

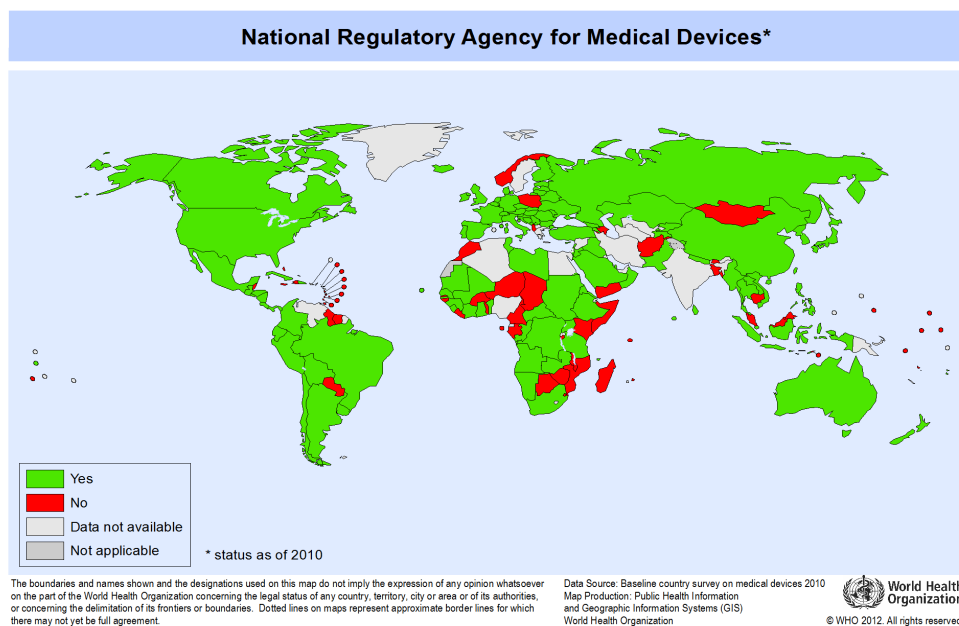
# Regulatory concerns

*Next Generation Vaccine Delivery Technology Meeting*  
Nora Dellepiane y Adriana Velazquez  
Department of Essential Medicines & Health Products



World Health  
Organization

# 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

# Medical device

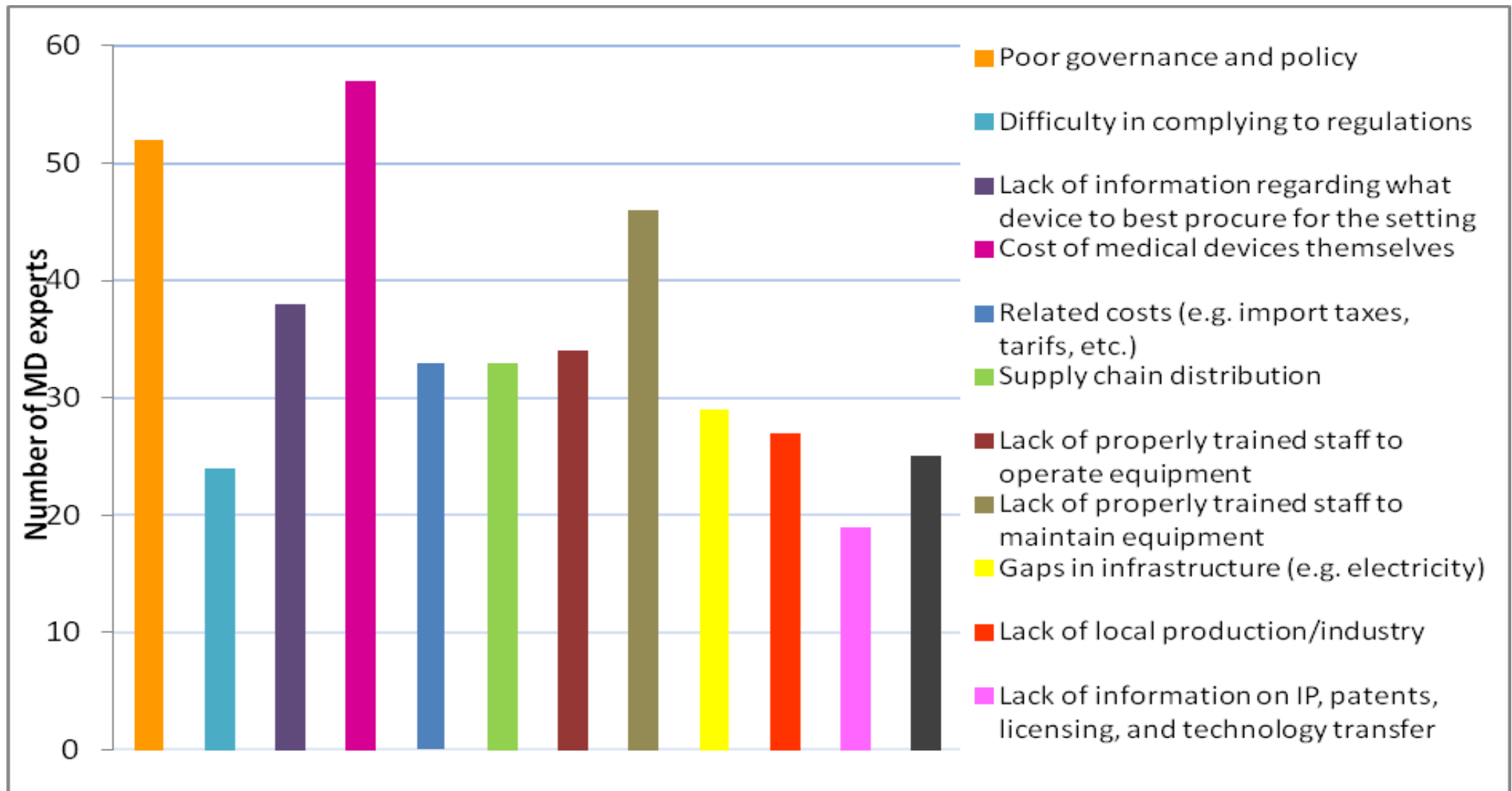


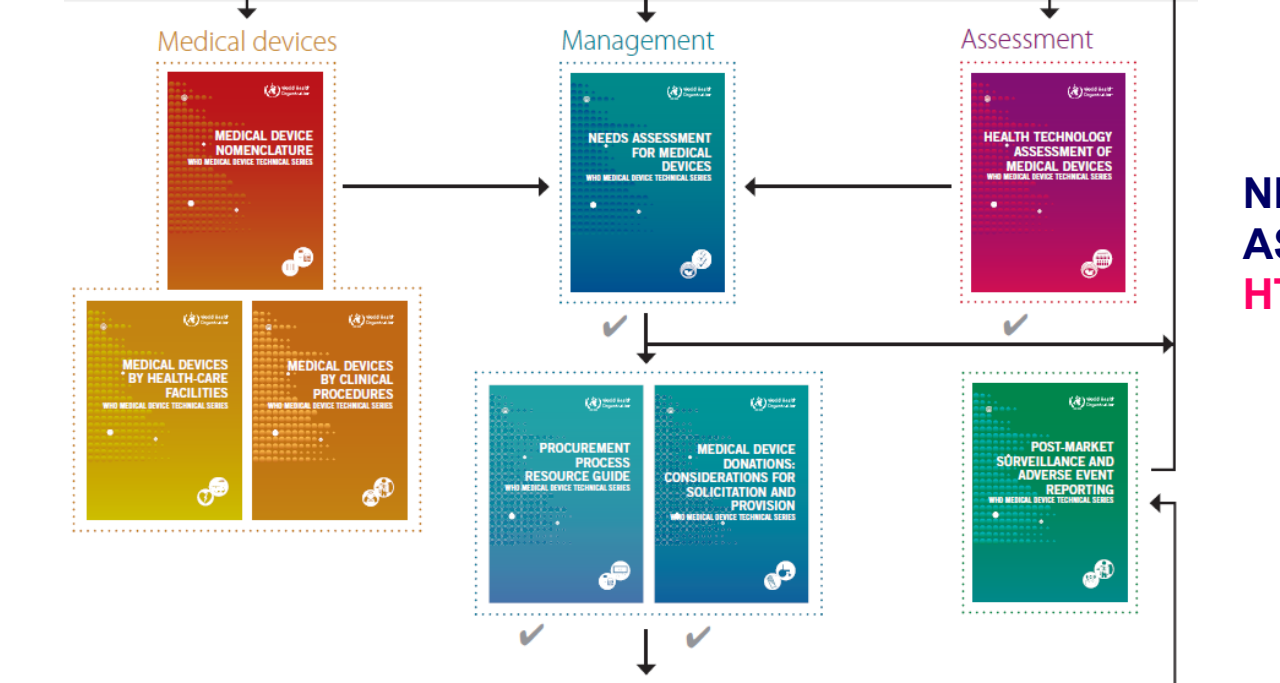
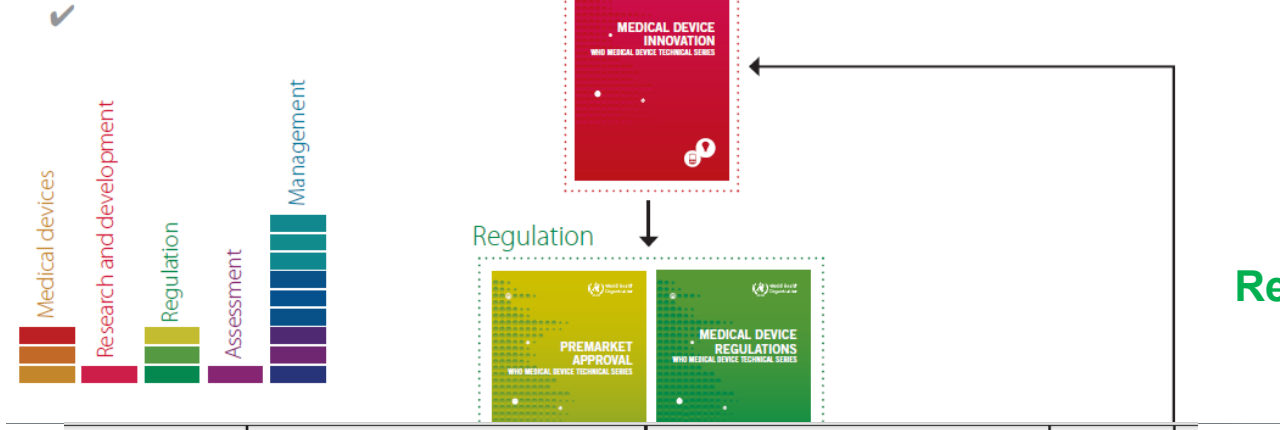
- An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring , restoring, correcting or modifying the structure or function of the body for some health purpose.
- Typically the purpose of a medical device is not 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





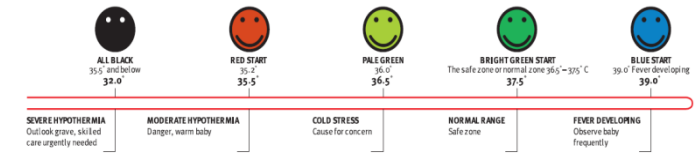
Regulations

NEEDS ASSESSMENT AND HTA

SAFE USE



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



## Self-powered pulse oximeter

Country of origin | United Kingdom

### Health problem addressed

10.8m children die every year. 99% of these deaths are in developing countries and 2.7m are due to congenital diseases that result in hypoxemia. Early detection of hypoxemia is essential in reducing mortality and morbidity.  $S_pO_2$  monitoring facilitates this.  $S_pO_2$  monitoring is also essential during anesthesia. It is called the 5th vital sign.

### Product description

Our pulse oximeter is a portable, easy to use monitor that measures blood oxygen saturation levels and the pulse rate. It is designed for use in low resource settings and is rugged, reliable and has its own on board human powered energy source.

### Product functionality

The oximeter offers the highest quality pulse oximetry on the market. It analyses the entire p/qraphic wave form, locating the onset of a pulse and resulting in extreme pulse detection. It has excellent low perfusion and motion-compensating performance, warning the user and preventing inaccurate readings.

### Developer's claims of product benefits

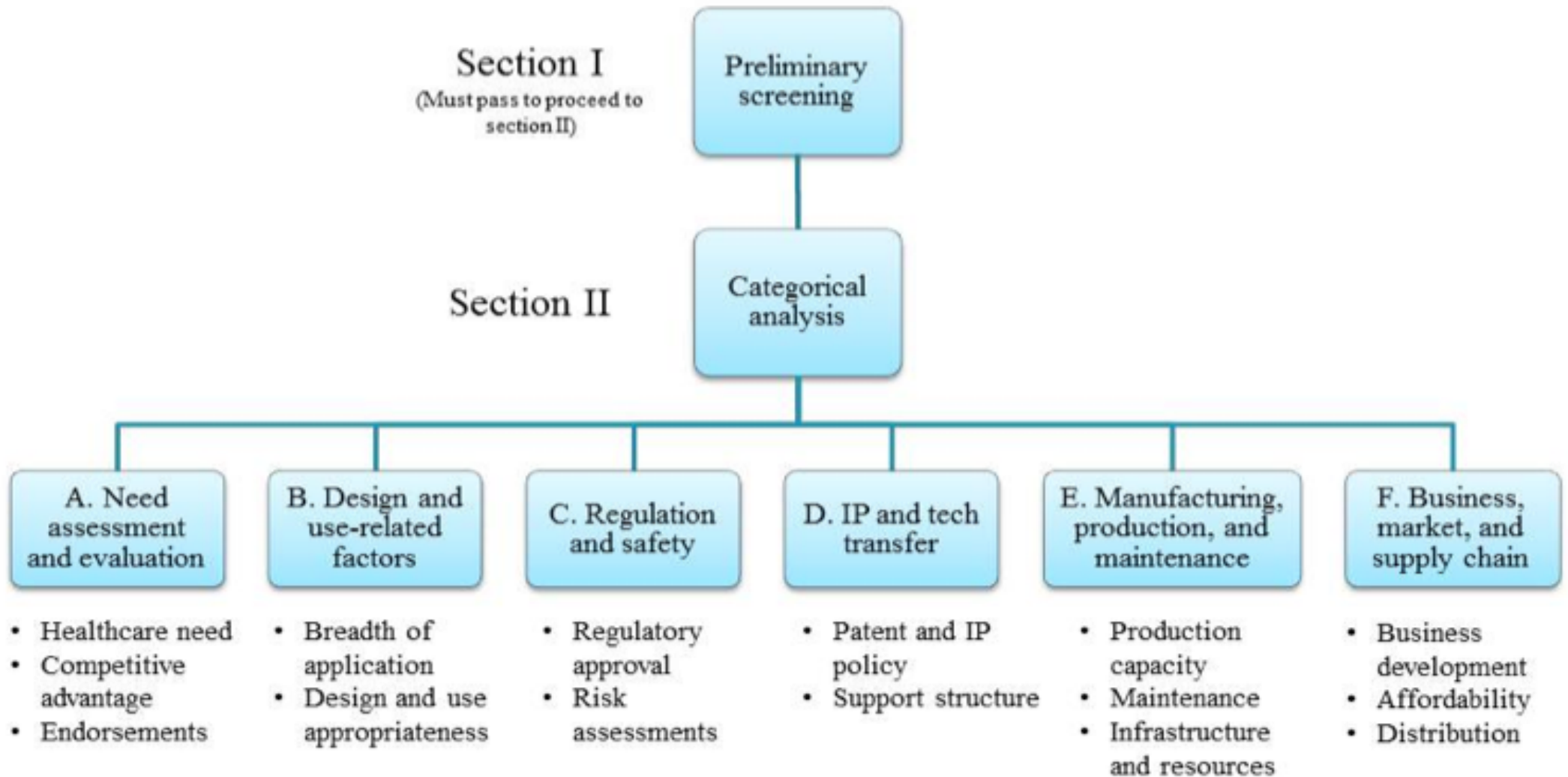
This a monitor specifically designed for use in low resource settings or where electricity supply is a problem. The  $S_pO_2$  monitor is rugged and reliable and has its own on-board power generator. Human energy is converted into electricity and saved in rechargeable batteries. The monitor gives 10-15 minutes of monitoring per minute of winding. The monitor may also be recharged using grid power when available. The pulse oximeter is designed to be compatible with a wide



Diagnostic

Commercialized

# Phase II feasibility tool conceptual framework



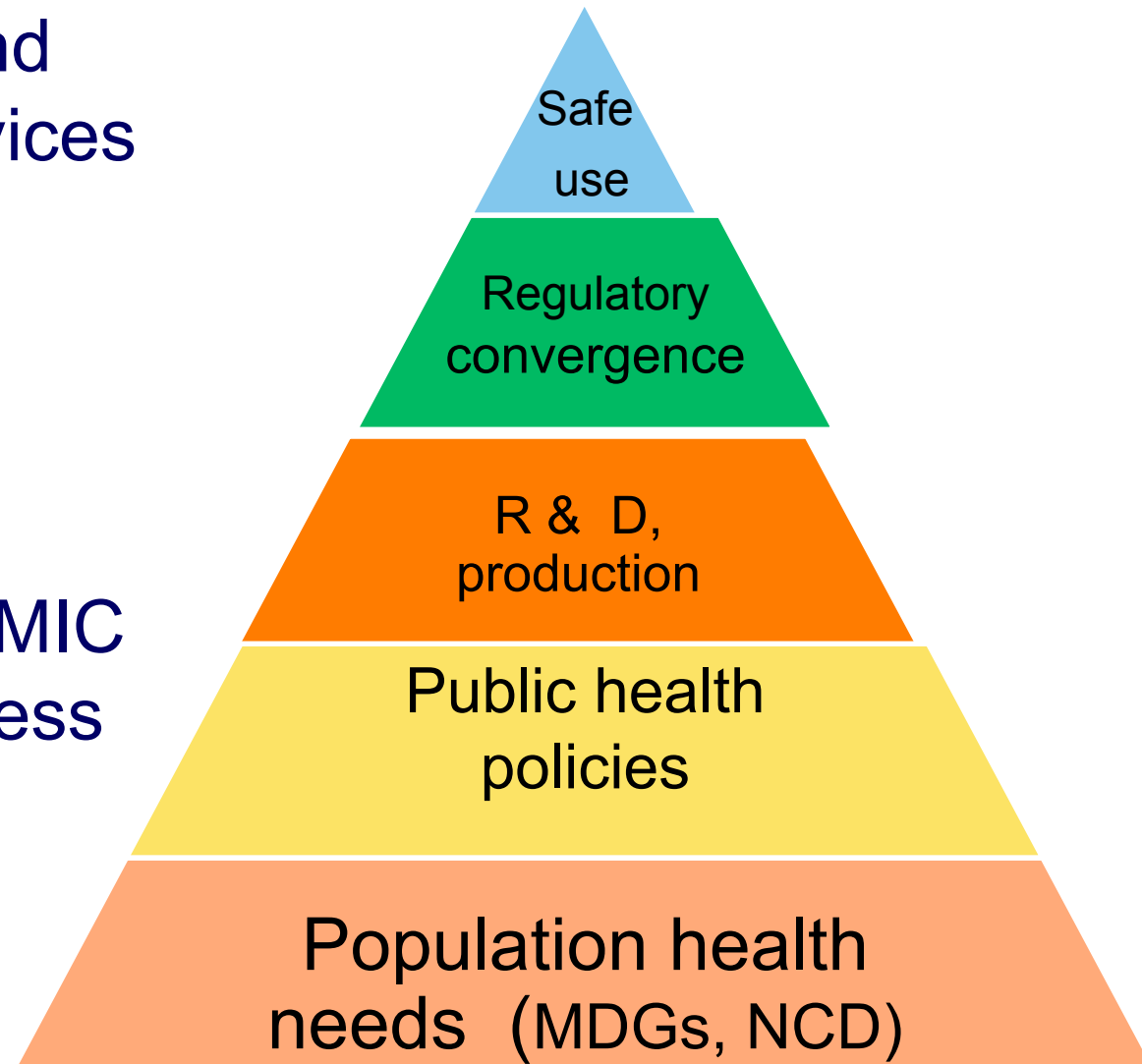


# Regulatory convergence in health products

- 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.