HALAL PHARMACEUTICALS:
A REVIEW ON MALAYSIAN STANDARD, MS 2424:2012 (P)

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ABSTRACT

The increasing of halal awareness in the pharmaceutical industry has a prominent impact on Malaysia's economic growth. The awareness surprisingly boosts customers' trust and confidence in every product claimed as halal compliant. As to uphold the trust of customers in halal products, halal pharmaceutical is introduced to the pharmaceutical industry. Aligned with the existence of the halal pharmaceuticals, MS 2424:2012 (P); a Malaysian Standard in Halal Pharmaceuticals-General Guidelines was developed. The standard is fully installed with the terms and definitions pertinent to the halal pharmaceuticals and all of the requirements to comply halal certification.

Keywords: *Halal industry; Halal pharmaceuticals; MS 2424:2012 (P); Malaysian Standards; halal compliant.*

1.0 INTRODUCTION

In advent of halal issues, grown and deemed by Muslim and non-Muslim vastly in Malaysia, pharmaceutical industry is entrusted to be one of the halal compliant industries, as a strategic economic segment for Malaysia whether in domestic usage or export agenda. As stated by Health Minister of Malaysia, Datuk Seri Liow Tiong Lai, the Malaysia's pharmaceutical industry is gaining global recognition with exports expected to grow 8% in 2012 to RM 610 million from RM 564 million in 2011. Such recognition shall be broadened more with the presence of halal pharmaceuticals.

To conduct large scale industry like halal pharmaceutical, there are no laws and regulation to be applied on the industry. Therefore, a guideline is needed to assure the halal pharmaceutical companies are all up to the same benchmark. The Department of Standards Malaysia (STANDARDS MALAYSIA), a national standards and accreditation body of Malaysia has developed MS 2424:2012

(P); a guideline for halal pharmaceutical. The standard describes the general guidelines in manufacturing and handling of halal pharmaceuticals and serves as a basic requirement for halal pharmaceuticals in Malaysia. The entity behind this standard is the Technical Committee on Halal Food and Islamic Consumer Goods under the authority of the Industry Standards Committee on Halal Standards.

2.0 TERMS AND DEFINITIONS

Through the first few pages of the main content in the standard, the terms are listed and defined as reference to the pharmaceutical companies to create a fine line as to avoid ambiguities. For instance, halal pharmaceuticals is defined in the standard as pharmaceutical products in finished dosage forms, and includes both prescription and non-prescription medicinal products for human use, which is registered under the Drug Control Authority, Ministry of Health Malaysia and contain ingredients permitted under the shariah and fulfill several conditions such as absence of any parts of non-halal animals, free from *najs*, safe to be consumed and many more.

All of the conditions listed are relevant to shariah (MS 2424:2010 (P), 2010a). The terms are continued with familiar Islamic words such as shariah, halal and *najs* (MS 2424:2010 (P), 2010a). Then, the list goes to the manufacturing terms like manufacture, materials and competent authorities (MS 2424:2010 (P), 2010a).

3.0 REQUIREMENTS

Next, the standard outlined major requirements that must be fulfilled by the pharmaceutical companies in order to be halal-certified. The requirements are generally broken down into nineteen (19) parts. Each one of the requirement shall be incorporated with Pharmaceutical Inspection Cooperation Scheme (PIC/S): Good Manufacturing Practice and Pharmaceutical Inspection Cooperation Scheme (PIC/S) Annexes currently being enforced by the relevant competent authority (MS 2424:2010 (P), 2010b).

At the top of the list is on the quality management. The pharmaceutical company shall ensure that the halal pharmaceuticals are manufactured according to halal requirement which has been outlined by the shariah (MS 2424:2010 (P), 2010b). The management for each company shall ensure that the Halal Assurance System shall be comprehensively designed and correctly implemented with application of halal, Good Manufacturing Practice (GMP), and Quality Control (QC). The designed system shall be fully documented and the effectiveness is monitored (MS 2424:2010 (P), 2010b). The Halal Assurance System itself shall be appropriate for the manufacturing of halal pharmaceuticals and shall be ensured that the pharmaceuticals production, control operations and processing line are designed and developed in a way that comply with the requirements of halal, Good Manufacturing Practice (GMP) and shariah (MS 2424:2010 (P), 2010b). The main control point in the GMP is on the source of materials and utilities that comes in-contact with the products (MS 2424:2010 (P), 2010b).

The requirements to the GMP listed in the standard emphasizing on the related materials of halal pharmaceuticals that shall be clearly defined with evidence of complying with shariah requirement and providing necessary facilities and resources for halal compliance such as the availability of appropriate qualified and trained personnel, adequate premises, space and services, correct materials, containers and labels, approved procedures and instructions and dedicated equipment, storage and transport. The GMP also emphasizes on the records that are made manually or by recording instruments during manufacture and the distribution of the products. The records shall demonstrate the steps required by the defined procedures and instructions were taken. Any

significant deviations are fully recorded and investigated. All records of manufacturing including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form. While for the distribution of the products, it shall minimizes any risk to the companies' halal integrity by applying shariah and it shall has a system that can recall any batch of products, either from sale or supply (MS 2424:2010 (P), 2010b).

Halal Quality Control likewise GMP, is a vital requirement in this standard, where it is implied as to ensure all materials used are halal compliance. The purchase, handling and sourcing of chemicals, reagents, apparatus, equipment and other items required for sampling and testing shall not be made from any source that is decreed as non-halal by shariah (MS 2424:2010 (P), 2010b).

Concerning with the requirements in the standard on personnel and responsibility, the halal pharmaceuticals company shall ensure that there are sufficient qualified personnel available to establish and maintain a satisfactory Halal Assurance System. All personnel shall be aware of the principles of halal and have gone through extensive training programmes that are relevant to their needs (MS 2424:2010 (P), 2010b). The company shall also establish a committee, which is led by trained Muslim personnel. The committee shall consist of purchasing personnel and 2/3 Muslim quorum and is responsible to ensure the effectiveness in the implementation of the Halal Assurance System (MS 2424:2010 (P), 2010b).

As one of the requirements to be involved wholly with the halal pharmaceutical, the company shall provide training for all personnel on the halal principles and its application. A continuous training shall be given, and its practical effectiveness shall be periodically assessed. The training programmes shall be available and approved by the halal committee organized by the company itself. All of the training shall be kept as reference for the auditors to check upon (MS 2424:2010 (P), 2010b).

Strict personnel hygiene is an integral requirement for halal and shall be adequately addressed in compliance with the PIC/S GMP Guidelines and PIC/S Annexes (MS 2424:2010 (P), 2010b). This requirement applied to personnel, premises, equipments and relating materials in halal pharmaceuticals. The premise involved in the production of halal pharmaceuticals shall be situated in an environment which, when considered together with measures to protect the manufacturing process, it presents no risk of causing contamination of non-halal materials or products.

The layout and design of the premise shall conform to the requirements of the PIC/S guidelines (MS 2424:2010 (P), 2010b). The premise shall be separated and well insulated from pig farm activities and others to prevent cross contamination through air, water, sewerage, personnel and equipment. The whole premise including equipments involved in halal pharmaceuticals production shall be bonded to Islamic value and practice (MS 2424:2010 (P), 2010b). The presence of non-conformance items shall be prohibited within premise and the equipments shall not be made of or contain any materials that are decreed as non-halal and *najs* by shariah and shall be used only for manufacturing of halal pharmaceutical products (MS 2424:2010 (P), 2010b). If the premise or the equipments were previously used or in contact with *najs Al-mughallazah*, it shall be washed and ritually cleansed as required by shariah (*samak*) (MS 2424:2010 (P), 2010b). The method of washing and ritual cleansing according to shariah for *najs Al-mughallazah* is attached with the standard in Annex A as reference. The same method is applied to the case of converting *najs Al-mughallazah* into halal production line. However, the procedure of *samak* shall be supervised and verified by the competent authority. Upon conversion, the line shall be operated for halal pharmaceutical products only. Repetition in converting the line to *najs Al-mughallazah* line and back to halal line shall not be permitted (MS 2424:2010 (P), 2010b).

As for the production and storage of halal pharmaceutical products, they shall be provided with dedicated and self-contained facilities to prevent the risk of product contaminated and thus becoming a non-halal product. When conducting quality control activities in the production area, the operations for control laboratories shall consider precaution steps as to prevent contamination on production line which also may lead to be non-halal product (MS 2424:2010 (P), 2010b).

Ancillary areas shall be provided to the workers such as prayer room that appropriately located. If the halal pharmaceutical involves with animal house, the barn shall be well isolated from other areas with separate entrance for animal access and air handling facilities (MS 2424:2010 (P), 2010b).

Documentation in each process, system, occurrence, events and such involved with the production of halal pharmaceuticals are one of the requirements listed in the standard. For instance, the Halal Assurance System shall be documented including evidence of materials origin and shall be approved, signed and dated by authorized Muslim personnel (Department of Islamic Development Malaysia, JAKIM). The documents required shall include but not limited to Halal Certificates from recognized certification bodies, product data sheet which contain complete description on the materials source of origin and method of processing and manufacturing formula and processing instructions. All of the documents involved shall be verified by the manufacturer (MS 2424:2010 (P), 2010b).

The requirement on manufacturing purpose materials in this standard covers all materials used in manufacturing of halal pharmaceuticals including starting and packaging materials. The materials may be from synthetically- or naturally-derived sources (MS 2424:2010 (P), 2010b). In the standard, it is highlighted that the synthesized and natural materials, whereby for natural materials can be divided into six categories, which are from animal, plant, minerals, microorganisms, natural chemicals and genetically modified organisms (GMO) sources that are lawful and permissible according to shariah.

The track of material source and design for packaging is also a requirement as to obey the halal pharmaceuticals standard. The consumable and non-consumable packaging and printed materials shall be from any origin that is decreed as halal according to shariah. While the packaging design, sign, symbol, logo, name and picture shall not be misleading and contravening the principles of shariah (MS 2424:2010 (P), 2010b).

If the halal pharmaceuticals involve with contract manufacture and analysis, both shall be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of satisfactory quality and that is decreed as halal by shariah. There shall be a written contract between the Contract Acceptor which clearly establishes the duties of each party, which include complying with the halal requirements (MS 2424:2010 (P), 2010b).

As to maintain the standard periodically, self inspection shall be conducted in order to monitor the implementation and compliance with halal and Good Manufacturing Practice (GMP) principles and to propose necessary corrective and preventive measures.

The legal requirements in complying halal pharmaceuticals are as important as the requirements from MS2424:2012 (P); the standard for halal pharmaceuticals. The company shall comply with legislation including other relevant requirements currently in force in Malaysia (MS 2424:2010 (P), 2010b).

4.0 COMPLIANCE

Upon all of the requirements, the compliance of this standard by the halal pharmaceutical companies is deemed to Clause 4 of this standard. The compliance also shall be verified through site inspection as deemed necessary by the competent authority (MS 2424:2010 (P), 2010c).

5.0 HALAL CERTIFICATION MARK

Although all of the requirements listed in the standard shall be complied vigilantly for the better of halal pharmaceuticals industry, the standard however, is not necessarily contains all requirements to obtain halal certificate. The halal certificates shall be issued by the competent authority in Malaysia, which is JAKIM itself as the main provider of halal certificates (MS 2424:2010 (P), 2010d). And to get the halal certification mark, an approval from drug control authority in Malaysia, which is the National Pharmaceutical Control Bureau (NPCB) on the products, is needed for each halal pharmaceutical to be marked with the halal certification mark of JAKIM, the Islamic authority in Malaysia (MS 2424:2010 (P), 2010e).

6.0 APPLICATION OF HALAL CERTIFICATE

To obtain a halal certification for halal pharmaceuticals industry from JAKIM, there are steps to be followed that have been outlined by JAKIM authority. Ahead of all steps, the relevant documents shall be accessible for JAKIM appraisal. The evaluation of application forms and supporting documents include a detailed analysis of the company's profile and registration, the local authority's license, declared ingredients, name and address of manufacturers/suppliers of ingredients, original status of halal ingredients, packaging material, manufacturing process and procedures, halal certification from supplier and slaughterhouse certification from the State Islamic Department if it is involved with the halal pharmaceutical production. On-site inspection session comes right after full payment of certification fees.

The inspection of the premises has to be in accordance with those application forms and all of the supporting documents as listed before. The site visit involves a meeting with senior officers of the company and questioning the production staff responsible for the hall requirements. The physical site will be inspected thoroughly including the inspection of ingredients declared, storage of raw materials and finished products, cold rooms, processing plant (manufacturing flows and handling aspects during production), packaging materials, general hygiene, quality control (QC) and assurance practices.

Then, the technical inspectors conducting the on-site visit and analysis will write a full report on the status of the application and the report will be presented and evaluated by a committee for issuing halal certificate and some recommendations on the application. JAKIM authority will then issues the halal certificate and give permission on using the Halal logo for the products supplied if the products confront no impediment in getting the halal status (Halal Journal, 2005). However, the validity period of the certificate is within two (2) years and subject to renewal of the application not more than three (3) months before the expiry date (Halal Journal, 2005).

As an exemplar of halal pharmaceutical compliant, the fast growing halal pharmaceutical industry and also the largest pharmaceutical manufacturer in Malaysia; Chemical Company of Malaysia Berhad had received JAKIM's halal certification and Malaysian Ministry of Health's (MOH) certification as a manufacturer meeting the GMP guidelines of the Pharmaceutical Inspection Convention and Cooperation Scheme (PIC/S) and the requirements of World Health Organization (WHO). The CCM's Pharmaceuticals Division had produced over 280 products and becomes the Malaysia's leading over-the-counter (OTC) product manufacturer with outstandingly well known brands such as CHAMPS, Proviton, Flavettes, Naturalle, Uphamol, Lipasu and Natberry. All of these branded pharmaceutical products from CCM are all halal certified.

The halal certification received by CCM is not only limited to OTC products but for all products manufactured at its Pasir Gudang, Malaysia facility such as liquid chlorine, sodium hydroxide,

hydrochloric acid, sodium hypobhlorite, polyaluminum chloride and ferric chloride. These halal certified products are supplied to various industries like water treatment, food and beverages, additives, edible oil, oleochemical and textiles for domestic use and exportation. These products are used as primary raw material or as additives which contribute to the quality and halal status of the final product (CCM, 2008).

7.0 CONCLUSION

As to conclude, MS 2424:2010 (P); a Malaysian Standard on Halal Pharmaceuticals – General Guidelines is a complete reference for halal pharmaceutical companies to comply. With the help of experts who develop the standard, it shall have no constrains. However, the standard and requirements for halal certification application are two separate identities to be complied with. This standard shall be complied before the application of halal certification. And compliance with this standard does not itself confer immunity from legal obligations.

REFERENCES

CCM. (2008). CCM – Forefront of the Halal Pharmaceutical Industry. 13th May 2008. ©Copyright 2012 Chemical Company of Malaysia Bhd.

Halal Journal. (2005). JAKIM Halal Certification Details. The Halal Journal Jan/Feb 2005. Kuala Lumpur: KasehDia Sdn Bhd.

MS 2424:2010 (P). (2010a). Terms and Definitions. Halal Pharmaceuticals – General Guidelines, MS 2424:2010 (P). Malaysian Standard. ©Copyright 2010 Department of STANDARDS MALAYSIA.

MS 2424:2010 (P). (2010b). Requirements. Halal Pharmaceuticals – General Guidelines, MS 2424:2010 (P). Malaysian Standard. ©Copyright 2010 Department of STANDARDS MALAYSIA.

MS 2424:2010 (P). (2010c). Compliance. Halal Pharmaceuticals – General Guidelines, MS 2424:2010 (P). Malaysian Standard. ©Copyright 2010 Department of STANDARDS MALAYSIA.

MS 2424:2010 (P). (2010d). Halal Certificates. Halal Pharmaceuticals – General Guidelines, MS 2424:2010 (P). Malaysian Standard. ©Copyright 2010 Department of STANDARDS MALAYSIA.

MS 2424:2010 (P). (2010e). Halal Certification Mark. Halal Pharmaceuticals – General Guidelines, MS 2424:2010 (P). Malaysian Standard. ©Copyright 2010 Department of STANDARDS MALAYSIA.