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Halal Labelling for the Malaysian Pharmaceutical Products: A Legal Review

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Abstract

This research outlines the obstacles in establishing a reformed legal framework in Malaysia that recognises the importance of halal labelling for pharmaceutical items. The desire of halal pharmaceutical consumer, that consist of Muslim and Non-Muslim is directed to acquiring advantages of halal certified product such as the hygienic and safety aspect. The findings to this study may help policymakers and the government identify the ideal legal regime for halal pharmaceutical labelling. Research employs a qualitative research method, using doctrinal study on halal pharmaceutical related regulations via content analysis approach. The findings are supported by data gathered through semi-structured interviews with various stakeholders that were selected using purposive approach. Later, all data were triangulated and analysed using designated coding and themes. This research suggests that present laws is unable to keep pace with the rapid developments within halal pharmaceutical manufacture, affecting several consumer rights. Regrettably, Malaysia does not have a specific Halal law and the fragmentary legislations are inadequate to protect the consumers. Further research on the best mechanism to accommodate to the halal related problems discussed in this research should be performed in the future, such as proposing a unified umbrella law to control it all.

Keywords Halal, Labelling of Drugs, Laws, Pharmaceutical, Halal Malaysia

Introduction

The global Muslim population is estimated to be approximately 1.9 billion Muslims today, making up 26% of the world's population (The Muslim 500, 2021). It is forecasted that the Muslim population will increase up to 2.2 billion (26%) by 2030 and will continue to grow to 2.6 (30%) billion by 2050 (Fleishman-Hillard Majlis, 2012). Within this development, the halal market is seen as one of the main global industries to blossom. What's more is the demand for the halal product is no longer confined to Muslim consumers, as reports show that non-Muslims have acknowledged halal products because of the safety and hygienic aspect of the product. Halal is closely linked with organic agriculture, fair trade, product safety, ethical

business practices, human behaviour with animal and ecological economics (Haleem et al., 2020).

In line with this development, the halal pharmaceutical industry has marked growth with the rise of the world halal market and is projected to reach USD 34.82 billion by 2026 as highlighted in Malay Mail in 2021 and The MarketWatch in 2022. Trent (2019) asserted that halal pharmaceuticals and cosmetic products are gaining awareness and increasing demand from 2.4 billion Muslim consumers worldwide. The global halal market is anticipated to expand at a compound annual growth rate of 6.8% until 2024. Malaysia is recognised to have the potential in championing halal pharmaceuticals manufacturing due to its membership to the Organisation of Islamic Committee (O.I.C.) and being the only O.I.C. country accepted as a member under the Pharmaceutical Inspection Cooperation/Scheme (PIC/s). To this development, the Malaysian government has formulated the Halal Industry Master Plan 2030 to catalyse the country's Halal industry holistically, and the halal pharmaceutical industry will experience the impact. The growth foresees the industry's rapid activities that require an effective legal and administrative framework to govern these activities.

The obligation of a Muslim to consume halal food derives from the Holy Quran, and the guidance of the Prophet Muhammad saw serves as a guideline for humankind in achieving success and tranquillity of soul here and hereafter. Thus, the Muslim must be supplied with the halal product, which connects him with his life and livelihood, a core human rights component. Halal products denote high quality, safe, and Shariah compliance (Al-Qaradhawi, 2001; Mian et al., 2003; Siddiqui, 2010). In response to this, the existing halal pharmaceutical-related laws require the manufacturers and sellers of halal pharmaceutical products to provide safe, efficient, and of good quality as provided in the Sales of Drugs Act 1952, Medicines (Advertisement and Sale) Act 1956 and Poison Act 1956. The Trade Description (Certification & Marking of Halal) Order 2011 (T.D.O. 2011) is the nearest that it has as a specific halal related law. The amendments of the Trade Description Act 2011 (T.D.A. 2011) and T.D.O. 2011 have brought main changes to the halal certification laws in this country. The Acts insert the specific provisions to administer halal issues, and the Order describes the procedures to deal with halal matters (Asa, 2019).

These laws do not directly provide for the monitoring of halal, thus inadequate to protect the rights of Muslim consumers. Currently, the producers and manufacturers opting not to label their products as halal are not obliged to disclose the non-halal ingredients inserted in their product (Othman et al., 2007; Othman et al., 2009; Abdul Aziz, 2007). This scenario is against the spirit of rights to information accorded to the consumers (Abdul Aziz, 2015). With the challenges of globalisation that have created the culture of high dependency on pharmaceutical products (Watson, 2012; Harker et al., 2007) and the use of advanced technology to manufacture pharmaceutical products in mass quantity, the traditional doctrine of *caveat emptor* (buyer needs to beware) needs to be replaced by the doctrine of *caveat venditor* (seller needs to beware). In short, disclosing information shall be the seller's duty rather than making the buyer disqualified from claiming for reasons of failure to investigate the information. This scenario sees the demanding need to disclose the ingredients in halal labelled and non-halal labelled products, which is absent in the current laws—attaching a halal label or certification assists in guaranteeing the rights of Muslim consumers. The halal label assures the purity of product manufacturing (Asa, 2019) and

compliance with the Islamic rules on halal (Utami and Geneveva, 2020). The halal pharmaceutical industry could not grow fast enough due to some fundamental issues that include the doubtful status of some medicine, which can be clarified by having labelling that may ascertain the halal status of the medicine (Hamid, 2014; Utami and Geneveva, 2020).

Apart from that, Ab Talib et al. (2015) suggested that a lack of a uniform halal certification system is a significant problem the halal industry faces and complicates halal integrity assurance. Although Malaysia is the pioneer in producing halal pharmaceutical standards, Malaysia does not have in place established laws and regulations that could serve as monitoring tools for the labelling of halal pharmaceuticals products. The MS 2424:2012 guideline, together with rather obsolete regulations, is not adequate to provide certainty and support for the growth of halal pharmaceuticals production in Malaysia. With the lack of an established and specific legal and administrative framework, many foreseeable risks may diminish the industry. This study aims at critically analysing the existing laws relevant to the halal pharmaceutical product to highlight the strength and deficiency of the laws in addressing the need to attach halal labels to pharmaceutical products and consumers' rights to information. The study seeks to suggest appropriate reformation of the existing laws to include a bigger scope of protection for consumers of halal pharmaceuticals.

Literature Review

Halal pharmaceutical products are now poised to be the new frontier for the global Halal economy, especially with the availability of the world's first Halal Pharmaceutical Standard MS2424:2012 Halal Pharmaceuticals General Guidelines, creating more avenues for consumers to make informed choices in choosing approved medicines that are safe, efficacious, of quality and hygienic whilst at the same time fulfilling the obligatory requirements under Shariah (Amirul, 2014). Following these developments, many pieces of research have been conducted within the area of halal pharmaceuticals. Young (2007) also pointed out that pharmaceutical products will long take place within the society where the consumers will demand more information on the social conditions at the production sites. Unfortunately, the consumers cannot voice any inconsistency between what is on paper with the practices being adopted by producers as there is a vulnerable legal basis provided in this field. In responding to this scenario, researchers (Markom, 2011; Fernandez, 2007) highlighted the demanding need to disclose the ingredients in halal and non-halal labelled products.

Halal labelling serves as a medium to strengthen the belief of Muslim consumers (Mohamed et al., 2013). There are many books (Al-Qaradhwai, 2001; Mian et al., 2003; Siddiqui, 2010) and studies (Hassan, 2011; Wan Norhana et al., 2012; Othman et al., 2009; Othman et al., 2007) that have listed and discussed the importance of Shariah principles without comparing them to the existing legal framework in Malaysia. Thus, the shortcomings of the existing legal framework governing the halal pharmaceutical industry were not highlighted. It is important to analyse these principles while considering the existing civil laws to strengthen the protection for the consumers.

Before halal penetrates the pharmaceutical market, the food industry has matured with the activities of halal (Latif, 2004; Mian et al., 2001; Alserhan et al., 2020). Thus, significant literature (Latif, 2004; Ali et al., 2001; Munawar et al., 2014; Fadzillah et al., 2011; Asa, 2019)

have focused on the development of halal concept within the food industry (Malek, 2014). This literature mainly concentrated on the key exporting strength in the current halal market, the causes for the rapid development of the halal food industry (Bohari et al., 2013; Nurdeng, 2009; Khattak et al., 2011), the technique to break through the halal food industry (Ramli, 2011), marketing of the halal brands (Wilson, 2012; Paul, 2011; Kohilavani et al., 2010) where some legal and administrative issues were highlighted and valuable recommendations were put forward (Noaman et al., 2001; Othman et al., 2009; Othman et al., 2008).

The studies on halal food have also been expanded to the logistics and transportation of halal food where these studies pointed out (Tieman, 2009; Muhammad et al., 2009; Abdul Aziz et al., 2009) that improper structuring of logistics and transportation would result in the gathering of halal products with the non-halal products and this violates the rules on halal. On this point, Heikal (2011) highlighted the need to avoid combining halal and non-halal food and products within one manufacturing premise. Noriah (2011) has written a chapter on various halal food production-related laws in Malaysia. The book has become a guide for manufacturers and sellers who wish to market halal food products in Malaysia. Although these studies included some discussions on the halal industry regulations that are also significant to the halal pharmaceutical industry, the discussions were confined to the halal food industry and logistics. The halal related laws discussed in the studies were not in-depth and suitable to the food industry.

Although discussions on halal food have championed halal research, the discussion on halal pharmaceutical-related issues has been growing fast in the past few years. There are various writings (Awang and Rahman, 2011; Rahman and Baco, 2010; Majeed, 2012; Mursyidi, 2009; Gross, 2014; Feisal, 2014; Buang, 2015, Utami & Geneveva, 2020; Rahem et al., 2021) on halal pharmaceuticals that include the growth of halal pharmaceutical industry (Nursabrina et al., 2014; Nurullhidayah et al., 2012) and the issues that surround the halal pharmaceutical industry such as halal certified living things mixed with non-halal derived genes to enhance the growth process (Nursabrina et al., 2014; Nurullhidayah et al., 2012), reports on doctors and pharmacists who were not adhering to labelling requirements, the need to have proper and transparent labelling for pharmaceutical products without which may impeach the rules of informed choice (Hargin, 1996; Mynors, 2004), the complex composition of modern drugs and medicine that requires the switch of the old rule (Sariff et al., 2012, Heikal, 2010; Zailani et al., 2010) from *caveat emptor* to *caveat venditor*, the discovery of non-halal ingredients in drugs (Sariff et al., 2012; Lee et al., 2012; Heikal, 2010; Zailani et al., 2010), the doubtful status of some medications and drugs and the need for legal and administrative frameworks for halal pharmaceuticals (Sariff et al., 2012; Lee et al., 2012; Aziz, 2017), issues and challenges of the halal pharmaceutical industry (Ramli et al., 2018), ethical issues associated with conformance of cosmetics' product (Sugibayashi et al., 2019), halal certificate as a marketing tool (Asa, 2019), halal certification through assessment and accreditation (HCAA) (Haleem et al., 2020). These writings represented a consolidated discussion on the issues that need to be addressed within the halal pharmaceutical industry with little emphasis on the discussion for appropriate legal and administrative mechanisms that may aid in solving the highlighted issues.

The yearly growth in the demand for halal pharmaceutical products shows that such products have become essential for consumers. Although vast studies have been conducted on halal pharmaceuticals, to the best of the researchers' knowledge, none of the studies rigorously

investigated the factors that can affect the consumers' attitude and purchasing intention of halal cosmetics and pharmaceuticals (Widyanto and Sitohang, 2021). As such, more investigation is needed to determine whether halal labelling and certification are significant given the increasing demand for halal pharmaceutical products, which are directly linked to the knowledge of the consumer.

A previous study propounded that halal knowledge (Bashir et al., 2018) and halal label intention (El-Bassiouny, 2016) are required to determine whether potential consumers understand the concept and system of halal. In addition, the research conducted by Widyanto and Sitohang (2021), which supports the notion of the significant impact of the halal certification on the purchasing intention of the customer, is likewise relied on to support the views mentioned above. In particular, these two factors are crucial to facilitate Muslim consumers' purchase intention. Consequently, they are regarded as the factors used to predict customer attitudes and purchase intentions by taking into account indicators such as halal issues, Islamic law, halal legality, and halal process (Maichum et al., 2017).

Interestingly, in contrast to the findings established by Widyanto and Sitohang (2021), the study conducted by (Genoveva and Utami, 2020) reveals that halal labels have no significant impact on the purchasing decision of consumers. However, it is submitted that halal certification involves thorough investigation in terms of raw materials, processing, packaging, and distribution and, thus, has become the key indicator in determining security, cleanliness (Nugraha et al., 2022) and quality of the pharmaceutical products (Jalil et al., 2018; Dian Luthviati and Jenvitchuwong, 2021).

While the legal and regulatory frameworks in respect of halal food industry are quite comprehensive, a different scenario is observed in respect of halal pharmaceuticals since existing laws and regulations are unable to provide legal certainty and guarantee to Muslim consumers in making their purchasing decision involving pharmaceutical products (Luthviati and Jenvitchuwong, 2021). This is particularly essential to give the Muslims an informed decision between halal and haram. As such, the findings may serve as a valuable guide to the relevant regulators in developing a comprehensive legal and regulatory framework governing the issue of halal labelling on pharmaceutical products. Since halal certification has a significant correlation with attitude and purchase intention, cosmetics product manufacturers should apply for and ensure the availability of the halal logo on their pharmaceutical products (Widyanto and Sitohang, 2021).

Methodology

This study adopts a qualitative research method engaging the doctrinal study using the content analysis approach on the relevant laws and regulations. The study analyses the halal pharmaceutical-related laws that include halal related law, sales of drugs, and consumer protection. The findings are supported by the information collected from semi-structured interviews and focused group discussions with several stakeholders, namely the Department of Islamic Development Malaysia (JAKIM), National Pharmaceutical Regulatory Agency (NPRA), pharmacists and academicians. The selection of the respondents was made using the purposive approach. The interviews were exploratory as the research sought to investigate how the respondents perceived the extent of effectiveness of the existing legal administrative regulations and monitoring tools. Accordingly, a list of interview questions was prepared to

inquire into the stated criteria. Predetermined themes based on study parameters were developed to construct interview questions that could guide the participants during the interviews. Data from doctrinal and semi-structured interviews were later triangulated and analysed using specific coding and themes.

Results

Halal labelling and the pharmaceutical product

Previously, the authority was not in favour of certifying halal for drugs or pharmaceutical products. Some of the authors mentioned few reasons for the negative perception of having halal labels attached to pharmaceutical products (Lokman, 2015; Luthviati and Jenvitchuwong, 2021). The contributing factor is the low awareness among the society and the Ministry of Health about the halal concept and its importance to Muslims (Buang, 2015; Luthviati and Jenvitchuwong, 2021). The low awareness of the importance of halal to Muslims has become the main barrier to the policymakers in directing them to formulate legal frameworks and policies relevant to halal pharmaceuticals. Thus, the pharmaceutical-related activities and management cannot impose the need to have halal pharmaceuticals in the system. The scope of pharmaceuticals has expanded to cosmetic products and sees the emergence of hybrid products like cosmeceuticals or nutraceuticals. Similarly, the demand for halal cosmetics remains unmet because cosmetics production is dominated by non-halal cosmetic manufacturers, whose production methods may not conform with the requirements of halal science (Sugibayashi et al., 2019).

Authors (Lokman, 2015; Aziz, 2017) explained that the negative perception was also contributed by the notion that pharmaceuticals are commonly associated with emergencies that give rise to the concept of necessity or '*darurat*'. Ailments and sickness are commonly construed as forming part of the emergency, the basis of necessity. When there is an absence of halal pharmaceuticals during an emergency, complications would arise and threaten the safety of a patient if the patient refuses to be treated with non-halal pharmaceuticals. The concept of necessity under Islamic law allows the general rule on the obligation to consume halal pharmaceuticals to be lifted (Samdani, 2021; Dayan et al., 2021). In such a situation, the concept of necessity will allow the usage of non-halal pharmaceuticals for the reason of necessity. Based on this reason, regulating that the pharmaceuticals should be halal certified seems inconsistent with the exception given to Muslims seeking medical treatment. It is assumed that halal labelling on pharmaceutical products is not a demanding need as everyone using pharmaceutical products is assumed to be sick, thus falling under the exception to consume halal pharmaceuticals. This has become the ground for the absence of halal certification for pharmaceutical products in the recent past.

Nevertheless, the actual concept of necessity under Islamic law underlines the limitation to necessity application. This is what Rasulullah S.A.W. said: "*Indeed, Allah S.W.T. gives the disease along with its cure, and creates a cure for every disease, then be cured.*" However, do not self-medicate with illegal substances (Abdul Aziz, 1999). There is a nuance between the emergency and non-emergency as it is subjected to various factors that may vary from one case to another (Samdani, 2021; Dayan et al., 2021). This narrow connotation has also involved the doctor's duty of care towards the patient of either to consider the patient's demand or to decide in the best interest of the patient.

The term 'best interest of the patient' has been highly discussed in the medico-legal field (Birchley, 2021). If the best interest of the Muslim patient is to give an option to the patient to choose either to consent or not to consent to the usage of non-halal medication for his treatment, it will complicate the practice. Moreover, the medical practitioners affirmed (Amrahi, 2015; Butler, 2018) that the majority of practitioners cannot ascertain the halal status of pharmaceutical products. To this, Sugibayashi et al (2019) believed that cosmetic ingredients derived from animals such as gelatin, lecithin, glycerol, fatty acids, and collagen are very difficult to verify as halal.

Another reason contributing to the absence of halal certification for pharmaceutical products is the possibility of halal certification that may mislead the consumer on the status of the medicine and its halal logo. When there are medicines with halal labels, it will create a notion that the halal medicine is not labelled as *haram* or non-halal (Rahman, 2015; Aziz, 2017). This will negatively impact the seller of pharmaceuticals that do not intend to apply for the halal logo.

The most recent literature divulges that the complicated and costly process of obtaining halal certification and labelling is one of the obstacles in pursuing halal labelling. The author suggested that diverse strategies need to be implemented to encourage more production of pharmaceutical products bearing the halal logo (Kasri et al., 2021). For instance, uncomplicated and cheap procedures may encourage the industry to implement halal logos for their products.

Due to several unwanted discoveries over the usage of non-halal ingredients in pharmaceutical products, the consumer demand for halal certification to be extended to the pharmaceutical product. In response to this demand, the authority has restricted halal certification to over-the-counter pharmaceutical products only. During the workshop, the NPRA representative explained during the workshop as presented in the Bengkel Pemantapan Mekanisme Pengurusan dan Tadbir Urus Halal, 2014 that halal certification is not extended to the prescribed medication on the same reason of necessity as explained above. However, it was contended by the representative at the same workshop, for the consumers and the industry that not all prescribed drugs are related to necessity or emergency. For example, diabetic medication is not consumed during emergencies, and there are many innovations of halal medication to provide alternatives for the consumer. Based on this statement, the consumer and industry representative requested that halal certification for prescription drugs be considered soon.

Based on the above discussion, the researcher finds that fixing halal certification to all categories of pharmaceutical product need to be analysed separately. The concept of emergency is subjective and applicable to the usage of all categories of pharmaceuticals. Emergency depends largely on the situation and not the types of pharmaceuticals. As the objective of fixing halal certification on pharmaceutical products is to assist the consumer's rights to know and to make informed choices, the policy to allow such an act is deemed necessary. However, in emergency cases, the laws on deciding 'the best interest of the patient', which include using the non-halal medication, must be applied.

*Prospects of having a law for labelling of halal pharmaceutical products**Rights to information*

In 1962 consumer rights have formally emerged through the word of President John F. Kennedy (Larsen and Lawson, 2013; Benohr et al., 2010) that has laid down four rights of consumer namely the right to safety, right to be informed, right to choose and right to be heard. The Consumers International (IOCU), a Consumer Unions which become the umbrella body for 240 organisations in over 100 countries, upholds eight consumer rights which include rights to information and rights to choose. The two universal rights of the consumer, namely rights to information and rights to choose, are sometimes associated. Most of the modern consumer laws protect the consumers from being misled and being positively informed to make informed choices (Howell et al., 2010).

In response to the growing demands of halal pharmaceutical products, halal certification and labelling have become one of the consumer's sources of information to avoid any deception (Karjoko et al., 2020). The absence of certification and labelling may entice the issue of misinformation and falsity among the consumers and consequently mislead the consumers (Talib et al., 2016; Rahem et al., 2021; Luthviati and Jenvitchuwong, 2021) since the prevalent and credible information on the halal status is not accessible. Access to the products information, specifically on the halal status of the products, directly influences consumers to choose the products, thus requiring detailed and accurate information to be supplied by the manufacturer (Karjoko et al., 2020).

All pharmaceuticals should be labelled or attached with an information leaflet to caution the consumer on all potential risks of the products. However, this basic rule is insufficient as the consumer needs to be supplied with information that the consumer wants to know (Howell et al., 2005). Concerning the modern consumer, D Kennedy (Kennedy, 1981) introduces the notion of 'false consciousness, which describes a situation where consumers in the modern economy cannot decide on the goods that they desire due to a lack of information. On the same point, disclosing ingredients in their scientific names will defeat informing the consumer of the information they require (Aziz, 2017). In support of this contention, Howell et al., (2005) states that in some markets, consumers are not even aware that they are under-informed, so the growth of a market for information provided will not readily help.

Generally, consumers want to know information that they can digest, as simple as whether the pharmaceutical product is halal or not. This degree of information supplied has to be higher than the one imposed in the food making industry as there is a higher risk attached to the pharmaceutical product. This can be explained by the usage of ingredients in the pharmaceutical composition. For example, in the first Gulf Conference on Halal and its Services which was held in Kuwait in 2011, the conference reaffirmed the right of consumers to know the slaughtering method used to be written clearly on the product label. The lack of international standards for the halal industry (Annabi and Ibadapo-Obe, 2017) and collaboration amongst the world's halal-certification authorities (Evans, 2011) have created doubts amongst the Muslim consumers on the authenticity of the halal certification process. At the same time, the increase of false labelling on non-halal products can impeach the consumer's sovereign power to receive what they want. Some suggest that incentives be offered to the suppliers or producers who supply information about their goods to the consumer (Benston, 1998).

Halal Product: The Dire Need for Reliable Information

The halal market is emerging as one of today's most profitable and influential market arenas in global business (Ali et al., 2002). Thus the rise of halal industries has also transformed the views and interests of various parties involved directly or indirectly within the halal industries, from religious obedience to financial gain (Mutadir, 2006).

Since Muslims are becoming more halal conscious (Genoveva and Utami, 2020), it is essential to ensure that the pharmaceutical products provide a minimum label consisting of crucial information such as the name of the product, raw materials, ingredients, nutritional information, expiration date and product contents (Apriyanto & Nurbowo, 2003) since the label is regarded as the key indicator for Shariah Compliance and fulfilment of standard measures (Genoveva and Utami, 2020). The demand of the society was ignited by various discoveries (Abdullah, 2011; Aziz, 2017; Adha, 2018; Zainalabidin et al., 2019) between 2006 and 2019 on the use of non-halal ingredients (porcine based) in the pharmaceutical products, particularly in the production of *claxane* and *fraxipane* and *Drixoral* (medicine for influenza). The issues on the use of non-halal ingredients had caught serious attention amongst the Muslim consumers in Malaysia when it was reported that the vaccine used for pilgrims, i.e., *ACYW 135-Menomune*, contained amino acids derived from duck, swine and bovine. (Abdul Rahman, 2011) In 2010, it was also reported that *Imodium Capsule*, which is used to treat diarrhoea, was said to have contained the same non-halal substances and has led to an immediate call off to its licence by the Ministry of Health (Ideris, 2010). A recent issue was on the halal status of the COVID-19 vaccine that becomes the main concern in Muslim majority countries like Malaysia.

The current administration of halal industry in general and halal pharmaceutical in specific involves many private companies and government departments with complementary, overlapping and competing roles. Furthermore, a strong task force does not support the existing administrative framework (Veeravu, 2010; Aziz, 2017; Aziz, 2022; Sahari, 2022). Following these worrying discoveries was the rise of unanimous halal pharmaceutical stakeholders concerned (Badrudli, 2012; Fischer, 2008; Tieman, 2011; Aziz, 2022; Sahari, 2022) to have good, structured regulations and comprehensive governance within the halal pharmaceutical industry.

Apart from the issue of halal ingredients used in pharmaceutical products, the certification and the attainment of halal status must abide by the fundamental requirements, including production, packaging, storage, distribution and service, which requires the process to conform to religious fulfilment. While the ingredients need to be halal, the safety (Kasri et al., 2021) and the quality of the contents and ingredients are requisites to Shariah conformation (Rahem et al., 2021).

Muslim and the Need to Consume Halal

Muslim consumer is different in their special commitment (Idris, 1987). Like other consumer fragments, they have their deliberate particularity and are eagerly engaged in getting healthy and quality goods that conformed to the shariah rule (Dincer, 2014). They are subject to the provision stated in the Holy Quran and the *hadith* of the Prophet Muhammad s.a.w. The main consideration in executing the consumerism activity is that it must be within the framework of halal and haram followed by selection on the priority of goods, hygienic goods and the

moderate practice of consumerism (Ghani et al., 2006). The psychological expectation is that the manufacturer and the marketers must have complete knowledge about Muslim consumers, whereby being a consumer, their internal motivation is that goods and services must be shari'ah compliant, whilst the external is the perceived characteristics of a shari'ah compliant product.

The globalisation phenomenon has bred the industrial revolution, dramatically increasing the availability of consumer goods. It is commented that globalisation which created a borderless world, has increased the need to have a unified halal standard across the globe (Evans, 2011), undoubtedly adding value to the halal industry (Annabi and Olajumoke Ibidapo-Obe, 2017). The contention supports this increasing need that the raw materials used by manufacturers are sourced from all over the world, and the products are processed and packaged in various locations leading to the national product can only hold on to its branding (Abdalhamid Evans, 2011). This has resulted in risk and complexities attached to the goods to be multiplied (Geraint Howell et al., 2010). It has also resulted in abusive market behaviour due to aggressive advertising and limited access to information and justice (Benohr et al., 2010). This has resulted in consumers purchasing with a lack of information and limiting their rights to choose (Howell et al., 2010). Based on these reasons, there is a dire need for information for halal and non-halal products.

Challenges

Inadequacy of the current laws

Currently, Malaysia does not have a specific statute on Halal; however, several piecemeal legislation falls under the criminal and civil laws that can be referred to in protecting the consumer of halal pharmaceuticals. Researchers (Ramli et al., 2018; Aziz, 2017, Aziz, 2022) and industry (Bengkel Pemantapan Mekanisme Pengurusan dan Tadbir Urus Halal, 2014) hinted that the absence of a clear and proper legal and administrative framework might lead to the occurrence of any foreseeable risks and diminish the industry. The most relevant statute under the criminal laws is the Trade Description Act 2011, as it was the statute that specifically provides for halal related offences. The Trade Description Act was enacted to combat misleading or false descriptions of goods, services, accommodation or facilities (Section 3(1)(a) and 3(1)(b) of Trade Description Act 2011). Under this Act, the Minister has called for the Trade Description (The Certification and Marking of Halal) Order 2011. This Act, unfortunately, limits the offences related to halal to false description only. In cases where an individual or company does not describe its pharmaceutical product as halal, JAKIM would not have any control over the product.

Aziz (2017); Ramli et al (2018) proposed that there shall be a specific agency to be in charge of the whole matter within the halal pharmaceutical industry. The status of JAKIM as the main governing body of halal affairs is unclear. Thus, its job becomes muddled without a clear description of JAKIM's administrative and regulatory authority. With an unstable governance structure, the halal business faced an untrustworthy position as the consumer's defender.

Malaysia has taken the lead in pursuing halal certification for pharmaceutical items, but significant obstacles remain, notably the absence of an efficient legal framework governing halal pharmaceutical products. However, Malaysia's halal pharmaceutical business is not well supported by an acceptable legislative and regulatory framework. This is one of the reasons

why the halal pharmaceutical business has been harmed. In Malaysia, there is no defined regulation governing the halal pharmaceutical business (Aziz, 2017; Ramli et al., 2018).

The main law which regulates public Order is the Penal Code, which aims at curbing and punishing criminals. The scope is limited to a vague provision that does not specifically address the misuse of halal logo/sign-on non-halal pharmaceutical products. The vital element that needs to be established by the prosecutor is that the manufacturer/supplier/seller does have a criminal mind. Criminal mind denotes intention, and the evidence of absence of knowledge must prove intention. In modern society, where mass production of pharmaceutical products is involved, problems arise along the supply chain. It becomes more challenging to prove complicated mixtures of pharmaceutical products as different ingredients sometimes are supplied by different raw materials suppliers. Tracing the person responsible for the insertion of non-halal ingredients in the halal pharmaceutical needs an expert, and the burden of proof is higher in a criminal case than civil litigation.

The legal framework on sales of drugs regulated by the NPRA is comprehensive and reliable in safeguarding the pharmaceutical product's safety, efficacy, and quality as provided in the Sales of Drugs Act 1952. Pharmaceutical products that have been registered with the NPRA and await halal certification from JAKIM can be guaranteed as safe for consumption but not necessarily halal which has been extensively discussed in the Focused Group Discussion held in 2014. It can be said that the control mechanism formulated in the NPRA guidelines, circulars and directives play a substantial role compared to JAKIM guidelines on halal pharmaceuticals without discounting the importance of both regulations to represent the complete governance of the halal pharmaceutical industry. The following table shows the pharmaceutical product category registered with the Drug Control Authority and can be certified halal.

Table 1: Category of Pharmaceutical Product & Halal Certification

(Source: Halal hub Department, JAKIM, and Putrajaya)

No	Types of Pharmaceuticals	Registration code	Halal Certification	Example
1.	Prescribed: Contain scheduled poison.	A	NO	Antibiotic, hypertension drugs, diabetics drugs
2.	Over-The-Counter: does not contain scheduled poison.	X	YES	Antiseptic, diagnostic agent, medicated plaster
3.	Health Supplement	N	YES	Homoeopathic medicine, Ayurvedic medicine, Noni juice
4.	Traditional Medicine	T	YES	Vitamin, amino acid, probiotic

Halal products are just like other products in the sale of goods law. Therefore, implied conditions and guarantees for consumer protection stipulated under Part II of the Consumer

Protection Act 1999(C.P.A.) apply to the sale or supply of false halal products. Although the liability for breach of guarantees under the C.P.A. is wider as the protection extended to a mere user of goods and the liability may be imposed on the manufacturer, the remedies are confined to a repair, replacement and reduction in the value of the good which arguably, are not so significant in cases of false halal product (Amin, 2007).

Finally, the State shari'ah criminal offences laws have many flaws in attending to the offence on the abuse or misuse of the halal logo in general and halal pharmaceutical in specific. The utmost inefficient existence of this particular law to govern halal related matters is its limitation of jurisdiction, which is only confined to Muslims. Many manufacturers of halal products are non-Muslim; thus, this law becomes inapplicable if the non-Muslim manufactured attach the halal sign to non-halal food and drink. The second issue is that all of the provisions confined the offence to food and drinks; thus, it does not apply to pharmaceutical products. Thirdly, the sentences provided are not uniform intrastate. Lastly, some state shari'ah criminal offences laws do not have a specific provision to regulate the misuse of halal logos.

In summation, it is submitted that a specific regulatory framework is required to guarantee conclusive Shari'ah compliance, which needs to be resolved through impregnable cooperation between all parties involved, namely manufacturers, pharmacists, governments, scientists, researchers, developers of vaccine and private entities in providing a piece of transparent and accurate information regarding the halal status of pharmaceutical products.

Issue of Trade Secrets

One of the issues highlighted by Johari (2015) is the confidentiality problems of the ingredients used for the pharmaceutical. Most of the manufacturers are reluctant to disclose all pharmaceutical ingredients because of the fear of duplication of product. It can be explained that the manufacturer and the seller have a moral obligation to inform the consumer of any material information of the pharmaceutical to the consumer. Material information includes all information that will aid the consumers in giving informed consent and deciding to consume the pharmaceutical. As halal is an important subject to consumers nowadays, information on the halal status of the pharmaceutical becomes significant. This can be seen when the issue of halal status of a product has, on many occasions (Habib et al., 2011) tampered with the sensitivity of Muslims in Malaysia and other parts of the world.

Ministry of Health imposes a regulation to ensure that pharmaceutical manufacturers list all the active and inactive ingredients on the leaflets of their products (Abd Aziz et al., 2014). The manufacturer contested this regulation as many pharmaceutical manufacturers were not keen to provide full information on inactive ingredients of their products, as they want to preserve the confidentiality of formulation to avoid competition among other pharmaceutical manufacturers (Latiff, 2015). This involves the issue of the manufacturers' intellectual property rights over the pharmaceutical ingredients and formulation. The NPRA has a special form for pharmaceutical manufacturers to ensure the confidentiality of the information in the submitted documents. However, JAKIM does not have a similar document and does not practice the same protection of intellectual property rights of the manufacturers.

In considering this matter, we can refer to the idea posed by Dukes (2006), which mentioned the need to strike a fair balance between the self-interest of the company and its investors on the one hand and the interest of the society on the other hand. This involves both ethical and legal questions. The importance of disclosure to the public has long been discussed. In the Netherlands, the law made no provision for any such disclosure as the information is said to be the property of the originator (Bucknell, 2011). On the other hand, in the United Kingdom, if a pharmaceutical company wants to market a new medicinal product, it has to comply with the mechanisms created under the legislation, which allow a limited period of exclusivity. In the case of *R v. Licensing Authority ex p Smith Kline (H.L.)* [1990] 1 A.C. 64, the House of Lords said:

"..the use of regulatory procedures to obtain protection from imitation amounted to misuse of the system."

The statement shows that the United Kingdom favours the right to disclose information of medicinal products to the public over the originators' rights. In contrast, the U.S. stands to favour the rights of the originators to retain exclusivity over the information of their innovations. However, it was commented by Dukes (2006) that the practice in the U.S. is inconsistent as there are some situations where the originator firms had successfully retained the usage of their information based on trade secrets. Nevertheless, data on the testing of antibiotics and additives were fully disclosed.

Issues of intellectual property rights within the pharmaceutical field usually involve the patent owner's rights. In some situations, the patent owners abuse the right by increasing the price and denying the right to access medicines to the poor (Dukes, 2006). Halal products have attracted many companies to innovate and formulate halal compliant products, and this scenario has also affected the halal pharmaceutical industry. As halal compliance involves understanding the halal concept in detail, those who can produce halal pharmaceutical formulations deserve to patent their products. The issue is not only about disclosure of the formulation to the public, but it also involves the adequacy of halal pharmaceutical formulation to be patented.

The existing practice sees that the innovator of pharmaceutical or medicine for critical diseases takes steps to patent their innovations to limit the other pharmaceutical companies. However, the usual practice in halal pharmaceutical research and design is to formulate an alternative to the patented formulation, known as generic drugs. For example, the patient who uses the medicine known as *claxane* and *fraxipane*, which contain porcine, now has a halal alternative known as *Arixtra* as deliberated in the 87th Muzakarah held in 2009. Another non-halal pharmaceutical is *Monumune Injection* as decided during 53rd Muzakarah in 2005 which now has a halal alternative named *Mencevax Injection* and the latest halal alternative discoveries are *Menveo*. Thus, it is suggested that JAKIM formulate a similar form to protect the intellectual property rights of the pharmaceutical formulator.

Conclusion

In encapsulation, the discussion demonstrates the operation of the existing law, which forms an important element to discuss the practicality of these laws to address issues within the halal pharmaceutical industry. It can be seen that the current laws could not keep abreast

with the rapid changes in the innovative technology within halal pharmaceutical production. This setback would, in turn, affect many consumer rights, especially the consumer rights to information. The halal pharmaceutical industry needs to be supported with clear legal injunctions to have not only a halal labelled pharmaceutical that does not contradict the undertaking of the label, but that can also ensure a reliable halal assurance system from farm to table.

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