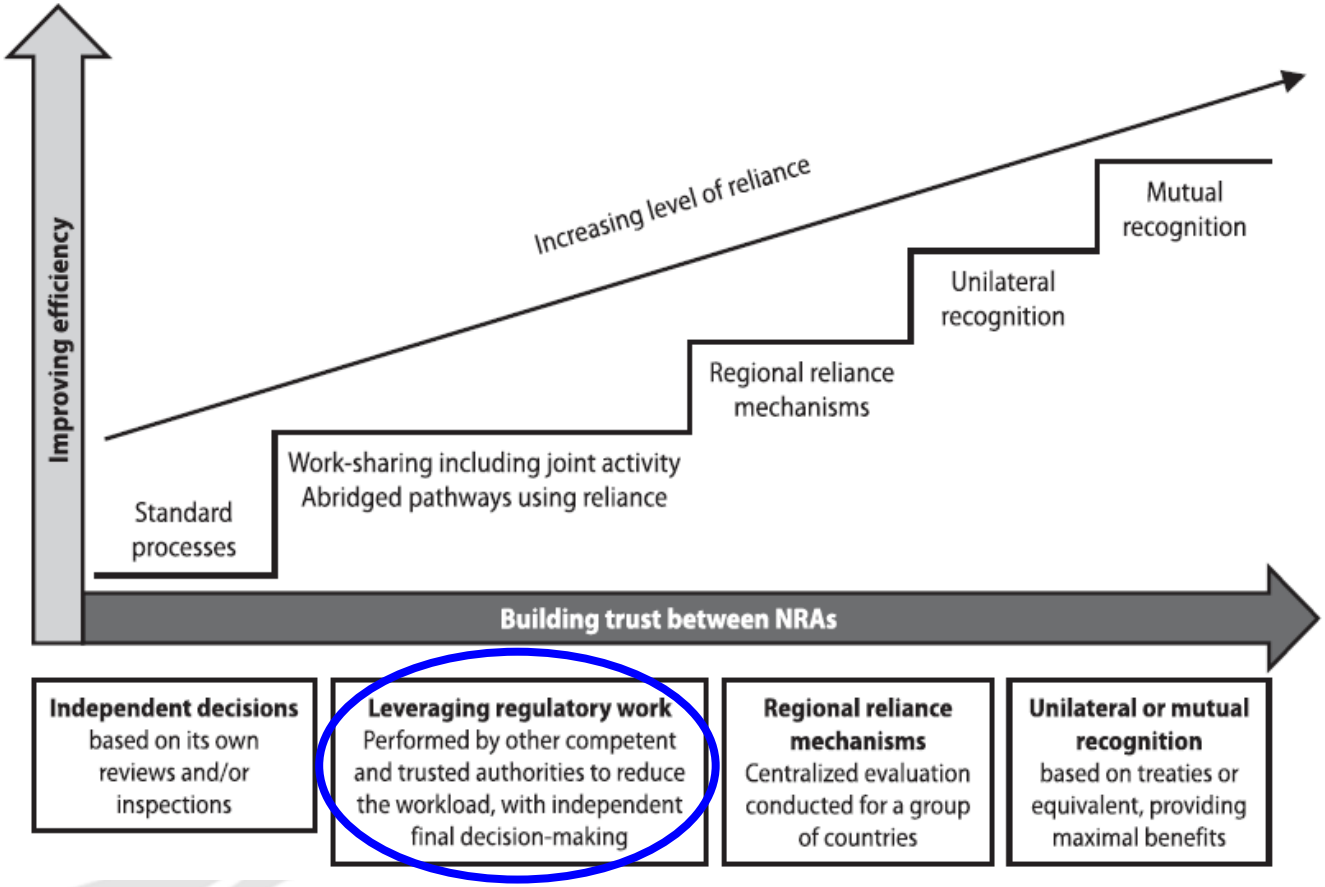
Use and Contextualization of Reliance Models to Streamline Medical Device Assessment

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

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*

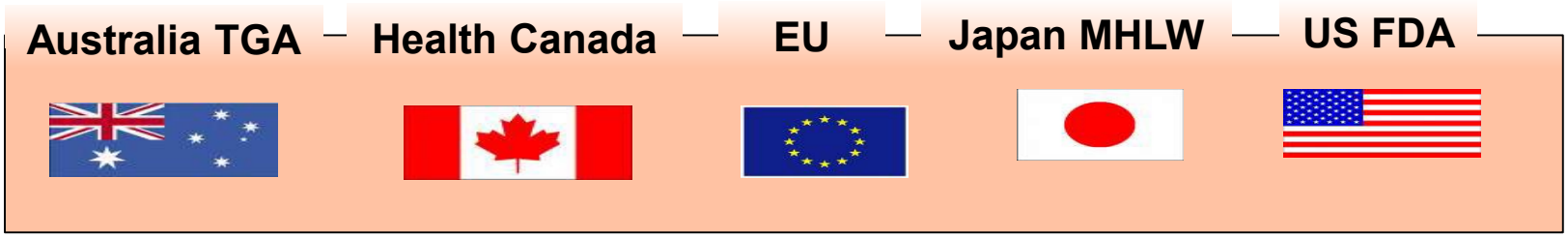
REGULATORY RELIANCE

- 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
- 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

Regulatory reliance

1. HSA adopts a reliance approach to leverage approvals granted by 5 reference regulatory agencies (from Australia, Canada, European Union, Japan and the US [1.]). This speeds up our regulatory evaluations and decisions for MDs

2. Prior **approval** from HSA's reference agencies (RAs), with identical labelled intended use.



3. Safe marketing history in the respective RAs.

→ Devices may go through an evaluation route with Shorter timeline + Lower cost + Less dossier requirements.

Australia's TGA listing HSA as a Comparable Overseas Regulator for Medical Devices

Australia's Therapeutic Goods Administration (TGA) has listed HSA as a Comparable Overseas Regulator (COR) for Medical Devices (MDs) [2.]

- TGA is the first of the 5 reference regulatory agencies to recognise HSA as a comparable regulator
- TGA will leverage HSA's evaluations and approvals to fast track their regulatory decision-making
- Other CORs listed by TGA include other reputable regulators from Canada, the EU, Japan and the US

[1.] A full evaluation pathway applies to all MDs without prior approvals from any of these 5 reference regulatory agencies, where rigorous evaluations are done to ensure that such MDs meet the appropriate standards of quality, safety and efficacy

[2.] TGA also recognises HSA as a COR for prescription medicines (from Jan 2018) and as a Comparable Overseas Body for complementary medicines (from Nov 2019)

Submission Requirements

ASEAN Common Submission Dossier Template (CSDT)

- *Harmonized format for submission in ASEAN member countries*

Documentary Requirements		Class B	Class C	Class D
1	Letter of authorization	✓	✓	✓
2	Annex 2 List of Configurations	✓	✓	✓
3	Executive Summary	✓	✓	✓
4	Essential Principles Checklist and Declaration of conformity	✓	✓	✓
5	Device description	✓	✓	✓
6	Design verification and validation, e.g. • Functional test, Biocompatibility studies, Software validations, Shelf-life studies, Sterilisation validation	✓	✓	✓
7	Clinical Evidence	If applicable	✓	✓
8	Proposed device labelling	✓	✓	✓
9	Risk Analysis	✓	✓	✓
10	Manufacturing information • Site's name & address • Proof of Quality Management System • Manufacturing Process – Flow Chart	✓	✓	✓

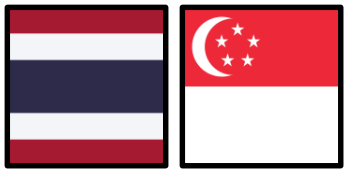
*Refer to **GN-17 / GN-18** for detailed documentary requirements based on respective evaluation route.*

THAILAND FDA – SINGAPORE HSA REGULATORY RELIANCE

- Singapore HSA and Thailand FDA 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

THAILAND FDA – SINGAPORE HSA REGULATORY RELIANCE

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:
    - MDs must have already been registered in Singapore and requires consent from Singapore Registrant of the MD in a prescribed format

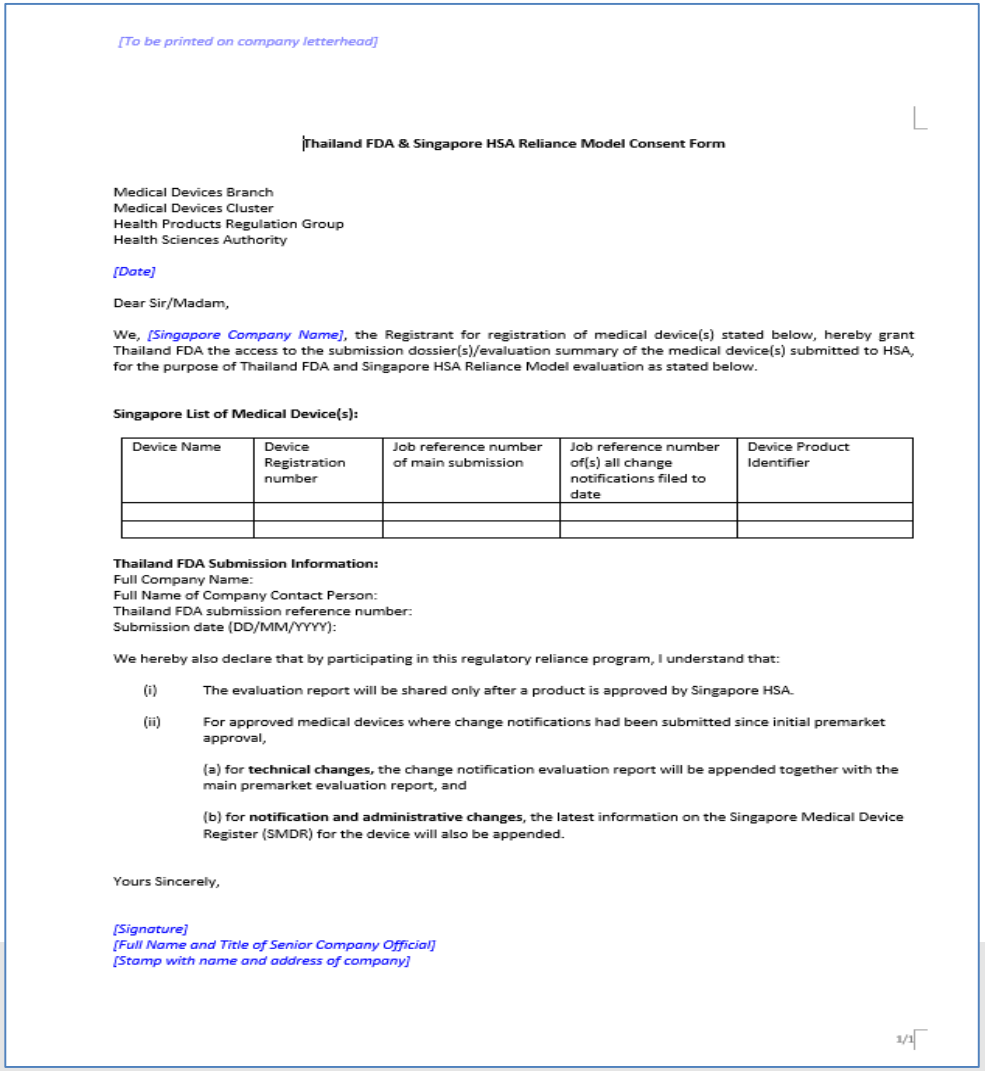
Key benefits of the Reliance approach as shared by Industry Stakeholders:

- 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

THAILAND FDA – SINGAPORE HSA 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]

1/1

THAILAND FDA – SINGAPORE HSA REGULATORY RELIANCE

Learnings so far

- 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
- Regulatory reliance - an important tool to manage strains on regulatory resources and improve patient access to medical devices
- Refer to Singapore Medical Device Register for Class B approvals

Thank You!