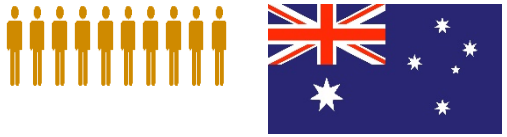
Reliance

The future of Medical device regulations?

The Challenge of a Small Agency

1,500

5,000
(?)



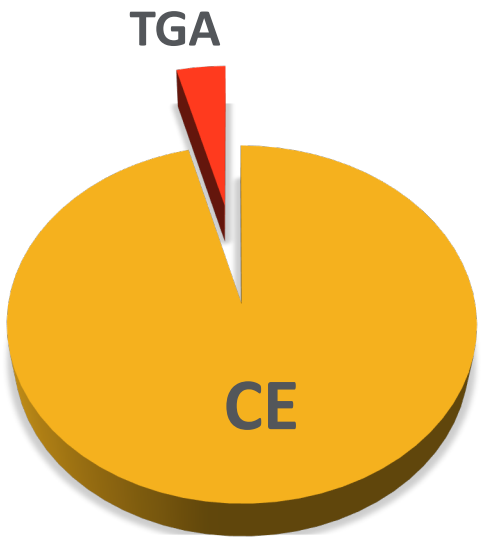
100

50,000+
Registrations

~1 Million Devices

= 10

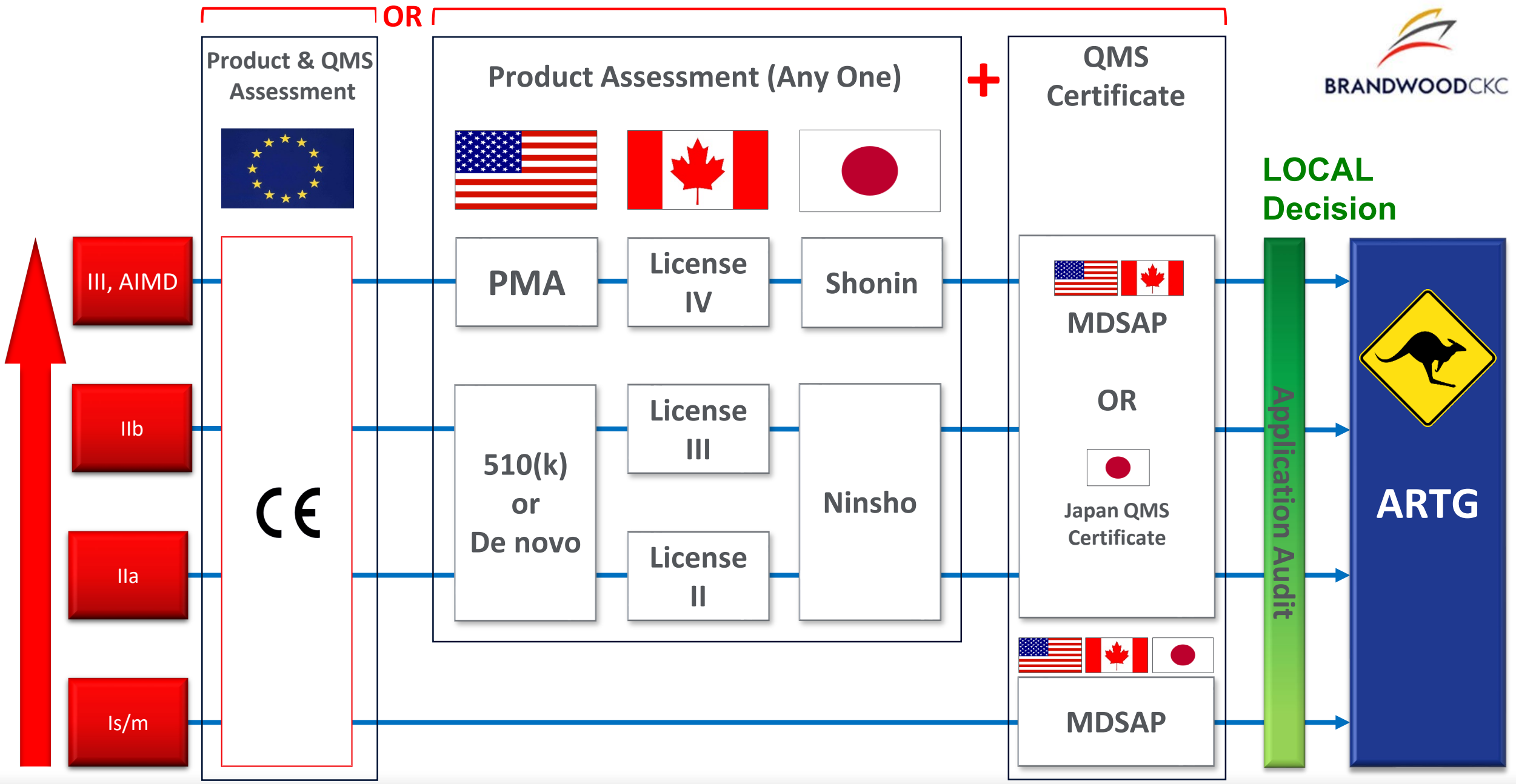
EU reference 93/42/EEC (MDD) and/or 90/385/EEC (AIMDD)	Australian reference Therapeutic Goods (Medical Devices) Regulations 2002 – Schedule 3
Annex II	Part 1 – Full quality assurance procedures
Annex II.4	Part 1, Clause 1.6 – Examination of design of Class AIMD or Class III
Annex III	Part 2 – Type examination procedures
Annex IV	Part 3 – Verification procedures
Annex V	Part 4 – Production quality assurance procedures
Annex VI (MDD only)	Part 5 – Product quality assurance procedures
Annex VII (MDD only)	Part 6 – Declaration of conformity procedures
Annex VIII & Article 12 (MDD only)	Part 7 – Procedures for medical devices used for a special purpose

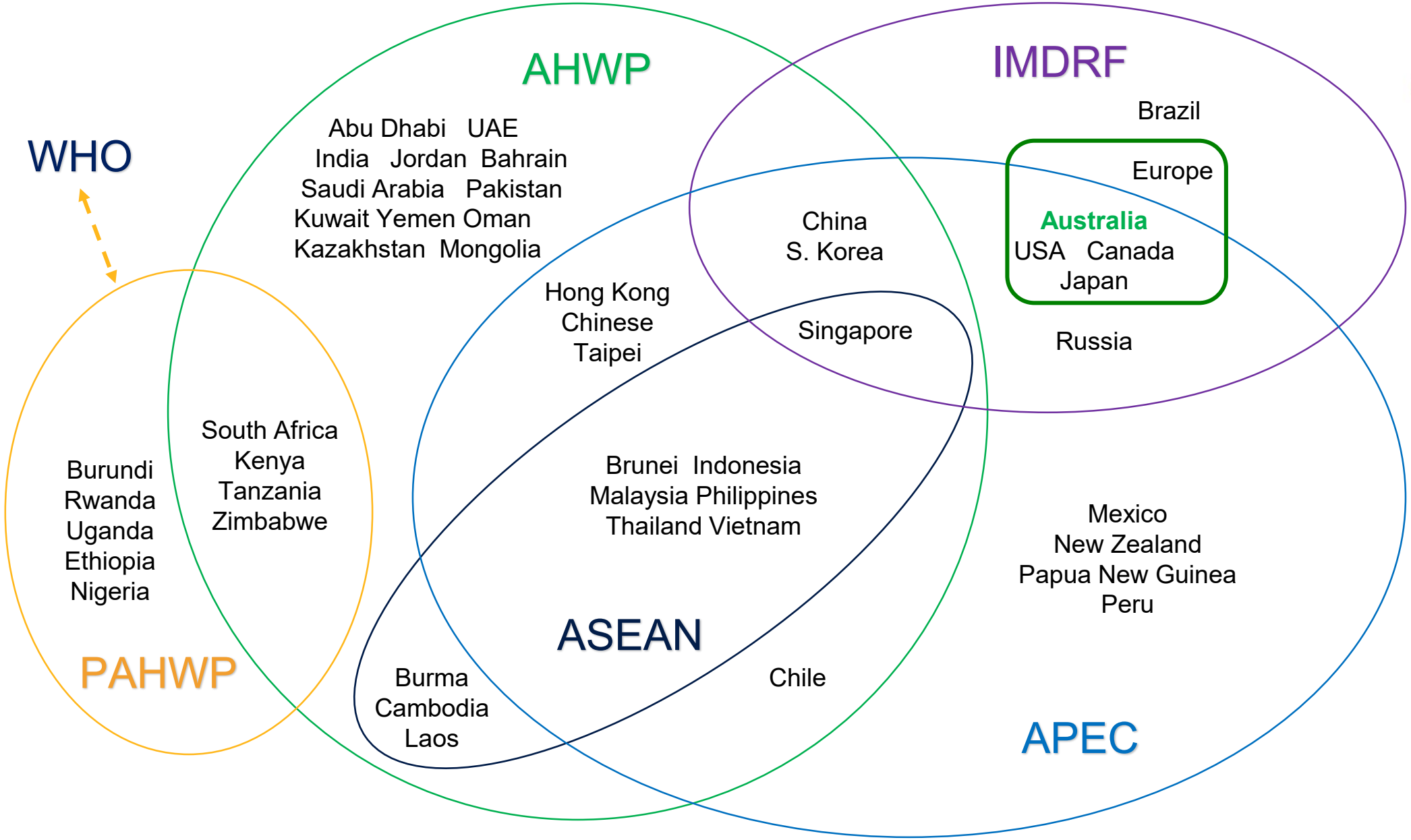


More than

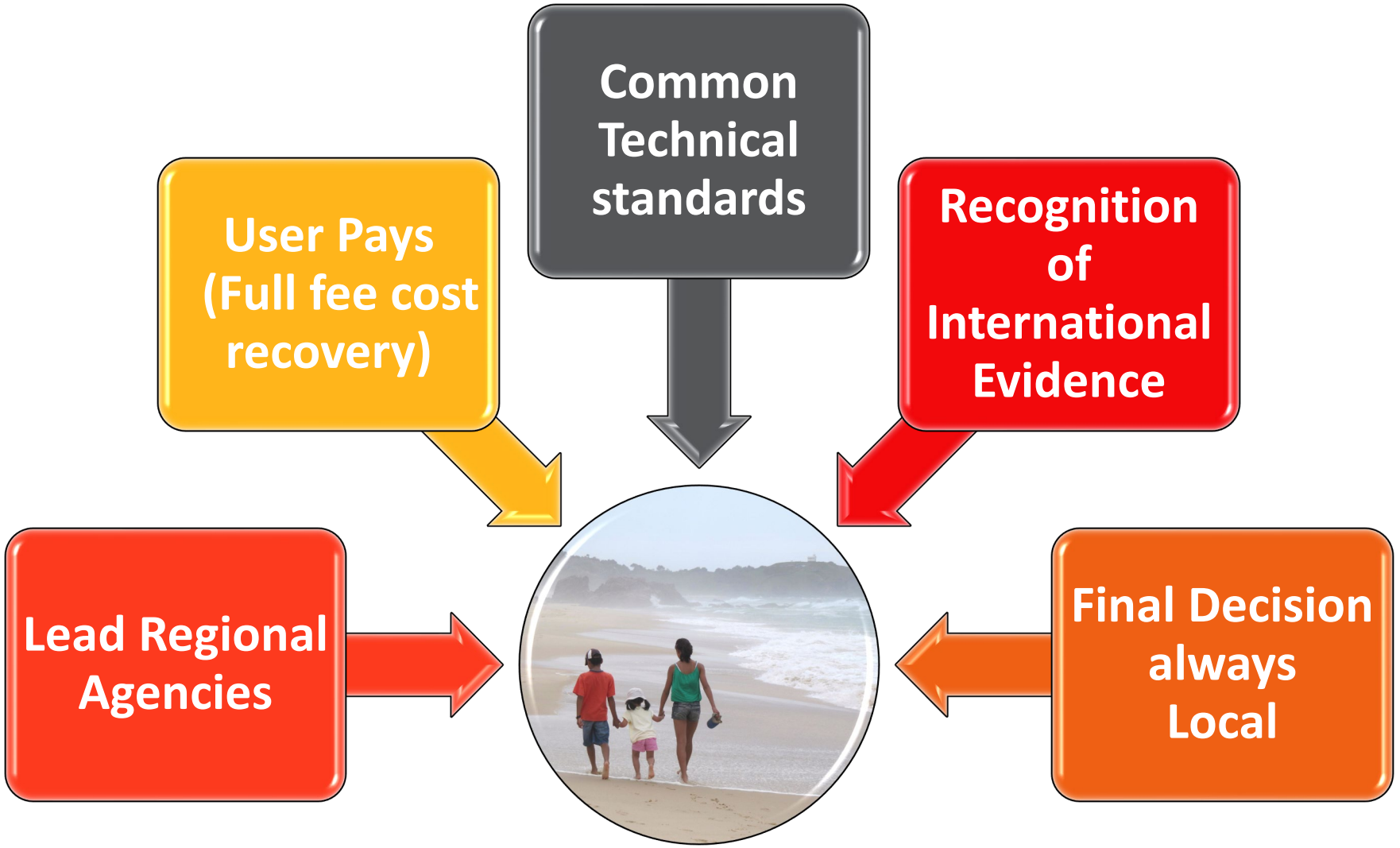
90%

of devices Subject to TGA review are registered based on prior CE certification





Global Harmonisation



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Thank You!