White Paper

# Position Paper on Indonesia Halal Policy for Medical Technologies

*An industry perspective*

**A joint strategic paper between IQVIA and APACMed**

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# Message to the Readers

I would like to thank all those who have worked with us in preparing this important piece of work. Since the Indonesian government stipulated medical devices fall under the purview of Halal labelling mandates in 2014, Asia Pacific Medical Technology Association (APACMed) has collaborated with key stakeholders across the healthcare ecosystem in Indonesia to publish this first position paper. The paper provides a comprehensive analysis of the Halal policy with a holistic outlook.

We look forward to further collaborations and open dialogues among key stakeholders in supporting this important initiative.

**Ms. Harjit Gill,**
*Chief Executive Officer, APACMed*

# Preface

In this position paper, IQVIA and APACMed, along with other stakeholders have collaborated to gather various perspectives from the ground. We made recommendations based on regulatory intelligence, and additional primary interviews, also giving due importance in equal measures to patients' right to informed consent, and concurring with legitimate complications shared by device manufacturers, as a consequence of the Halal law.

Ever since the Indonesian government mandated that all products (across industries) distributed within Indonesia will have to be Halal certified, there have been concerns over its implications in the medical device industry, and impact to other countries with the Halal regulation. This position paper gives insights to discuss the issues around products supply chain, end-to-end material procurement, and the overall healthcare system in Indonesia, bringing attention to industries, governments, regulatory stakeholders to work together in supporting the Muslim population in the world.

**Dr. Sherry Wang Xueying,**
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# Foreword

In today's globalized world, consumers are becoming increasingly conscious about the products and services they use, and the impact they have on their health, the environment, and their values. The Islamic community, in particular, has a growing demand for halal-compliant products and services that are in line with their religious and cultural beliefs. The MedTech industry is no exception, and the development of halal regulations in this sector has become increasingly important.

Halal regulations in the MedTech sector refer to the set of guidelines and standards that govern the production, processing, and labeling of medical and technological products to ensure that they are compliant with Islamic law. These regulations cover a wide range of products, including medical devices, pharmaceuticals, personal care products, and food additives. The aim of halal regulations is to provide assurance to consumers that the products they use are free from ingredients that are forbidden by Islamic law, such as alcohol, pork, and certain animal products.

Despite the growing demand for halal-compliant products, the development of halal regulations in the MedTech sector has been slow and fragmented. Companies face significant challenges in ensuring compliance, including a lack of clear and consistent guidelines, limited technical expertise, and difficulties in securing halal certification. These challenges can result in significant costs and delays for companies, and can also lead to confusion and mistrust among consumers.

This position paper aims to provide a comprehensive overview of the current state of halal regulations in the MedTech industry and the challenges faced by companies in ensuring compliance. It also outlines potential solutions and best practices for achieving and maintaining halal compliance in the industry. The paper includes perspectives from industry experts, halal certifying organizations, and stakeholders in the Islamic community, and provides valuable insights into the future of halal regulations in the MedTech sector.

We believe that this position paper will be an important resource for MedTech companies, Islamic financial institutions, and individuals looking to understand the growing importance of halal regulations in the MedTech industry. We hope that it will encourage further discussions and initiatives towards establishing a clear and comprehensive framework for halal compliance in the MedTech sector. This will not only benefit the Islamic community and halal-conscious consumers, but it will also contribute to the growth and development of the MedTech industry as a whole.

**Dr. Feras Mahdi,**
*Head of MedTech SEA & APAC RHQ, IQVIA*

# Executive summary

## BACKGROUND

Indonesian Government Regulation (PP) No. 39, conceived in 2021, expresses Halal mandates for all products, especially those goods and services related to food, beverages, drugs, cosmetics, chemical products, biological products, genetically modified products, and medical devices. The regulation clearly states that animal derived materials (ADMs) used in all goods – including medical devices – must be disclosed. However, there is not much clarity on specific standards, requirements and guidance that are medical devices specific, given the various classes of devices with unique specifications.

The industry may face significant challenges in marketing their products in Indonesia because of the complicated requirements for Halal compliance. On top of that, the government also has to anticipate the risk of limited patients' access to advanced technologies for disease treatment. As medical device lifecycle is very fast, advanced technology adoption will be delayed due to the Halal certification process. Indonesia is the **first and the only** country enforcing the mandatory of Halal certification for medical devices, including the option of a non-halal labeling disclaimer, which may create complexities for detailed assessment. Significant difference is that the scope of Halal certification in other countries is limited to food and beverages, whereas in Indonesia, Halal standard applies to all products, including medical devices and its allied services. Mandatory compliance of Halal policy for all classes of medical devices (MD) in Indonesia, impacts not only MD manufacturers, but also physicians, healthcare professionals (HCPs), MD importers, distributors, healthcare insurance and patients. Halal compliance also has implications on MD products and its supply chain, beginning with end-to-end material procurement for the same product, and ultimately impact the entire healthcare system in Indonesia.

## CHALLENGES

It is imperative to comprehend deep-rooted challenges and impact on various stakeholders, with a neutral and holistic perspective, in the path of implementing Halal compliance. This aspect is the very purpose of this industry position paper, where current perspectives of MD manufacturers, distributors, etc. are taken into account while also giving due credit to the Indonesian government's initiative to uphold patient rights. It is important to note that APACMed received overwhelming response from various stakeholders in the MD supply chain, indicating a genuine interest to participate in the research study and eagerness to know outcomes. In other words, this industry position paper deep-dives into the current stature – or position – of key stakeholders with a holistic view, so that recommendations for the way forward on Halal compliance are supported with convictions, in a manner that all stakeholders tend to better align.

Large-scale challenges – arising as a result of implementing Halal compliance – are analyzed from both implementation and manufacturing perspectives.

**Key metrics considered under implementation include:** Government stakeholders' coordination, bureaucratic changes in the Halal enforcement organizations, gaps in policy interpretation between governmental authorities and applicants (distributors and manufacturers), scarcity in Halal subject matter experts, difficulty in end-to-end material traceability, lack of Halal-certifiers in non-Islamic countries where end-to-end materials originate, lack of clarity in cost calculations associated with regulatory authorities and manpower increase to enforce Halal compliance.

**Manufacturing related challenges include:** Lack of alternatives for some ADMs used on in life-saving MDs, complexity of an impurity-free manufacturing process, contamination due to Halal-centric inspections, and unsurmountable costs due to establishing Halal-compliant production lines. The consequences of these challenges and impact to the local patient access and Indonesia healthcare system have been disclosed in detail in this paper.

## RECOMMENDATIONS

Following thorough analysis of contemporary Halal mandates by the Indonesian government, large-scale challenges and impact on various stakeholders, APACMed has published six-fold recommendations, by giving due importance in equal measures to patients' right to informed consent, and concurring with legitimate complications shared by MD manufacturers, as a consequence of Halal implications.

### Recommendation 1:

Leveraging global harmonization of the definition on medical device categorization within Halal certification, while defining MD with ADM and non-ADM based on human body contact risk-based approach.

- Focus on the halalness of medical devices with human body contact as a risk-based approach.

### Recommendation 2:

Indonesia Government to publish list of medical devices out of scope of Halal certification as per global standard of medical devices for ADM; including but not limited to:

- Non- Invasive Medical Device
- In-Vitro Diagnostic devices, including Research Use Only (RUOs) and Lab Use Only (LUOs)
- Active Medical Devices: Electro medical equipment, Capital products, machines including accessories and spare parts
- All metal instruments, contact lenses made from synthetic materials, surgical instruments/surgical instruments made from plants, synthetic and metal, synthetic surgical threads, cardiology instruments, cardiac catheters, patient tubing devices, ECG sensors, medical device disinfectants, instruments that are in contact with or contain tallow

### Recommendation 3:

Specific consideration through *fatwa* on product categories that are critical/lifesaving

- Unlike other consumer goods, most medical devices are used not because of the patient's choice, but to diagnose and treat certain conditions and cure patients (according to the definition of medical equipment in the ASEAN MD Directives & Ministry of Health Regulation PERMENKES 62/2017)
- Clear instructions from the Ministry of Health to guide healthcare professionals to continue prioritizing the principles of evidence-based medicine (including treatment and diagnosis) by referring to the Disease Management Guidelines that apply to diagnosis, treatment, and therapy

### Recommendation 4:

Encouraging alignment among authorities of Halal implementation

- The industry would like to see better coordination and alignment among authorities such as Ministry of Health (MoH), Ministry of Religious Affairs (MoRA), Halal Product Assurance Organizing Agency (BPJPH) and Majelis Ulama Indonesia (MUI) to resolve multiple opinions and areas of regulation that lack clarity. It will be desirable if MoRA consults with the MoH (the Medical Device expert) during the development and implementation of Halal regulation. Thus, it won't disrupt the availability of life-saving devices in the market.
- The technical requirements of the Halal certification process should be in line with international quality standards for medical devices and IVDs
- Establish a clearly defined pathway for certification, especially for overseas manufacturers. Further, it is necessary to create clear guidance on overseas Halal certification bodies that are participating in the process. Indonesian Halal authorities may establish consulting and advisory services to MD companies in order to accelerate the Halal compliance process

### Recommendation 5:

Encouraging the government to explore other possibilities in recognizing and leveraging the Halal requirements and implementation across Halal agencies in other jurisdictions

- The Mutual Recognition Agreement or Memorandum of Understanding could be explored between the Indonesia government and other Halal certification bodies to recognize Halal certification from other jurisdictions. The acknowledgement of overseas Halal certification or assessment reports should not be limited to raw materials, manufacturing process, or the finished products etc., but should also include all Halal-related assessment pieces under the umbrella of Halal laws and regulation to be flexible

### Recommendation 6:

Halal certification and labeling requirements to be required only for products that fall under Halal certification scope

- For products out of scope for Halal certification (as proposed in **Recommendation 2**), there should be NO additional requirements on labeling
- For products with Halal certification or that are in the middle of Halal certification process, they should conduct comprehensive assessments of the raw materials and should comply with the labeling requirements as required by the Halal law
- For products within the scope of Halal regulation and containing Haram materials, we recommend to only require a “Non-Halal” Disclaimer in the product IFUs or on the product packages. There should be NO additional requirements on a detailed list of Haram materials in the product IFUs or on the product packages. Also detailed raw material assessment should NOT be required for these “non-Halal” products, because of significant costs that may negatively impact product affordability with no additional benefits for patients safety or access

On the contrary, any unnecessary requirements that require manufacturers/distributors to invest significant amount of resources to fulfill will lead to negative impact to the affordability of the products, and then increase the burden on the Indonesia national healthcare system and hinder the patient access.

# Chapter 1: Introduction of halal regulations

## 1.1 BACKGROUND OF HALAL REGULATIONS IN INDONESIA

Islam is the second largest religion in the world. According to a 2020 study, Islam has 1.9 billion adherents, who make up about 24% of the world's population. Indonesia has the largest Muslim population in the world. Based on a report from The Royal Islamic Strategic Studies Center (RISSC), there are 231 million Indonesians who are Muslims who comprise of 86.7% of the total population. The proportion of the Muslim population in Indonesia represents 12% of the world total population. All these make Halal a very important and critical issue in Indonesia.

For manufacturers, Halal compliance is not just about a product assessment but a system of continuous process that is prepared, implemented and maintained to manage materials, production processes, products, human resources and procedures in order to maintain the continuity of the Halal production process in accordance with the requirements.

Initially, the Government's intention in releasing Halal law is to protect Muslim right to get Halal products according to direction from Islamic syar'i. The Indonesian government issued Halal Law no. 33 in 2014 which mandated that all products distributed within Indonesia territory must be Halal certified, where the scope also covers medical devices falling under the "Consumer Goods or Associated Goods" categories. The law of the Republic of Indonesia – Number 33-2014 – states that:

a. The constitution of the Republic of Indonesia of 1945 mandates and states that it is the independence of each resident to embrace their religion and to worship according to religious belief;

b. To ensure worship and practice of faith, the state is obliged to provide protection and assurance of Halal products consumed and used by the people;

c. All products circulating in society are not guaranteed Halal;

d. Regulation of Halal products at this time does not guarantee legal certainty and the need to be regulated in a legislation;

e. Based on the considerations set forth in paragraphs a, b, c, and d is necessary to establish the Law of Halal Product Guarantee

Government Regulation No. 39 Year 2021 stated that Medical Devices is categorized as consumer goods or associated goods that are worn, used, or utilized. Consumer goods or associated goods that are worn, used, or utilized shall only be the goods that originate from and/or contain animal ingredients.

Halal law is implemented gradually, and for medical device, it will be implemented according to their risk classification. There are 4 stages for Medical Device Mandatory Halal Certification period:

a. Medical Device Class A: Starting from 17 Oct 2021 to 17 Oct 2026

b. Medical Device Class B: Starting from 17 Oct 2021 to 17 Oct 2029

c. Medical Device Class C: Starting from 17 Oct 2021 to 17 Oct 2034

d. Medical Device Class D: Will be decided in Presidential regulation

Based on the Halal Law, companies have two options which is either having a Halal certification or providing non-Halal labeling on their products. For details on Halal labeling please refer to section 1.4 and for non-Halal labeling, section 1.5.

## 1.2 HALAL DEFINITIONS

Halal is an Arabic term, which means lawful or permissible in Islam. In Quran, the word Halal contrasts with Haram. Halal is specifically related to meat which is prepared and processed as per the requirements of the laws. On the other hand, Haram means "forbidden" or "prohibited". As indicated in Quran, there are many products, such as dead animal before slaughter, alcohol, pork and stunned meat (without Halal process), blood and its by products, that are Haram. Halal and Haram are parts of Islamic teachings (written in Al Quran dan Al Hadits). Adhering to the rules of Halal and haram is mandatory for all Muslims.

### 1.3 HISTORY AND TIMELINE OF INDONESIA HALAL DECREE

There are more than 20 regulations that are related to Halal at the moment including law, government regulations, ministerial regulations, decree that were issued as a technical guidance document from various government bodies such as President, Government of Indonesia, Ministry of Religious Affairs, Halal Product Assurance Organizing Agency (BPJPH) and Majelis Ulama Indonesia (MUI). Details of Halal Regulations journey captured in Appendix 2.

### 1.4 HALAL LABELING

Halal Label is the Halalness mark of a Product. As per Regulation No. 39, 2021, BPJPH shall be authorized to issue and revoke the Halal Certificate and Halal Label on a Product. Previously, Halal Certificate and Logo/ Label were issued by MUI.

The Company shall be obliged to include a Halal Label on the Product that has received a Halal Certificate. Halal label shall be attached on product package; certain parts of the product; and/or a certain areas on the product.

**Figure 1. Old and new halal labels**

**Previous: Halal logo MUI**

**Current: Halal logo BPJPH (As per BPJPH decree no 40 year 2022)**

### 1.5 NON-HALAL LABELING

Currently, non-Halal labeling scheme is implemented on products related to food and beverages, medicines, traditional medicines, and dietary supplements category. It is not yet readily available for medical devices, since the technical guidance from the respective authority is not defined till date.

Non-Halal information available for food and beverages (F&B), medicines, traditional medicines and dietary supplement categories currently refer to National Agency of Drug and Food Control or The Indonesian Food and Drug Authority of Republic Indonesia (BPOM) regulation.

For medical devices category, statement for non-Halal information is following the practice from other authorities such as BPOM RI and applied to haram materials only (e.g porcine). There is no official technical guidance on non-Halal information for other products and it needs to be further clarified through collaborative and strategic dialogues with relevant stakeholders.

In general, according to the latest regulation no. 39, 2021, non-Halal information applies to products that originate from haram materials only. Any company that produces products from materials that originate from haram materials shall oblige to include non-Halal information in the form of pictures, writing, and/or the material names using different color schemes in the composition of materials.

Inclusion of non-Halal information as mentioned above, shall be obliged to be visible and readable as well as not be easily wiped, removed and tampered by observing the provisions of legislations.

### 1.6 INVOLVEMENT OF MULTI GOVERNMENT STAKEHOLDERS

In Indonesian, BPJPH stands for Badan Penyelenggara Jaminan Produk Halal (Halal Product Assurance Organizing Agency). Since October 2017, it has been enacted by the Indonesian Government to conduct and authorize Halal certification registration and process under the Law number 33 of 2014 through Halal Product Assurance. Although BPJPH acquires its own authority to deal with certification of Halal products in Indonesia, the Halal provisions of this agency still refer to the written fatwa of MUI.

Due to the fact that Muslims are the majority in Indonesia, the main purpose of BPJPH is to increase sense of security and comfort of the products they use, while assuming all products are feasible to be Halal certified. It should be noted that there are only a few Halal alternatives available at the time while patients do not have any other treatment options especially for life-saving purpose. Therefore, involvement of multi government stakeholders is highly encouraged to define the most possible assessment and implementation routes. This is poised to ease industry's alignment with the policy making authorities.

This list of stakeholders is intended to provide an overview of important government stakeholders which relate to the implementation of Halal regulations for medical devices. The list is provided in Appendix 3.

### 1.7 HALAL IMPLEMENTATION IN OTHER JURISDICTIONS

In general, the main purpose of the government to release Halal requirements is to protect their citizens from forbidden/haram food and to provide legal certainty especially for Muslims. This commitment shows that the government plays an important role in Halal certification.

The issue of Halal law is no longer solely a matter of religious affairs as it has a major impact on the economic growth in many Islamic countries. However, how these countries regulate Halal is vastly different from what we see in Indonesia. As of today, Indonesia is the only country that regulates Halal certificates as a mandatory requirement. Another significant difference is that Halal coverage in other countries is limited to food and beverages only, whereas in Indonesia, Halal law is applied to all products including medical devices all commodities, and services.

With the current situation in Indonesia, industries may face significant challenges in selling their products in the country, most critical aspect being how government anticipates any risk of implication of patients' access to advanced technology in the interest of best disease management and treatment.

# Chapter 2: Background of the problem and challenges in halal law implementation to various stakeholders

## 2.1 CHALLENGES

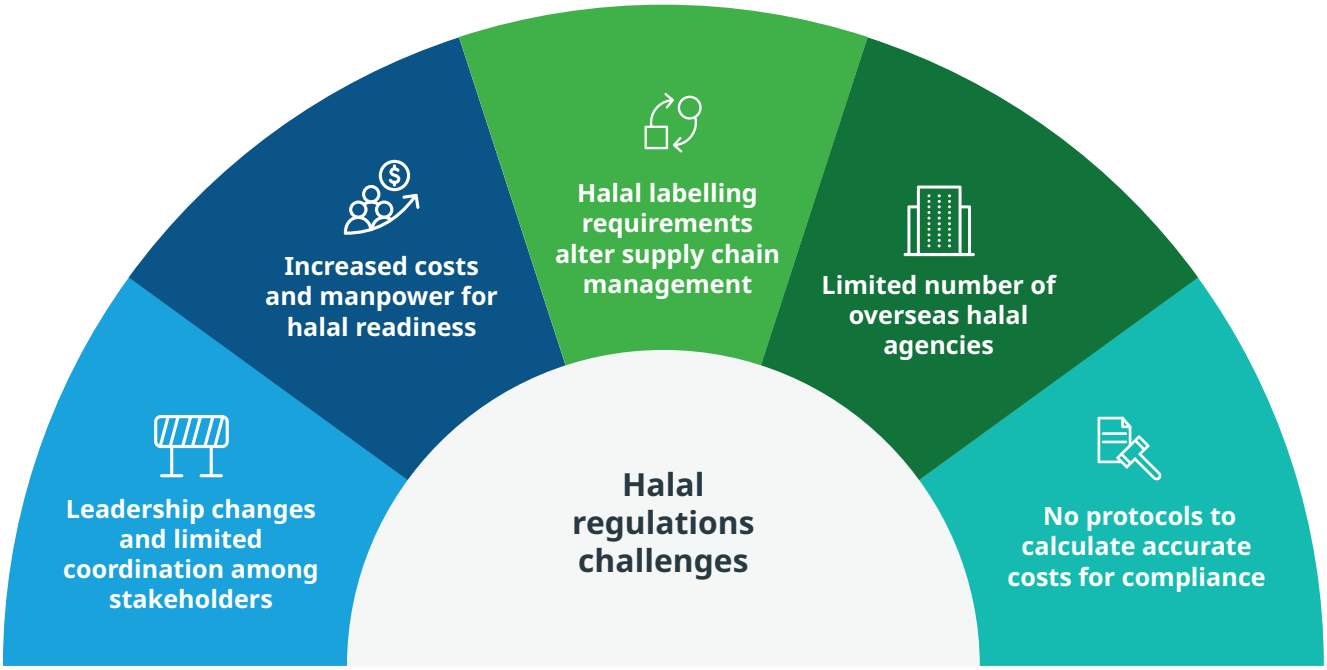
Though the new Halal product law is clearly well intentioned to protect Muslim Indonesian citizens in getting their Halal products, it poses many challenges to various stakeholders, such as importers, manufacturers, distributors etc. Several such challenges have been depicted in Figure 2. These challenges also impact other stakeholders who are part of the ecosystem, such as customer, patients, and HCPs etc., which have been described in detail in this chapter.

### 2.1.1 Involvement of multiple government stakeholders

There are serious concerns and challenges faced by the Medical Device industry related to involvement of multiple government stakeholders and inconsistent interpretation of the law:

1. Leadership changes between MoRA and BPJPH during transition of Halal certification from MUI to BPJPH create complexities in certification process adaptability
2. Limited coordination between stakeholders creates unclear guidances and incongruent alignments
3. Many Halal regulations and technical guidance documents are issued without specific focus on medical devices categories
4. Lack of harmonized definition of products which contain animal derivative between MoRA, BPJPH, MoH and International Standards which creates misunderstanding
5. Since the medical device's lifecycle and nature is totally different compared to other products, holistic understanding on the technical complexities of medical devices is lacking which needs to be addressed and considered by MoRA
6. Limited involvement of industry associations during the creation of new regulation or guidance for Halal

**Figure 2. Challenges posed by halal regulations in Indonesia**



**2.1.2 Complexity in factory/manufacturer and distribution center readiness**

There are several challenges identified in factory and distribution center readiness where the critical aspects are captured in Table 1, including:

1. Policy
2. Halal Management
3. Traceability
4. Substances
5. Tools and Premises
6. Hygiene

This poses substantial challenges to the companies, such as an increase in time, resources and expenses to allocate. These significant challenges may also have an impact on industry capability to develop in the Indonesia market. This situation will create limited options for patients to access an innovative device for their treatment.

Furthermore, these challenges will increase products' price that leads to a higher treatment cost. Hence, it will restrict the affordability of patient's access to advanced technology. Ultimately, we can also foresee the impact on the Indonesia's healthcare environment, where the options for medical device and treatment will be very limited.

**Table 1. Critical aspects in factory and distribution centre readiness**

| POLICY | HALAL MANAGEMENT | TRACEABILITY | SUBSTANCES/ RAW MATERIALS | TOOLS AND PREMISES | HYGIENE |
|---|---|---|---|---|---|
| Halal Policy and SOP (HAS) implementation | Halal Organization: It is stated under Indonesian Law No. 33 year 2014 on Halal Product Assurance that a company that submits Halal certificate application must have a Halal Supervisor. The reference of competency for Halal supervisor is based on The Indonesian National Working Competency Standard (SKKNI No.21, 2022), which is issued by the Indonesian Government. Thus, it is advised that Halal supervisor from overseas company require to adjust with the provisions to have the same competency based upon SKKNI | Slaughtering process | Further tracking on material composition | Facility is pork-free | Must follow HAS Standard, GMP Standard |
| Whether one needs to update the current QMS, how does this impact other countries including Halal labelling process | Certified Training: Each of the Halal committee member must attend the Halal training. Government has even started the training for people to get certifications. | Direct Materials Assessment | No cross contamination in storage/ warehouse, laboratory, production, packaging and distribution | Environmental Control, No cross contamination from surround-ing area outside plant | |
| New Policy must be official, all related stakeholders have to undergo the right training | MOU with logistic provider for Halal compliance | Supporting Materials Assessment | Halal critical points *(titik kritis)* | Line changeover with cleaning process | - |
| - | Halal Internal Audit and Management Review | Primary Packaging Materials Assessment | - | Staff rotation process | - |
| - | - | Assembly process, Sterilization site, Packaging site. As medical devices have the complexity in the process. Each critical process has different site/ Location | - | Manufacturer and Distribu-tion Center process to implement additional Halal label in each of the product | - |
| - | - | - | - | Segregation of manufacturing facility between Halal and Non Halal products | - |

### 2.1.3 Labelling requirements (Halal logo and non-halal labels/information)

Labeling requirements with either Halal or non-Halal labels require the implementation of additional processes that will affect the manufacturing chain and bring more complexity to supply chain management. It is resulting in substantial cost increment and delaying product availability to patients.

On top of the difficulties in operational aspects for labeling, detailed assessment of Halal or non-Halal category is the most significant challenge for the implementation. Hence, we believe allowing general disclaimer (Halal or non-Halal) on the product labels would largely relieve the burden for the industry while safeguarding patient safety and access to essential medical products in Indonesia.

### 2.1.4 Mutual Recognition Agreement (MRA)

MRA is stated in MoRA regulation No. 2 year 2022; however, there is no clarity on acknowledgment of Halal certification for finished imported products. In practice, BPJPH has MRA with a limited number of overseas Halal agencies and only acknowledges Halal certificates for raw materials. This situation triggers the company to conduct re-certification for finished goods to BPJPH in order to enter Indonesia's Market, making the process time consuming and expensive.

This redundancy in the process creates complexity, additional cost, and additional lead time to provide access for the patients to innovative products and advanced medical treatment.

### 2.1.5 Additional cost

Currently, the Halal certification process is still unclear. The certification fee depends on several factors such as product type, number of raw materials used for finished products, as well as total number and location of the manufacturing sites. Furthermore, there will be additional cost whenever (a) there is a change in the layout of the factory that is dedicated for Halal product and (b) there are additional needs for specific labeling.

## 2.2 PERSPECTIVES ON HALAL REGULATIONS

The new Halal regulations in Indonesia have brought a lot of different perspectives amongst the people as well as business owners. The expansion of the Halal space covers primarily two main issues: (a) creation of a new market and (b) significant rise of Sharia-based piety in Muslim consumption.

### 2.2.1 Perspectives from the business community

When the Halal law was officially stipulated in Indonesia, the response from the business community was not positive. Nonetheless, industry was aware of the potential of the Halal market as approximately 86% of the Indonesian population is Muslim, which is the largest Muslim market in Asia.

### 2.2.2 Perspectives from importers (overseas companies)

Significant proportion of medical devices in Indonesia is still imported but only few companies have secured Halal certification. Considering the lack of Halal certified manufacturers, the sustainability of products should be taken into consideration. It becomes more important to ease patient access to advanced medical technologies in Indonesia.

Currently there are several overseas Halal agencies that have been acknowledged by BPJPH. However, The Halal Mutual Recognition Agreement is limited to raw materials and not yet applicable for finished products. To this extent, foreign companies who have been certified by overseas Halal agencies should check the agency compliance with Indonesian Halal standards before exporting their products to Indonesia.

To enter the Indonesian market, foreign companies need to get mandatory certification by a BPJPH appointed Muslim as a Halal supervisor, since there are many misconceptions about Halal implementation that is carried out overseas. Considering these difficulties, it might discourage foreign companies to enter the market. Another challenge is related to the requirement of Halal assurance team in the manufacturing facilities. The team must undergo rigorous training by Indonesian Halal Agencies to ensure that the Halal assurance is properly implemented. In addition, the need to audit all facilities is expensive and requires substantial resources.

### 2.2.3 Perspectives from distributors

The Halal policy benefits only companies that run big businesses in Indonesia as it all depends on the size of the market. If a company's size and market in Indonesia is huge, then the company may see the benefits because of the buoyant Halal market in the country. For the others it may consume a lot of resources making it less viable. This holds good for local manufacturers and distributors.

### 2.2.4 Perspectives from Indonesian HCPs on halal and its impact on the patients

Based on the interviews with some local HCPs, we observed an increased level of interest in the "Halalness" of medical products. It is important to highlight that, according to Islamic rule, a critical situation for saving lives justifies the use of non-Halal products.

Therefore, it is essential for HCPs to continue educating patients about this particular element in the Islam rule, so that patients don't deny themselves from access to non-Halal life-saving medical products in the event there is no Halal alternatives.

However, the implementation of Halal law in the healthcare environment might create some misconception among patients and even HCPs in their medical decisions regarding the safety, quality and performance of medical products. Hence, it is paramount to clarify from a scientific and evidence-based medicine perspective that, the safety, quality and performance of medical products remain the same regardless of the Halal certification status or Halal vs Non-Halal labels.

It is also desirable for HCPs to give their best advice and service to patients, based on the patient health conditions and availability of medical devices and technologies (Halal vs Non-Halal products) in the market.

There needs to be emphasis on highlighting that government agencies should also give special considerations to the Halal implementation processes for critical life-saving medical products, especially products that do not come in direct contact with the human body in scenarios where there will be insufficient supply of Halal-certified alternatives.

# Chapter 3: Recommendations from APACMed to Indonesian decision makers

Given the significant impact of the Halal regulations to patients and all stakeholders involved in healthcare sector including healthcare facility and medical device industry, APACMed would like to propose the following recommendations to the Indonesia government for consideration. These recommendations would bring successful implementation of Halal certifications in a manner that benefits everyone involved in the healthcare sector.

### Recommendation 1:

Leveraging global harmonization of the definition on medical device classifications within Halal certification, while defining MD with ADM and non-ADM based on human body contact risk-based approach.

| Proposal | Details of recommendation |
|---|---|
| The category of medical devices included in the scope of Halal certification is to focus on the medical devices based on a risk based approach on evaluating human body contact | • Focus on the halalness of medical devices with human body contact as a risk-based approach<br>• MoRA/BPJPH to clarify the information in the Halal Law and Government Regulation No. 39, 2021 regarding medical devices that require Halal Certification in alignment with MoH on the risk based approach of human body contact and criticality<br>• Government (MoRA/BPJPH/MoH) to leverage global harmonization of the definition on medical device classifications within Halal certification, while defining MD with ADM and non-ADM based on human body contact risk based approach, such as GHTF/AMDD Classification, FDA Guidance, EU Regulation (Commission Regulation) No. 722/201 |
| Remove details of product categories that required Halal certification from Ministry of Religion Affair Decree (KMA 748, 2021) | • A harmonious product category is highly recommended to avoid industries' misconception and confusion by using product categories in scope of Halal certification issued by MoH as an expert party for medical devices.<br>• This will also avoid several changes in regulations especially when product categories are changed in the future. MoH's role is important in determining the above product categories. |

### Recommendation 2:

Indonesia Government to publish list of medical devices outside the scope of Halal certification as per global standard of medical devices for ADM

To align with global standard and classification on medical devices with ADM, below are examples of products that are outside the scope of medical devices containing ADM:

| Product criteria | Examples (but not limited to) |
|---|---|
| Medical devices that do not enter the patient's body. | • Non- invasive medical device<br>• In-vitro diagnostic devices , including Research Use Only (RUOs) and Lab Use Only (LUOs) |
| Medical devices that do not contain ADM based on international standard (i.e ISO 2242-1:2020-Medical Devices Utilizing Animal Tissues and Their Derivatives)<br><br>Scope: Medical devices other than in vitro diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable | • Active Medical Device: Electro medical equipment, Capital products, Machines including accessories and spare parts<br>• All metal instruments, contact lenses made of synthetic materials, surgical instruments/surgical instruments made from plants, synthetic materials and metals, synthetic surgical threads, cardiology instruments, cardiac catheters, patient tubing devices, ECG sensors, medical device disinfectants, instruments contacts with or contains tallow. |

**Recommendation 3:**

Specific consideration through *fatwa* on product categories that are critical/lifesaving

Unlike other consumer goods, most medical devices are not used as per patients' choice, but to diagnose, treat and cure different disease conditions (according to the definition of medical equipment in the ASEAN MD Directives & Ministry of Health Regulation PERMENKES 62/2017).

APACMed recommends clear instructions from the Ministry of Health to guide healthcare professionals to continue prioritizing the principles of evidence-based medicine (including treatment and diagnosis) by referring to the Disease Management Guidelines that apply to diagnosis, treatment, and therapy.

**Recommendation 4:**

Encouraging alignment amongst Halal implementation authorities

In order to provide clarity on Halal implementation requirements to industries, APACMed encourages alignment amongst authorities in defining requirements, category of in-scope and out-of-scope of products, Halal certification process and labeling requirements with the following actions:

- The industry would like to see better coordination and alignment amongst authorities such as MoH, MoRA, BPJPH and MUI to resolve multiple opinions and provide clarity on areas of regulation that lack it. It will be desirable if MoRA consults with the MoH (the Medical Device expert) during the development and implementation of Halal regulation. By doing so, there would not be a disruption in the availability of life-saving devices in the market. This alignment will minimize dual regulation from MoRA and MoH, and enhance awareness of the importance of risk based assessment between Halal requirements and safety/quality aspects while treating patients.
- The technical requirements of the Halal certification process need to be in line with international quality standards for medical devices and IVDs.
- It is recommended to establish a clearly defined pathway for certification, especially for overseas manufacturers. Furthermore, it is necessary to create clear guidance on overseas Halal certification bodies that are participating in the process. Indonesian Halal authorities may establish consulting and advisory services to MD companies in order to accelerate the Halal compliance process.

### Recommendation 5:

Encouraging the government to explore other possibilities in recognizing and leveraging the Halal requirements and implementation across Halal agencies in other jurisdictions.

- The Mutual Recognition Agreement or Memorandum of Understanding could be explored between the Indonesia government and other Halal certification bodies to recognize Halal certification from other jurisdictions. The acknowledgement of overseas Halal certification or assessment reports should not be limited to raw materials, manufacturing process, or the finished products etc., but should also include all Halal-related assessment pieces under the umbrella of Halal laws and regulation to be flexible.

### Recommendation 6:

Halal certification and labeling requirements to be required only for products that fall under Halal certification scope.

- For products out-of-scope (as proposed in Recommendation 2), there should be NO additional requirements on labeling
- For products with Halal certification or that are in the process of getting Halal certification, there should be comprehensive assessments of the raw materials that should comply with the labeling requirements as required by the Halal law
- For products within the scope of Halal regulation and containing Haram materials, we recommend to only require a “Non-Halal” Disclaimer in the product IFUs or on the product packages. There should be NO additional requirements on a detailed list of Haram materials in the product IFUs or on the product packages. Also detailed raw material assessment should NOT be required for these “non-Halal” products, because of significant costs that may negatively impact product affordability with no additional benefits for patients safety or access

On the contrary, additional requirements that require manufacturers/distributors to invest significant amount of resources to oblige will have significant negative impact on the affordability of the products, and which would in turn increase the burden on the Indonesia national healthcare system and hinder patient access to good quality medical devices.

# Conclusion

In conclusion, there are several proposals made by APACMed to address the challenges and ensure continuity of patients in getting safe, high quality products during diagnosis and treatment of various disease conditions, and there are:

- Categorization and prioritization of medical devices that require (within Halal scope) and which do not require Halal certification (outside of scope) are important
- Clear roles and responsibilities of the Ministry of Health in the implementation of Halal regulations for medical devices:
  - » Propose BPJPH to consider the recommendations from 1-6 as written in chapter 3
  - » Determine the list of categories and types of products that require Halal certification by considering the characteristics of medical devices and applicable international standards
  - » Provide labeling guidelines for not yet Halal certified (products with general statement without mentioning raw materials in detail) and products that cannot be certified Halal because they are made from haram according to Islamic Sharia

APACMed would like to reiterate that we as an Industry Association, fully understand the intentions of the Government to ensure the marketed products in Indonesia are Halal certified and safety for usage. We would also like to bring to the notice of the Government that during situations where only a few Halal alternatives are available, patients would end up suffering by not having access to advanced devices and technologies.

We also desire a more coordinated and aligned involvement of multiple Government authorities to define the most practical and easy assessment and implementation process.

In order to ensure continuous supply of high-quality medical devices and technologies to the patient community without compromising on their safety, quality and performance, we suggest the policy makers and influencers to consider our recommendations provided above. Lastly, we also bring to the notice of the policy makers that barring Indonesia, Halal implementation is mandatory in other Islamic countries only on food and beverages and not on medical devices.

# Appendices

### Appendix 1. Indonesia (APACMED - IQVIA)

| ENGLISH TERM | INDONESIAN TERM | ABBREVIATION | DEFINITION |
|---|---|---|---|
| Fatwa | | | Islamic legal opinion regarding the legal position or status of a certain matter. With regard to the Halal Certification, the fatwa output is the Halal or haram status of a product based on the inspection and examination performed by the LPH |
| Government Regulation No. 31 Year 2019 | | GR 31/2019 | Government Regulation regarding the Implementation of Law 33/2014 |
| Halal Assurance System | Sistem Jaminan Produk Halal | SJPH. | A system designated and implemented by the business entity to ensure the Halal-ness of a product |
| Halal Auditor | Auditor Halal | - | The person with the competency to examine and assess the Halal-ness of a Product. The LPH appoints three Halal auditors to examine a product in order to obtain the Halal certification |
| Halal Certificate | Sertifikat Halal | - | Halal recognition of a Product issued by BPJPH based on written Halal fatwa issued by MUI. This document guarantees that products and/or services meet the requirements to be labelled as Halal under Islamic law and principles |
| Halal Certification | | | The procedures taken by a business to obtain Halal certificate, to prove that materials and production process comply with the prevailing standards |
| Halal Examination Agency | Lembaga Pemeriksa Halal | LPH | The agency established to conduct inspection or examination of products to assess the Halal-ness of the product |
| Halal Product Assurance | Jaminan Produk Halal | JPH | Legal certainty of the Halalness of a Product that is proven with Halal Certificate |
| Halal Product Assurance Agency | Badan Penyelenggara Jaminan Produk Halal | BPJPH | The agency established by the government to conduct the implementation of Halal Product Assurance (JPH) |
| Law No. 33 Year 2014 | | Law 33/2014 | Is the Law concerning Halal Product Assurance (JPH) |
| Ministry of Religious Affairs Regulation No, 26 Year 2019 | | MORA Reg 26/2019 | Minister regulation regarding the Facilitation of Halal Product Assurance |
| MUI Fatwa Assembly | Sidang Fatwa MUI | | An assembly comprised of experts, ministries/institutions, and/or related agencies conducted to determine the Halal status of a product. It is part of the procedure to obtain a Halal certification. The determination is stipulated in a Decree of the MUI Halal Fatwa Assembly (“Decree”) and signed by the head and the secretary of the fatwa commission of MUI and acknowledged by the Chairman of the MUI |
| MUI Fatwa Committee | Komisi Fatwa MUI | | MUI Fatwa Committee is one of the MUI committees tasked to produce an Islamic legal opinion about legal position and status on various matters, including the Halal-ness of a product. Members of fatwa committee are representative of Islamic organizations in Indonesia |

| ENGLISH TERM | INDONESIAN TERM | ABBREVIATION | DEFINITION |
|---|---|---|---|
| MUI Food and Drugs Supervisory Agency | Lembaga Pengawasan Pangan Obat dan Makanan Majelis Ulama Indonesia | LPPOM MUI | Halal Certification Agency appointed by BPJPH to examine products and assess the Halal-ness of a product. It was established by the MUI |
| Non-Halal Label | Keterangan Tidak Halal | | A mandatory labelling placed on Non-Halal Products to mark them as non-Halal |
| Non-Halal Products | Produk Tidak Halal | | Products that are derived from non-Halal materials/ ingredients. Materials include raw materials, processed materials, supporting and additional materials that are derived from animals, plants, microbes, or chemical/ biological/genetically modified process |

## Appendix 2. Halal regulations journey

| NO | REGULATION | DETAILS | REPLACEMENT | DETAILS |
|---|---|---|---|---|
| 1 | Ministry of Health Regulation number: 280/Men. Kes/Per/ XI/76 | Provisions for Distributing and Marking of Foods Containing Ingredients from Pork | - | - |
| 2 | Joint Decree between Ministry of Health and Ministry of Religion No. 42/Menkes/SKB/ VIII/1985 and No. 68 of 1985 | Inclusion of Halal Wording on Food Labels | - | - |
| 3 | Ministry of Health Decision no 82/Menkes/SK/I/1996 | Implementation for Joint Decree point 2. | Ministry of Health Decision No. 924/Menkes/SK/ VIII/1996 | Inclusion of Halal wording must be examined by MUI and decided by Komisi Fatwa MUI |
| 4 | Halal Law no 33 Year 2014 | Halal Product Assurance | - | - |
| 5 | Government Regulation no 31 Year 2019 | Governs implementation of Halal Law 33 Year 2014 | Replaced by Government Regulation no 39 Year 2021 | Governs implementation of Halal Law 33 Year 2014 |
| 6 | Ministry of Religion (MORA) regulation no 26 Year 2019 | Governs implementation of Halal Law 33 Year 2014 | Replaced by Government Regulation no 39 Year 2021 | Governs implementation of Halal Law 33 Year 2014 |
| 7 | MoRA Decree no 464 Year 2020 | Product Types Mandatory to be Halal Certified | Replaced by MORA Decree no 748 Year 2021 | Product Types Mandatory to be Halal Certified |
| 8 | MoRA Decree No 1360 Year 2021 | Halal positif list for raw material, exempted from Halal Certification | - | - |
| 9 | Head of Agency Decree No. 141/2021 on Agency Service Tariff Fixing General Services Organizing AgencyHalal Product Assurance | General Service Fee of BPJPH | - | - |
| 10 | BPJPH Regulation No. 1 Year 2021 | BPJPH Service Fee Payment Procedure | - | - |

| NO | REGULATION | DETAILS | REPLACEMENT | DETAILS |
|---|---|---|---|---|
| 11 | Ministry of Finance Regulation No.57/PKM.05/2021 | General Service Fee of BPJPH to MORA | - | - |
| 12 | MoRA Decree No. 2 Year 2022 | International Cooperation for Halal Certification | - | - |
| 13 | BPJPH Decree no 88 Year 2022 | Usage of Halal logo for products obtaining Halal Certificate | - | - |
| 14 | BPJPH Decree no 40 Year 2022 | Halal Labelling | | |

## Appendix 3. List of government stakeholders

| NO | GOVERNMENT DEPARTMENT | COMPETENCIES |
|---|---|---|
| 1 | MoRA | Ministry of Religious Affairs is an Indonesian ministry that administers religious affairs. MORA reports to The President of Indonesia Republic. |
| 2 | BPJPH | Halal Product Assurance Organizing Agency AKA BPJPH, is the agency established by the Government to organize Halal Assurance Products. It is under the Ministry of Religious Affairs (MORA). |
| 3 | MUI | Indonesian Ulema Council, is a government funded organization who act independently as a deliberation forum of the ulemas, Muslim leaders and scholars. |
| 4 | Halal Examination Agency such as LPPOM MUI | The agency carrying out the activities of examination and/or testing against the Product Halalness status |
| 5 | MoH | Ministry Of Health is Ministry that regulates the products under Medical Devices and Household Products |
| 6 | BPOM | The Indonesian Food and Drug Authority of RI (BPOM) is the agency that regulates F & B Dietary, Food Supplements, Medicines, Traditional Medicines, and Product Biology |
| 7 | Kemenlu | Ministry of Foreign Affairs |
| 8 | Kemendag | Ministry of Trade |
| 9 | Kemenperin | Ministry of Industry |

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Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific. Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, APACMed works proactively with bilateral, regional, and local government bodies to shape policies, demonstrate the value of medical technology, and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific. APACMed is also host to the annual Asia Pacific MedTech Forum.

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