WHO Update

Irena Prat

World Health Organization

Beijing, 18-20 September 2018

Prequalification of IVDs

- In 2018*, 17 PQ applications:
  - 10 HIV: 5 RDT, 1 EIA, 2 NAT, 2 CD4
  - 3 HCV: 1 RDT, 1 EIA, 1NAT
  - 1 HIV/syphilis: RDT
  - 1 malaria: RDT
  - 1 cholera: RDT
  - **1 G6PD: RDT**
- …and 43* Change Notifications

** to September 2018*

Prequalification of IVDs

- Implementation of ToC format:
  - Pilot of dossier report template* - 2018
  - Dossier format requirement – 2019:
    - PQDx18 ‘Instructions for compilation of a product dossier’
    - Technical specifications series
- PQ scope expanded to syphilis (only) RDTs and HPV IVDs beyond PoC
- 11 laboratories listed as evaluating sites for PQ purposes

Prequalification of IVDs

- Review of IMDRF documents:
  - Principles of Labeling for Medical Devices and IVD Medical Devices
  - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

WHO Guidance For Manufacturers I

- Technical specification series (TSS)
  - http://www.who.int/diagnostics_laboratory/guidance/technical_specification_series/en/
    - TSS 1: **HIV** RDT for professional and/or self-testing
    - TSS 2: IVDs to identify **G6PD** activity
    - TSS 3: **Malaria** RDT
    - TSS 4: IVD used for the detection of high-risk **HPV** types in cervical cancer screening
    - TSS 5: RDT used for surveillance and detection of an outbreak of **Cholera**
  - In development (lay out according to the IMDRF IVD MA table of content)
    - TSS 6: **Syphilis** RDT (Consultancy meeting 2018 Q3)
    - TSS 7: **HCV** RDTs (Consultancy meeting 2018 Q4)
    - TSS 8: **HIV** Enzyme Immunoassays
    - TSS 9: **HCV** Enzyme Immunoassays (Consultancy meeting 2018 Q4)
    - TSS 10: NAT to detect **HCV** (quantitative) (Consultancy meeting 2019 Q1)
    - TSS 11: NAT to detect **HIV-1** (quantitative) (Consultancy meeting 2019 Q1)
    - TSS 12: NAT to detect **HIV-1** & **HIV-2** (qualitative) (Consultancy meeting 2019 Q1)

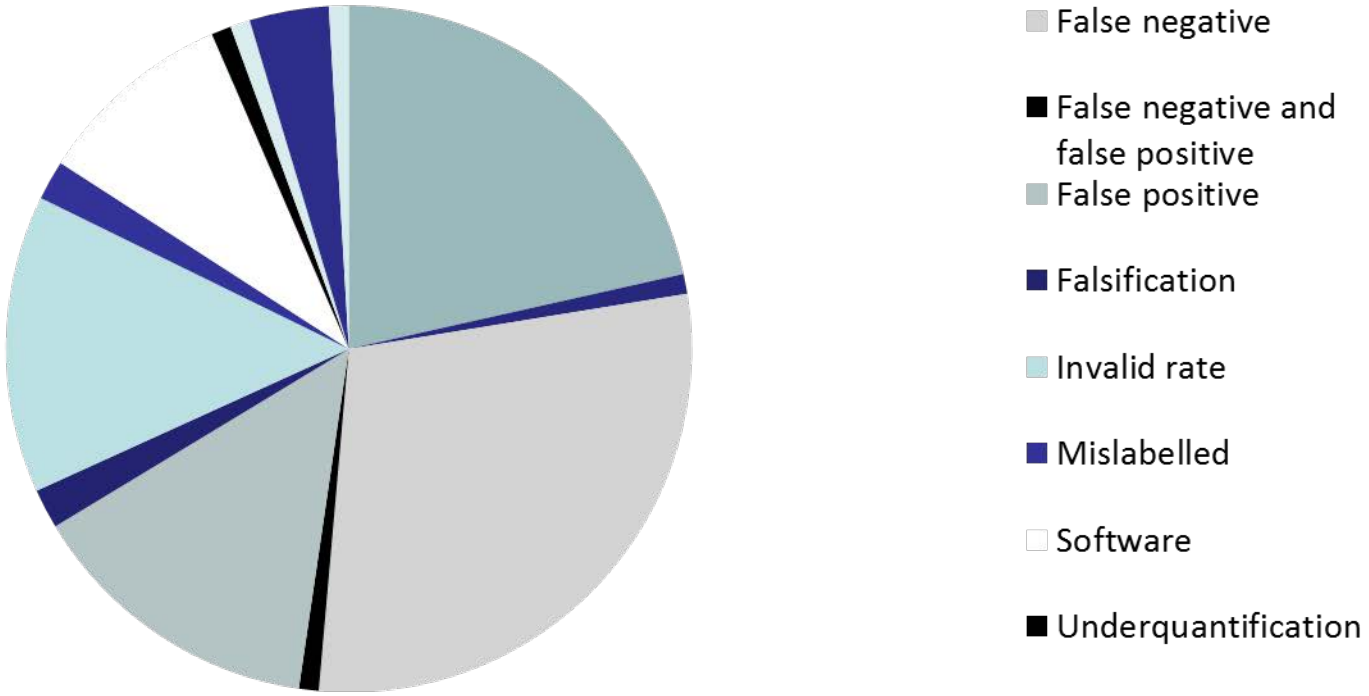
WHO Guidance For Manufacturers II

- Technical guidance series (TGS)
  - http://www.who.int/diagnostics_laboratory/guidance/technical_guidance_series/en/
    - TGS 1 **Standards** applicable to the WHO prequalification of IVD
    - TGS 2: Establishing **stability** of an IVD for WHO prequalification (TGS2 Annex: component stability)
    - TGS 3: Principles of **performance studies** of an IVD for WHO prequalification
    - TGS 4: Guidance on test method **validation** for an IVD
    - TGS 5: Designing '**instructions for use'** for IVD
    - TGS 6: **Panels** for QA and QC of IVD
    - TGS 7: **Risk management** for manufacturers of IVD (draft)
  - In development
    - TGS 8: Use of **biological reference materials** in the development of IVDs
    - TGS 9: **Precision** and **robustness**
    - TGS 10: **Accessories**

WHO post-market guidance roll-out

- Workshops for testing providers & regulators
  - Anglophone Africa
  - Francophone Africa
  - Russophone
  - Ukraine

Type of IVD complaints received by WHO (n=107)



PMS: Relevant IMDRF working groups

- Adverse event reporting terminology
  - Must be relevant for low resource-settings, where different IVD types are used to IMDRF regulators
- Unique device identification
  - Must be relevant for post-market surveillance activities
- Labelling
  - Must be relevant for instances when labelling is revised following post-market investigation - FSCA

Thank you