IMDRF International Medical Device Regulators Forum

# Update on WHO work

**Irena Prat**

**World Health Organization**

**Brasilia, 8-10 March 2016**

# What's new since September 2015

- Prequalification of IVDs
- Zika and Ebola-related work
- Regulatory strengthening

# PQDx Dossiers

- Positive trend: Dossier submissions quality is increasing
- Innovators and emerging manufacturers in general still struggle to meet basic requirements
- A number of manufacturers who failed in previous attempts are responding with greatly improved new submissions
- The lack of both general and product specific guidance remains a major issue

# PQDx Changes notification and assessment

- Reporting of changes to a WHO prequalified IVD in place since June 2014
- Result has been variable compliance and significant work load for PQDx
- Lack of substantive international guidance on changes/variations makes it difficult for manufacturers
- Updated WHO guidance adds granularity to ensure consistency and transparency in decision making process
  - Open for public comment until 31/03
- Need for international harmonized approach to changes

# Technical Guidance Series and Sample dossiers

WHO developing a technical guidance series (TGS) for manufacturers on issues considered of critical importance when developing and gathering data to support manufacturers' claims.

- Published in 2015 for public comment
  - **TGS 1 Standards, TGS 2 Stability**
- To be published Q1/Q2 2016
  - **Instructions for use, Test method validation, Principles of performance studies, Kit component stability**

WHO developing additional sample product dossiers for WHO prequalification of IVDs

- Published in 2015 for public comment
  - **Sample Product Dossier for an RDT intended for HIV self-testing.**
- To be published Q1/Q2 2016
  - **Sample Product Dossier for a Qualitative NAT for HIV and a Quantitative NAT for HIV**.

# Emergency Use Assessment and Listing Procedure for IVDs

- Still ongoing for Ebola IVDs
  - Need remains for quality IVDs for surveillance especially using oral fluid from cadavers
- An EOI was published on 5 Feb 2016 inviting manufacturers to submit to EUAL for Zika IVDs
- Meeting 14-16 March Geneva to finalise EUAL requirements and seek input from NRAs and NRLs
  - aim to achieve internationally harmonised requirements and cooperation
- Numerous companies have an interest in submitting
  - Shortage of specimens for validation remains a critical aspect

# PQDx post-market surveillance

- Launch of WHO guidance on post-market surveillance for in vitro diagnostics in 2015 http://www.who.int/diagnostics_laboratory/postmarket/en/
- Continuation of WHO complaint handling procedure through standardized IVD complaint form
  - Positive reporting trend but much advocacy and capacity building still needed

# Model regulatory framework for medical devices: where are we

- Target audience established: regulatory authorities in countries with little or no regulation for medical devices in place
- Definition of a medical device and IVD as a medical device accepted: GHTF definitions
- Life cycle of a medical device: pre-market, placing on the market, post-market
- Stepwise approach: two levels: basic level and expanded
- Reliance is an important approach

# LEGAL FRAMEWORK

## ENFORCEMENT

### Expanded level controls

| Pre-market | Placing on the market | Post-market |
|---|---|---|
| In-country clinical trial oversight | Advertising and promotion controls | In-country dissemination of alerts |
| Issue guidelines | Criteria for reliance | Post-market surveillance including vigilance |
| Appoint and oversee CABs | In-country QMS audit | Testing lab |
| Recognize standards | Pre-market review of compliance with essential principles | Patient registries |
| Nomenclature | | In-country inspection |
| Classification rules | Exemptions of regulatory requirements for public health emergencies | Inspection international |
| x | | Exchange of alerts international |
| x | x | Monitor FSCA |

### Basic level controls

| Pre-market | Placing on the market | Post-market |
|---|---|---|
| * Definition of a medical device<br>* Essential principles of quality, safety and performance<br>* Classification of devices<br>* Labelling and IFU (instruction for use)<br>* Declaration of conformity<br>* QMS<br>* Reliance<br>* Donations<br>* Advertising<br>* Authorized representative/ manufacturer/importer distributor<br>* Transition period | * Listing of medical devices<br>* Registration of establishments<br>* Import controls | * Mandatory reporting death and serious injury<br>* FSCA including recall<br>* Market surveillance |

# Next steps

- First draft was discussed 9-10 February 2016
- Public Consultations Q1 and Q3 2016
- Adoption by Expert Committees (ECSPP and ECBS)
- Model Regulatory Framework for medical devices: 2016
- Implementation workshops 2016-2017
- Model will be used as basis for developing the NRA assessment tool for medical devices

# Thank you