



## Halal requirements for Pharmaceuticals and Biologicals in ASEAN

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### Executive Summary

Some governments in ASEAN countries, such as Indonesia and Malaysia, are introducing measures to implement Halal requirements (Halal certification and Halal logo) to all consumables, including pharmaceutical and biological products, to address the religious sentiment of consumer population in those countries.

The implementation of such requirements might have unintended adverse impacts, such as treatment refusal by patients, business hindrance and additional costs to consumers. Moreover, for public health sake, it is necessary to distinguish pharmaceutical and biological (including vaccines) products from food, beverages and cosmetics.

EFPIA respects people's religion and beliefs. EFPIA also believes that it is vital for government decisionmakers and religious leaders to consider critical health implications when proposing or endorsing any new Law or Regulation. The interest of patients and optimal health treatment are the driving motivation for EFPIA members. This paper details the potential health consequences and challenges for patients needing pharmaceuticals and biologicals should Halal requirements be mandated. Accordingly, for the reasons stated in the paper, we encourage the ASEAN governments to exclude healthcare products from the scope of Halal certification and retain the option of voluntary Halal certification to ensure that patient health remains paramount.



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## 1. Introduction

Recently, some ASEAN countries have been considering implementing Halal certification and Halal/non-Halal logo to pharmaceuticals, biologicals (including vaccines) and even medical devices, to address the religious sentiment of consumer population.

Such measures might hinder the treatment options of patients relying on Halal medications.

### • **Potential impact on public health and access to medicines**

If patients refuse to receive certain treatments and/or preventive care (vaccines) because the products to be administered are not labeled Halal, it will limit patients' access to optimal health treatment. In addition, given the life-saving nature of many pharmaceutical products and vaccines, these products cannot be consumed by choice like food and beverages. They are generally prescribed by doctors according to the patients' specific conditions and there might be no other alternative to these prescribed products.

Refusal of medication may not only limit treatment options to patients, it inadvertently also elevates the risk for their health condition. In cases where patient refuse to get vaccinated or refuse vaccination for their children, disease conditions that could have been eliminated or under controlled situation in a country could resurface and pose serious hazard to public health.

### • **Increased complexity in managing logistics, administrative cost and implementation on the ground due to separation of facilities for halal and non-halal commodities**

Conforming to Halal assurance requires the establishment of (but not limited to): (i) separated Halal and non-Halal (i.e. containing porcine, blood) manufacturing facilities, (ii) additional cleaning process (iii) applications for Halal certification and audit, (iv) affixing of Halal or non-Halal label, and (v) a Halal Supervisor in the manufacturing facility.

All relevant assessments will need to be repeated/re-validated in order to incorporate the aspects of Halal assurance. Achieving the rigor in the repeated studies is extremely costly and time-consuming (many years). If companies are not able to complete and obtain Halal approval on time, it will impact the product supply and can result in market shortage of life-saving products. Additionally, multinational companies extensively engage third-party services (e.g. raw material supplier), who will be required to be Halal certified and audited for compliance.



### \* Increased cost to consumers

Halal certification process, separation of Halal and non-Halal manufacturing facilities, additional cleaning process, setting up of Halal assurance systems, training of qualified Halal personnel, Halal certification renewal, Halal on-site inspection, as well as the use of Halal transportation and distribution facilities will inevitably lead to additional costs for the industry, to be subsequently passed on to consumers. Increased cost of medicines will create barriers for consumers to access life-saving products.

## 2. Background & Current situations in ASEAN

### Indonesia & Malaysia

#### \* INDONESIA

The Indonesia government issued a Law on Halal Product Assurance (so called the “Halal Law”) on 17 October 2014 (UU Jaminan Produk Halal No. 33/2014<sup>1</sup>), making Halal certification and labeling mandatory for food and/or services related to food and beverages, medicines, cosmetics, chemical products, biological products, genetically-engineered products, and any other products which are applied, used or utilized by people in Indonesia. The Halal Law requires pharmaceutical and biological products to comply with Halal certification and labeling from October 2019 onwards.

The Halal Law needs implementation Regulations, that were planned to be issued within 5 years after 17 October 2014. However, due to ongoing discussions between the different official governing bodies, including Indonesia Ministry of Health (MoH) and Ministry of Religious Affairs (MORA), as well as the Industry’s constant advocacy efforts on the Halal Regulations, the implementation of the Halal Law remains uncertain until today. The Indonesia MoH supports the Industry’s position<sup>2</sup> requesting the exclusion of pharmaceuticals and biologicals from the scope of the Regulation, or alternatively implementing Halal requirements for pharmaceuticals and biologicals on a voluntary basis, and without display of a non-Halal logo on the packs. The Ministry of Industry has also expressed concerns over the negative impact of the Halal Law on the economy.

In April 2018, the Indonesia MoH and the Halal Product Assurance Agency (BPJPH – Badan Penyelenggara Jaminan Produk Halal in Bahasa Indonesia) have agreed on a ‘voluntary’ Halal implementation to pharmaceuticals and biologicals, i.e. that non-Halal products could stay on the market and will not need to be labeled non-Halal as long as the Halal alternatives are not yet available. Moreover, in October 2018, the Government has agreed in principle to remove the implementation deadline for pharmaceuticals and biologicals from the Halal Implementing Regulation, meaning that they will be last in the



implementation stage. The above recent developments need to be further confirmed and regulated by a Presidential Decree, currently expected to be released before end of 2018.

For a final assessment of the impact and implications of the Halal Law, the industry must wait for the finalization and publication of the implementation Regulations, which should further detail the technical parameters for Halal certification.

The Halal Law contains provisions stipulating that Halal certificates can only be issued by the Halal Product Assurance Agency (BPJPH), and Halal labels will be made mandatory on packaging materials of food and beverages, cosmetics, chemical products, pharmaceutical and biological products.

BPJPH was established in 2017 under the Ministry of Religious Affairs (MORA) and will lead the Halal certification services.

**We can expect the following changes and impacts if the Halal Regulations mandate the application of Halal requirements to pharmaceuticals and biologicals in Indonesia:**

- Halal and non-Halal logo/label will become mandatory;
- 'Halal By Design' concept (similar to 'Quality by Design' concept) will start;
- Halal supervisor(s) will need to be employed in the pharmaceutical organization;
- Index Book on Halal API and Excipients will be released;
- Halal Good Manufacturing Practices (GMP) for pharmaceutical and biological products will be developed.

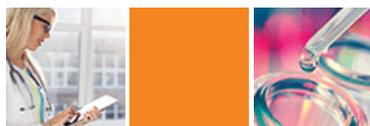
If it is confirmed that all the requests for Halal certification, from any drug product manufacturers as well as API, excipient and raw material manufacturers, should be submitted to the BPJPH, it will be highly challenging to operate on time. Certification also implies inspections of all relevant production sites by BPJPH.

**\* MALAYSIA**

The Malaysia Halal Standards for Pharmaceuticals "MS 2424:2012 – General guidelines"<sup>3</sup> are the first Halal certification standards published in the world. The Malaysian government allows companies to apply for Halal certification on a voluntary basis ([www.halal.gov.my](http://www.halal.gov.my)).

JAKIM (Jabatan Kemajuan Islam Malaysia) is the Halal certification body<sup>4</sup> in Malaysia and the Halal certificate must be renewed every 2 years with on-site inspection.

MS 2424:2012 outlines the major Halal requirements that must be fulfilled by the pharmaceutical companies in order to be halal-certified. The requirements are detailed



into nineteen (19) parts (reference to section 4.). At the top of the list is the requirement on the quality management: the pharmaceutical company shall ensure that the Halal pharmaceuticals are manufactured according to the Halal requirements outlined by the Shariah and Fatwa (reference to MS 2424:2010 (P), 2010b). The Management staff of each company shall ensure that the Halal Assurance System is comprehensively designed and correctly implemented as per the Halal requirements, cGMP and Quality Control (QC). The main control point in the GMP is on the source of materials and utilities that come in contact with the products.

A Halal logo may be displayed voluntarily on the labels of the following product categories, providing that such products have already been registered by the Malaysia regulatory authority, and Halal certified by JAKIM certification body:

- a. Non-scheduled poison (OTC)
- b. Health Supplements
- c. Natural products
- d. Cosmetics

**The Halal logo is currently not allowed on the label of registered products of other categories than the ones listed above.**

More recently, in 2017 and 2018 respectively, the Department of Standards Malaysia reached out to the Pharmaceutical and Medical Device companies to get their viewpoints on the revision of the Malaysia Halal Standards for Pharmaceuticals 'MS 2424:2012' to incorporate Halal vaccine requirements, and on the new developed Malaysia Halal Standards for Medical Devices. The Industry's standpoint<sup>5</sup> is to withhold pharmaceutical, biological and medical device products from mandatory Halal requirement implementation, and maintain its voluntary application.

## \* Recommendations

EFPIA respects people's religion and belief. However, EFPIA believes that the mandatory application of Halal requirements to pharmaceuticals and biologicals poses important public health issues (re-emphasized below):

- Hurdles to patients' access to optimal and affordable health treatment and disease prevention, and in some cases to life-saving drugs (possibly elevating risk to their health conditions);
- Possible withdrawal of products due to high investment, or non-compliance with the Halal certification requirements;
- The role of health care practitioners, who prescribe drugs in the best interest of patients' health, could be jeopardized, as patients may disregard the



practitioner's recommendations to avoid non-Halal certified drugs due to religious sentiments.

Therefore, **EFPIA would like to advocate:**

- \* **Pharmaceutical and biological products shall be exempted from the Halal requirements.**
- \* **Alternatively, Halal implementation to pharmaceutical and biological products should be considered on a voluntary basis and should not be mandatory in any case.**
- \* **Application of a Halal logo should be applied on the pack of Halal certified products on a voluntary basis only. Products which are not Halal certified should not be required to display a non-Halal logo on their packs (though current requirements related to porcine content, in application to the Shariah Law, should be maintained).**

### 3. Glossary

- \* Halal: Halal originates from the Arabic word which means allowed or permissible by the Shariah Law and Fatwa. When food or goods are described as halal it means:
  - a. neither is nor consist of or contains any part or matter of an animal that is prohibited by Shariah Law for a Muslim to consume or that has not been slaughtered in accordance with Shariah Law and Fatwa;
  - b. does not contain anything which is impure / najis according to Shariah law and Fatwa;
  - c. does not intoxicate according to Shariah Law and Fatwa;
  - d. does not contain any part of a human being or its yield which are not allowed by Shariah Law and Fatwa;
  - e. is not poisonous or hazardous to health;
  - f. has not been prepared, processed or manufactured using any instrument that is contaminated with najis according to Shariah Law and Fatwa;
  - g. has not in the course of preparing, processing or storage been in contact with, mixed, or in close proximity to any food that fails to satisfy paragraph
- \* BPJPH (Badan Penyelenggara Jaminan Produk): Halal Product Assurance Agency established under the Indonesia Ministry of Religious Affairs (MORA)



- ✨ MORA: Ministry of Religious Affairs in Indonesia
- ✨ JAKIM (Jabatan Kemajuan Islam Malaysia): Department of Islamic Development of Malaysia. Halal certification body in Malaysia

## 4. References

1. Law of The Republic of Indonesia, Number 33 2014, about Halal product certification.
2. IPMG (International Pharmaceutical Manufacturers Group of Indonesia)'s position paper on Halal.
3. MS 2424:2012- Halal Pharmaceuticals-General guidelines, Department of Standards, MALAYSIA (<http://www.jsm.gov.my/ms-2424-2012-halal-pharmaceuticals-general-guidelines#.Wv5F7aSF0Uk>, and <https://law.resource.org/pub/my/ibr/ms.2424.2012.pdf>).
4. JAKIM (Department of Islamic Advancement of Malaysia): Manual procedure for Malaysia Halal certification (Third revision) 2014 (MPPHM).
5. PhAMA (Pharmaceutical Association of Malaysia)'s position paper on Halal.

Other references of interest:

- EuroCham (the European Business Chambers of Commerce of Indonesia) position paper on Halal Law (<http://www.eurocham.id/index.php/publications/category/372-2018-eurocham-position-paper-halal-law-head-folder.html>)
- International Business Chambers Joint Position Paper on Law No. 33/2014 concerning Halal Products Assurance (<http://cloud.chambermaster.com/userfiles/UserFiles/chambers/9078/File/Indonesia/InternationalChambers-JointPositionPaperonHalal-Final.pdf>)

