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Regulatory Reliance

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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

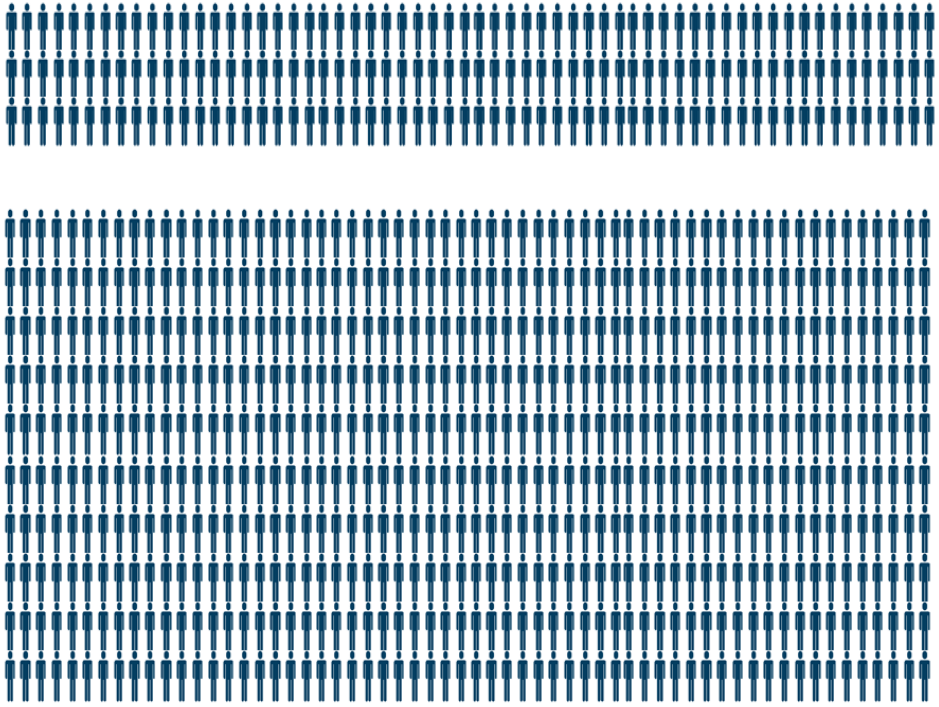
APACMed

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

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

Challenge of a Small Agency



1,500

5,000

100

50,000+

Registrations

~1 Million Devices

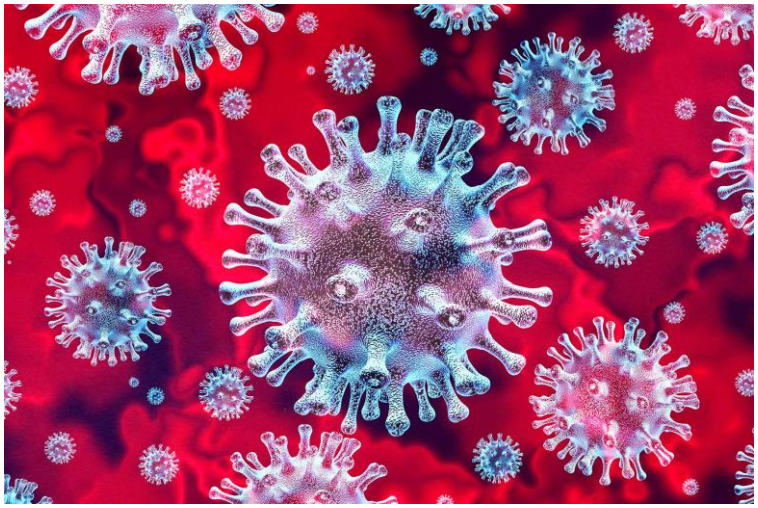
= 10

Rapid Advancement of Technologies

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

Emergence of New Threats

COVID-19



Ebola

SARS

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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 pursing cooperation, convergence and reliance

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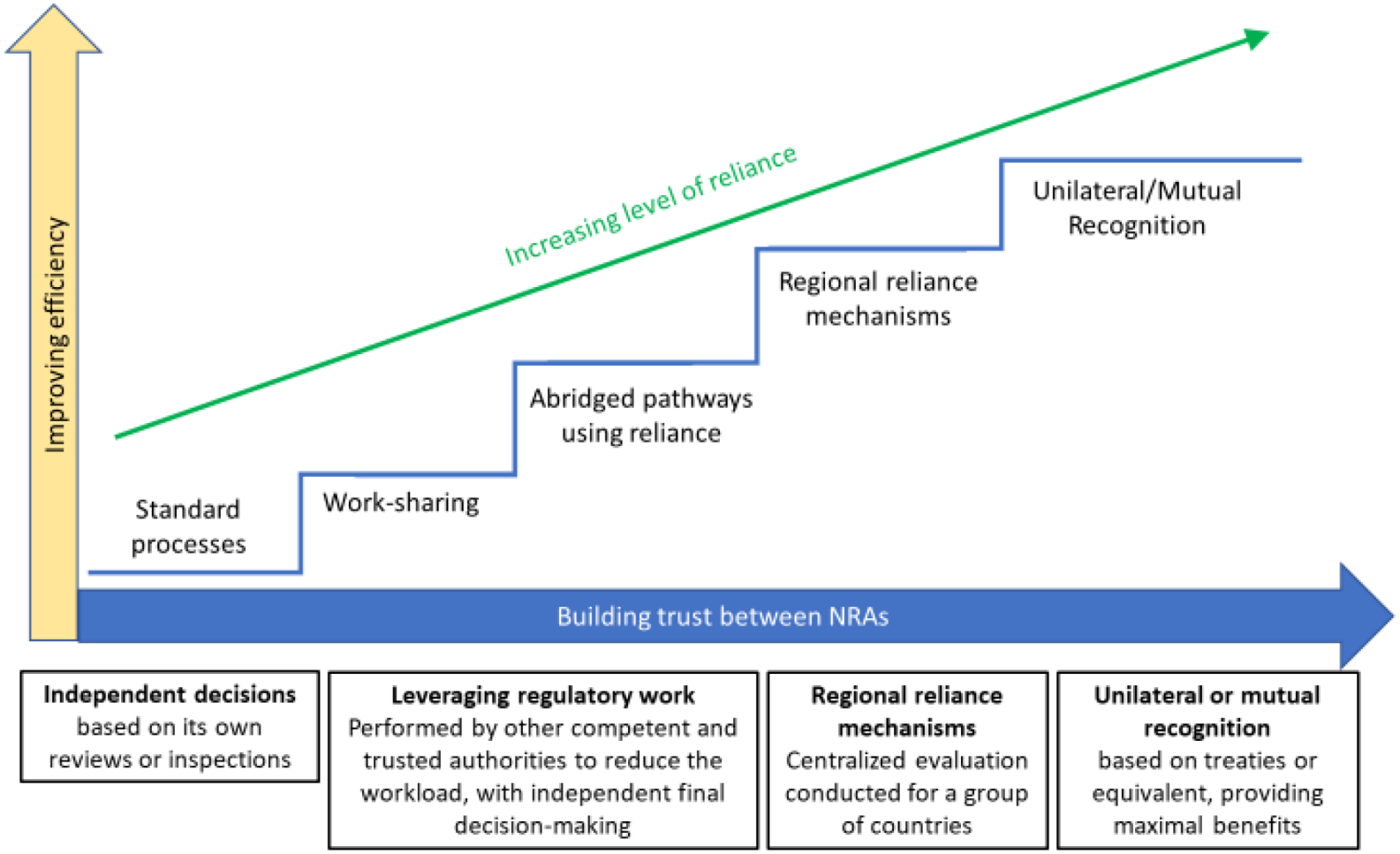
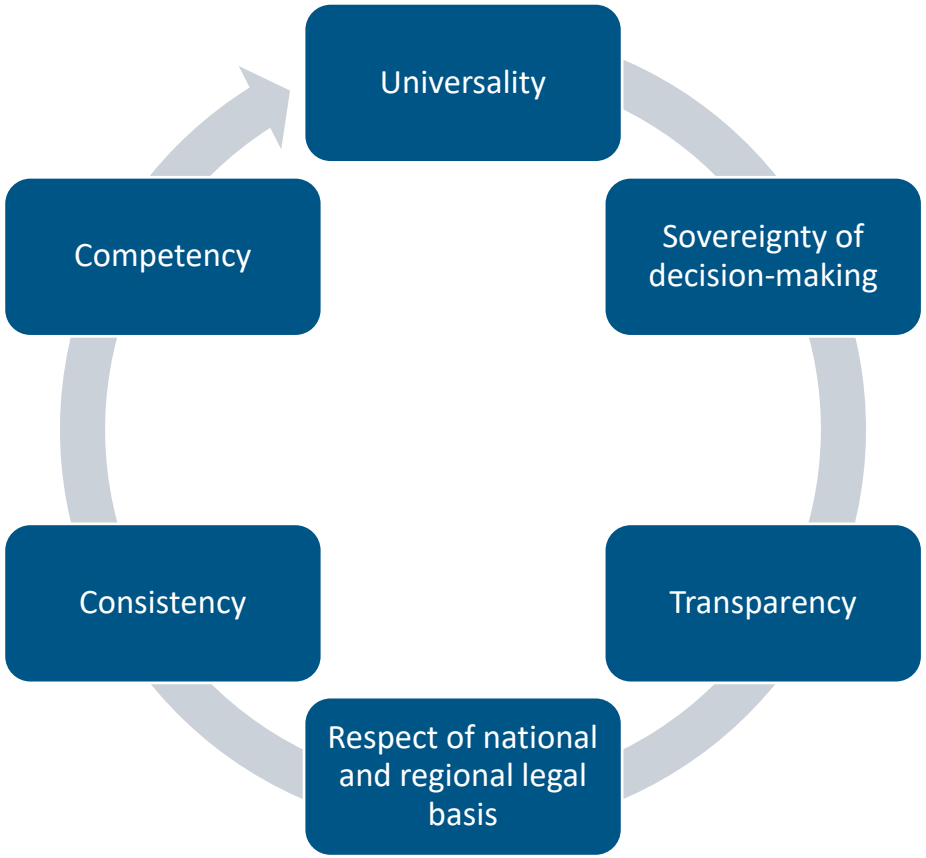
WHO – Key Concepts of Reliance



WHO – Principles for Reliance



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

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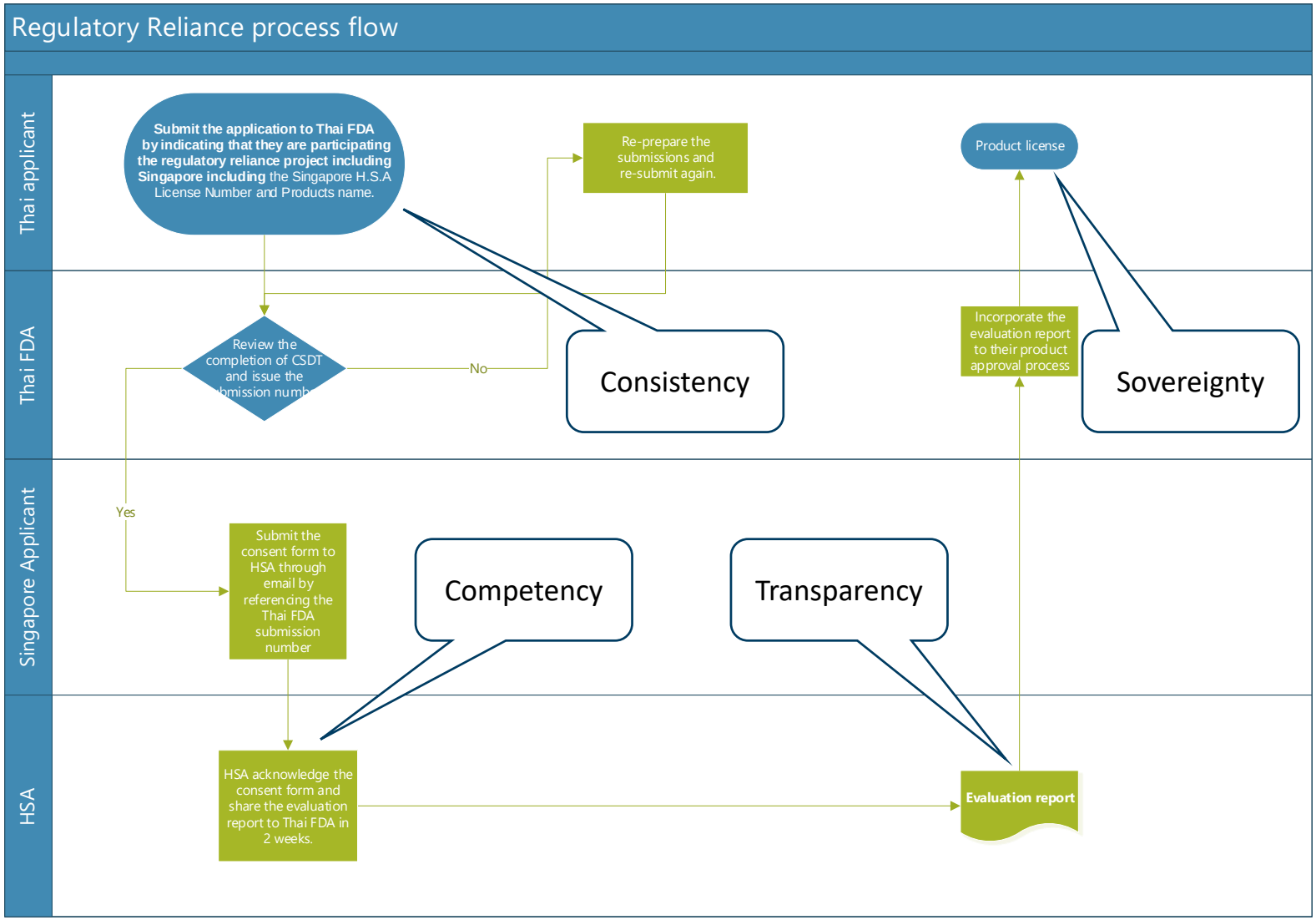
Singapore-Thailand Reliance Pilot



Example of Tool Used for Singapore-Thailand 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.

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

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