En. Ahmad Sharif Bin Hambali
Chief Executive Officer
Pihak Berkuasa Peranti Perubatan
(Medical Device Authority)
Kementerian Kesihatan Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyber Jaya

Singapore, 25 May 2021

Dear En. Ahmad Sharif,

RE: APACMed Position Paper with Recommendations to Facilitate Adoption of the Requirements for Labelling of Medical Devices

The Asia Pacific Medical Technology Association (APACMed) represents over 200 members from across the Asia Pacific region. Together, we are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

The Medical Device Authority (MDA) Malaysia published MDA/GD/0026, November 2018 Third Edition, Requirements for Labelling of Medical Devices. The proposed requirements for the labelling of medical devices are intended to improve and supplement shortcomings of the current system.

APACMed recognizes the topic on the implementation of the Medical Device labelling requirements is not new to MDA or industry and would like to acknowledge the collaboration MDA has shown with the local industry association MMDA. The previously implemented three-years transition has been extremely welcomed. APACMed together with MMDA wishes to further partner with MDA and continue the dialogue, with the aim of reducing regulatory burden on industry and ensuring business continuity for healthcare facilities and patients through the ongoing supply of safe and efficacious technologies to the Malaysian market.

APACMed is looking forward to the Malaysia Medical Device Authority's consideration of our below proposals.

- **[PROPOSAL -1]: Confirmation of Requirements: Electronic Instructions for Use**

Per section 3.4 and 4.3 of the guidance documents, it is our understanding MDA is accepting of an electronic instruction for use eIFU for both healthcare professional and home use devices.

This would align Malaysia with the reference countries who is adopting the e-IFU. The flexibility of implementing eIFU allows for better compliance by the industry.

Most of the industry members have already implemented the e-IFU since the publication of the Labelling Guidance by MDA, and the recently published FAQ's mentioned below:

- Electronic IFU (e-IFU) is eligible for devices that are limited to those intended for use by professional users only and
- Paper-form IFU is required and additional electronic IFU is optional for home use devices.

contradicts the requirements in the guidance document. This puts the industry under massive distress as most companies have already implemented the labelling processes per the guidance. The efforts and cost of reversing to comply would be exorbitant and an additional burden on companies.

We seek MDA's confirmation to continue to allow the industry to have flexibility of implementing the labelling requirements with e IFU for all medical devices. The hard copy of the IFU would be provided upon request for home-use devices.

- **[PROPOSAL 2]: <u>Translation of essential information for home-use devices in Malaysia</u>**

APACMed supports the proposal by the local associations (MMDA and AMMI) in seeking the acceptance of MDA to allow the industry to have the translation to Bahasa Malaysia of the essential information only.

This list of essential information will contain the important details that has the highest impact for public safety while ensuring practicality for enforcement. Over regulation may result in unintentional device misuse due to possibility of misinterpretation from the local translation. In the event of discrepancies in Bahasa Malaysia translation, English language version shall be referred to. The lesser information to be translated will reduce the risk of inaccuracy.

As the Malaysian market is still not comparable in volume with other established markets, we hope that this proposal can provide lesser impact to the increased cost and shorten the implementation time without compromising the requirement of the translation.

<u>Proposed information for translation</u>:

1) Intended Use
2) Warnings and Precautions (if any)
3) Contraindications (if any)
4) Symptoms to seek physician advise (if any)
5) Directions or Instructions for Use (where picture illustrations alone are not sufficient)
6) Storage condition (if not represented by comprehensible symbols according to international standards)

- **[PROPOSAL 3]: <u>New Requirements which were incorporated in the FAQs</u>**

APACMed would like to highlight that the FAQs published by MDA is intended to provide clarification to industry on the labelling requirements and not to incorporate additional requirements as that would put a lot of strain to companies in complying with the original requirements (Guidance no - MDA/GD/0026), and hence the additional requirements listed in the

FAQs may kindly be removed. The list of new requirements in the FAQ is enclosed as annexure to this letter for your kind perusal and reference

APACMed recognizes MDA's efforts in protecting patients in Malaysia by improving the regulatory systems for medical device technologies in the country. We look forward to the opportunity to further discuss the above proposals with MDA and to support the Agency in its responsibilities for ensuring patient safety with the use of medical device technologies.

The medical device industry remains fully committed to collaborating with the Medical Device Authority to advance our common objectives of increasing patient access to quality, affordable medical technology, while ensuring a robust and sustainable ecosystem that encourages investment and innovation.

We hope to seek a common ground between our members and the regulators to uphold public safety for medical devices in optimal regulated environment.

Your special consideration to our above recommendations is much appreciated.

I include here the contact details of our Secretariat for your response: anirudh_sen@apacmed.org

Yours Sincerely,

Best regards,

Harjit Gill (Ms)
Chief Executive Officer
Asia Pacific Medical Technology Association (APACMed)

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About APACMed

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific. As a non-profit organization, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonization. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, code of ethics and share best practices.

APACMed Corporate Members