WHO Update

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What's new?

• Prequalification of IVDs
  – New guidance documents
  – Post-market surveillance
  – Inspections

• Regulatory strengthening
Impact of new WHO PQ documents and guidance

- Revised instructions *Reportable changes to a prequalified IVD*
  - Changes identified as reportable or non reportable *c.f.* first version (minor or substantial)
  - Provides greater clarity on what to report
  - Increased compliance

- *TGS 2 Establishing stability of an in vitro diagnostic for WHO Prequalification (draft)*
  - Includes multiple examples of how to undertake the stability studies for IVDs required by existing standards (ISO, CLSI) in a WHO context
  - A number of manufacturers have had to request extensions to complete the studies
Impact of new WHO PQ documents and guidance

- **Technical Specification Series (TSS)**
  - Clear requirements leading to improved processes at WHO
  - Timelines reduced for screening of dossiers
  - Greater consistency in assessments by external assessors

- **TSS1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self testing**
  - Positive responses by industry to the detailed guidance on validation of HIV self tests
  - Manufacturers needing more time to complete the requested studies

- **TSS 2 [Draft] Malaria rapid diagnostic tests**
  - Many manufacturers of malaria rapid tests are not familiar with the compilation of dossiers and lack many of the requested studies
  - Several have withdrawn due to significant gaps in requirements
WHO normative guidance on PMS

- Description of roles/ responsibilities of each stakeholder
  - Manufacturers, NRAs, NRLs (as testing laboratories), end-users, and WHO

- Template forms harmonized with MEDDEV and IMDRF
  - IVD complaint report, manufacturer investigation report, field safety corrective action report, lot testing data collection & report, field safety notice
Status of WHO complaint monitoring activities

- 42 complaints submitted to WHO since November 2014
  - Mostly for WHO prequalified IVDs
  - Mostly in low resource settings, but for IVDs that are marketed worldwide
  - Typical FSCA were revised labelling and recall/destruction
- 2 falsified products reported, including one HIV IVD supplied to customer within EEA
Global relevance of WHO PMS activities

Global Diagnostics Working Group will establish a sub-group on post-market surveillance

- Exchange of information on complaints and coordinated action

Survey at recent WHO capacity-building workshop on PMS showed that most NRAs don't have capacity for PMS of IVDs
Inspections: April 2015 -2016

Number of sites

South Africa
Europe
USA and Canada
Asia (Including China, Sth Korea and Japan)
India
Results: deficiencies

Deficiencies

- Level 1: 40
- Level 2: 5
- Level 3: 86
- Level 4: 15
- Level 5: 3
Regulating Medical Devices

Bridging gaps on a global scale

World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland

www.who.int/medical_devices/
WHO Global Model Regulatory Framework for medical devices

- Approved by expert committees in October 2016
- Implementation plan:
  - Workshops at regional level
  - Pilot countries to implement the Model
  - Model will be used as basis for developing the Global Benchmarking tool for medical devices.
New

• Essential diagnostics list

• Upcoming: Third Global Forum on medical devices
  10-12 May 2017, Geneva
Thank you