The APACMed mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.
Outline

• Need for regulatory reliance
• Concepts and principles of regulatory reliance
• Successful examples of regulatory reliance
  • Medical Device Single Audit Program
  • Singapore-Thailand pilot
  • Australia-Canada-Singapore-Switzerland Consortium
• APACMed’s role in regulatory reliance
• Next steps
• Conclusion
Challenge of a Small Agency

5,000
1,500
5,000

100

50,000+
Registrations

~1 Million Devices

= 10
Rapid Advancement of Technologies
Emergence of New Threats

COVID-19

SARS

Ebola

* WHO: Good reliance practices in regulatory decision-making: high-level principles and recommendations
Need for Regulatory Reliance

• Improve efficiency and access to health products
• Global approach for regulatory reliance
• Opportunity to concentrate limited market resources on areas where efforts are most needed
• In line with WHO’s Good Reliance Practices* – smarter way for strengthening the regulatory systems by pursuing cooperation, convergence and reliance

* WHO: Good reliance practices in regulatory decision-making: high-level principles and recommendations
WHO – Key Concepts of Reliance

- **Unilateral/Mutual Recognition**
- **Regional reliance mechanisms**
- **Abridged pathways using reliance**
- **Work-sharing**
- **Standard processes**

**Building trust between NRAs**

- **Independent decisions**
  - based on its own reviews or inspections

- **Leveraging regulatory work**
  - Performed by other competent and trusted authorities to reduce the workload, with independent final decision-making

- **Regional reliance mechanisms**
  - Centralized evaluation conducted for a group of countries

- **Unilateral or mutual recognition**
  - based on treaties or equivalent, providing maximal benefits
WHO – Principles for Reliance

- Universality
- Competency
- Sovereignty of decision-making
- Consistency
- Transparency
- Respect of national and regional legal basis
Medical Device Single Audit Program (MDSAP)

• Mutual recognition

• Goal: Single regulatory audit of medical device manufacturers for participating markets

• Launched by IMDRF for a global approach to auditing and monitoring the manufacturing of medical devices

• Members: Australia, Brazil, Canada, Japan and U.S.

• Observers: WHO and EU

• Affiliate members: Argentina and South Korea

• Pilot program between Jan 2014 and Dec 2016, and formally adopted in Jun 2017
Singapore-Thailand Reliance Pilot

Regulatory Reliance process flow

Thai applicant
- Submit the application to Thai FDA by indicating that they are participating in the regulatory reliance project including Singapore including the Singapore H.S.A license number and product name.
- Review the completion of CSDT and issue the submission number.

Thai FDA
- No
- Re-prepare the submissions and re-submit again.
- Yes
- Incorporate the evaluation report to their product approval process.
- Product license

Singapore Applicant
- Submit the consent form to HSA through email by referencing the Thai FDA submission number.
- Yes
- Competency
- Transparency
- Evaluation report

HSA
- HSA acknowledge the consent form and share the evaluation report to Thai FDA in 2 weeks.
- Evaluation report
Example of Tool Used for Singapore-Thailand Reliance

Thailand FDA & Singapore HSA Reliance Model Consent Form

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

We, [Singapore Company Name], the Registrant for registration of medical device(s) stated below, hereby grant Thailand FDA the access to the submission dossier(s)/evaluation summary of the medical device(s) submitted to HSA, for the purpose of Thailand FDA and Singapore HSA Reliance Model evaluation as stated below.

Singapore List of Medical Device(s):

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Device Registration number</th>
<th>Job reference number of main submission</th>
<th>Job reference number of all change notifications filed to date</th>
<th>Device Product Identifier</th>
</tr>
</thead>
</table>

Thailand FDA Submission Information:

Full Company Name:
Full Name of Company Contact Person:
Thailand FDA submission reference number:
Submission date (DD/MM/YYYY):

We hereby also declare that by participating in this regulatory reliance program, I understand that:

(i) The evaluation report will be shared only after a product is approved by Singapore HSA.

(ii) For approved medical devices where change notifications had been submitted since initial premarket approval,

   (a) for technical changes, the change notification evaluation report will be appended together with the main premarket evaluation report, and

   (b) for notification and administrative changes, the latest information on the Singapore Medical Device Register (SMDR) for the device will also be appended.
ACSS Consortium

- Work sharing
- Goal: International cooperation, reduce duplication and increase agency’s capacity
- Australia-Canada-Singapore-Switzerland Consortium
- Like-minded, medium-sized regulatory authorities
- Focus: Biosimilars, complimentary medicines, generic medicines, IT for information sharing and new chemical entities
- Emergency, e.g.: ACCS regulators pledged support to tackle COVID-19

Figure 1: Example of the possible division of labour
APACMed’s Role in Regulatory Reliance

- Objective: Improve the standards of care for patients through innovative collaborations among stakeholders

- Represents manufacturers and suppliers of medical equipment, devices and *in-vitro* diagnostics in Asia Pacific

- What we do:
  - Improve access to high quality healthcare for patients
  - Support innovative new technologies
  - Drive common approaches aligned with international best practices

- Regulatory reliance:
  - Thought leader e.g. position papers such as *Building Regulatory Agility for Adequate Access to Quality SARS-Cov-2 Test Kits During Global Pandemic*
  - Initiated talks amongst regulators and industry members to encourage regulatory reliance
Key Next Steps

• Reliance opportunities
  • Assessment of national/regional laws, regulations and guidelines to identify areas for potential reliance (e.g. defining the degree of similarity vs. other jurisdictions)
  • Evaluation of areas where reliance should be encouraged based on national/regional strategic priorities (e.g. emergency test kits, products equivalent to existing products approved via 510(k) by US FDA, etc.)

• Toolboxes
  • Identification/creation/sharing of practical tools to facilitate/encourage the adoption of reliance, e.g.:
    • Sharing of existing reliance initiatives such as reliance agreements and arrangements
    • Organizing observation sessions on existing reliance projects as learning opportunities
    • Conducting joint pilot assessments for identifying like-minded regulatory agencies for potential reliance
The Future Is in Our Hand

Full reliance may be difficult to achieve as various jurisdictions have different strategic priorities, however, we must all prioritize reliance, albeit partial, if we want to improve efficiency and access to health products.
Thank you

The voice of MedTech