WHO Update

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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)
    • 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)
    • 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