En Ahmad Shariff Bin Hambali
Chief Executive
Medical Device Authority (MDA)
Ministry of Health Malaysia

Singapore, 23 November 2021

Dear En Ahmad Shariff,

MDA's Re-registration process, its challenges and recommendation by APACMed

The Asia Pacific Medical Technology Association (APACMed) represents over 250 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.

APACMed conducted a survey on the re-registration process in Malaysia after being made aware of the challenges faced by the industry in obtaining the medical device approvals in a timely manner. We would like to bring to your attention the findings of the survey seeking your kind consideration and looking forward to an improved and robust process altogether.

Key highlights of the survey are illustrated through the following figures:

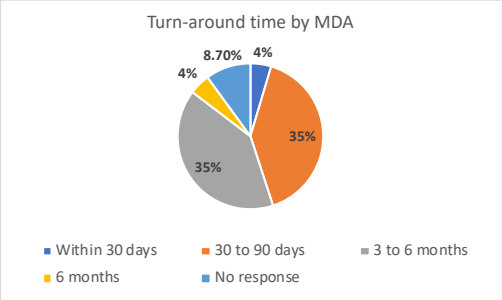

Fig 1. Turn-around time by MDA

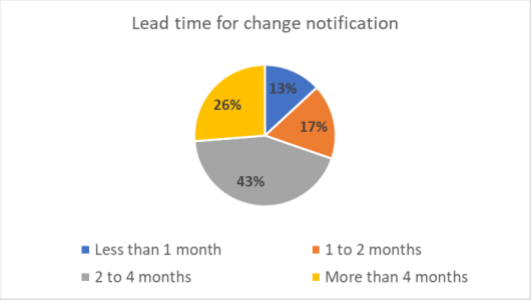

Fig 2. Lead time for change notification

The significant challenges faced by APACMed members are as follows:

1. Turn-around time by MDA doesn't adhere to the stipulated timeline of 30 days.
2. Change notification process causing further delays on re-registration; (i) turn-around time, (ii) inability to group Cat 2 & 3 changes and (iii) Print certificate to complete stage can take up to 7 months.
3. Additional mandatory documents requested during return application for re-registration are not listed in the guidance documents.
4. Insufficient re-registration guidance causing unnecessary return of application. (e.g., request by MDA to re-upload information into other sections of Medcast, when already presented in CSDT section).

5. Re-registration slides state to submit updated pre-clinicals, clinical evidence and risk analysis. However, applicants are not allowed to submit new pre-clinicals.
6. Reclassification by MDA despite CAB's verification for class B,C,D medical devices. Reclassification of class A devices to a higher risk class for products that was approved initially.
7. Inability to re-register obsolete or out of lifecycle part numbers. For example, loaner units at the healthcare facility requiring ongoing servicing, reusable instruments to support the case in hospital.
8. Multiple rounds of input requests per application prolonging evaluation time.
9. Disruption to import and/or supply of medical devices due to re-registration delays at MDA. This strongly impacts and hinders the tender and procurement process at the healthcare facility.

APACMed strongly believes that a delay in the re-registration of medical devices acts as a barrier to continuous supply of medical devices into the Malaysian market. This could in turn significantly impede and impact patients' access to quality healthcare services. **Hence, APACMed, as a representative of the industry, would like to kindly recommend the following key suggestions to MDA, especially in view of higher re-registration submissions expected in 2022 & 2023**.

1. MDA to consider adopting a stipulated and consistent turnaround time for re-registration.
2. MDA to consider eliminating reclassification and regrouping during re-registration.
3. Since medical devices undergo changes throughout their life cycle, MDA may want to consider adhering to a reasonable turnaround time.
4. MDA to consider allowing all types of changes to be submitted as part of the re-registration process.
5. MDA to be flexible in allowing the industry to combine Categories 2 and 3 into just one change notification submission.
6. MDA to consider removing print certificate status from the Medcast system which would enable the industry to proceed with subsequent submissions.
7. MDA to consider allowing continued supply of products under re-registration process.
8. MDA to consider simplifying the re-registration process as the current change management program is already comprehensive in ensuring safety and quality of the devices.
9. MDA to upgrade Medcast system to indicate the MDA officer in-charge with direct phone number and email address to allow applicants to respond to individual input requests for better traceability and transparency of correspondences.
10. MDA to allow industries to apply for 'Notification of obsolete and discontinued medical device' route to continue supporting hospitals with reusable instruments/ equipment which cannot be re-registered due to obsolescence or being out of life cycle.

On behalf of APACMed's members, I would like to thank you for providing us with this opportunity to share our comments and recommendations on this important subject. As a trade association, we always strive to seek a common ground between our members and the policy makers/regulators to uphold public safety for medical devices in optimal regulated environment and remain committed to ensuring timely patient access to safe and effective medical devices of the highest ethical standards.

We hope our recommendations are considered favorably and welcome an opportunity for further discussions and deliberations.

I hereby include here the contact details of Dr.G.Praveen Kumar for your response:
gpkumar@apacmed.org

Yours Sincerely,

Best regards,

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

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3. **Anis Syahirah Binti Dahalan – Personal Assistant to En Ahmad Shariff**

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.

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