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
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

- Poor governance and policy
- Difficulty in complying to regulations
- Lack of information regarding what device to best procure for the setting
- Cost of medical devices themselves
- Related costs (e.g. import taxes, tariffs, etc.)
- Supply chain distribution
- Lack of properly trained staff to operate equipment
- Lack of properly trained staff to maintain equipment
- Gaps in infrastructure (e.g. electricity)
- Lack of local production/industry
- Lack of information on IP, patents, licensing, and technology transfer
SAFE USE

NEEDS ASSESSMENT AND HTA

REGULATIONS

POLICIES
Medical devices and eHealth solutions

Compendium of innovative health technologies for low-resource settings

2011-2012

World Health Organization

Self-powered pulse oximeter

Country: Nigeria | United Kingdom

Health problem addressed:
10-15% of children die every year. 95% of these deaths are in developing countries. And 3-5% are due to respiratory diseases that result in pneumonia. Early detection and appropriate treatment of pneumonia in children can save lives. To facilitate this, pulse oximetry is also essential during anaesthesia. It is called the golden hour.

Product description:
Our pulse oximeter is a portable device 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 internal human-powered energy source.

Product functionality:
The oximeter offers the highest quality pulse oximetry on the market. It analyses a number of different parameters, including the level of blood and monitors for abnormal performance, alerting the user and preventing inaccurate readings.

Developer's claim of product benefits:
This monitor is specifically designed for use in low-resource settings or where electricity supply is a problem. The pulse oximeter is rugged and reliable and has its own internal power generation. Heart rate energy is converted into electricity and stored in rechargeable batteries. This monitor gives 10-15 minutes of monitoring per minute of winding. This model will then run the device for weeks and requires no maintenance. Pulse oximetry is important in the early treatment of children who are sick.

Phase II feasibility tool conceptual framework

Section I
(Must pass to proceed to section II)

Preliminary screening

Section II

Categorical analysis

A. Need assessment and evaluation
   - Healthcare need
   - Competitive advantage
   - Endorsements

B. Design and use-related factors
   - Breadth of application
   - Design and use appropriateness

C. Regulation and safety
   - Regulatory approval
   - Risk assessments

D. IP and tech transfer
   - Patent and IP policy
   - Support structure

E. Manufacturing, production, and maintenance
   - Production capacity
   - Maintenance
   - Infrastructure and resources

F. Business, market, and supply chain
   - Business development
   - Affordability
   - Distribution
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.