BENEFITS OF REGULATORY RELIANCE

SINGAPORE EXPERIENCE

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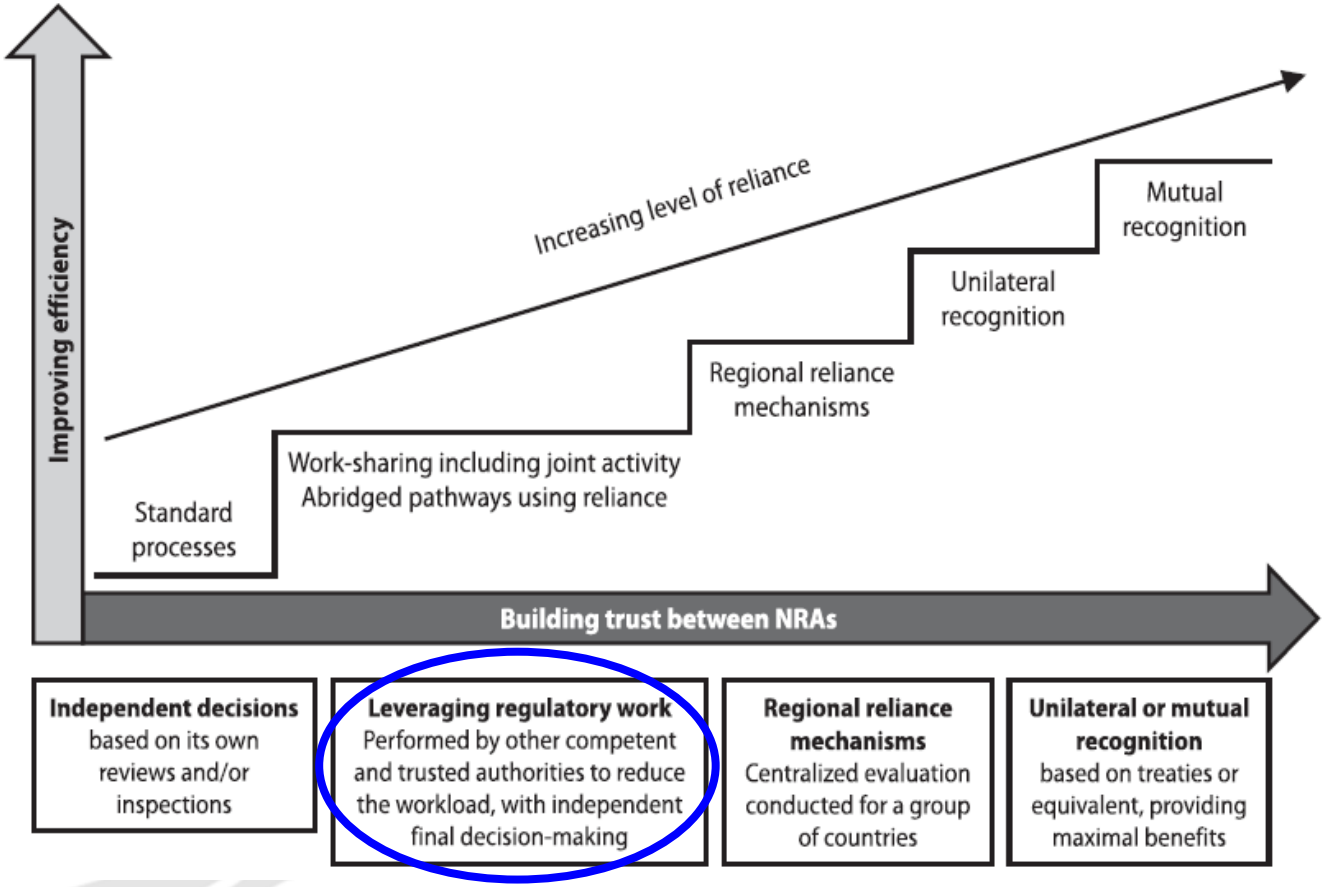
Dr Rama Sethuraman
Director – Medical Devices,
Medical Devices Cluster
Health Sciences Authority, Singapore

REGULATORY RELIANCE

Regulatory 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.



Source:
WHO - *Good Reliance Practices in the Regulation of Medical Products: High Level Principles and Considerations*

REGULATORY RELIANCE

- Promotes regulatory efficiency by leveraging the work done by other trusted agency/institution
- Enhances accessibility to safe, effective and good quality medical devices
- Allows the relying regulatory authority to retain its jurisdictional independence
  - Relies on the assessments or decisions from others
  - Retains sovereignty of decision making
  - Remains responsible and accountable for regulatory decisions taken

1. ADOPTING REGULATORY RELIANCE

- Implementing confidence based pathways for pre-market evaluation of Medical Devices

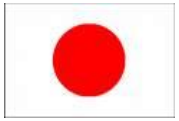
HSA's Reference Regulatory Agencies (RA)

GHTF Founding Members


Australia TGA


EU


Health Canada


Japan MHLW


US FDA

Reference Agencies

- Prior approval from RAs, with **identical** labelled intended use.

Type of recognized approvals can be found in GN-15

Marketing History

- Safe marketing history in the respective RAs.

Devices may go through pre-market evaluation route(s) with Shorter timeline + Lower cost + Lesser dossier requirements

CONFIDENCE BASED PATHWAYS - Benefits

Regulators

- Avoid duplication of regulatory oversight – Not re-invent the wheel
- Effective resource management – Prudent use of limited resource pool

Manufacturers

- Least burdensome regulatory process
- Cost and resource savings
- Faster market access

Patients

- Timely access to essential MDs for clinical needs
- Faster access to safe and effective technologies

2. SUPPORTING REGULATORY RELIANCE

- Singapore HSA and Thailand FDA initiated conversations on a possible regulatory reliance approach for medical devices
- Establishing an effective reliance approach requires:
  - Relying agency: Build **confidence** in the evaluations and assessments conducted by the other trusted agency
  - Other trusted agency: Be **transparent** on the evaluation and assessment criteria and practices including the decision making processes
- Sustaining the reliance approach requires on-going engagement and collaboration between the agencies to build trust and confidence

SINGAPORE HSA – THAILAND FDA REGULATORY RELIANCE

- Singapore HSA and Thailand FDA, with the support of APACMed, launched the **regulatory reliance pilot project in September 2020**
- Confidence building measures - Prior to the launch of the pilot in 2020,
  - A team from Thai FDA spent two weeks in Singapore HSA to understand HSA's medical device evaluation and assessment procedures in depth
  - Singapore HSA shared our evaluation criteria, processes and decision making procedure with Thai FDA
- Prior to the launch of the pilot, a confidentiality agreement was signed between Singapore HSA and Thai FDA to allow the two agencies to freely share submission-related information with each other
- The pilot was also an opportunity to establish a practical approach to incorporate reliance into the Thai FDA's medical device evaluation process

SINGAPORE HSA – THAILAND FDA REGULATORY RELIANCE

Developing the approach

- **Phase I of pilot (Sep 2020) –** opened to entire industry
  - 12 applications accepted on first-come-first-served basis
  - To be eligible for pilot, the following criteria to be met:
    - Medical devices (MDs) classified as Class C or D
    - MDs have an existing import license in Thailand

      >> MDs registered under the old Thai regulations could be re-submitted for the pilot to facilitate the re-assessment of existing medical device products for the transition to the new Thai regulations implemented in February 2021)
    - MDs must have already been registered in Singapore

- **Phase II of pilot (Feb 2021)**
  - 12 applications accepted on first-come-first-served basis
  - To be eligible for pilot, the following criteria to be met:
    - Class C, or D MDs
    - MDs falling 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
    - MDs must have already been registered in Singapore.

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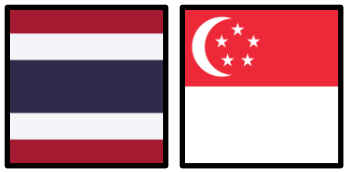
Implementing the approach



- **Singapore HSA, officially announced as a reference agency for Thailand FDA (Oct 2021)**
  - Expedited medical device registration program in Thailand with a shorter duration of registration
  - To be eligible, the following criteria to be met:
    - Class D MDs
    - MDs must have already been registered in Singapore and requires consent from Singapore Registrant of the MD in a prescribed format

Key benefits of the Reliance approach as shared by Industry Stakeholders:

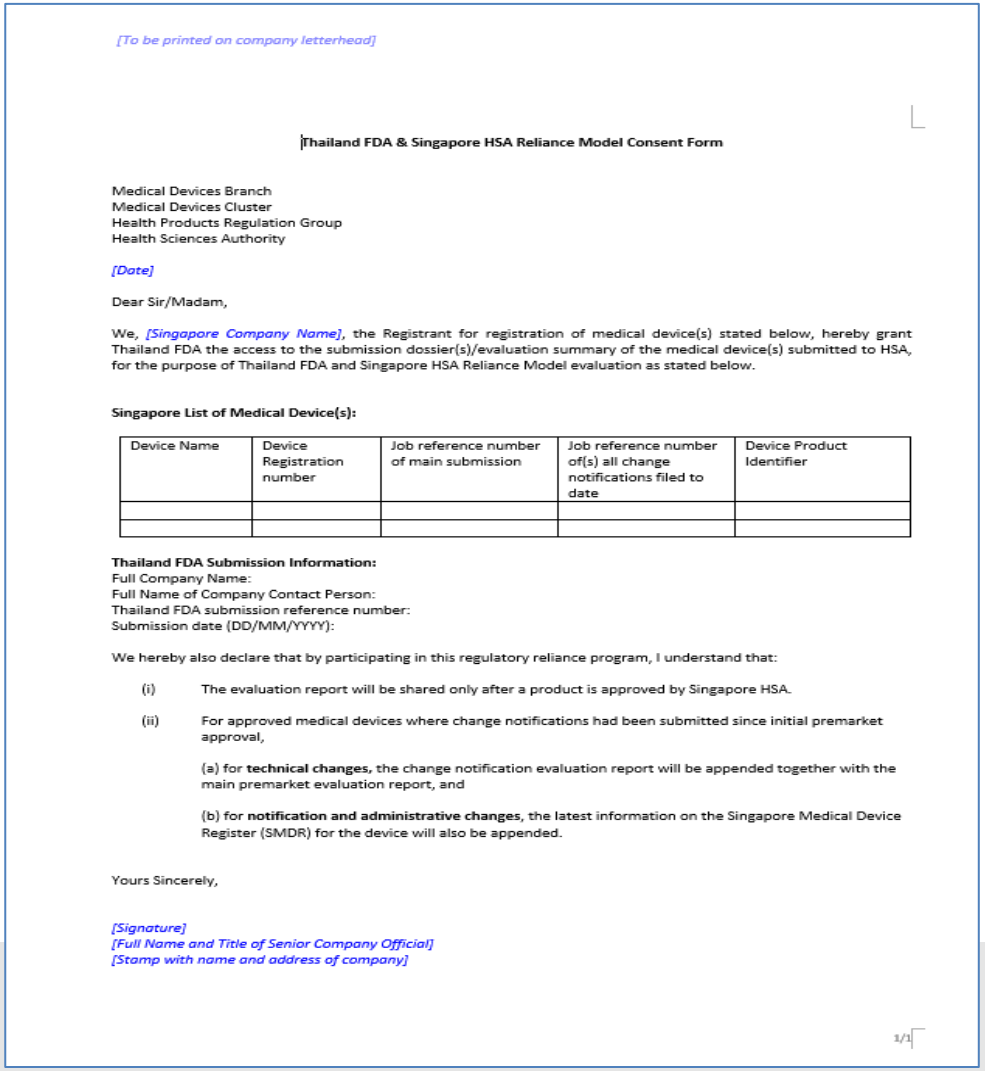
- Increase in regulatory efficiency by reducing redundancies
- Reduction in the overall registration cost for their MD in Thailand
- Significant decrease in the average review time for MDs qualifying for the reliance approach in Thailand

SINGAPORE HSA - THAILAND FDA REGULATORY RELIANCE

The actual process

- Thai business operators with MD establishment license sign a letter to request participation in the Regulatory Reliance Program
- The manufacturer or importer submits an application for a medical device license through the Thai electronic submission
- After receiving an application number in the e-submission system, the Singapore registrant signs Consent Form authorizing Singapore HSA to release their evaluation report for the MD to Thai FDA and submits it via the Thai e-submission system
- Singapore HSA will share the evaluation report with Thai FDA for only those MDs for which the Singapore Registrant has signed a consent and authorised the sharing the evaluation report

Consent Form Template for the Singapore HSA-Thai FDA Reliance:



[To be printed on company letterhead]

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):

Device Name	Device Registration number	Job reference number of main submission	Job reference number of(s) all change notifications filed to date	Device Product Identifier

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.

Yours Sincerely,

[Signature]
[Full Name and Title of Senior Company Official]
[Stamp with name and address of company]

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SINGAPORE HSA – THAILAND FDA REGULATORY RELIANCE

Learnings so far

- To date, Singapore HSA has shared 29 evaluation reports for various MDs with the Thailand FDA

- Resources required for the Reference Agency to share evaluation reports for a submission to the Relying Agency hence importance of planning of requests for evaluation reports
  - Post-registration in the reference agency, the MD would likely have gone through changes including significant ones that could have since modified the MD's performance or safety profile
  - Need to share the evaluation outcome, if any, for these post-registration updates with the relying agency

- Where there is new information regarding the quality, safety or efficacy of the MD, reference agency to share these, as applicable

- On-going engagement and communications

- Regulatory reliance - an important tool to manage strains on regulatory resources and improve patient access to medical devices

Thank You!