独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Regulator Perspectives – Importance of Global Harmonization of Requirements

PMDA, JAPAN

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Harmonized Requirements as a Common Language/Understanding among Stakeholders around the world

Statement from Global Medicines Regulators on the Value of Regulatory Reliance

Global relevance and key principles (excerption)

ICMRA recognises that each NRA will decide the levels and approaches of reliance suitable for their context, and that the adoption of regulatory reliance must follow overarching principles. These principles include sovereignty of decisions, transparency of processes and standards, consistency of products and practices, legality of procedures and mandates at national levels, competency of all stakeholders involved, and universality as reliance applies to all NRAs irrespective of their levels of maturity and resources. While there is a relevant role for reliance mechanisms, they should not replace the importance of continuously developing expertise within NRAs.

ICMRA: International Coalition of Medicines Regulatory Authorities

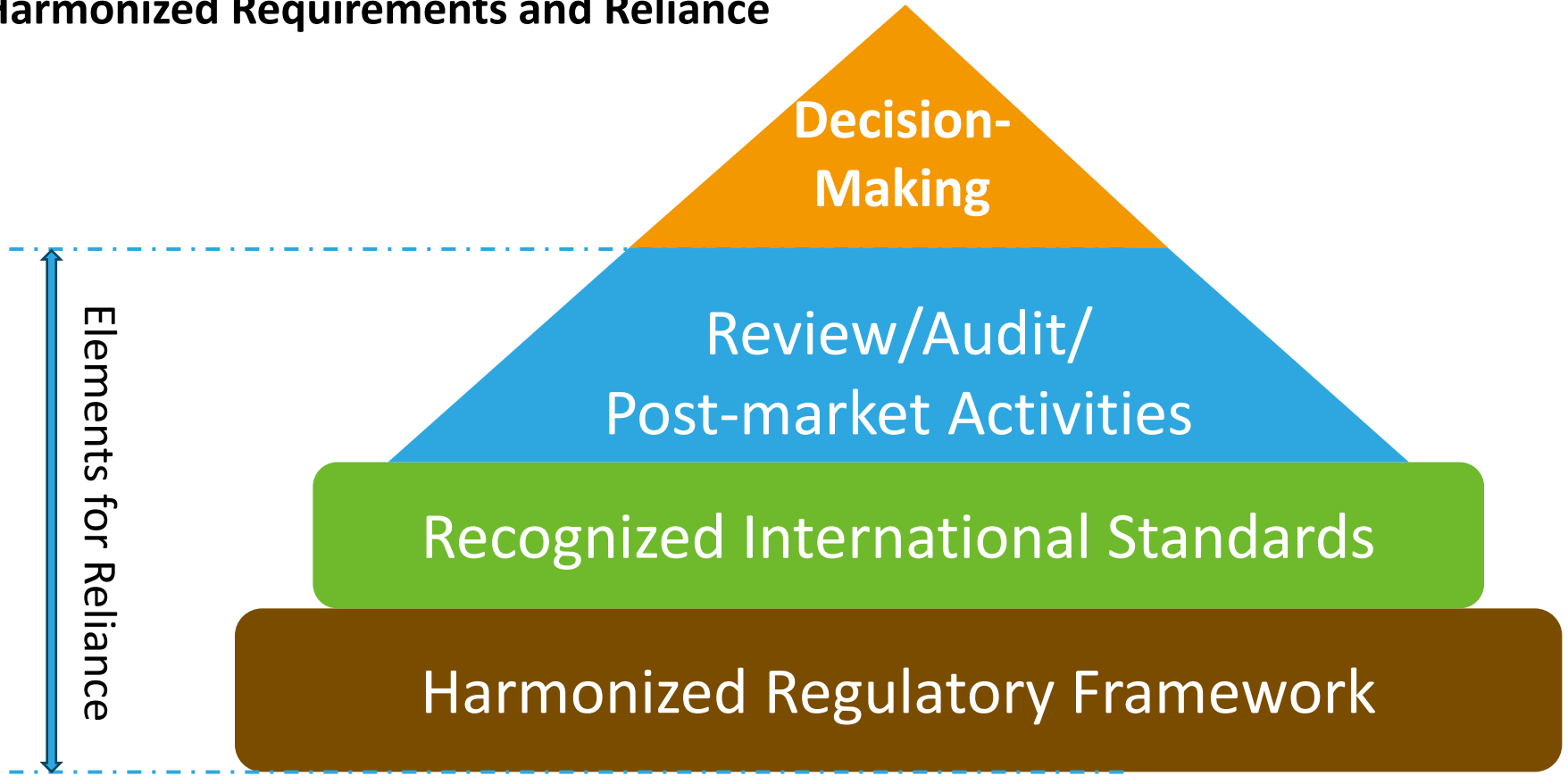
Statement from Global Medicines Regulators on the Value of Regulatory Reliance

Call on Stakeholders (excerption)

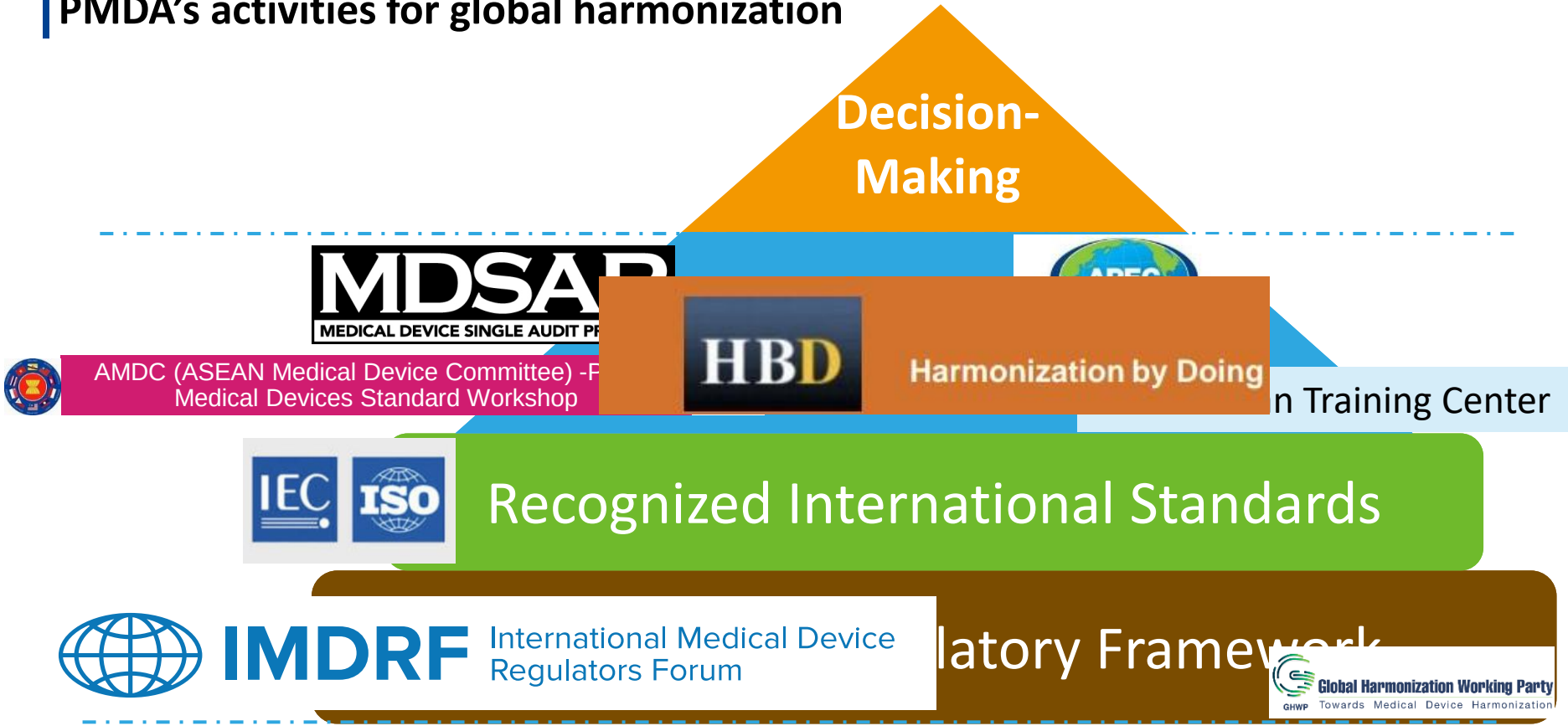
- **ICMRA calls on NRAs**
  - ✓ to continually assess regulatory capacities;
  - ✓ to establish clear and transparent decision-making processes;
  - ✓ to participate in international harmonization and regulatory convergence;
  - ✓ to engage with the development of international regulatory collaboration and cooperation;
  - ✓ to share information on their practices to strengthen regulatory capacities with other NRAs;
  - ✓ to seek the adoption of reliance mechanisms.

These initiatives work to build robust and efficient regulatory systems and, consequently, to further develop trust.

Harmonized Requirements and Reliance



PMDA's activities for global harmonization



Trust can't be built in a day!

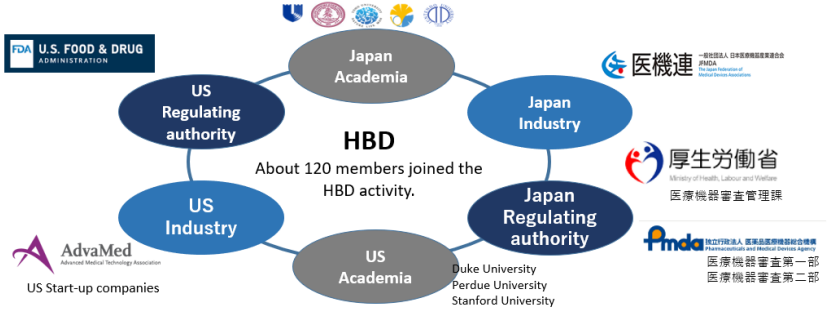
GHTF/IMDRF: 1992 -

GHTF

IMDRF International Medical Device Regulators Forum

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

HBD (Harmonization by Doing): 2003 -



In-practice Regulatory Harmonization Activity among US-Japan Regulator-Industry-Academia

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Thank you!