



IMDRF

International Medical
Device Regulators Forum

Update on WHO work

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World Health Organization

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What's new since March 2016

- Prequalification of IVDs
- Zika emergency use assessment
- Regulatory strengthening



PQDx Dossiers

- Submissions quality is increasing although lack of guidance remains a challenge

Sample product dossiers

Available

- ✓ CD4 POC IVD
- ✓ IVD for HIV self-testing
- ✓ Qualitative NAT for HIV1 and HIV2
- ✓ Quantitative NAT for HIV1



Technical Guidance Series

Available

- ✓ TGS 1 Standards applicable to the WHO Prequalification of IVDs
- ✓ TGS 2 Establishing stability of an IVD for WHO Prequalification
- ✓ TGS 3 Principles of performance studies

Soon to be published

- ❖ TGS Test method validation
- ❖ TGS Instructions for use
- ❖ TGS Kit component stability
- ❖ TGS Panels for quality assurance and quality control of IVDs
- ❖ TGS Quality control process management for IVD reagents and kits

Planned

- ❑ TGS Risk management



Technical specifications series

Available

- ✓ TSS 1 HIV RDTs (professional use and self-testing)

Soon to be published

- ❖ TSS Malaria RDTs
- ❖ TSS G6PD
- ❖ TSS HPV NAT (POC)

Planned

- HCV RDTs
- HBsAg RDTs
- HIV/Syphilis combination RDTs

- Positive feedback received from manufacturers/international/regulatory bodies in bridging the gap in information available
- WHO faces challenges finding available experts who understand the requirements for resource limited settings



Emergency Use Assessment and Listing Procedure for IVDs

- EUAL for Zika IVDs
- Meeting 14-16 March 2016 Geneva finalised EUAL requirements
 - Close alignment with USFDA requirements
- Numerous companies have submitted applications
 - 1 product listed
 - 16 applications in process
 - 12 applications closed or withdrawn
 - Some withdrawals due to need to redesign assays
 - A number have not met WHO QMS requirements
- Largest challenge has been securing a laboratory to undertake the performance evaluation



PQDx post-market surveillance

- Roll-out workshop for WHO guidance on post-market surveillance for IVDs in Arusha, Tanzania (October 2016)
http://www.who.int/diagnostics_laboratory/postmarket/en/
- WHO continues to receive IVD complaints (n=20 in 2016) through standardized IVD complaint form
 - Manufacturers mostly notify us of complaints, end-users less so
- Participation in IMDRF working group on adverse event terminology has been useful
 - More specificity for simpler IVDs that contribute to indirect harms (rapid diagnostic tests) is desirable



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Regulating Medical Devices

Bridging gaps on a global scale



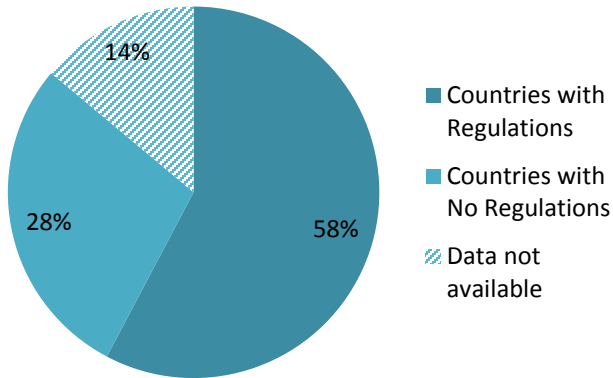
World Health Organization
20 Avenue Appia
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www.who.int/medical_devices/



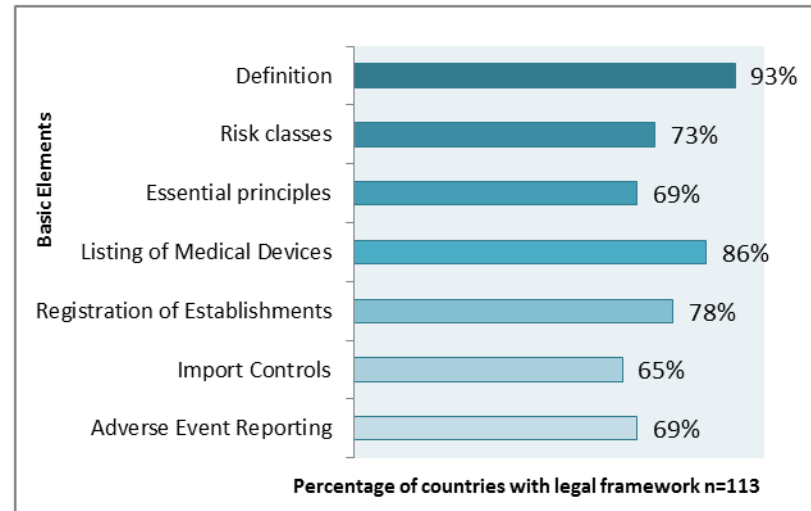


Current status of regulation



- Countries with Regulations
- Countries with No Regulations
- ▨ Data not available

N=194





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WHO Global Model regulatory framework for medical devices

- Stepwise approach: basic level and expanded level
- Basic level
 - Regulatory framework
 - Market oversight
 - Reporting system
- Expanded level: according to priorities of the country
- Reliance and recognition are key elements



LEGAL FRAMEWORK

Expanded level controls and enforcement		
Pre-market	Placing on the market	Post-market
Create oversight of clinical investigations	Perform in-country quality management systems audits	Establish within the regulatory authority a post-market surveillance and vigilance reporting system
Appoint and have oversight of conformity assessment bodies (CAB)	Perform review of submissions for compliance with Essential Principles	Require mandatory reporting by manufacturers of adverse events
Recognize standards		Inspections of registered establishments
Adopt a medical device nomenclature system		Provide for testing laboratories
Control advertising and promotion		
Basic level controls and enforcement		
Pre-market	Placing on the market	Post-market
<ul style="list-style-type: none"> • Publish law, including definition, and regulations with transition period • Establish medical device classification for regulatory purposes • Establish Essential Principles of safety and performance • Establish basis for reliance and recognition • Establish requirements for Declaration of Conformity • Establish requirement for manufacturers for a Quality Management System • Establish requirements for labels and labelling • Prohibit deceptive, misleading and false advertising • Establish provisions for exceptional pre-market situations 	<ul style="list-style-type: none"> • Registration of establishments • Listing of medical devices • Import controls 	<ul style="list-style-type: none"> • Establish a system for vigilance reporting • Require mandatory notification by the manufacturer of field safety corrective actions • Establish a procedure to withdraw unsafe medical devices from the market • Establish procedure to issue safety alerts to users • Undertake market surveillance



Steps

- First Public Consultation: over 600 comments from 43 parties. IMDRF members response
- Second public consultation: until 1 September 2016
- Draft WHO Global Model Regulatory Framework for medical devices for adoption during meeting of Expert Committees October 2016
- Implementation workshops 2016-2017
- Model will be used as basis for developing the NRA assessment tool for medical devices.



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Thank you