

April 14, 2022

To:

Mr. Muhammad Aqil Irham
Head of Indonesia Halal Product Assurance Agency (BPJPH)

Re: Concerns over the Draft Presidential Regulation on Halal Certification of Medicine, Biological Products, and Medical Devices

Dear Sir:

The Advanced Medical Technology Association (AdvaMed) and the Asia Pacific Medical Technology Association (APACMed) would like to extend our warm greetings to you. Our associations are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies and support strong and thriving healthcare systems globally.

Our associations represent manufacturers of products that improve, extend, and save lives. Our member companies are headquartered in countries throughout the world and range from the largest to the smallest medical device manufacturers. Over the years, our member companies have been providing patients and doctors in Indonesia with important medical services and products that help improve patient outcomes as well as quality of life.

We recognize the efforts of the Government of Indonesia regarding the ongoing implementation of the Halal Product Assurance policies to ensure the halal certification of products in Indonesia.

While these policies will further enhance the legal framework for halal product-related matters, we are particularly concerned over the scope of the Draft Presidential Regulation on Halal Certification of Medicine, Biological Products, and Medical Devices which will limit access by patients to potentially life-saving advanced medical tests and treatments, as well as the availability of innovation to Indonesian hospitals and practitioners. This could have a negative impact on Indonesia's current priority of elevating its healthcare deliveries and boosting medical tourism in the country if these medical tests and treatments are not easily accessible compared to other countries in the region.

Article 2 of the Draft Presidential Regulation mandates that any medicine, biological products, and medical devices entering, being traded, or circulated in Indonesia are required to go through the halal certification. This provision applies to medical devices originating from animals and/or containing animal elements.

However, Article 2 provisions are yet unclear for medical products that are not derived from animal materials, thus leaving room for varied interpretation. We believe the intent of Article 2 is to limit the scope of medical device products requiring halal certification to those derived from animal materials. For clarity, we respectfully ask for clear provisions within the Article that all devices in final product form that do not come into contact with patients, as well as all devices that do not contain derived animal materials, are exempt from mandatory halal certification and non-halal labelling.

We strongly recommend that Indonesia establish a strong linkage between the competent authorities involving MoRA and BPJPH with MOH and BPOM to streamline and create consistency in the interpretation and implementation of the Halal Law, such as the international standard definition from

global ISO standards and US FDA on what constitutes a medical device and which of these are considered to contain an animal source. This will reduce the workload on BPJPH and allow it to focus on the products within the scope mentioned in Article 2, as well as speed up its certification process, which then will alleviate existing concerns from manufacturers. Furthermore, it will also demonstrate clear alignment with international standards that will raise the credibility of the Indonesian agency in the global trade community.

AdvaMed and APACMed commit to supporting the government's ongoing efforts to enhance ease of doing business in Indonesia. The implementation of halal policy in Indonesia will require close coordination between the public and private sector. We stand ready to work with your government and relevant agencies in pursuit of this goal and would welcome multistakeholder dialogues to further discuss halal certification for medical devices.

We include here the contact details of Association Secretariats for your response:

AdvaMed:

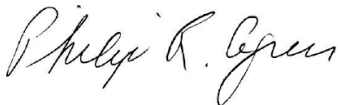
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Sincerely,



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Budi Gunadi Sadikin, Minister of Health

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