IMDRF International Medical Device Regulators Forum

WHO Update

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World Health Organization

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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

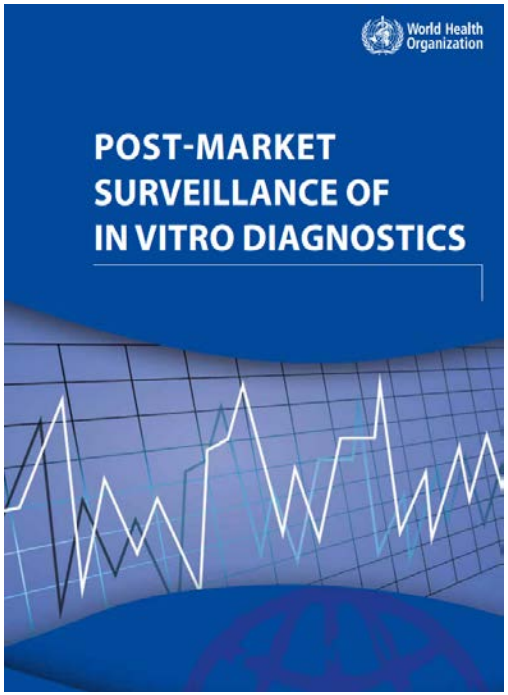
- *TGS 2 Establishing stability of an in vitro diagnostic for WHO Prequalification (draft)*
  - Includes multiple examples of how to undertake the stability studies for IVDs required by existing standards (ISO, CLSI) in a WHO context
  - A number of manufacturers have had to request extensions to complete 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  - Several have withdrawn due to significant gaps in requirements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

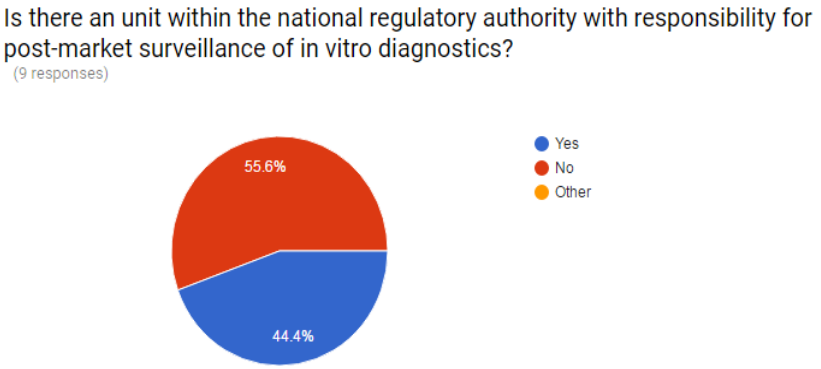
- 42 complaints submitted to WHO since November 2014
  - Mostly for WHO prequalified IVDs
  - Mostly in low resource settings, but for IVDs that are marketed worldwide
  - Typical FSCA were revised labelling and recall/destruction
- 2 falsified products reported, including one HIV IVD supplied to customer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

Global relevance of WHO PMS activities

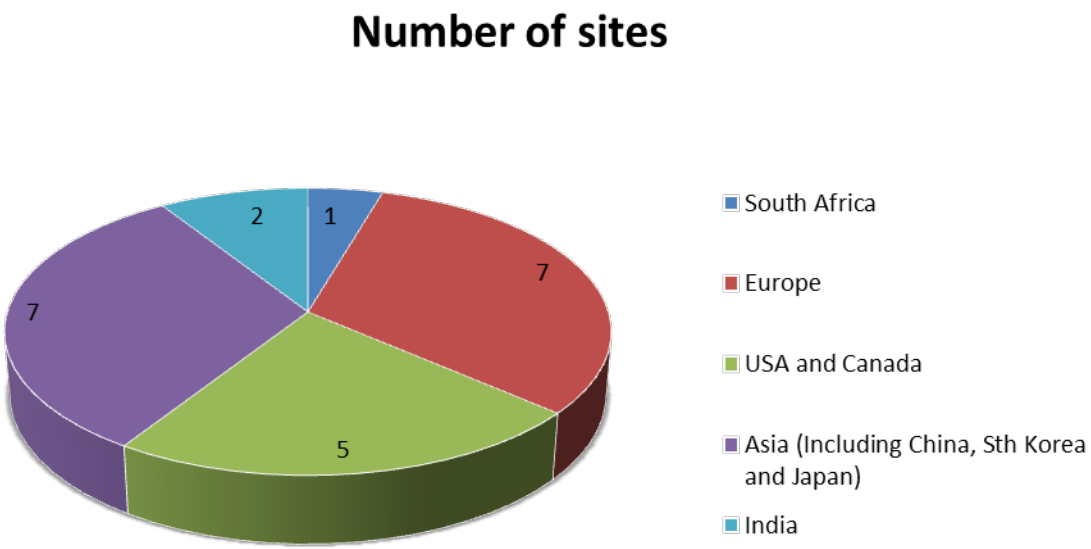
Global Diagnostics Working Group will establish a sub-group on post-market surveillance

- Exchange of information on complaints and coordinated action

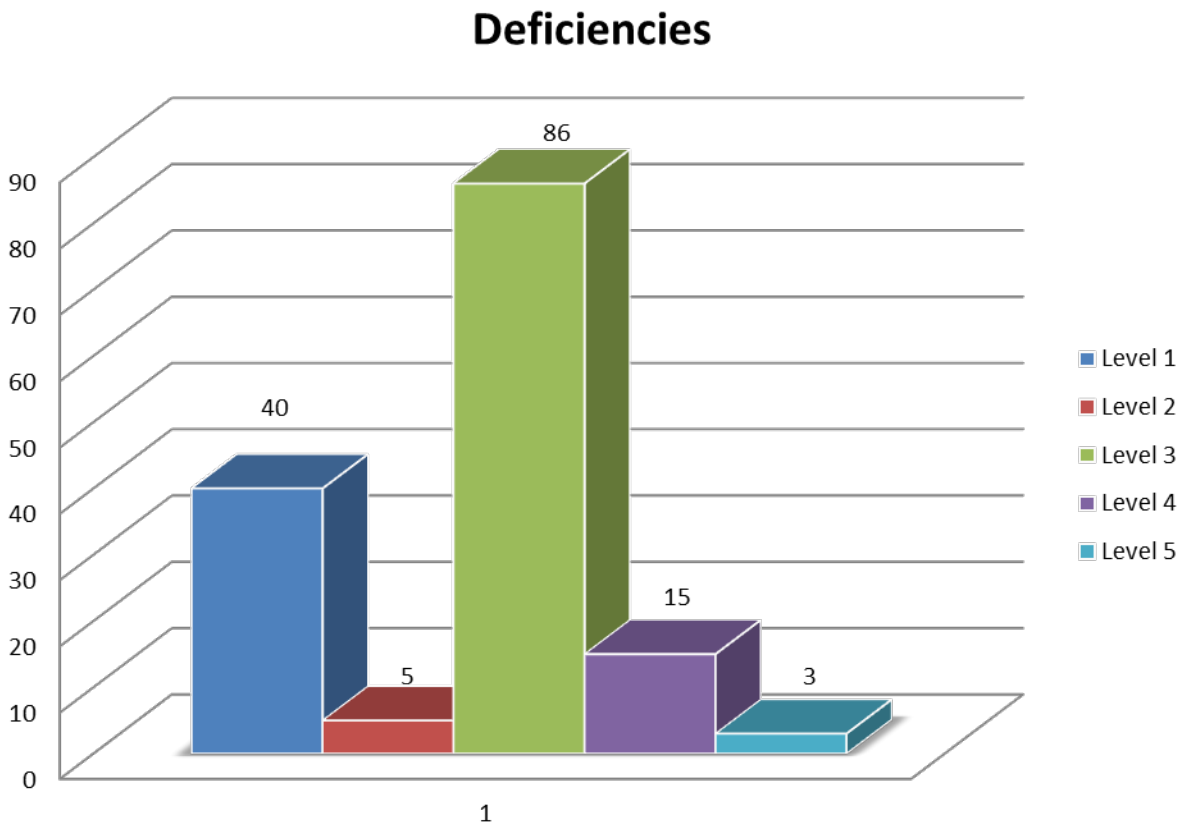
Survey at recent WHO capacity-building workshop on PMS showed that most NRAs don't have capacity for PMS of IVDs



Inspections: April 2015 -2016



Results: deficiencies



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

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
  - http://www.who.int/selection_medicines/committees/expert/21/applications/essential_in-vitro_diagnostics_other/en/
- Upcoming: Third Global Forum on medical devices
  10-12 May 2017, Geneva
  - http://www.who.int/medical_devices/global_forum/3rd_gfmd/en/

Thank you