

# REGULATORY RELIANCE FOR THE REGISTRATION OF MEDICAL DEVICES IN ASIA PACIFIC



28 June 2021

## A Case Study with Singapore Health Sciences Authority and the Thai Food and Drug Administration

This document provides a brief introduction of the regulatory reliance concepts as proposed by the World Health Organization and a case study on the implementation of the regulatory reliance pilot project between Singapore Health Sciences Authority and the Thai Food and Drug Administration with the support from the Asia Pacific Medical Technology Association to accelerate patient access to medical devices in Asia Pacific.

# Regulatory Reliance for the Registration of Medical devices in Asia Pacific

## A CASE STUDY WITH SINGAPORE HEALTH SCIENCES AUTHORITY AND THE THAI FOOD AND DRUG ADMINISTRATION

### SPONSOR

Asia Pacific Medical Technology Association (APACMed)

### PARTICIPATING REGULATORY AUTHORITIES

Singapore Health Sciences Authority

Thai Food and Drug Administration

### PARTICIPATING APACMED MEMBER COMPANIES

Abbott Core Diagnostics, Alcon, Baxter Healthcare, Becton Dickinson, Boston Scientific, ConvaTec, Johnson & Johnson, ResMed, Roche Diagnostics, Stryker, Thermo Fisher Scientific, Varian (a Siemens Healthineers Company)

### APACMED'S STEERING COMMITTEE

Miang Tanakasemsub, Regulatory Affairs Committee Chair and Head of Quality Assurance commercial and Regulatory Affairs, APAC, Cardinal Health

Adelheid Schneider, Regulatory Affairs Committee Vice Chair and Head of Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd

Priscilla Koh, Southeast Asia Centre of Excellence Chair and Lead-Director, Regulatory Affairs, Johnson & Johnson

Anirudh Sen, Regional Regulatory Affairs & Country Lead, India, APACMed

Yu Liang, Consultant, Regulatory Affairs, APACMed

### OTHER CONTRIBUTORS

Alex Budiman, Regulatory Affairs Committee Vice Chair and Vice President of Regulatory Affairs, Greater Asia, Becton Dickinson

Jason Guo, Regulatory Affairs Committee Vice Chair and APAC Director, Regulatory Affairs, Quality and Compliance, Abbott

Nishith Desai, Regulatory Affairs Committee Vice Chair and Vice President of Quality and Regulatory Affairs, Asia Pacific, Medtronic

Georgia Swan, Government Affairs & Market Access, APACMed

Panawan Ratanapreukskul, Regulatory Affairs Lead (Medical Device Sector) – Thailand, Cambodia, Myanmar, and Laos at Johnson & Johnson

Rhoel Laderas, Lead for the Philippines at APACMed and Associate Director, Regulatory Affairs Asia Pacific at Baxter Healthcare

Weerisa Yathai, Associate Regulatory Affairs & Quality Assurance Manager at ConvaTec

Yasha Huang, *In Vitro* Diagnostics Working Group Vice Chair and Regional Regulatory Affairs and Policy Lead Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd

### ACKNOWLEDGEMENTS

APACMed would like to thank the following organizations for their contribution in this publication:

Bill and Melinda Gates Foundation

Philippine Food and Drug Administration

Therapeutic Goods Administration of Australia

World Health Organization

## ABOUT ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

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. Today, APACMed represents close to 200 members across the region. 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 and share best practices. Together, we are committed to working with 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.

## INTRODUCTION

Quality, safety, and efficacy have been the main pillars for the modern regulations on medical products. In 1938, the United States (US) implemented the Federal Food, Drug and Cosmetic Act (FD&C Act) with the premarket notification requirement for new drugs as a result of over 100 people who died of diethylene glycol poisoning due to the use of a solvent without safety testing.<sup>1</sup> Between 1956 and 1960, the introduction of the sedative hypnotic Thalidomide in 46 different countries resulted in an estimated 10,000 babies being born with phocomelia and other deformities. Consequently, for the first time in 1962, the US required that the Food and Drug Administration (FDA) approve all new drug applications and a new drug be shown to be safe and effective with the passage of the Drug Amendments Act. The FDA was also given the authority to require compliance with current Good Manufacturing Practices. In 1976, the Medical Device Amendments to the FD&C Act was implemented.<sup>2</sup> For the first time in the history, a three-class, risk-based classification system was created for all medical devices and regulatory pathways were established for new medical devices. Almost six decades after the US implemented the Drug Amendments Act, the regulation of medical products has become a global norm to protect patients, with several Regulatory Authorities in Asia Pacific (APAC) taking on a leading role in promoting best regulatory practices to ensure the quality, safety and efficacy of medical products.

As Regulatory Authorities around the world have substantially strengthened the regulatory systems over the past decades to ensure the quality, safety and efficacy of medical products, patient access has recently emerged as a fourth pillar for the registration of medical products. First, medical products have become significantly more complex and diverse with the arrival of new technologies such as biotechnological products, nanotechnologies, cell & gene therapies, and digital health products. It is a sizeable challenge for one single Regulatory Authority to possess the expertise necessary to assess different technologies. Second, regulatory systems were developed in a context of a much less connected world but there is now the opportunity to mend the growing gap between quality, safety and efficacy, and access through cooperation. The need of better access has been highlighted by the recent global COVID-19 pandemic where Regulatory Authorities were required to be more agile and rely on other Regulatory Authorities to guarantee access to essential medical

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<sup>1</sup> Drug Regulation: History, Present and Future, World Health Organization ([https://www.who.int/medicines/technical\\_briefing/tbs/Drug\\_Regulation\\_History\\_Present\\_Future.pdf](https://www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf)) (accessed on 23 March 2021)

<sup>2</sup> <https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states> (accessed on 19 May 2021)

products to tackle the pandemic (also refer to APACMed’s publication on *Building Regulatory Agility for Adequate Access to Quality SARS-CoV-2 Test Kits During the Global Pandemic*<sup>3</sup>). Finally, since Regulatory Authorities recognized that resources are limited, it may be helpful for all stakeholders to work together to identify more efficient approaches for the commercialization of medical products without impacting the quality, safety and efficacy of these products.

Regulatory reliance could be the approach forward.

## PURPOSE

The purpose of this report is to promote regulatory reliance as an effective tool to accelerate patient access to medical devices in APAC without compromising on the safety, and performance of the products. The report also shares the key achievements and takeaways from the Singapore Health Sciences Authority (HSA) and Thai Food and Drug Administration (Thai FDA) regulatory reliance pilot project in the hope to support the implementation of regulatory reliance in other markets in APAC.

## SCOPE

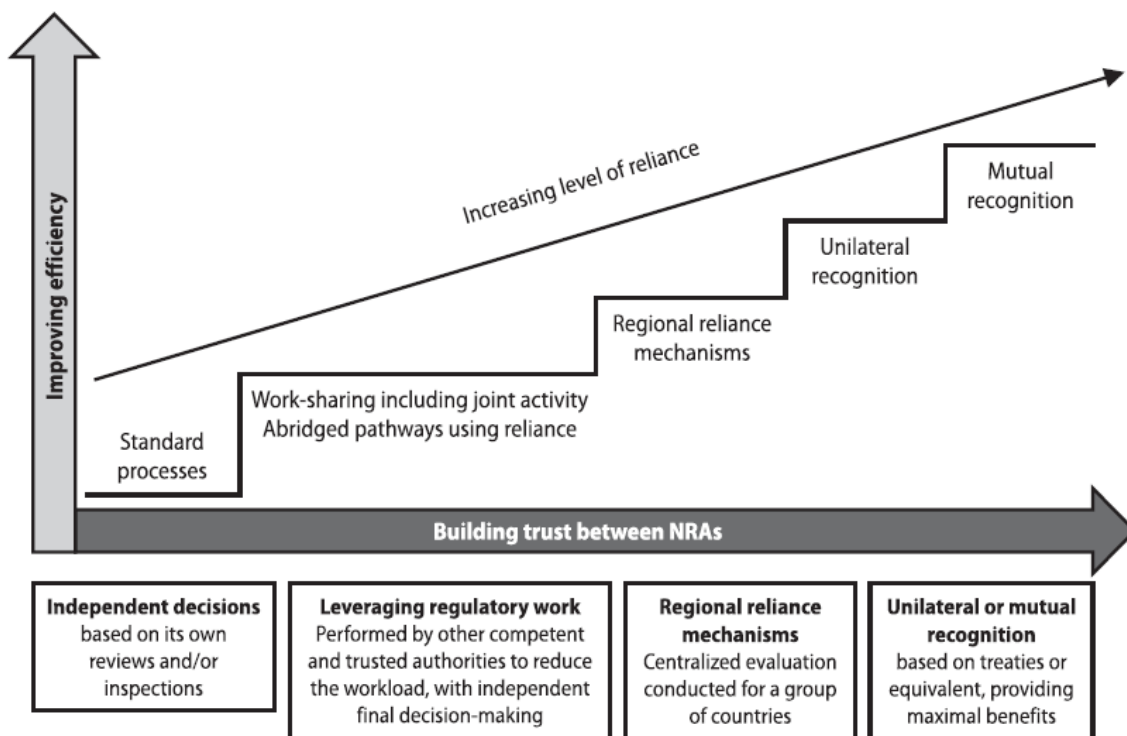
The regulatory reliance concepts can be applied to all sectors of the healthcare industry, however, this report focuses on the medical device industry in APAC.

## CONCEPTS OF REGULATORY RELIANCE MODELS

Regulatory reliance is where an Authority (“Relying Authority”) relies on the assessment and/or decision made by another market (“Reference Authority”) or trusted institution such as the World Health Organization (WHO), whether fully or partially, for the approval of medical products. WHO proposed various concepts of regulatory reliance in its recent publication *Good Reliance Practices in the Regulation of Medical Products: High Level Principles and Considerations*. Refer to the diagram below extracted from the publication summarizing the various concepts of regulatory reliance. The most basic form of regulatory reliance is to leverage the work that has been performed by another Regulatory Authority to support the decision-making process and retain independence in the approval of a medical product. The more advanced form of reliance is to formally accept decisions made by another Regulatory Authority based on agreements such as treaties or mutual recognition, without duplicating any assessment.

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<sup>3</sup> [https://apacmed.org/content/uploads/2020/09/APACMed-Position-paper-submission\\_Access-to-COVID-19-test-kit\\_EN.pdf](https://apacmed.org/content/uploads/2020/09/APACMed-Position-paper-submission_Access-to-COVID-19-test-kit_EN.pdf) (accessed on 23 March 2021)



**Figure 1: Concepts of regulatory reliance as per WHO**

Furthermore, WHO recommended a set of principles to govern the practice of regulatory reliance: universality, sovereignty of decision-making, transparency, respect of national and regional legal basis, consistency, and competence. Of all the principles, it is important to highlight that reliance does not require the Relying Authority to relinquish its jurisdictional independence.

Though it is best to have legislation in place to explicitly encourage the implementation of regulatory reliance, countries should be able to freely adopt this practice if there is no legislation prohibiting it. As explained by the National Academies of Sciences, Engineering, and Medicine in its publication *Regulating Medicines in a Globalized World: The Need for Increased Reliance Among Regulators (2020)*, a Consensus Study Report dated March 2020, reliance typically falls into one of the two categories below, with the second category not requiring legislative reform:<sup>4</sup>

**Recognition:** The routine acceptance by the Regulatory Authority in one jurisdiction of the work products and regulatory decisions of another Regulatory Authority or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition may be unilateral, bilateral, or multilateral, although recognition is usually manifested as the subject of mutual recognition agreements.

**Reliance:** The act whereby the Regulatory Authority in one jurisdiction may take into account and give significant weight to (i.e., totally or partially rely on work products by) another Regulatory Authority or trusted institution in reaching its own decision. The Relying Authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

<sup>4</sup> <https://www.nap.edu/read/25594/chapter/1> (accessed on 23 March 2021)

In the latter category, regulatory reliance means that the Relying Authorities can identify potential tools (e.g., evaluation reports from another Regulatory Authority) to help them expedite the review and approval process without the need to have formal legislation in place to allow for the acceptance of decisions made by another Regulatory Authority as the Relying Authority retains the responsibility in making its own decisions.

## EXAMPLES OF REGULATORY RELIANCE

### Work sharing

The Australia-Canada-Singapore-Switzerland-United Kingdom (ACCESS) Consortium was originally formed in 2007 by Australia, Canada, Singapore, and Switzerland as a medium-sized coalition of 'like-minded' Regulatory Authorities that work together to promote greater regulatory collaboration and alignment of regulatory requirements.<sup>5</sup> The Consortium's goal is to maximise international cooperation, reduce duplication, and increase each Authority's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products. It explores opportunities in the areas of generic medicines registration, new prescription medicines, information sharing and investigations into post-market medicine safety, IT system alignment for information sharing, and development of technical guidelines.

### Abridged pathways

Singapore HSA proposed alternative abridged and expedited pathways for the approval of medical devices which have received market authorizations from overseas referenced Regulatory Authorities.<sup>6</sup> For a Class D device (highest-risk devices), for example, the approval time is 310 days, 220 days and 180 days for full evaluation pathway, abridged evaluation pathway and expedited evaluation pathway, respectively.<sup>7</sup> The major difference between the abridged pathway and the expedited pathway is whether the product has received market authorizations from overseas referenced Regulatory Authorities for at least three years with no safety issues.

The Therapeutic Goods Administration of Australia (TGA) also provides the opportunity for abridged review for medical devices which have been approved by the US FDA, Health Canada, the Japan Pharmaceuticals and Medical Devices Authority, and Notified Bodies in the European Union.<sup>8</sup> TGA retains the responsibility for making decisions regarding market authorisations in Australia. TGA will continue to assess applications for medical devices which have not been authorised by the above listed Authorities and certain families of medical devices, and for the inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG).

### Regional reliance mechanisms

The Medical Device Single Audit Program allows an MDSAP-recognized auditing organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the Regulatory Authorities participating in the program (Australia TGA, Brazil Health Regulatory Authority, Health

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<sup>5</sup> <https://www.tga.gov.au/australia-canada-singapore-switzerland-united-kingdom-access-consortium> (accessed on 23 March 2021)

<sup>6</sup> <https://www.hsa.gov.sg/medical-devices/registration/overview#toggle=togglepanel-overseas-reference-regulatory-agencies> (accessed on 13 April 2021)

<sup>7</sup> <https://www.hsa.gov.sg/medical-devices/fees> (accessed on 13 April 2021)

<sup>8</sup> <https://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds> (accessed on 13 April 2021)

Canada, Japan Ministry of Health, Labour and Welfare (MHLW) and US FDA).<sup>9</sup> The manufacturer is audited only once, the audit report is shared through a database accessible to all Members of the IMDRF which then provides a great opportunity for manufacturers to gain access to multiple markets through an efficient audit process. There are also observers and affiliate members participating in this program including the European Union (EU), United-Kingdom Medicines and Healthcare products Regulatory Authority, WHO, Argentina National Administration of Drugs, Foods and Medical Devices, South Korea Ministry of Food and Drug Safety (MFDS) and Singapore HSA.

## Unilateral recognition

Further to abridged review for the registration of medical devices, Australia TGA may also decide to automatically recognize the approval that has been granted by a reference overseas Regulatory Authority without further assessment depending on the level of information provided in the dossier.<sup>10</sup>

## Mutual recognition

The certification of medical devices in the EU is an example of mutual recognition. Manufacturers are free to choose a Notified Body that has been designated by a country within the EU to conduct conformity assessment of a medical device.<sup>11</sup> Once the product is certified, it can be legally placed on any market within the EU.

# SINGAPORE HSA-THAI FDA REGULATORY RELIANCE PILOT PROJECT

## Background

To explore new ways to address the challenges faced by Regulatory Authorities discussed earlier, and improve patient access to medical devices, Singapore HSA and Thai FDA, with the support of APACMed, launched the regulatory reliance pilot project in September 2020 after some confidence building between the two Authorities. Prior to the COVID-19 pandemic, Thai FDA was able to send three evaluators to spend two weeks with HSA in Singapore to become familiar with HSA's assessment approaches. This pilot project was also an opportunity for HSA and Thai FDA to exchange information for capacity building purposes on the targeted categories of medical devices as part of the project.

Prior to the start of the pilot project, a confidentiality agreement was signed between HSA and Thai FDA to allow the two Authorities to freely share submission-related information with each other.

## Scope of the project

For phase I of the pilot that was implemented in September 2020, Thai FDA proposed to accept 12 applications on a first-come-first-served basis. The pilot was open to the entire industry. To be eligible for the pilot, the following criteria needed to be met:

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<sup>9</sup> <https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap> (accessed on 23 March 2021)

<sup>10</sup> <https://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds> (accessed on 30 April 2021)

<sup>11</sup> <https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies/> (accessed on 13 April 2021)



- Medical devices that are classified as Class C or D
- Medical devices that had an existing import license in Thailand under the old regulations could be re-submitted for the pilot (the intention was to facilitate the re-assessment of existing medical devices for the transition to the new regulations that were implemented in February 2021)
- Medical devices that have been registered with Singapore HSA

Following phase I, Thai FDA announced phase II of the pilot in February 2021. Thai FDA agreed to accept 12 applications on a first-come-first-served basis. To be eligible for the pilot, the following criteria needed to be met:

- Medical devices that are classified as Class B, C or D
- Further to the classes suggested above, the proposed medical devices must fall under one of these categories: COVID-19 test kits, automated external defibrillators, active implants, and medical devices containing animal cells, tissues and/or derivatives of cells, tissues and/or derivatives of microbial or recombinant origins
- Medical devices that have been registered with Singapore HSA

## Proposed workflow

Applicants were required to follow a relatively simple procedure to participate in the regulatory pilot project:

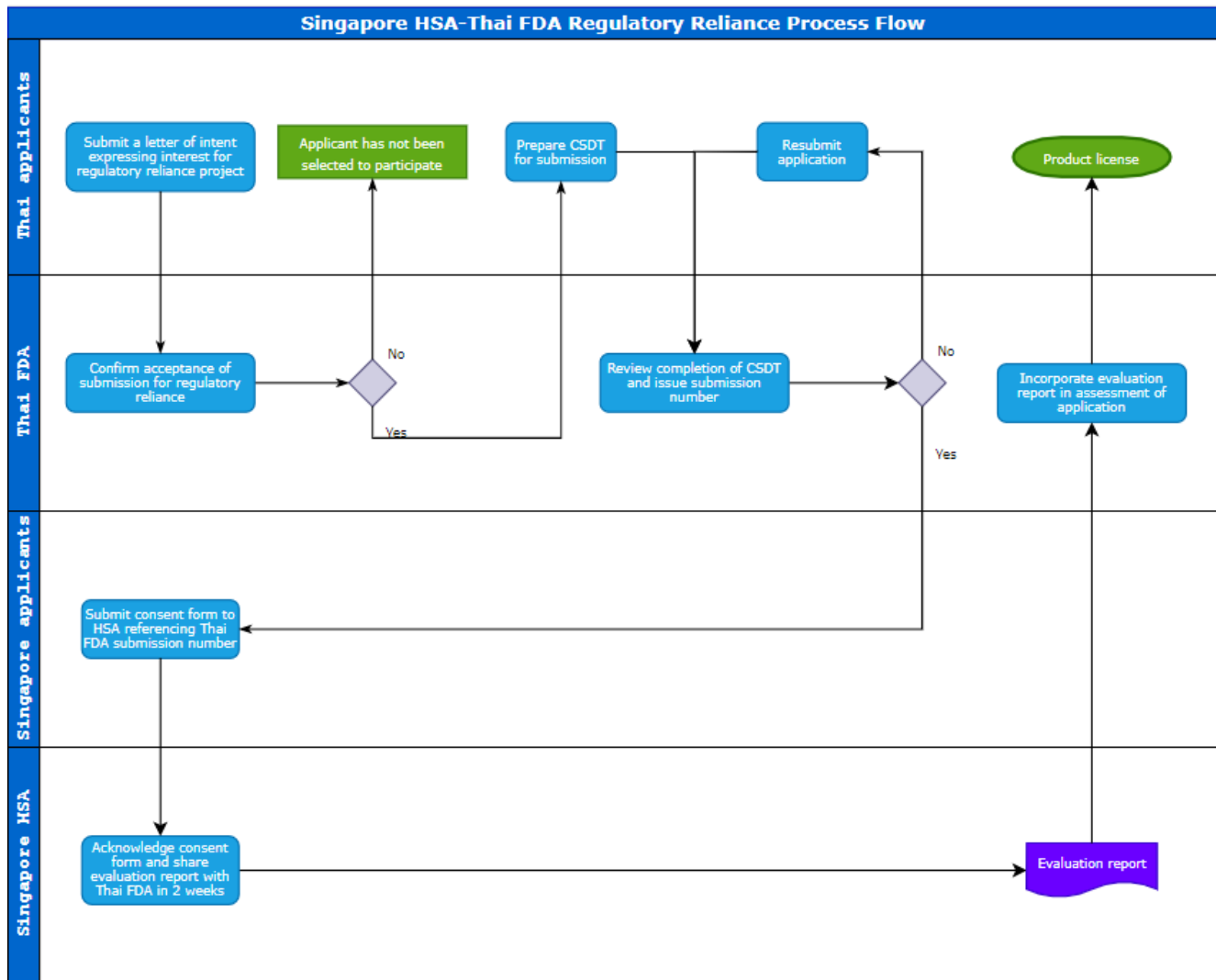
- Submit the following information to Thai FDA prior to the participation in the pilot project:
  - A letter of intent signed by the local license holder in Thailand
  - The registration record (e.g., registration number) of the same products as per the Singapore Medical Device Register
  - Import certificate for a previously imported device, if applicable

If a manufacturer is selected by Thai FDA for participation in the pilot project:

- Submit the following information to Thai FDA:
  - Full dossier in CSDT format of the original new device application and the subsequent change notifications approved by HSA (if applicable)
  - List of the MEDICS job reference numbers of the original new device application and the subsequent change notifications approved by HSA (if applicable)
- Submit the following information to HSA:
  - A completed consent form allowing HSA to share information associated with the registered product including the assessment reports
  - A list of all job reference numbers (original new device application and subsequent change notifications) as recorded in HSA's Medical Device Information Communication System to aid HSA to identify relevant submissions related to the registered product



Refer to Figure 2 below for a flowchart of the proposed submission process for the regulatory reliance pilot project.



**Figure 2: Workflow for Singapore HSA-Thai FDA regulatory reliance pilot**

### Expected outcome

The expected outcome was for Thai FDA to significantly reduce the approval timelines for applications filed under the regulatory reliance pilot project as compared to applications submitted via normal pathways.

There was also the expectation for a decrease in the submission fees due to the reduction of the resources required for the evaluation of applications submitted under the pilot project.

### Results

The review of applications submitted in phase I has been completed. However, the issuance of the approval may still be pending as manufacturers were required by Thai FDA to re-submit the dossier in the new IT system under the new medical device regulations in Thailand that were implemented in February this year. Based on

the preliminary feedback from APACMed's participating member companies and Thai FDA, the review time has considerably shortened from ten months for the normal review pathway to about two months under the regulatory reliance project. It would require another month for the issuance of the approval once manufacturers have submitted the required documents in the new IT system. The total approval time under the reliance project would require about 3 months.

Submissions for phase II of the pilot project are still ongoing.

## Feedback from stakeholders

To better assess the value of the HSA-Thai FDA regulatory reliance pilot project, APACMed conducted a survey with its members on phase I of the project. A total of 25 respondents completed the survey. Twelve of the respondents participated in the project whereas the remainder did not. It was important to gather feedback from companies who did not have the chance to participate to understand their overall expectation as we progress with this project. APACMed also organized a tripartite meeting with representatives from HSA and Thai FDA in March to further understand their perspective on this pilot project. Below is a summary of the observations:

- **Value of regulatory reliance**

All stakeholders see the value of regulatory reliance in APAC in the longer term as it could be an important tool to improve patient access to medical devices by potentially significantly reducing the review and approval time for new product registrations. During the tripartite meeting, Regulators acknowledged that **resources** are a limiting factor to expedite the review and approval of medical devices so regulatory reliance would allow them to accelerate the process and redirect some of the resources towards the core focus areas of the Authorities (e.g., COVID pandemic). As a result, stakeholders from both the industry and Regulatory Authorities will continue to support this project.

- **Capacity building**

Regulatory reliance will provide an opportunity to Regulators for **capacity building** as the exchange of information between Regulatory Authorities will allow Regulators to build on their expertise. During the tripartite discussion with HSA and Thai FDA, Regulators took the opportunity to exchange views on best practices to maintain the same level of assurance in terms of safety and performance of a medical device when an application is assessed via the abridged evaluation pathway (i.e., against the full evaluation pathway). Both Regulatory Authorities agreed to conduct a learning session on this topic for further confidence building. This is an example on the benefit of information sharing because it will allow Regulatory Authorities to acquire additional expertise through regulatory reliance.

As Regulators in APAC continue to gain expertise in the assessment of medical devices through regulatory reliance, and with five of the ten IMDRF members located in the region (i.e., Australia TGA, China National Medical Products Administration, Japan MHLW, Singapore HSA, and South Korea MFDS), this will eventually incentivize manufacturers to submit applications within APAC in the first wave of submissions. This will in turn result in earlier access to medical devices within APAC as the selected Reference Authorities will have completed the assessment at an earlier date and the Relying Authorities will have earlier access to the decisions made by the Reference Authorities through regulatory reliance.

Furthermore, manufacturers could also play a more significant role in regulatory reliance. Regulatory Authorities suggested that manufacturers could proactively provide additional **product training** for a better understanding of the technologies prior to and during the evaluation of the dossier, and openly share important information (e.g. overseas assessment reports) with Regulators to facilitate the review and approval process.

- **Processes**

Stakeholders generally agreed that the proposed workflow for the regulatory reliance pilot project is clear and simple to follow. The main challenge is the human resources required for the Reference Authority to supply assessment reports for a submission to the Relying Authority, but this could be addressed relatively easily through better planning for information sharing between the Authorities.

Moreover, it would be critical to establish **performance targets** (e.g., approval timelines) in future to accurately measure the success of regulatory reliance. Thai FDA proposed an initial target approval time of three months after submission and APACMed will continue to support various Regulatory Authorities' efforts in formalizing the processes with timelines that would result in meaningful reduction as compared to the normal evaluation pathways, especially with the additional efforts required for supporting regulatory reliance. However, as the HSA-Thai FDA pilot project is in the early stages, it may be necessary to further evaluate the process before making the timelines official.

Eventually, to formalize regulatory reliance as a permanent practice, standard operating procedures would be required.

- **Dossier requirements**

Several stakeholders proposed to have more detailed **guidelines** to unambiguously define the dossier requirements for submissions to help manufacturers avoid rejections of and reworks on submissions (e.g., list of all documents related to the original submission and documents related to post-approval changes expected from the Reference Authorities and the manufacturers).

- **Technical review**

A number of stakeholders would like to have a better understanding of the decision-making process for the requirements with respect to **external technical review** as this could potentially be an area for improvement under regulatory reliance as the Relying Authority will already have access to additional tools including assessment reports from the Reference Authorities to perform the evaluation of new product registrations. If an external technical review is required, it would be helpful to establish a set of criteria in a procedure to provide more predictability for planning purposes (e.g., budget for submission fees as these can vary depending on whether Thai FDA would seek external review).

## KEY TAKEAWAYS OF THE HSA-THAI FDA REGULATORY RELIANCE

Regulatory Authorities are increasingly seeking opportunities to cooperate amongst themselves but also becoming more open to involve other stakeholders such as the medical device industry to improve patient access without compromising the safety and performance of medical devices. The unprecedented level of commitment from different Regulatory Authorities to partner with these stakeholders in the creation of more robust regulatory systems should be commended. In this particular example, APACMed recognizes the openness from HSA and

Thai FDA to involve APACMed as a contributor in the regulatory reliance project to expedite patient access to medical devices within APAC.

## Timing

With patient access in mind, APACMed believes that it is always the right time to implement regulatory reliance. However, in the face of major regulatory challenges recently, there is more urgency now than ever to implement regulatory reliance within APAC.

As several markets including Thailand are transitioning to the new regulations with the implementation of the AMDD, regulatory reliance could provide tremendous benefit in accelerating the acceptance of medical devices under the new regulations. The experience gained by the Reference Authorities will provide good learnings in simplifying and expediting the review and approval process.

Regulatory reliance could also be applied to managing the sudden increase in workload created by the implementation of the new European Medical Device Regulation (MDR) and *In Vitro* Diagnostic Regulation (IVDR). Further to APACMed's recommendation on not overburdening both the Regulators and the manufacturers with unnecessary submission of administrative changes in one of its recent publications<sup>12</sup>, Regulators can explore regulatory reliance to expedite the approval of other changes associated with the implementation of the MDR and IVDR. As the transition to the new regulations will only be completed in the EU in 2027, the resources required for handling these changes will be colossal.

Finally, the global COVID-19 pandemic has highlighted the importance of regulatory reliance. Not a single country would have had sufficient resources to assess the registration of products fast enough to meet patients' needs without a form of regulatory reliance.

## Need of legislative framework

The need of a formal legislative framework to explicitly provide the scope for administrative and enforcement discretion to Regulatory Authorities is key in facilitating the implementation of regulatory reliance as per WHO's good reliance practices. However, it is APACMed's opinion that the lack of such a legislative framework should not prevent Regulatory Authorities from exploring regulatory reliance. As discussed earlier, regulatory reliance does not have to result in a change in legislations. In fact, as long as the legislations do not prohibit regulatory reliance, countries should be able to explore such a practice. The additional information such as assessment reports provided by a Reference Authority are additional tools to support the Relying Authority with the review and approval process. In this specific example of regulatory reliance between HSA and Thai FDA, a relatively simple confidentiality agreement between the two Regulatory Authorities was sufficient to initiate the project.

## Jurisdictional independence

Jurisdictional independence is a contentious issue and may be seen as a barrier by Regulatory Authorities for achieving regulatory reliance as Regulators may suppose that they will have to relinquish their decision power if they rely on decisions made by other Regulators. On the contrary, jurisdictional independence is part of good reliance practices as Regulatory Authorities are encouraged to retain the decision power on the products that should be marketed in their own countries as there are various factors that could have an impact on the need of a particular medical product in addition to the registration. Such factors include the epidemiology of a

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<sup>12</sup> *Establishing Regulatory Agility to Manage Changes due to EU Medical Device Regulation in Asia Pacific* published, December 2020

disease, the healthcare system, and the availability of other treatments. With the HSA-Thai FDA regulatory reliance, Thai FDA retained the power to decide on the medical devices that should be marketed in Thailand. Referencing the assessment reports provided by HSA to support the decision-making process does not oblige Thai FDA to approve a product without further consideration.

## MOVING FORWARD

As APACMed continues to work with Singapore HSA and Thai FDA to refine the regulatory reliance project, the short-term aspiration is to support Regulatory Authorities in APAC to routinely consider regulatory reliance as a tool for accelerating patient access to medical devices in the region.

In the midterm, the goal is to build an extensive network for cooperation and regulatory reliance in APAC. APACMed is currently working closely with other Regulatory Authorities to explore the possibility of expanding the regulatory reliance network in APAC, whether as relying markets, reference markets or both. APACMed conducted an introductory meeting with the Philippine Food and Drug Administration (Philippine FDA) to share the HSA-Thai FDA regulatory reliance project in April and the Philippine FDA provided a preliminary indication that they would be open to join the initiative, pending the official endorsement by its Director General. APACMed has also had several discussions with Australia TGA and TGA showed interest in being part of the regulatory reliance initiative but this is dependent on the outcome of wider cooperation that is being negotiated between TGA and Thai FDA at the moment. APACMed welcomes all Regulators in the region to participate.

In the longer term, regulatory reliance could be the driver for achieving harmonization and convergence in APAC as stakeholders continue to collaborate closely with each other and share best regulatory practices. This will ensure that the availability of safe and effective medical devices in the region in the shortest time possible.

Ideally, there should be collaboration with all Regulators and other organizations around the world such as WHO, IMDRF and Global Harmonization Working Party to implement a common framework for regulatory reliance in its most efficient form – recognition. APACMed is currently in discussion with WHO to explore the opportunity for collaboration on regulatory reliance.