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The Need for Legal Intervention within the Halal Pharmaceutical Industry

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Abstract

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. Pharmaceutical products are not categorized as certifiable under the current JAKIM’s Halal certification procedure Manual. Whether the medicines are halal certified or not, has not been made transparent. An overview of medicine and permitted drug supply in hospitals and clinics indicates that most of the pharmaceutical products supplied are not certified Halal. Simultaneously, Muslims and non-Muslims consumers are becoming more discerning and demanded the assurance that the medicines and health supplements are of the highest quality and halal certified. Shocking revelation was made in November 2009 where almost 30 per cent of 100 health products tested at Universiti Sains Malaysia's (USM) Pharmaceutical Science Studies Centre laboratory were found not to be halal as gelatin from bovine was used in making the product capsules. The objectives of this paper are firstly, to critically look into the role of law in governing the halal certified pharmaceutical products and secondly, to justify the need to review the current legal framework. This research embarks into a qualitative conceptual study. Primary data obtained from an in depth interview, statutes, rules and procedure from the Ministry of Health and JAKIM and Hansard is analysed. The secondary data is generated from statistics, annual reports and reliable article and book writings. The results suggest an appropriate reformation to the current legal framework and justifies the effort that should be geared towards formalising rules for the manufacture of halal medicines.

Keywords: Halal; Law; pharmaceutical product

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1. Introduction

Issue of Halal products has invited debates in various aspects of Muslim lives. Under the Shariah law the products that the followers consume, must be hygienic, pure, clean and of quality, or also known as ‘Halalan toiyibban’. The narrow understanding of the meaning ‘halal’ is that, it must be free from non halal ingredients or substances that contain pork and alcohol, whereas the true concept of halal is to ensure that the whole process in preparation of the product has met the Shariah rites. Halal promotes that not only what we consume must be Halal (follow the approved Shariah procedure) but the product must be ‘toyyib’ (of good quality). Assurance of good quality can be achieved through halal assurance system exercised along the production of the products. Quality also anticipates issues of consumption of products that can preserve and prolong one’s healthy live. These days, pharmaceutical product are associated with debates on the hazardous effects resulting from the consumption of the products, the insertion of the debated ingredients of GMO(Genetically Modified Organism) within the production process, and the undisclosed non-halal ingredients. These issues are within the prohibition under the true concept of ‘Halalan Toyibban’.

2. Development of Halal Industries in Malaysia

In 2004, JAKIM’s draft was circulated to various countries for comments. It results in the new halal standard, known as Malaysian Standard MS 1500:2004 to be approved by Government. It was developed under the Malaysian Standard Development System under the responsibility of Department of Standards Malaysia (DSM), Ministry of Science, Technology and Innovation. Saifol Bahli in his writing pointed out that due to its comprehensive and explicit nature, the halal standards have been accepted by the United Nations. The credibility of JAKIM Halal Certification has long been recognized by many multinational companies especially those in the region. Further, it has been proposed that MS 1500:2004 to be a global standard for halal products. MS 1500:2004 has effectively promulgated Malaysia as the world’s first to issue standards for the manufacturing, preparation, managing and storage of halal food. However, literatures commented that this guideline was not comprehensive enough to adequately govern the pharmaceutical product. Pharmaceutical product deals with different component of ingredient and its whole process are more detrimental than food. In response to this, the new Malaysian Standard MS2424:2010(p): Halal Pharmaceutical: General Guidelines was introduced on 2 March 2011. Simultaneously the government of Malaysia has appointed two Compliance Monitoring Authorities within the Pharmaceutical industry which are the NPCB and Standards Malaysia.

3. Issues Within the Halal Pharmaceutical Industries


References

2 Johan Fischer, Proper Islamic Consumption, Shopping among the Malays in Modern Malaysia ( Bordes 2008) at pg 74; Mian N. Riaz; Muhammad M Chaudry, Halal Food Production (CRC Press 2004) at pg 21
3 Note 14
This Manual prepares the procedure for food only which is not inclusive of pharmaceutical or medicinal product. One of the most commented issues are of the certification of Halal. In Malaysia Halal logo is only produced by JAKIM (current practice), nevertheless JAKIM authorizes various certification bodies from other countries. The current practice of certification in other countries is different from the one conducted by JAKIM. Recently the Malaysian society has been alarmed by many shocking revelation of raids that disclose the abuse of this delegated authority. This calls for a revisit into the current administrative regulation and enforcement tools governing Halal Supply Chain.

This Manual8 was introduced by JAKIM in cooperation with various government ministries, all State Islamic Religious Departments or State Islamic Religious Council. It was prepared to give an understanding and clarification to all inspection officers, manufacturers and consumers on halal aspects according to Shariah Laws and Malaysian Laws. This manual was produced to give a uniform guideline to all halal certificate owners and also forms as a standard which needs to be met by all halal producers. In turn, it also assists the consumers on how to obtain halal product sources in the open market. The companies which managed to pass through all the procedures be awarded the logo certificates. The halal logo then should be printed clearly on all manufactured products and labeled on each package. Application for Halal Certification Certificate for national and international market must be forwarded directly to JAKIM.

Article 6 of the Manual underlines the general requirements for halal certification and among the requirements are that: during the preparation, handling, processing, packaging or transporting of product, the product must be clean and free from any non halal ingredient and the transportation is only used for halal products. The manual seems to narrow down its control over the procedure and manufacturer. Review of the literature10 reveals that by having this halal standard, the possibility of manufacturers to cheat the consumers can be reduced. Conformity to the halal standard will provide assurance about quality, safety and reliability of the products. Literature11 also emphasizes the need to strengthen the system on the reason that this matter does not affect the Muslim consumers only, but the non-Muslim as well. Malaysia does not have any specific law on Halal food products except for the misrepresentation by manufacturers or producers as provided under the Trade Description (Definition of Halal) Order 2011 and Trade Description(Certification and Marking of Halal) Order 201112 which was formally addressed as the Trade Description (Use of Expression ‘Halal’) Order 1975. Part II of Consumer Protection Act 1999 has general application to any products, but it is still relevant in the case of false or misleading representation that the goods are of a particular kind. Norazlina13 opine that the right of Muslim consumers to get halal foods is not seriously guarded.

3.2. Scattered Laws
3.2.1. Trade Description Act 2011

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8 Manual Procedure of Halal Certification Malaysia, 2005
9 Available online at http://malaysiahalalfoods.com/halalcert.html accessed on 15 July 2011
12 Refer to Order 28 and 29
The Trade Description Act 2011 has repealed the Trade Description Act 1972. This new regulation has also replaced the Trade Description (Use of Halal Expression) Order 1975 and the Trade Descriptions (Halal Labelling) Order 1975. To strengthen the implementation of the new Trade Description Act, few subsidiary laws have been designed namely; 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. Although the advent of the new law has to a certain extent improved certain area such as the definition of halal, uniform halal logo to be issued solely by JAKIM and MAIN, some issues still need to be addressed. Trade Description Act 2011 is an act for the purpose of promoting good trade practices by prohibiting false trade description and false or misleading statements conduct and practices in relation to the supply of goods and services and to provide for matters connected therewith. It is not the main act governing halal matters. The amendment was made under previous Trade Description Act 1972 provides that JAKIM enforcement officers are given the power as “assistant controller” where they can take action against the offender. Nonetheless, neither the said amendment nor the latest Trade Description Act 2011 has granted powers to JAKIM officers to prosecute individuals or companies which violated the Act. It does not make it an obligation for the food to be marked as halal. It only specifies that once the food is marked as halal, then the trader or the manufacturer/producer of the food is responsible to ensure that the food is actually ‘halal’.14

3.2.2. Consumer Protection Act 1999

Consumer Protection Act 1999 specifies that any act that is capable of leading the consumer’s into error, such as using false, misleading or deceptive information in relation to a product, presentation or practice is prohibited. A false statement inducing the consumer into believing that the goods are of particular kind, standard, quality, grade, quantity, style or model or that the goods are under any sponsorship, endorsement approval, performance, characteristics, accessories user or benefit is prohibited. Unlike Malaysia, our neighbouring country, Indonesia, has specific provision on halal products in their Consumer Protection Act. Article 8 of the said Act states that any business entities must comply with the provisions for Halal production if they intend to produce or trade any goods or services which are express as halal. Business entities which violate the provisions as intended in Article 8 shall be sentenced with imprisonment for not more than five years or fined for maximum amount of two billion rupiah. The above sanctions are provided under Article 62. Even though the provision in their Consumer Protection Act is remarkably brief, they do recognize the rights of their consumers and deliberate their approval into the statute.

The Malaysian Consumer Protection Act 1999 has no provision on halal food products or halal certification. However, Part II of the Act has a relevant provision on false representation in relation to conduct or practice which is capable of leading a consumer into error. Article 9 of the Act provides that no person shall engage in conduct in that relation to goods, is misleading or deceptive, or is likely to mislead or deceive, the public as to the nature or manufacturing process. Article 25 further provides that any person who contravenes any of the provisions of Part II commits an offence.

3.2.3. Food Act 1983

Govern aspects of food quality control, standards, and labeling. The Ministry of Health has drafted a provision amending the Food Regulations 1985 which calls for mandatory labeling of GM foods. The

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Food Act 1983 and the Food Regulations 1985 are the Malaysian food legislation that form the backbone of the food safety programme. This Act stipulates that it is an offence for any person to prepare, pack, label or sell any food in any false, misleading or deceptive manner as to its character, nature, value, substance, quality, composition, merit or safety strength, purity, weight, age, origin, and proportion. It is relevant for this study to invoke the provisions of this Act as it governs all matters pertaining to food production in Malaysia as well as the imported ones.

However, provisions of this Act have given the authorized officer with wide range of power to control and take action upon any misconduct along the whole process of food production. This may be interpreted to include any misconduct of failure to comply with requirements specified in other related provision. This act also provides that the Director or an officer authorized by him may order the closure of any premises preparing or selling food where either one is of the opinion that such premises is in a condition that fails to comply with the sanitary and hygienic requirements and such that it is likely to be hazardous to health, and the proprietor, owner or occupier of the premises who fails to comply with the order commits an offence and is liable on conviction to imprisonment for a term not exceeding five years or to fine or to both.

3.2.4. Syariah Enactments

There are also various state enactments for example section 59 of Sabah Shariah Criminal Offences Enactment 1995 provides that whoever displays or indicates any prohibited foods as halal committing an offence punishable with fine not exceeding RM500 or imprisonment not exceeding 6 months or both. On the other hand, similar offence if charged under the Trade Descriptions (Definition of Halal) Order 2011 will be fined not exceeding five million ringgit and for a second or subsequent offence, the fine does not exceed ten million ringgit. This gap is extremely huge and will create double standard treatment for the offender charged.

3.2.5. Animal Rules 1962

This regulation provides for the control of the slaughtering of animals. It empowers the Veterinary Department to issue a slaughtering certificate/licence to abattoirs or individuals with a view to ensuring that the intended animal to be slaughtered is healthy and free from any diseases. Nonetheless this piece of law has no capacity to ensure that the slaughtered animals are halal. Healthy and free from diseases comply partially to the requirement of Halal. These rules do not cater for the Halal certification of the slaughtered animals.

3.2.6. Penal Code

Fraud and Cheating are offences under the Penal Code. Knowingly expressing that any products or services are Halal when in fact they are not will be an offence under the Penal Code. The important element for the prosecution team is to prove the mens rea (wrongful mind with the intention to deceive) and the actus reas (the wrongful conduct). The prosecutors need to present evidence and argument on the occurrences of these two elements at a level of beyond reasonable doubt. Therefore the duty of a defense counsel is to raise doubt. Prosecuting a wrongdoer of fraudulently certifying halal on their products would be a challenging task to the prosecuting team as the scientific recovery of non halal ingredients within the halal certified products varies. Admissibility of evidence would be extremely important.

3.3. Upholding the Principle of Safety, Quality and Efficacy

The administrative policies and procedure of the Ministry of Health, Ministry of Science, Technology and Innovation and National Pharmaceutical Control Bureau (NPCB) i.e Good Laboratory Practise(GLP),
Compliance Monitoring Programme (GMP), a Directive under Regulation 29 of the Control of Drugs, requires the upholding of the principle of Safety, Quality and efficacy. This is in line with the global requirement for the pharmaceutical industries. Ensuring the three ruling that the pharmaceutical product need to be safe, of good quality and efficient do form part of the requirement of Halal. Yet the same argument will be best referred to stating that ensuring these products are halal would be an extension of the existing rule.

3.4. Compliance With PIC/s

In Malaysia, all pharmaceutical products has to undergo a quality control inspection by the National Pharmaceutical Control Bureau (NPCB). While another Compliance Monitoring Authority appointed by the Malaysian Government within the industry is the Department of Standards Malaysia. In the process of monitoring the pharmaceutical industry, NPCB has produced the GLP Compliance Programme Manual. It was acknowledged that Halal certification on Pharmaceutical Product would be an added value to the product as it is a known that Halal ensure safety.

3.5. Capsules

Gelatins are popularly associated with the capsules and liquid based of the pharmaceutical product. Under the Sales of Drugs Act 1952 (revised 1989) and Trade Description (Certifying and Marking of Halal) Order 2011, a seller or a company who attached misleading labels or statements on the drugs may commit an offence under this statute. Labels usually disclose the ingredients of the drugs. There is no liability imposed on the manufacturer to disclose the source of capsules. The prior statute only applies to the seller and not the manufacturer. The statute further provides for an offence to sell any drug containing any substance the addition of which is prohibited in the stated scheduled. However the terms ‘prohibited’ is define as not to include non halal substances.

3.6. GMO

Another issue associated to the pharmaceutical product evolves around the escalating evolution of Genetically Modified Organism (GMO) that had intervened the natural growth process of living things. Likewise, literature acknowledges that the Halal concept has penetrated the pharmaceutical industry worldwide. Recent developments are directed towards the disclosure of unsafe and non halal GMO (Genetically Modified Organism) within the ingredients of pharmaceutical product. Literature reviews have also revealed the happening of event where the insertion of non Halal derived genes along the growing process of a Halal certified living things. The existing administrative regulations are not able to

15 NPCB is the national Compliance Monitoring Authority appointed by the Ministry of Health to monitor the compliance to the Principles of Good laboratory Practice(GLP)
16 Standards of Malaysia are attached to the Ministry of Science Technology and Innovation
17 GLP (Good Laboratory Practise) is a quality system concerned with the organisational process and conditions under which non-clinical health and environment safety studies are planned, performed, monitored, recorded, archived and reported
18 This is the current administrative regulation used for the licensing and monitoring of pharmaceutical industry
19 Refer to Note 6 at pg 74-81
20 Refer to section 10(1) of the Sales of Drugs Act 1952(revised 1989)
21 Refer to Order 28 and 29
22 Study has revealed that certain soybeans have been mixed with the genes from a pig to create resilient and bountiful harvest. Taken from the writings of Heikal Abdul Mutadir, “The Great Halal Debate”, Malaysian Business, Kuala Lumpur, (March 2006)
24 Amish feed is made with vegetables based ingredients but the absence of regulation and supervision can still create doubts;
address the matter. The Poison Act 1952\textsuperscript{25} provides for the safety and handling of poison as not to be misused and lead to the damaging effect of a purchaser. Similarly, the Biosafety Act 2007 focused on the need to properly label the GMO foods. This is partially in line with the concept of Halal. Nevertheless the other half of ensuring that it is not only safe but its halal has not been addressed. Using non-halal substances can also be safe. The reliance was only made through the gazette fatwa.

Trade problems arise when countries have different regulations regarding the testing and approval procedures necessary to place Genetic Modified Organism (GMOs) and their products on the market. They sometimes disagree about labeling and identification requirements. Some countries ban imports and sales of GMOs and their products altogether. In other countries, a large part of the production of some crops, such as maize or soybeans, is from genetically modified seeds, and is mixed with non-modified varieties during storage, transport and processing. These countries argue it would be unnecessary and very costly to keep GMOs separate, and consider that labeling requirements or import bans are unnecessary trade barriers (WTO, 2005). Thus labeling requirement has become a necessity and has to be highlighted by the law makers to provide the customers the right to informed choice while selecting Halal GMOs or non Halal GMOs pharmaceutical.

3.7. Informed Consent

One of the legal issue within the halal pharmaceutical industry relates to the ‘over the counter drugs’ or prescribed medicine. It anticipates a critical analysis on the issues of informed consent. Current practice does not impose any obligation to the clinics or pharmacy department to adequately label the micro packaging of the drugs or medicine. Muslim patients who were not informed on the presence of non Halal substances in the drugs would have consented to purchase and consume the prescribed drugs. In some cases they would agree to receive treatment using non Halal vaccines. This results in the will encroachment of the rule of informed consent under the medical law. Informed consent literally means to do or to allow something to happen only after all relevant facts are made known. In contract law, informed consent means consent of parties to be legally bound by a contractual relationship when there is full disclosure of what they consider as significant information to the agreement. Kennedy and Grubb\textsuperscript{26} define informed consent as the duty of completely disclosing information to a patient as to medical treatment. In the case of Sidaway v Bethelium Royal Hospital Governors[1984] 1 All ER 1018, the court held that a doctor is bound merely to disclose in broad terms such information as is reasonable to allow the patient to make a rational choice, whether or not to accept the treatment. Further, in the case of Allan v New Mount Sinai Hospital[1980] 28 Ont (2d) 356, Linden J reinforces that consent is not merely formality; it denotes the individual rights to have control over one’s own body particularly when medical treatment is involved. Ironically, informed consent usually related to risk. Failure to pre-inform the potential risk before suggesting a patient to undergo treatment, would amount to breach of the rule of informed consent. In the Halal treatment, it rarely associated with a physical risk within the definition of medical ambiance. Nonetheless, the underlying principles of the Islamic teaching on the prohibition of Haram product are associated with future risk of harming the body system.

\textsuperscript{25} Refer to Section 9 of the Poison Act 1952

5. Conclusion

An overview encapsulation of the above study points that Malaysia Halal certification has been recognized worldwide. The commitment of the Malaysian government into gearing towards the effort of becoming halal hub country is positive. Nevertheless, in contrast, the domestic escalation of raids has denied the good governance of the existing Halal regulations and enforcement system to govern the whole system and in specific the pharmaceutical industries. Malaysia is only recognized as having a good set of guidelines of certification nevertheless the continuous report on the abuse of the guideline has demonstrated the weaknesses of the existing administrative rules and its enforcement tools. There is a need to strengthen and extend the law as there is a development of trend, where society becomes dependent on the pharmaceutical products.

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Manual Procedure of Halal Certification Malaysia, 2005


Sales of Drugs Act 1952 (revised 1989)


The Poison Act 1952