IMDRF International Medical Device Regulators Forum

Update on WHO work

Irena Prat

World Health Organization

Florianopolis, 13-14 September 2016

What's new since March 2016

- Prequalification of IVDs
- Zika emergency use assessment
- Regulatory strengthening

PQDx Dossiers

- Submissions quality is increasing although lack of guidance remains a challenge

Sample product dossiers
Available
✓ CD4 POC IVD
✓ IVD for HIV self-testing
✓ Qualitative NAT for HIV1 and HIV2
✓ Quantitative NAT for HIV1

Technical Guidance Series

Available
✓ TGS 1 Standards applicable to the WHO Prequalification of IVDs
✓ TGS 2 Establishing stability of an IVD for WHO Prequalification
✓ TGS 3 Principles of performance studies
Soon to be published
❖ TGS Test method validation
❖ TGS Instructions for use
❖ TGS Kit component stability
❖ TGS Panels for quality assurance and quality control of IVDs
❖ TGS Quality control process management for IVD reagents and kits
Planned
❑ TGS Risk management

Technical specifications series

Available
✓ TSS 1 HIV RDTs (professional use and self-testing)
Soon to be published
❖ TSS Malaria RDTs
❖ TSS G6PD
❖ TSS HPV NAT (POC)
Planned
❑ HCV RDTs ❑ HBsAg RDTs ❑ HIV/Syphilis combination RDTs

- Positive feedback received from manufacturers/international/regulatory bodies in bridging the gap in information available
- WHO faces challenges finding available experts who understand the requirements for resource limited settings

Emergency Use Assessment and Listing Procedure for IVDs

- EUAL for Zika IVDs
- Meeting 14-16 March 2016 Geneva finalised EUAL requirements
  - Close alignment with USFDA requirements
- Numerous companies have submitted applications
  - 1 product listed
  - 16 applications in process
  - 12 applications closed or withdrawn
    - Some withdrawals due to need to redesign assays
    - A number have not met WHO QMS requirements
- Largest challenge has been securing a laboratory to undertake the performance evaluation

PQDx post-market surveillance

- Roll-out workshop for WHO guidance on post-market surveillance for IVDs in Arusha, Tanzania (October 2016) http://www.who.int/diagnostics_laboratory/postmarket/en/
- WHO continues to receive IVD complaints (n=20 in 2016) through standardized IVD complaint form
  - Manufacturers mostly notify us of complaints, end-users less so
- Participation in IMDRF working group on adverse event terminology has been useful
  - More specificity for simpler IVDs that contribute to indirect harms (rapid diagnostic tests) is desirable

Regulating Medical Devices

Bridging gaps on a global scale

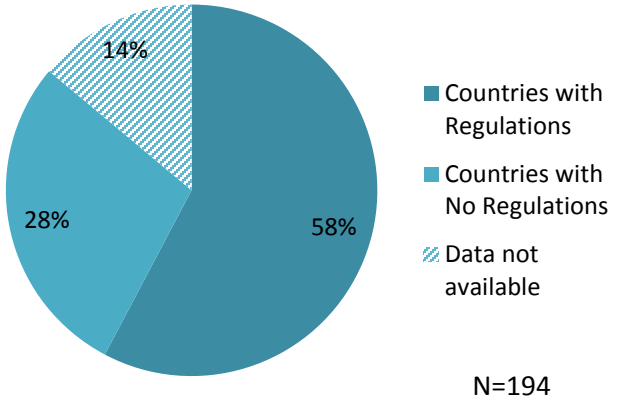
World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland

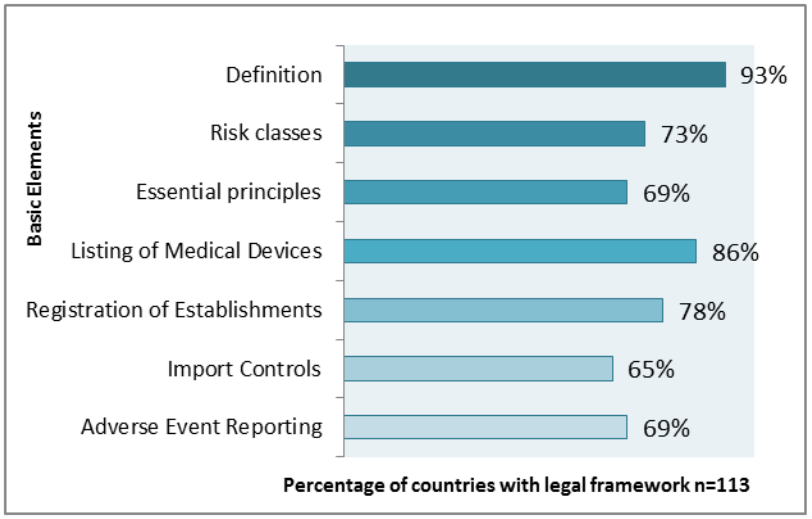
www.who.int/medical_devices/

World Health Organization

World Health Organization

Current status of regulation

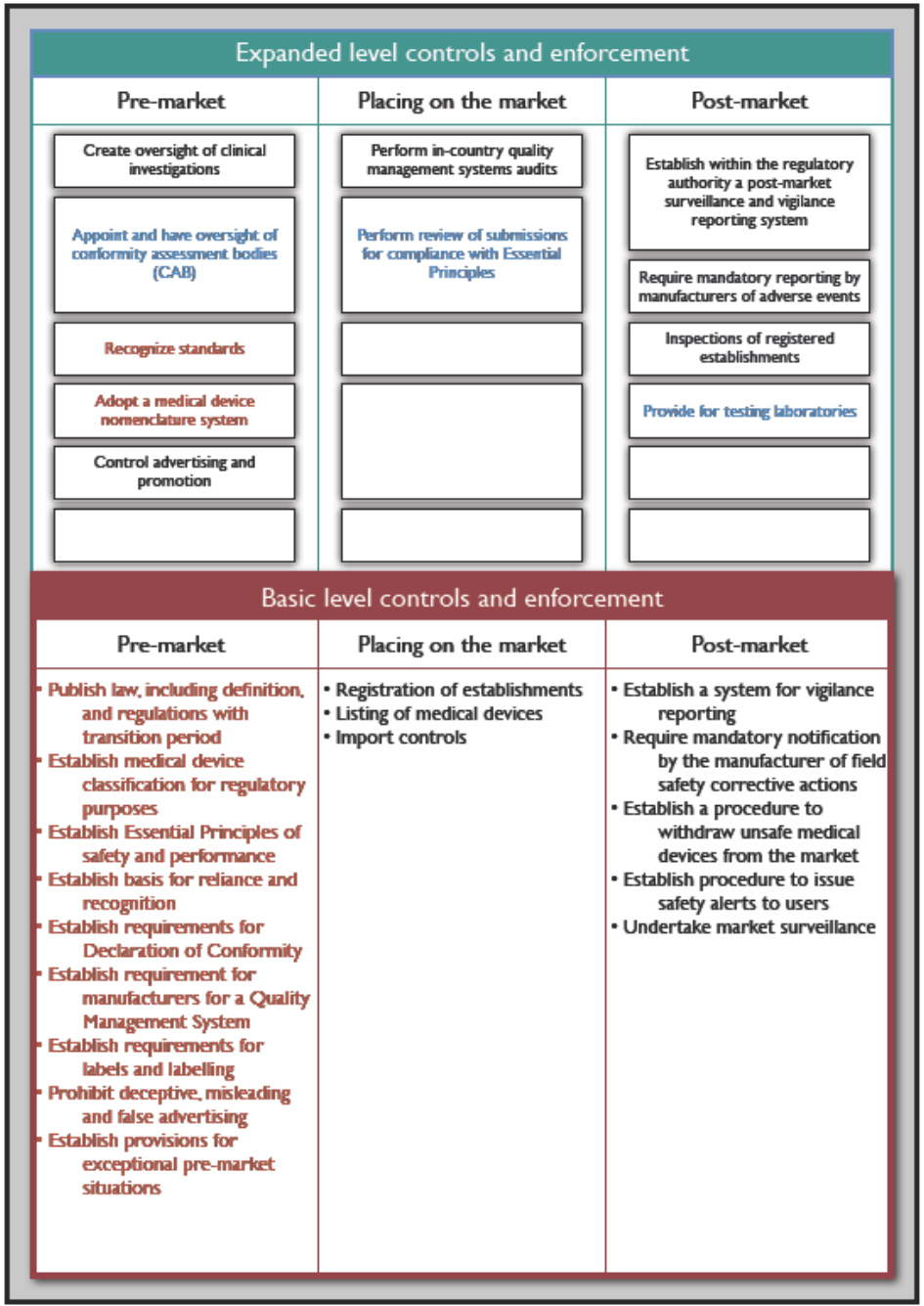




WHO Global Model regulatory framework for medical devices

- Stepwise approach: basic level and expanded level
- Basic level
  - Regulatory framework
  - Market oversight
  - Reporting system
- Expanded level: according to priorities of the country
- Reliance and recognition are key elements

LEGAL FRAMEWORK



Steps

- First Public Consultation: over 600 comments from 43 parties. IMDRF members response
- Second public consultation: until 1 September 2016
- Draft WHO Global Model Regulatory Framework for medical devices for adoption during meeting of Expert Committees October 2016
- Implementation workshops 2016-2017
- Model will be used as basis for developing the NRA assessment tool for medical devices.

Thank you