn al-Ash'ath, 1952). In that *hadith*, Prophet Muhammad (p.b.u.h) asked them to use other cask besides the cask which had been filled with liquor. However, if there is no other cask to be found they have to wash the cask used to fill the liquor before using it. It is because liquor is *najs* which is *najs mutawassitah*. According to the late Pehin Dato Dr Haji Ismail bin Umar Abdul Aziz (former *Mufti* of Brunei), treating diseases with the original liquor (*najs*) is forbidden unless it is mixed with other things. (Fatwa Series 34/70).

Ibnu Hajar commented in the *hadith*:

يجوز التداوي بحافر الميتة وعظامها بسائر النجاسات صرفها ومخلوطها الا الخمر فلا يجوز التداوي بصرفها ويجوز بمخلوطها.

“Should seek treatment by nail, carcass, bones and all sorts of *najs* either essence or mixtures, except liquor, should not be impregnated with a substance (*ain*) of wine, but had to mix it with other things.”

6. THE NATIONAL MEDICINE POLICY

Currently, it is estimated that 52 million people died in the year 1997, of which 40 million live in developed countries, caused by pneumonia, malaria, and tuberculosis (TB) (Ab Fatah Ab Rahman, 2006). According to the World Health Organization, by improving the access to current interventions for the spread of diseases and others, more than 10.5 million people can be saved a year until 2015 (Ab Fatah Ab Rahman, 2006). It has been reported that 2 billion people, which is approximately one quarter of the world citizen do not have access to basic medicines (Ab Fatah Ab Rahman, 2006). Subsequently, every country has to serve basic medicines to their citizen. The medicine does not necessarily have to be expensive, but should be adequate such as cheap affordable supplements like iron and folic acid which can decrease the death rate of pregnant women and babies from the lack of blood (anaemia) (Ab Fatah Ab Rahman, 2006). The National Medicine Policy (*DUK*) is one of the commitments to achieve the goal and a guideline to act in ensuring all the medicines are good quality, safe and effective. It is able to get with the lower price so that all people afford to buy it (Ab Fatah Ab Rahman, 2006).

6.1. Contents of National Medicine Policy

The policy consists of all the components including (Ab Fatah Ab Rahman, 2006):

1. The legal, guidelines and rules.
2. The choice of medicines.
3. The storage and contribution of medicines.
4. The guarantee of quality of pharmaceutical products.
5. The rational use of the medicine.
6. The economic strategy regarding medicines.
7. Monitoring and evaluation of DUK.
8. Research.
9. Development of human resource.
10. The technical contribution among countries.

6.2. Role of National Medicine Policy (DUK)

The National Medicine Policy (DUK) is needed to ensure that all people get the exact medicine for their need. Some people do not know how much medicine they must take such as paracetamol. Paracetamol (p-Acetylamino-phenol, Acetaminophen) is an analgesic drug which is increasingly encountered in overdose cases (Ishaq, 1997). In such patients, it may have fatal consequences, as a result of massive liver damage several days after ingestion. Paracetamol overdose can be treated with drugs such as cysteamine (Ishaq, 1997). The plasma level of paracetamol can be determined by gas-liquid chromatography, by its UV absorption spectrum following extraction, and by its colourimetric reaction with nitrous acid to form a yellow coloured nitrophenol (the Glynn and Kendal method) (Ishaq, 1997).

7. MALAYSIAN STANDARD OF HALAL PHARMACEUTICAL – GENERAL GUIDELINES

In Malaysia, to produce halal food, manufacturers must refer to the Malaysian Standard of Halal *Food* – Production, Preparing, Handling, and Storage – General Guidelines. There is also a Malaysian Standard for pharmaceutical known as Halal *Pharmaceutical* – General Guidelines to produce halal pharmaceutical products. It is the most current Malaysian Standard introduced by the Department of Standards of Malaysia in 2010 (Malaysian Standard, 2010). This standard was developed under the Malaysian Standard Development system under the wing of Department of Standardization Malaysia, Ministry of Science, Technology and Innovation of Malaysia to provide guideline for producer in preparing and handling halal product (Ab Halim and Nur Najihah Khipli, 2014).

In this standard, the Technical Committee on Halal Food and Islamic Consumer Goods consists of representatives from the following organization Department of Agriculture Malaysia, Department of Fisheries Malaysia, Department of Development of Malaysia, Department of Veterinary Services, Federal Territory Mufti Office, Federation of Malaysian Manufactures, Federation of Marketing Authority, Halal Industry Development Corporation Sdn. Bhd., Institute of Islamic Understanding Malaysia, Malaysian Agricultural Research and Development Institute, Malaysian Association of Standards Users, Ministry of Agriculture and Agro-based Industry,

Ministry of Domestic Trade and Consumer Affairs, Ministry of Domestic Trade, Cooperative and Consumerism, Ministry of Health Malaysia, Ministry of International Trade and Industry, Muslim Consumers' Association Malaysia, Royal Customs of Malaysia, SIRIM Berhad (Secretariat), SIRIM QAS International Sdn. Bhd. (Chemical and Consumer Section), Universiti Kebangsaan Malaysia, Universiti Putra Malaysia, Universiti Teknologi MARA, (Malaysian Standard, 2010).

The co-opted members are Department of Islamic Development Malaysia (Halal Hub Division), Malaysian Organization of Pharmaceutical Industries, Ministry of Health Malaysia (National Pharmaceutical Control Bureau), Ministry of Health Malaysia (Pharmaceutical Services Division), Pharmaceutical Association of Malaysia, Science University of Malaysia (Malaysian Standard, 2010).

The Halal Pharmaceutical – General Guidelines outlines the basic requirement for halal pharmaceuticals in Malaysia. This standard is referred for inspection by the Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products and Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products Annexes (Malaysian Standard, 2010).

7.1. The Contents of the Malaysian Standard of Halal Pharmaceutical – General Guidelines

Among the contents of Malaysian Standard of Halal Pharmaceutical – General Guidelines are:

(a) Halal Pharmaceutical

Pharmaceuticals referred in this standard are pharmaceutical products in 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).

Halal pharmaceuticals are products that contain ingredients permitted under the *Shari'ah* law and fulfil the following conditions (Malaysian Standard, 2010) :

- 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 *najs* 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 *najs* 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), e) or any other things that have been decreed as *najs* by *Shari'ah* law.

Najs according to *Shari'ah* law are (Malaysian Standard, 2010):

- 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 najjs.)
- e) *Maitah* or carrion or halal animals that are not slaughtered according to *Shari'ah* law and; *Khamar* and food or drink which contains or mixed with *khamar*.

Basically, for the medicine to be classified as permissible not only the resources used as medicine materials must be permissible, the material itself must be pure from filth according to *Shari'ah* law and used for legal treatment purposes. (Lokman, 2001)

فنداووا ولا تداووا بالحرام

So seek treatment, but do not use as medicine that which is *haram* (Hadith narrated by Bukhari)

Basically, alcohol is haram. The Prophet Muhammad (p.b.u.h) said

“Wine is a disease, which will not reduce illness, because it itself is an illness” (Late Maulana Mahmood Ahmed Mirpuri, 1998).

Therefore, it is considered wrong to use it even as medicine. However, in exceptional cases, it may be allowed if there is no other medication available or as a last resort to save from death. Similarly, anything haram may be allowed as a last resort if for example you are certain that if you do not eat it, you will die (Late Maulana Mahmood Ahmed Mirpuri, 1998).

To make something halal or haram, the criteria stated in the Quran as in *Surah Al-A'raaf* says (Late Maulana Mahmood Ahmed Mirpuri, 1998):

ويحل لهم الطيبات ويحرم عليهم الخبائث

“He allows them as lawful what is good (and pure) and prohibits them from what is bad (and impure)”(Al-Quran 7:157. Translation by Yusuf Ali)

Whatever has been made haram for us will have some harm and disadvantages, and scientific research has confirmed this. Alcohol was forbidden in three stages (Late Maulana Mahmood Ahmed Mirpuri, 1998):

Firstly, in *Surah Al-Baqarah*:

يسئلونك عن الخمر والميسر قل فيهما إثم كبير ومنافع للناس وإثمها أكبر من نفعهما

They ask thee concerning wine and gambling. Say: "In them is great sin, and some profit for men; but the sin is greater than the profit (Al-Quran 2:219. Translation by Yusuf Ali)

Secondly in *Surah An-Nisa*:

يأيتها الذين ءامنوا لا تقربوا الصلاة وأنتم سكرى حتى تعلموا ما تقولون

“O ye who believe! Approach not prayers with a mind befogged” (Al-Quran 4:43. Translation by Yusuf Ali)

Thirdly in *Surah Al-Maidah*:

يأيتها الذين ءامنوا إنما الخمر والميسر والأنصاب والأزلام رجس من عمل الشيطان فاجتنبوه لعلكم تفلحون إنما يريد الشيطان أن يوقع بينكم العداوة والبغضاء في الخمر والميسر ويصدكم عن ذكر الله وعن الصلاة فهل أنتم منتهون

“O ye who believe! Intoxicants and gambling, (dedication of) stones, and (divination by) arrows, are an abomination— of Satan's handiwork: eschew such (abomination), that ye may prosper. (90) Satan's plan is (but) to excite enmity and hatred between you, with intoxicants and gambling, and hinder you from the remembrance of Allah, and from prayer: will ye not then abstain? (Al-Quran 5:90-91. Translation by Yusuf Ali)

(b) Requirement for Halal Pharmaceutical

Furthermore, for the purpose of halal pharmaceuticals, some of the requirements shall be incorporated within Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products and Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products Annexes currently being enforced by the relevant competent authority (Malaysian Standard, 2010).

Among the requirements are (Malaysian Standard, 2010):

Halal Assurance System

It shall be appropriate for the manufacturing of halal pharmaceuticals and shall be ensured that:

- a) The pharmaceuticals are designed and developed in ways that comply with the requirements of halal and Good Manufacturing Practice (GMP).
- b) The production and control operations are clearly specified and Good Manufacturing Practice adopted.
- c) The processing line be operated for halal pharmaceuticals only and in the case of converting the processing line which contained or contaminated with *najs al-mughallazah* to a halal production line then the ritual cleansing method, refer to Annex A, by *Shari'ah* law shall be required.

Fundamentals for Halal Pharmaceutical in GMP

The requirements described in the PIC/S GMP Guidelines and PIC/S Annexes are integral and shall be referred for Halal Pharmaceuticals. The main control points are the source of materials and utilities that come into contact with the products.

The requirements to Good Manufacturing Practice (GMP) for Halal pharmaceuticals are listed in the Malaysian Standard

Halal Quality Control

Halal Quality Control is to ensure all materials used are halal compliant.

Personnel and Responsibility

- a) The organization shall ensure that there are sufficient qualified personnel available to establish and maintain a satisfactory Halal Assurance System.
- b) The organization shall establish a committee that is led by trained Muslim personnel around 2/3 Muslim quorums.

Training

Training is provided for all the personnel on the halal principles.

Sources

They are some medicinal resources, which are human resources, animal resources, plantation resources, land and water resources (Lokman, 2001).

Halal Certification and Halal Certification Mark

1. The competent authority in Malaysia, JAKIM, shall issue the halal certificate.
2. Upon approval by the drug control authority in Malaysia, each halal pharmaceutical may be marked with the halal certification mark of the Islamic authority.

8. CONCLUSION

As a conclusion the use of medicine mixed with alcohol and gelatine carries the same *hukum* with treating diseases with *najis* during emergency cases, which is permissible but with conditions as stated. There are many cases regarding the food and pharmaceutical products today. Many of the products have been produced because of the increasing population and decrease in the sources. The government should be aware of the offences made by the manufacturers so that we can restrain irresponsible manufacturers from continuously producing the products illegally. As pharmaceuticals are a highly regulated industry in most countries, healthcare marketers need to be aware of regulations in the countries where they sell the products. Health is the most important aspect that should be concerned. Consumption of bad products will have a bad impact to the body. People must be concerned with the medicine they take because wrong medicine can cause fatality. Currently there are many health and slimming products offered in the market. People should be careful because the product may not have the same effect to their body. Besides, some products allegedly can cause other health condition and some of them can cause fatality. Hence, health must start with taking a balanced and healthy diet.

The manufacturers must be aware of the material they use in their products to avoid any non-halal element, which may give bad impact to the consumers. The Malaysian Standard of Halal Pharmaceutical is the most important document that should be followed to standardize the quality and the safety of halal pharmaceutical products and to ensure that the consumers take the right medicine without any doubt about its permissibility.

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