HSA'S REGULATORY JOURNEY & REGULATORY RELIANCE

SINGAPORE EXPERIENCE

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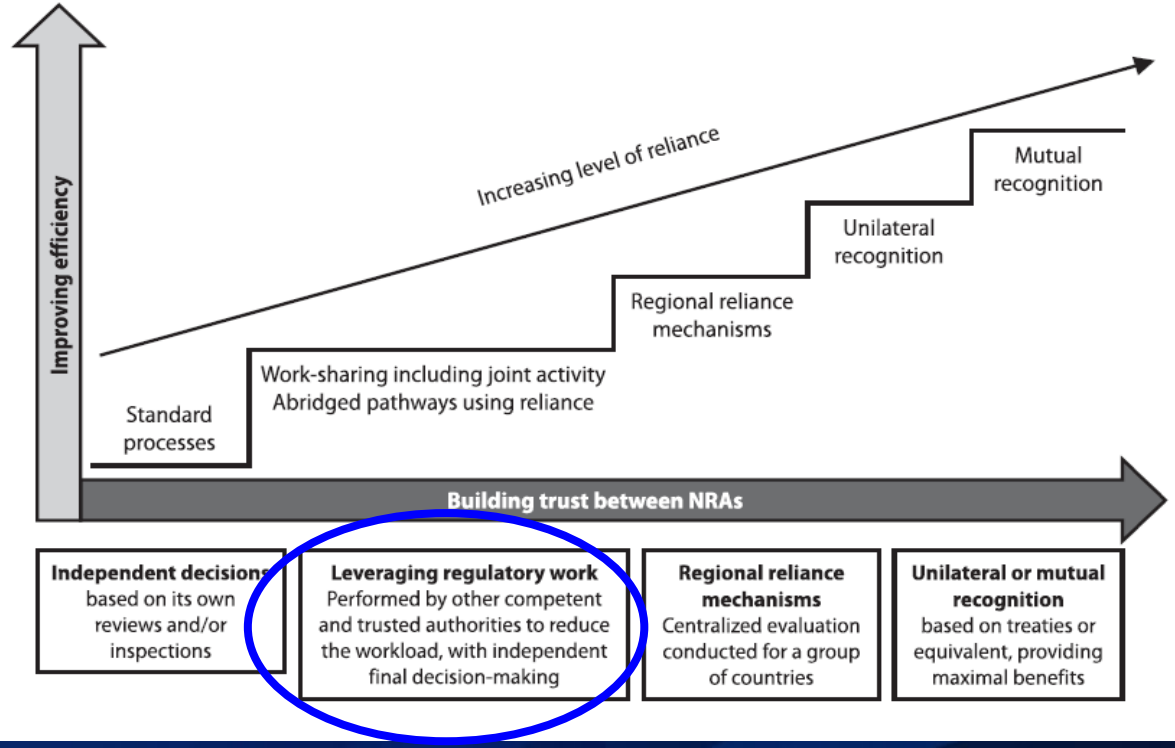
REGULATORY RELIANCE

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

HSA'S JOURNEY IN REGULATORY RELIANCE

FDA U.S. FOOD & DRUG ADMINISTRATION

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ADOPTING REGULATORY RELIANCE

- HSA adopted a reliance approach to leverage approvals granted by 5 reference regulatory agencies (from Australia, Canada, European Union, Japan and USA)

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

- Safe marketing history in the respective RAs

-Devices may go through an evaluation route with Shorter timeline + Lower cost + Less 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

FACILITATING REGULATORY RELIANCE

1. **Australia TGA listing HSA as a Comparable Overseas Regulator (COR) for medical devices**
   - 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

2. **HSA – Thailand FDA Regulatory Reliance**
   - Expedited medical device registration program in Thailand with a shorter duration of registration for MDs already registered in Singapore

3. **WHO recognition of HSA as Stringent Regulatory Authority (SRA) for high risk in vitro diagnostic devices (IVDs)**
   - Class C&D IVDs registered with HSA will qualify for abridged prequalification assessment by WHO. Recognition enable manufacturers of IVDs that have been approved by HSA to obtain faster clearance for WHO prequalification, thus gaining faster access to various global markets for their IVDs

KEY LEARNINGS

- Importance of resource planning for the Reference Agency for sharing of information to the Relying Agency
- Where there is new information regarding safety, quality 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
- Reliance represents a “smarter” form of regulatory oversight, that facilitates and promote convergence and the use of international standards and guidelines, resulting in more predictable, timely access of medical devices


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