Dr Paisarn Dunkum
Secretary General
Thai Food and Drug Administration
Ministry of Public Health Thailand
Bangkok, Thailand

Singapore, 7 June 2021

Dear Dr Dunkum,

APACMed Position Letter on New Medical Device Regulations in Thailand

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.

As always, we commend the Thai Food and Drug Administration (Thai FDA) for its work towards aligning the new medical device regulations in Thailand with the ASEAN Medical Device Directive (AMDD). This is a testimonial of the efforts put in place by Thai FDA to converge and harmonize with regulatory requirements for the registration of medical devices to facilitate patient access in the Asia Pacific region.

In addition to the position letter that we submitted to Thai FDA on 15 December 2020 on the same topic, i.e. the new medical regulations in Thailand (refer to Appendix A for a copy of the letter), in which we took the opportunity to raise some matters around the implementation of the new regulations, we would like to follow up with this letter to further elaborate on several of our previous recommendations but also include a few other points for consideration as the medical device industry (the "Industry") continues to gain experience with the new regulations.

APACMed would like to humbly highlight the following key concerns:

- **Marketed Medical Devices: To** re-evaluate the need for re-submission for products have been in the market under new regulation and only to limit for products which have major safety and performance concerns arise during the lifecycle of the device, taking into consideration post-market experience. This is to ensure a more efficient approach to ensure the safety and performance of the device.
- **Transition period:** The Industry, including both multinational companies as well as local manufacturers, would benefit from a longer transition period of 5 years to ensure a smooth transition to prevent any disruption to the supply of medical devices to patients and consumers. To maximize the benefit of the transition period, mandatory submissions for different classes of medical devices should be staggered to avoid a sudden spike in the workload for both Thai FDA and the Industry (i.e., risk-based starting with products with the highest risks). Throughout the transition period, manufacturers would have the option to voluntarily submit for any class of medical devices prior to the pre-established deadlines, if ready.

- **Registration requirements for low-risk medical devices:** There is the opportunity for stakeholders to work together to propose a risk-proportionate system to manage low-risk medical devices aligned with international practices (i.e., exemption for registration of Class 1 device products). A proposed approach could be the implementation of a notification system for Class 1 device products including the requirement of a declaration on the correct classification of a device product. This will allow Regulators and the Industry to focus resources on high-risk products without any compromise on the quality, safety and efficacy of low-risk device products.

Further to the key concerns above, APACMed would like to bring to Thai FDA's attention the following specific challenges that the Industry will face with the implementation of the new medical device regulations in Thailand:

- **Labelling**: An adequate transition period of 2 years for labelling will be important to ensure that the Industry will have sufficient time to communicate the necessary changes to be integrated into the global manufacturing systems to avoid disruption to the supply of medical devices in Thailand.

- **TH FDA Review Lead Time:** Clarity of maximum review lead time during pre-submission process would help industry to exercise effective launch plan for market.

- **Expert review requirements:** Properly defined criteria for the requirement of an expert review and the associated fees will provide additional predictability to the Industry for planning purposes (e.g., associated submission fees).

A more detailed discussion of the above-mentioned concerns, including the analysis of the best practices in some of the major markets, can be found hereafter.

Finally, APACMed is of the opinion that there is the prospect to maximize the potential of regulatory reliance between Thai FDA and other Regulatory Authorities such as the Singapore Health Sciences Authority (HSA) to simplify the transition to the new medical device regulations by relying on the assessment that has already been completed by other Regulatory Authorities without duplicating the assessment, at least not in full, in Thailand, whenever it is deemed feasible (e.g., abridged review, recognition, etc.).

The Industry remains fully committed to collaborating with the people and government of Thailand to advance our common objectives of increasing patient access to quality, affordable medical technology, while ensuring a robust and sustainable ecosystem that encourages innovation.

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

Yours Sincerely,

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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 organisation, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonisation. 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

Detailed Comments on APACMed's Position

Marketed Devices

For a medical device marketed in Thailand, Thai FDA requires the reporting of defects or adverse events related to the device occurring either in Thailand or outside Thailand when the device is suspected of causing serious threats to public health, deaths or serious injuries, or potentially causing deaths or serious harms to patients and consumers. To address such concerns that could impact the safety and performance of the device, the manufacturer is required to undertake Field Safety Corrective Actions such as product recalls, device modifications, product exchanges, device destructions and/or safety notification updates and changes.

Recommendations

APACMed believes that the most efficient approach to optimize the resources available for the oversight of medical devices for both the Regulators and the Industry in Thailand is to maximize the benefits of post-market surveillance by focusing on the monitoring of medical devices that could present major safety and performance concerns without re-evaluating all the existing medical devices on the market under the new regulations. Post-market real-world evidence is a much better indication of the safety and performance of the devices as major concerns could be more easily detected in a population that is generally much larger than the size of the population that could be included in the pre-market clinical evaluation.

Transition Period

A transition period was non-existent, or the transition period was exceptionally short (one month for certain activities) for the implementation of new medical device regulations in Thailand. A transition period with a reasonable timeframe would be crucial in preventing any potential disruption in the supply of medical devices. Below are a couple of examples in the European Union and Singapore.

European Union

In May 2017, the new Medical Device Regulation 2017/745 (MDR) entered force in the European Union (EU), replacing the Medical Device Directive 93/42/EEC (MDD).[1] The European Commission proposed a total transition time of eight (8) years in which the existing certificates issued under the MDD would remain valid for the next four (4) years until May 2021. From May 2017 to May 2021, manufacturers can decide to comply voluntarily to the MDR. More importantly, medical devices that have already been placed on the market may continue to be made available until May 2025. Refer to Figure 1 below for the detailed timelines for the transition to the MDR in the EU.

[1] https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/timeline_mdr_en.pdf (accessed on 27 March 2021)

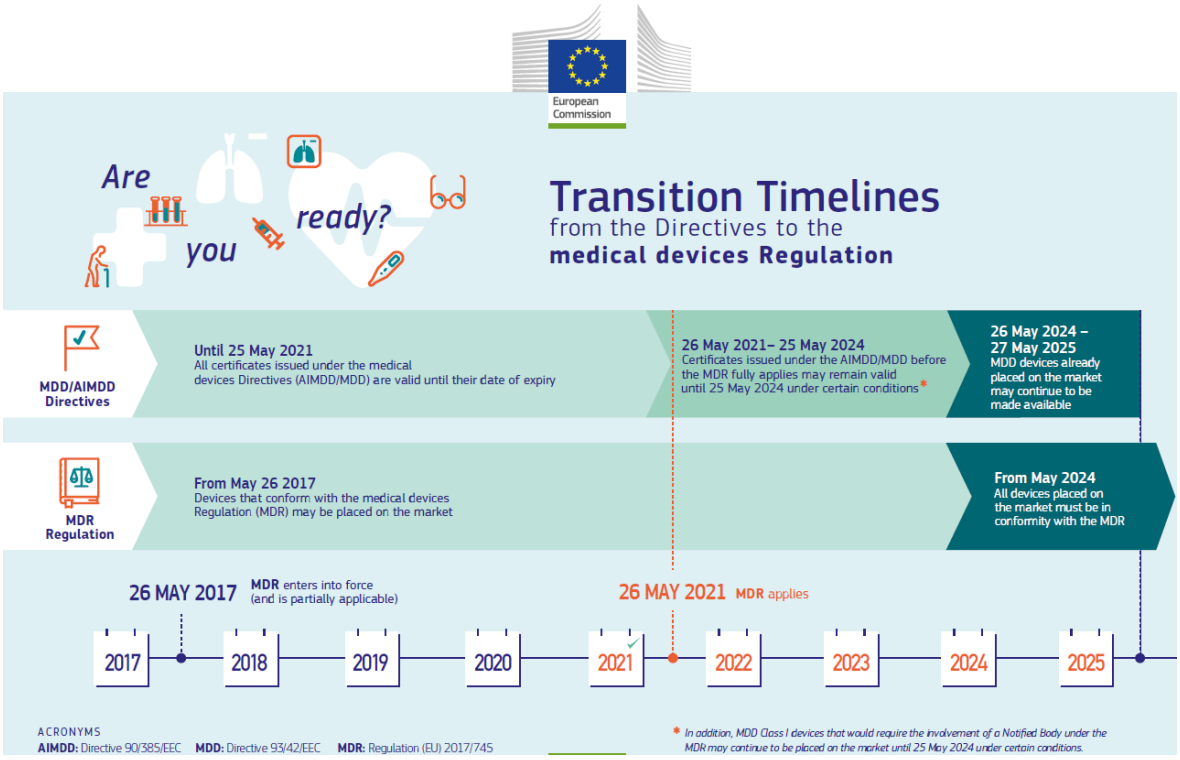

Figure 1: Transition Timelines for the New MDR in EU

Singapore Health Sciences Authority

In the Asia Pacific region, Singapore HSA adopted a similar approach as the EU for the transition to the new medical device regulatory framework.

From April 2002 to March 2007, the Voluntary Product Registration Scheme (VPRS) was introduced by HSA for manufacturers to voluntarily comply with the new medical device regulatory framework. Subsequently, the framework was implemented in a phased approach over a period of five (5) years between 2007 and 2012. Refer to Figure 2 for the detailed transition plan proposed by HSA.[2]

[2] https://www.hsa.gov.sg/docs/default-source/announcements/nex2us-newsletter/hsa-connects---october-2010.pdf (accessed on 28 March 2021)

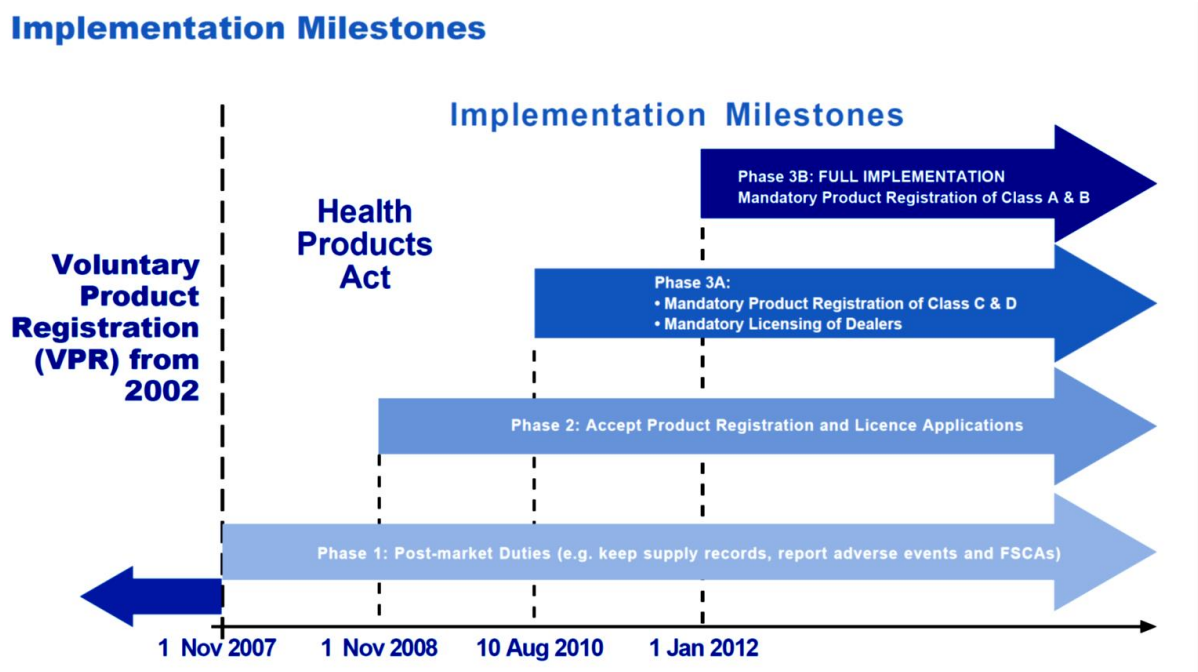

Figure 2: Transition Timeline to New Medical Device Regulatory Framework in Singapore

A risk-stratified and confidence-based approach was adopted, in-line with international practices to ensure that patients and consumers will continue to have access to safe, good quality and efficacious medical devices. The proposed approach also placed focus on post-market surveillance to facilitate prompt recalls of medical devices when defects and/or serious adverse events are detected.

Furthermore, barring a few exceptions, medical devices that were submitted by 30 April 2010 and were still under evaluation processing were placed on a separate listing – Transition List (T-List). These products could continue to be imported and supplied in Singapore, preventing the disruption of supply to patients and consumers. The T-List was reviewed periodically. Even without the VPRS, the Industry had around 4.5 years to apply for dealer's licenses and register their products.

Recommendations

Drawing on the experience of other countries for a major overhaul of the regulatory framework, APACMed would like to hereby propose a transition period of five (5) years to ensure a smooth transition in Thailand. This is in line with best practices from major regulatory agencies around the world for changes of a similar magnitude. This will help prevent disruption to the supply of medical devices in Thailand.

Furthermore, we recommend that submissions be staggered by risk classes of the medical devices (e.g., aiming to have the highest risk products to be submitted to Thai FDA in the early phases due to its potential impact) to reduce the sudden spike in workload for both the Regulators and the Industry, in line with practices of other major regulatory agencies for similar transitions.

Registration requirements for low-risk medical devices

The regulatory system under the new medical device regulations in Thailand requires the registration of medical devices of all classes. Some major regulatory agencies around the world adopted a much more differentiated regulatory system to manage different classes of medical devices to better focus on the assessment of high-risk products. Below are a couple of examples in US and Singapore.

U.S. Food and Drug Administration

In the U.S., most Class I and some Class II devices are exempt from 510(k) requirements, subject to certain limitations, with Class I being the lowest-risk medical devices and Class 3 being the highest-risk medical devices.[3]

According to U.S. FDA's requirements, "[i]f a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S."[4] Manufacturers are only required to register their establishment and list the generic category or classification name.

Singapore Health Sciences Authority

In the Asia Pacific region, Singapore HSA adopted a similar risk-proportionate approach to exempt Class A medical devices (lowest risk) with a self-declaration mechanism to significantly reduce the workload for the regulator and industry. A list of basic information such as the name of the device, the intended purpose and the device identifier should be provided to include class A medical devices in HSA's register. Post-market activities such as adverse event reporting and field safety corrective actions help to ensure the safety of these devices.

Although Class A medical devices have been exempted from registration, these products must conform to the Essential Principles for Safety and Performance for Medical Devices prior to their placement on the market. Dealers are to ensure that there is a Quality Management System (QMS) in place for dealing with any Class A medical devices. For Class A medical devices supplied in a sterile state, dealers are to ensure that the sterilisation processes for any Class A sterile medical devices conform to international standards for sterilization (such as ISO 11135, ISO 11137, ISO 17665 and ISO 13408) of medical devices or equivalent.

Australia Therapeutic Goods Administration

In Australia, manufacturers need to provide a manufacturer's Declaration of Conformity with their application to list the device in the Australian Register of Therapeutic Goods (ARTG) for Class I non-sterile and non-measuring devices.[5] If TGA is satisfied the product meets all the requirements, TGA will include the device in the ARTG within four (4) business days of receiving the application. TGA may choose to conduct audits of these medical devices if it believes that, for example, the product is incorrectly classified, or the product does not comply with the essential principles. The Declaration of Conformity ensures that all Class I medical devices that are eligible for notification comply with the necessary requirements. Manufacturers providing false or misleading information may be subject to criminal penalties.

Recommendations

APACMed believes that this international practice to exempt low-risk medical devices (e.g. Class 1 products in Thailand) from registration should be adopted in Thailand as a risk-proportionate approach will considerably reduce the workload of both Regulators and the Industry without compromising on the quality, safety and efficacy of such products. This will allow stakeholders in the

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[3] https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions (accessed on 28 March 2021)
[4] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm (accessed on 28 March 2021)
[5] https://www.tga.gov.au/changes-artg-inclusion-process-non-measuring-non-sterile-class-i-medical-devices-0 (accessed on 28 April 2021)

medical device industry to focus the limited resources on products that may truly have impact on the safety of the products without a more thorough assessment (i.e., high-risk products).

Thai FDA may opt for the inclusion of the requirement for a Declaration of Conformity by the manufacturers such as the approach adopted by TGA to ensure that a medical device meets all the necessary requirements via a notification process.

Labelling

Labelling changes under the new medical device regulations are particularly challenging for the Industry to adopt due to the extremely short transition period. To comply with the new labelling requirements such as the inclusion of the license number, manufacturers must allow sufficient time for certified distribution centres to make necessary changes before the proposed changes can be implemented for products to be supplied in Thailand. If local relabelling is performed, service providers or distributors will need time to establish proper systems and processes to incorporate new labelling requirements as per the new medical device regulations to minimize the risk of human errors and reduce the number of recalls.

Recommendations

APACMed would like to propose a transition period of at least two (2) years to accommodate the new labelling requirements under the new medical device regulations. This will provide sufficient time to the Industry to ensure all the systems and processes are in place to meet the new requirements.

TH FDA Review Lead Time

Prolong lead time on pre-submission process takes up to 2 months in some cases. It would help the Industry to understand what the bottle neck at Thai FDA and maximum review lead time is especially during pre-submission for effective launch plan

External expert review

Under the current requirement of Medical Device Act B.E.2551 - Section 22, Thai FDA may opt to send the dossier for the registration of a medical device for review by external experts. The decision is based on Section 22. We are of the opinion that the current guideline is unclear on the criteria to be met for Thai FDA to send the dossier for external review. As a result of this, manufacturers find it challenging to have proper planning such as budgeting for the correct submission fees for new product registrations.

Recommendations

APACMed believes that a well-defined set of criteria with respect to the need of an external review will be tremendously helpful for the Industry for planning purposes (e.g., certain families of products that may require specific expertise that may not be available with in-house evaluators).