Regulatory concerns

Next Generation Vaccine Delivery Technology Meeting

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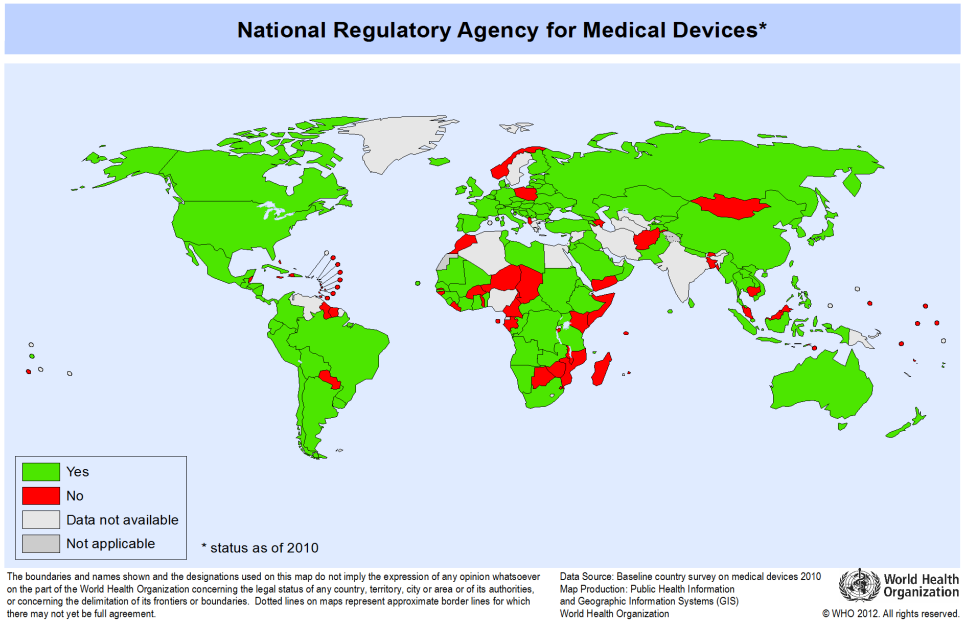
Regulations of medical devices



Only 65% of member states have any form of medical devices regulation

Approximately only 33% have IVD regulation

- **In LMIC:**
  - lack of specialized knowledge, staff and resources to perform medical devices regulations.
  - Very weak post market surveillance
  - Lack of regulation, identified as a barrier to safe and effective medical devices

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Medical device

- An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring , restoring, correcting or modifying the structure or function of the body for some health purpose.

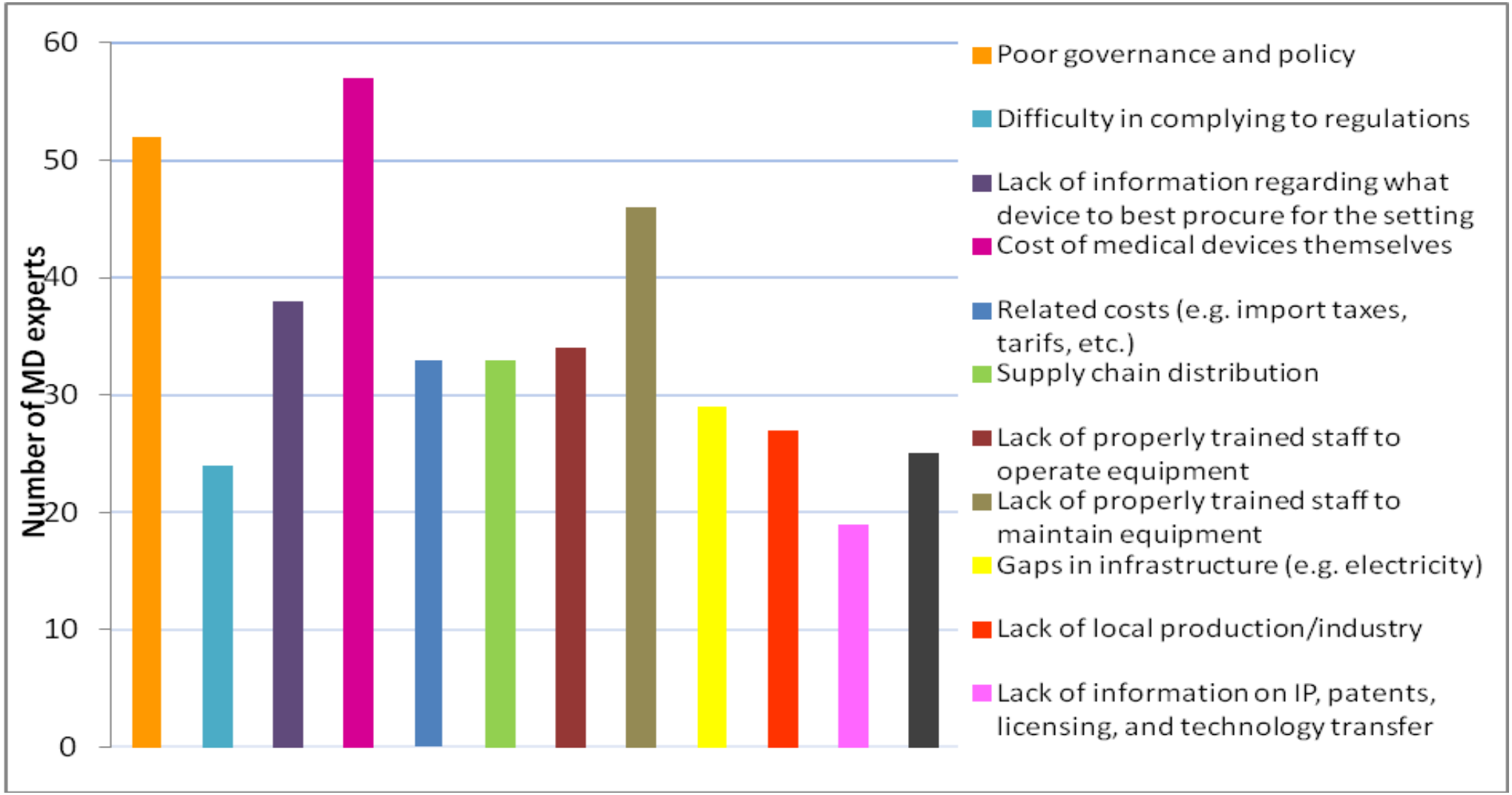
- Typically the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.
  Reference to GHTF, 2005.

- *Examples: syringes, intraocular lenses, ophthalmoscopes, pacemakers, hip replacements, defibrillators, anesthesia machine, scalpel, stents, iv lines, hearing aid, ultrasound, PET scanners…*

Lack of regulatory convergence affects patients

- Hinders access to medical products
- Increases final cost of medical devices
- Slows access to innovative products
- Decreases responsiveness to post-market problems
- Increases possibilities of counterfeit devices
- Quality and safety cannot be assured in an equitable manner.

Phase I survey :Main barriers to access to medical devices in low-resource settings



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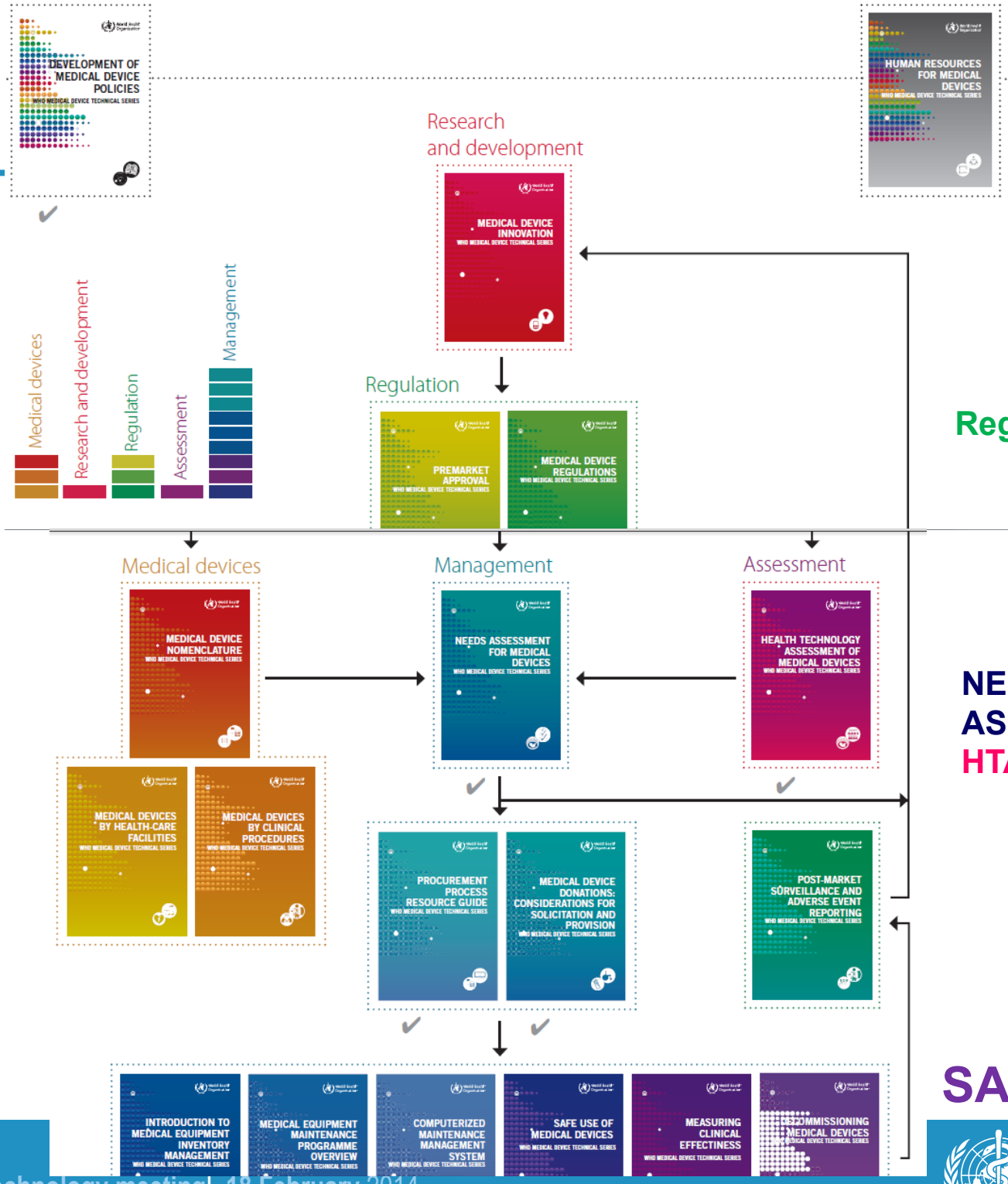
Policies

Human resources



Regulations

NEEDS ASSESSMENT AND HTA

SAFE USE

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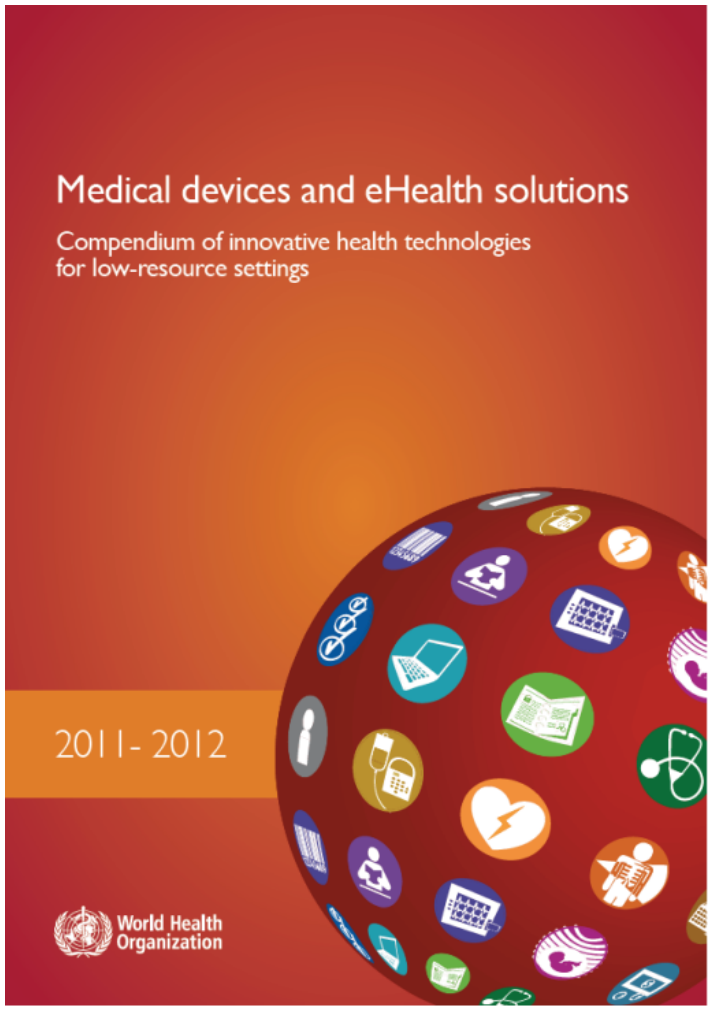
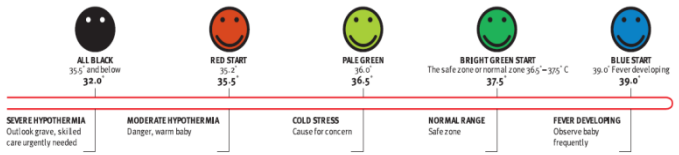
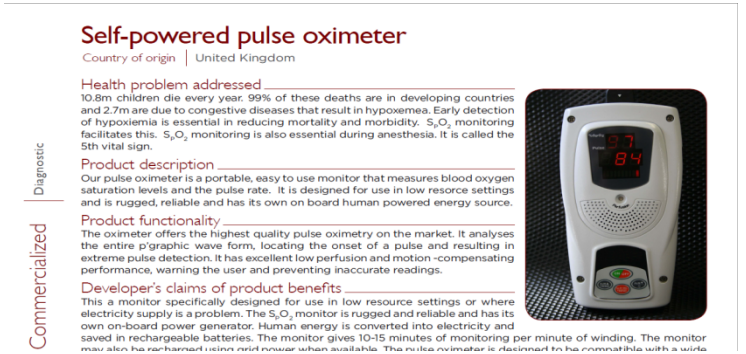
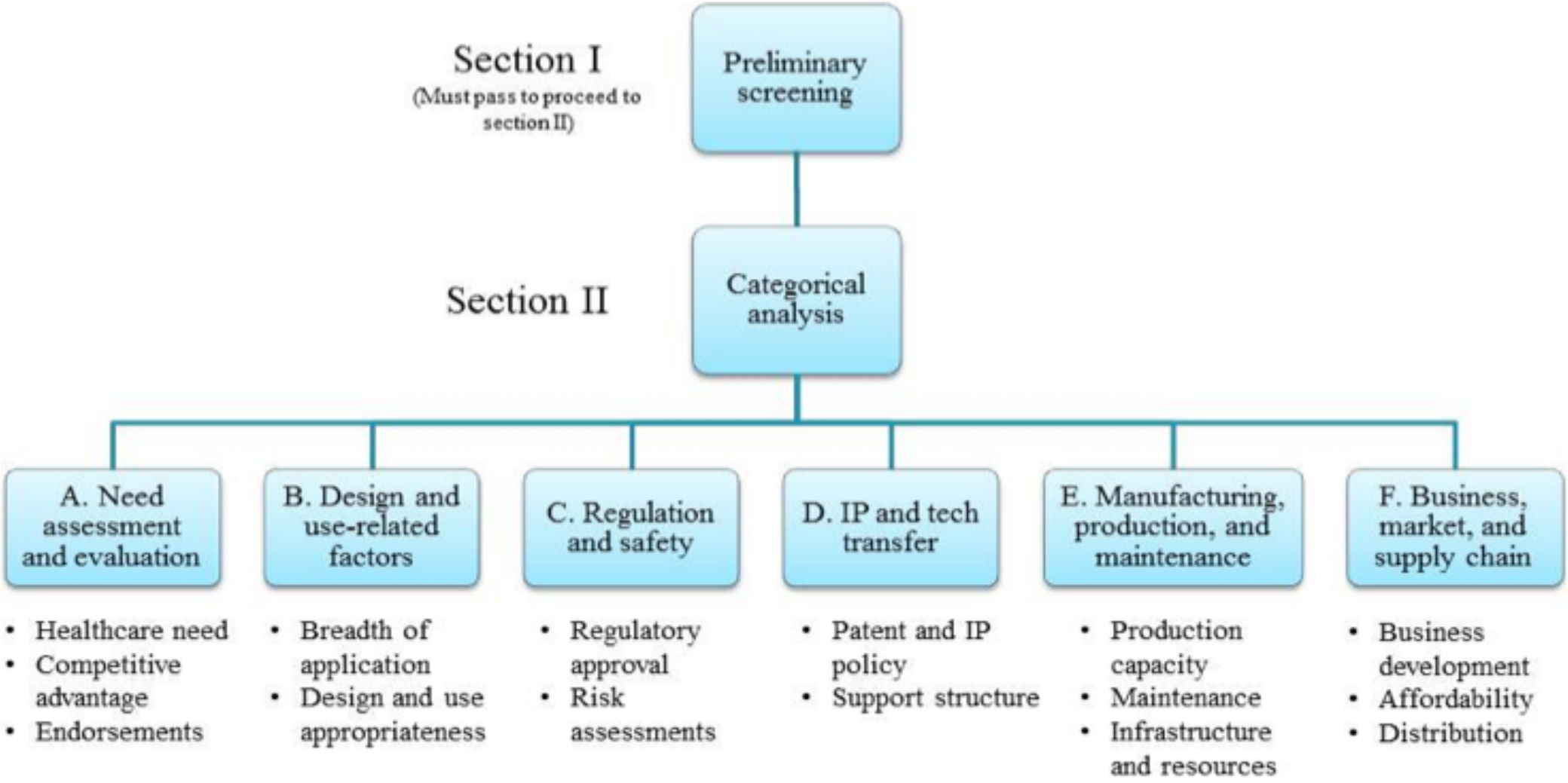
Compendium for innovative health technologies for low resource settings, 2010, 2011, 2012, 2013, …







Phase II feasibility tool conceptual framework



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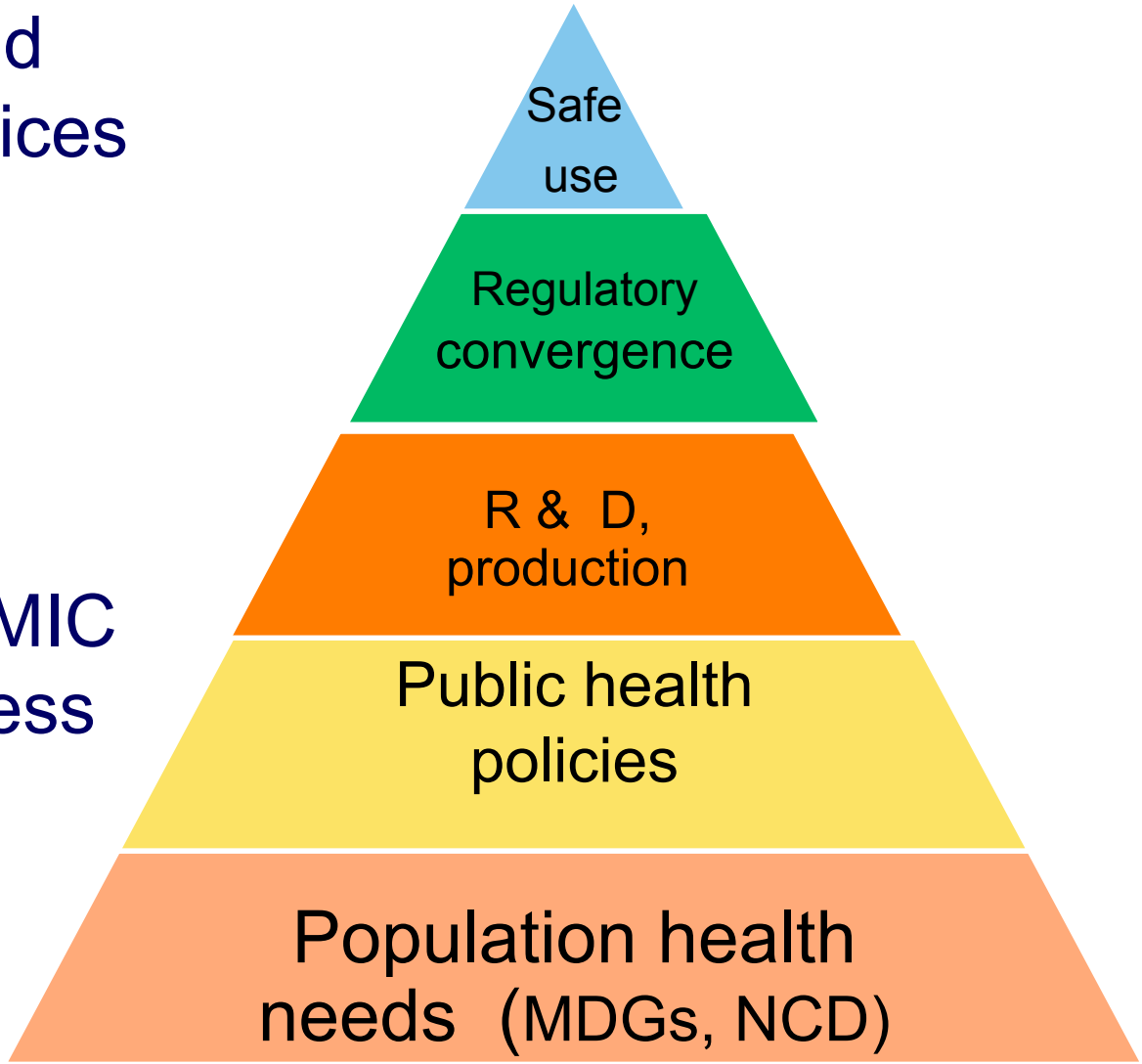
Regulatory convergence in health products

- WHO Expert Committees guidelines + norms/standards
- ICDRA, topic of this years meeting
- ICH guidelines
- (sub-)regional collaboration initiatives : EU, PANDRH, ASEAN; ARMH; APEC, …..
- IMDRF, International Medical Devices Regulators Forum
  - Regulated Product Submission
  - Single Audit Programme
  - Standards recognition
  - Post market surveillance

WHO challenges and next steps: promote access to safe medical devices of good quality

- Need for global norms and standards for medical devices
- Promote regulatory strengthening and convergence
- Capacity building
- Balance participation of LMIC in global regulatory process of medical devices.



Global challenges

- Lack of guidance on how to regulate vaccines & vaccine delivery technologies
- Lack of information to manufacturers and regulators
- Lack of information of innovative technologies for vaccine delivery, comparative effectiveness, cost, acceptance and regulatory pathways

Next steps?

- Develop WHO Guidelines for regulatory pathways for combination products (vaccines and medical devices)
- Propose to IMDRF, ICH, ICDRA a task group for combination products , specific for vaccines.
- Workshop to industry and regulators on options to improve regulatory convergence, to facilitate innovation uptake.