

Towards a Halal Certification Module and Training Programme Development for the Pharmaceutical Industry

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Abstract: The Halal pharmaceutical industry is relatively new and offers untapped opportunities to be further developed. The objective of this study is to develop Halal certification modules and training programmes to cater to the differing groups of auditors, industry, health professionals and consumers. In January 2012, Standards Malaysia announced the debut of the new Malaysian Standard for Halal pharmaceuticals, MS 2424:2012, a great leap forward in allowing pharmaceutical manufacturers to obtain Halal compliance certification for their products. With the advent of this Halal standard, there is now a growing demand from the pharmaceutical industry for training programmes in order to apply and achieve Halal certification for their products. The MS 2424:2012 standard is studied in depth and organizations involved in the development are consulted to develop appropriate training modules. Experts from various fields including medicine, dentistry, *shariah*, science and others are recruited and trained to become module instructors. The graduate interns involved in the project undergo attachments and extensive training in view of upscaling into halal pharmaceutical executives. The launch of the modules and training programme is expected to contribute significantly to greater ability of the pharmaceutical industry to cater to Halal requirements and thus satisfy public demand, while at the same time promising higher sales and export potential. There is a growing awareness and thus corresponding demand for medicines that comply with shariah requirement from the Muslim *ummah* or public. Thus, the research perspective of halal pharmaceutical industry in Malaysia becomes wider. The development of the training module is an effort to facilitate the pharmaceutical industry to comply with the *shariah* requirements.

Key words: Pharmaceuticals • Halal • Training Module • MS2424:2012 • Certification

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INTRODUCTION

As narrated by Abu Darda, a companion of the Prophet Muhammad (saw), “The Prophet (saw) said Allah has sent down both the disease and the cure and He has appointed a cure for every disease, so treat yourself medically, but use nothing unlawful.” [1]. Thus the obligation and requirement for Halal pharmaceuticals holds true for each and every Muslim. However up to the present, there has been little effort to ensure that medicines taken by the more than 1 billion Muslims worldwide are certified as Halal and comply with *shariah* requirements [2]. As such, there are numerous examples of pharmaceuticals such as vaccines, injectable suspensions, tablets, pills and capsules that contain ingredients from animals not slaughtered according to the *shariah* methods and even porcine origin considered as unacceptable *mughallazah najis* or filth, as well as mixtures that contain high percentages of alcohol [3]. Therefore, the Islamic obligation for Halal pharmaceuticals is undoubtable and has yet to be fulfilled.

This is a vast untapped area with huge economic potential; the global pharmaceuticals market is estimated to be worth some US\$800 billion annually. The Muslim market share is estimated to be in the hundreds of billions, considering Muslims constitute around 2 billion of the world’s total population. Recent days has seen very promising developments. The Chemical Company of Malaysia (CCM) has become the first pharmaceutical manufacturer to obtain Halal certification for its products [4]. In January 2012, Standards Malaysia announced the debut of the new Malaysian Standard for Halal pharmaceuticals, MS 2424:2012, a great leap forward in allowing pharmaceutical manufacturers to obtain Halal compliance certification for their products. Therefore the objective of this study is to develop Halal certification modules and training programmes targeted (but not limited) to pharmaceutical manufacturers to assist with compliance with the MS2424:2012 thus enabling the production of pharmaceuticals that are certified to be halal.

Halal Pharmaceutical Industry: In contrast to the Halal food industry, the Halal pharmaceutical industry is relatively untapped. However there is growing recognition of the vast prospects of Halal pharmaceuticals considering the global pharmaceutical market is worth some US\$800 billion annually, together with the fact that Muslim comprise some 2 billion people and rising.

In 2012, Standards Malaysia unveiled the new Malaysian standard for Halal pharmaceuticals, MS 2424:2012: Halal Pharmaceuticals: General Guidelines [5]. Nevertheless, there is a current vacuum of Halal pharmaceutical training or certification programmes despite rising industry demands. In addition, the launch of the new version of the Malaysian Halal Certification Manual Procedure 2011 (Second Revision) by the Islamic Development Department of Malaysia (JAKIM) marked the opening of its pharmaceutical certification scheme starting by February 2012 [6]. Therefore, this is a novel effort to develop a module for training and certification of the industry and to engage other stakeholders involved in Halal pharmaceuticals. This project is in collaboration with Halal Industry Development Corporation (HDC), an organization with extensive Malaysian and global experience and expertise in conducting Halal certification training programmes, for example in Halal logistics and in the Halal food industry.

The challenges faced by the Malaysian halal pharmaceutical industry lie in the approach towards process and system management to achieve seamless integration throughout the raw material supply chain and manufacturing process. The goal is to fulfill the *Shariah* and monitoring agencies legislative requirements [7]. There is a prominent lack of databases for Halal, Haram and *Syubhah* ingredients and additives in pharmaceuticals. There is an urgent need for a Halal pharmacopoeia [8]. Further development of novel Halal pharmaceutical alternatives and technological innovation are also much needed. Scholars need to research and analyse potentially conflicting legal-ethical issues of *shariah* compliance of medicines and the *shariah* concept of *dharurah* in facing life and death. Another area needing attention is consumer rights towards informed choice [9]. This is just the tip of the iceberg of undeveloped Halal frontiers for pharmaceuticals in the effort to fulfill the needs of the Muslim nation. Universiti Sains Islam Malaysia (USIM)’s IHRAM Halal pharmaceutical training modules, targeting the industry, monitoring agencies, health care providers and consumers offer promising solutions towards this important goal of providing vast access to halal medicines for the Muslim *ummah*.

Development of a Halal Certification Module and Training Programme: According to the Malaysian Standard MS 2424:2012 Halal Pharmaceuticals – General Guidelines, subtopic 4.7 (Training), clause 4.7.1 states that, “The organisation shall provide training for all

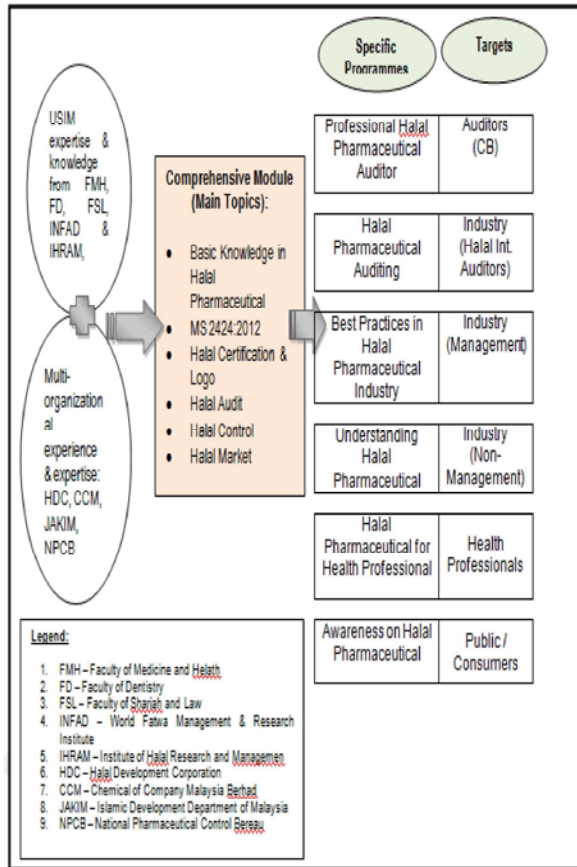


Fig. 1: Summary of the Module

personnel on the Halal principles and its application”. Therefore, comprehensive training is a requirement of the pharmaceutical industry especially for the management and members of the Halal committee to ensure the Halal requirements are fully understood and implemented.

Apart from that, this training module will facilitate manufacturers, suppliers, health professionals and consumers to integrate knowledge, understanding and awareness accordingly by its target, programmes and topics that had been proposed as shown in Figure 1 above.

This module was developed by synchronizing the available expertise and knowledge at USIM which includes current team members as well as a small number of subject matter experts mostly from other Malaysian public universities, as well as other organizations including from industry. Once the expertise and knowledge to be transferred had been clearly identified, the next stage was to develop multi-organizational networks and relationships in particular with HDC, Malaysian Standards, Ministry of Health, National Pharmaceutical Control Bureau (NPCB), JAKIM, CCM and

others to allow the efficient and comprehensive transfer of such knowledge to HDC in the form of a module or training programme. A pool of expert trainers and module instructors has been developed mainly amongst USIM lecturers. They consist of medical, dental, Islamic studies, *shariah*, law, science and technology and other experts. They have all undergone Halal training of trainer programmes and have been certified as Halal trainers by HDC. Furthermore, the graduate interns involved with this project have undergone various attachments, seminars and meetings with the aim of upscaling to become highly competent halal executives.

The Significance of Training Module to the Pharmaceutical Industry: The development of the training module that enables compliance with the MS 2424:2012 standard and JAKIM’s manual of procedures or protocols requirements, can contribute significantly to the overall growth of the Halal pharmaceutical industry not only in Malaysia but also at the international level. This innovation ultimately fulfills our responsibility as Muslims, raises public awareness and achieves public acceptance as well as public satisfaction on Halal pharmaceuticals. It will fulfill the consumers’ (*ummah*) needs by having a pharmaceutical product that delivers the concept of “halalan thoyyiban” meaning not only Halal, but good and safe to be consumed. Hence, it will enhance the general consumers’ (*ummah*) confidence in using the Halal pharmaceutical products and reduce the current dependency on pharmaceutical products that do not comply with *shariah* requirements.

This initiative will create greater recognition for the USIM academia and catalyze further improvement of the on-going modules contained within the Halal Executive Programme conducted by IHRAM and HDC. In addition, this innovation is expected to generate greater revenue for HDC as well as to bridge the existing gap between the needs of the Muslim *ummah* and the pharmaceutical industry.

In addition, this training and certification module programme is an organized and structured body of information that integrate; *shariah* and technical aspects of Halal certification with experts from the medical, dental, *shariah*, science and various other fields. This module will help the pharmaceutical industry to understand the principles of *shariah* in manufacturing and in producing Halal pharmaceutical products, as outlined by the Halal Pharmaceutical standards of MS 2424: 2012. It will allow HDC to conduct relevant and highly marketable training or certification programmes on Halal pharmaceuticals both locally and internationally.

Research Perspective of Halal Pharmaceutical Industry in Malaysia:

The global pharmaceutical industry has grown rapidly, reaching an estimated value of US\$800 billion per annum and pharmaceutical manufacturers are among the largest corporations in existence. The industry is dominated by massive pharmaceutical manufacturers based in industrialized countries specifically Western Europe, North America and Japan. Despite little shareholdings or ownership by the Islamic populace, the companies are also becoming increasingly aware of the requirements of Muslims considering the huge segment that Muslim consumers constitute.

In Malaysia, the pharmaceutical industry has shown progressive growth over the years, particularly over the last one decade. The industry has invested substantially to upgrade itself in the last few years to meet the latest Good Manufacturing Practices (GMP) requirements, in accordance with the domestic as well as international Guidance [10].

In view of nascent halal pharmaceutical issues and with Malaysia taking the leadership position to address them, the 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 [11]. Thus, the MS2424:2012 standard plays a crucial role as a guideline to ensure the pharmaceutical industry complies with shariah requirements.

Currently the industry has the capacity to produce medicines in all dosage forms such as tablets (coated & non-coated), capsules (hard and soft gelatine), liquids, creams, ointments, sterile eye drops, small volume injectable (ampoules and vials), large volume infusions, dry powders for reconstitution and active pharmaceutical ingredients (API). Pharmaceutical manufacturing is already highly regulated for example by GMP and Pharmaceutical Inspection Co-Operation Scheme (PICS) [12-15]. For halal pharmaceuticals, the paradigm is that halal should be inbuilt throughout the manufacturing process. Therefore, this comprehensive training module would assist halal compliance for each and every stage of production, as overseen by the internal halal committee of the pharmaceutical manufacturer themselves.

CONCLUSION

This halal certification module and training programme contributes significantly to the ultimate aim of ensuring that pharmaceuticals used by the *ummah* are Halal. While fulfilling Islamic obligation or “*fardu kifayah*”, the module will also help provide a clearer understanding of halal pharmaceuticals by the *ummah*,

building greater public satisfaction and confidence in pharmaceutical products. The module is not only limited to local applications, but appropriate to be applied on an international basis for example to the main pharmaceuticals giants, considering the increasing awareness and economic strength of the Muslim *ummah* worldwide.

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