WHO Update

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PQ Statistics

WHO PREQUALIFICATION STATISTICS			
	2015	**2016**	**2017**
No of applications	22	65	20
No of new manufacturers	3	5	19
No Prequalified IVDs	17	16	5
No withdrawn		23	9
No of changes reported	13	33	22

TECHNICAL GUIDANCE SERIES FOR WHO PREQUALIFICATION		
TGS 1	Standards applicable to the WHO Prequalification of IVD	**Final**
TGS 2	Establishing stability of an IVD for the WHO Prequalification	**Final**
TGS 3	Principles of performance studies	**Final**
TGS 4	Test method validation for an IVD	**Final**
TGS 5	Designing Instructions for use for IVDs	**Draft for comment**
TGS 6	Panels for quality assurance and quality control of IVDs	**Draft for comment**
TGS x	The use of biological reference materials in the design, verification, validation and post market surveillance of IVDs	**Under development**
TGS x	Risk Management	**Under development**
TGS x	Control material for malaria RDTs	**Under development**

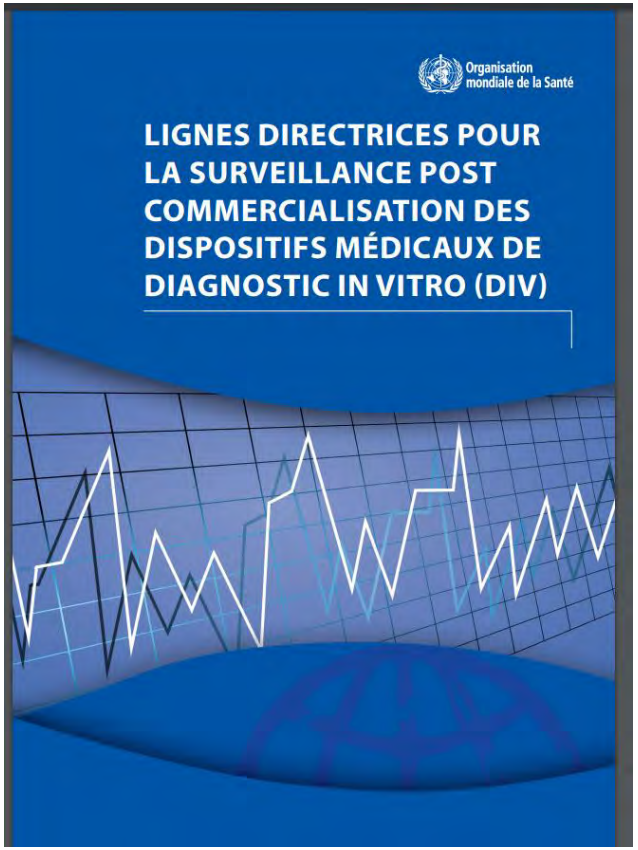
TECHNICAL SPECIFICATION SERIES FOR WHO PREQUALIFICATION		
TSS 1	Technical specifications for WHO prequalification of HIV rapid diagnostic tests for professional use and/or self-testing	Final
TSS 2	Technical specifications for WHO prequalification of IVD medical devices to identify Glucose-6-phosphate dehydrogenase (G6PD) activity	Final
TSS 3	Technical Specification Series for submission to WHO Prequalification – Diagnostic Assessment: Malaria rapid diagnostic tests	Final
TSS 4	Technical Specification Series for submission to WHO Prequalification – IVDs used for the detection of high-risk Human Papillomavirus (HPV) genotypes in cervical cancer screening	Under development
TSS 5	Technical Specification Series for submission to WHO Prequalification – Rapid diagnostic tests (RDTs) used for surveillance and detection of an outbreak of cholera	Under development

TRAINING FOR DOSSIER ASSESSORS FOR WHO PREQUALIFICATION		
July 2017	Dossiers for malaria RDTs	ITM Antwerp
Sept 2017	Dossiers for malaria RDTs	ITM Antwerp
Q1 2018	Dossiers for HIV RDTs (incl self testing)	In planning

SUPPORT FOR DOSSIER ASSESSORS FOR WHO PREQUALIFICATION	
Activity	**Outcome**
Improved guidance on good regulatory reporting practice (under development)	• Great transparency in assessors decision making
Improved reporting templates that mirror the requirements of each TSS (under development)	• Great transparency in assessors decision making, • Greater consistency between reviewers

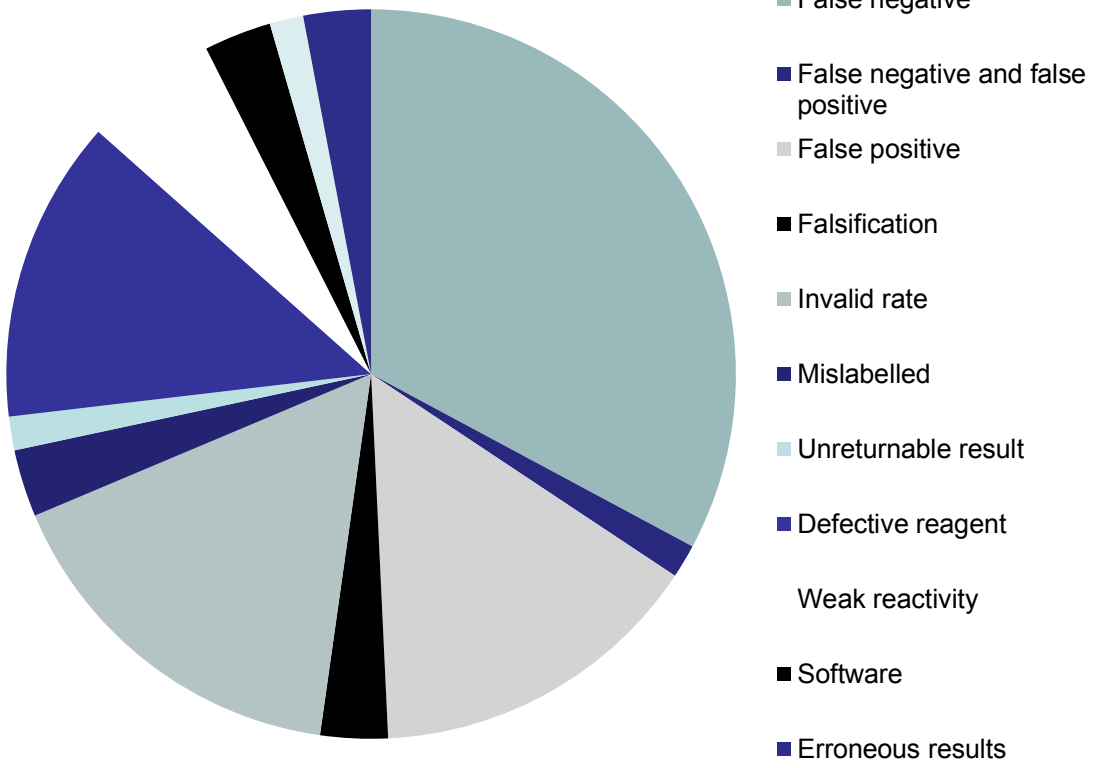
WHO Guidance on Post-market Surveillance

- 2 workshops to roll-out guidance
  - 8 Anglophone African countries
  - 11 Francophone African countries
- National action plans for implementation drafted

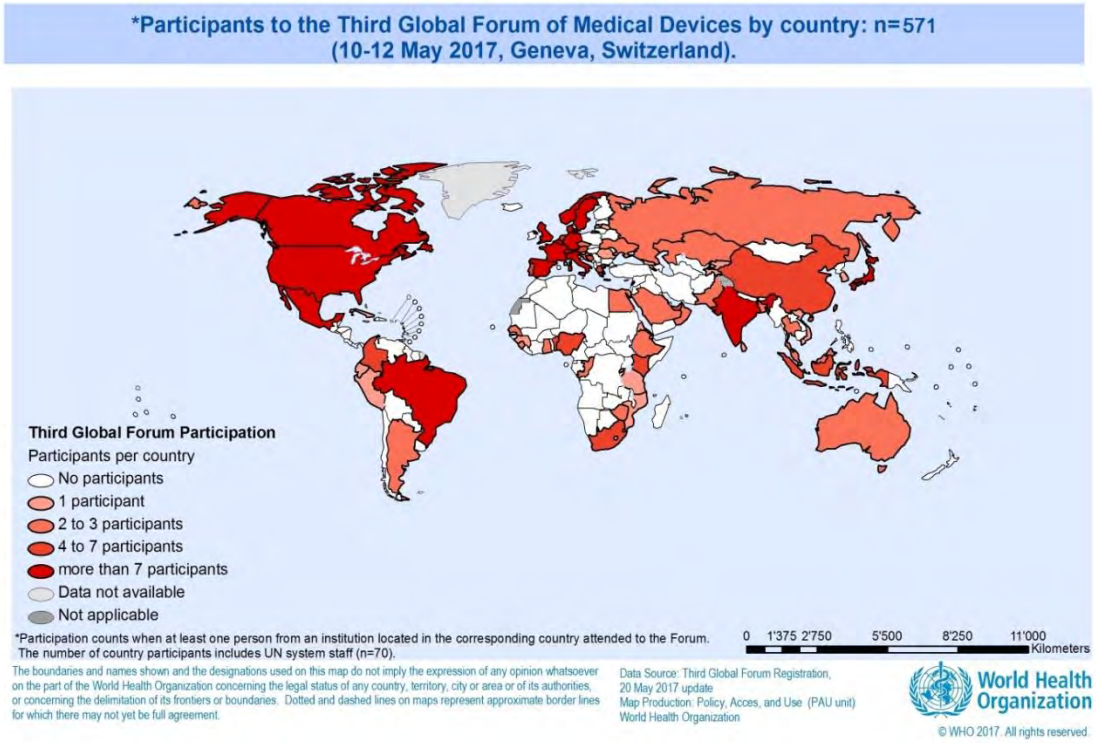


WHO complaint handling (n=67)

- In order of frequency
  - False negative results
  - ↑ invalid rate
  - False positive results
  - Defective reagent



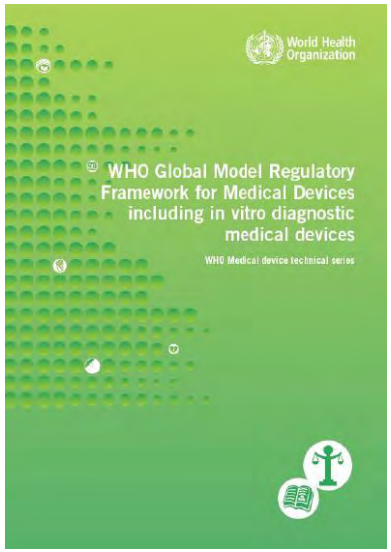
Report of the 3rd Global Forum on Medical Devices



Numeralia of 3rd Global Forum on Medical Devices	
Participants	571
Oral parallel session presentations	130
Posters	104
Plenary presentations	64
Workshops	46
Exhibitions	42
Videos	7

http://who.int/medical_devices/global_forum/3rd_gfmd/en/

New WHO Books, launched at 3rd Global Forum May 2017



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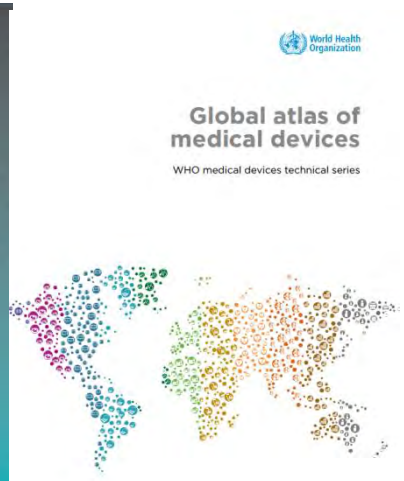
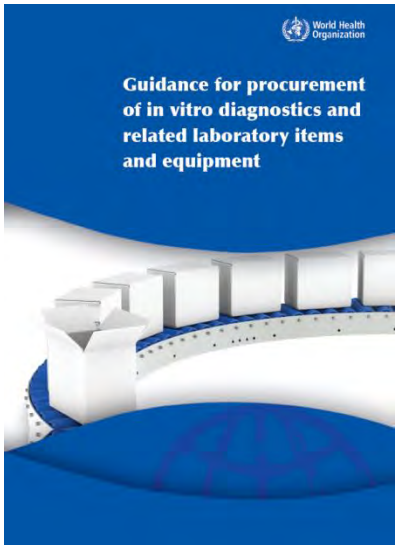
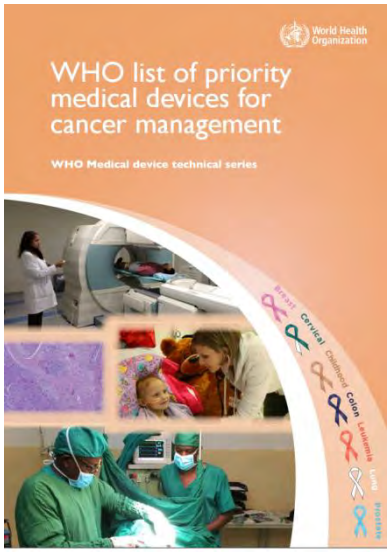
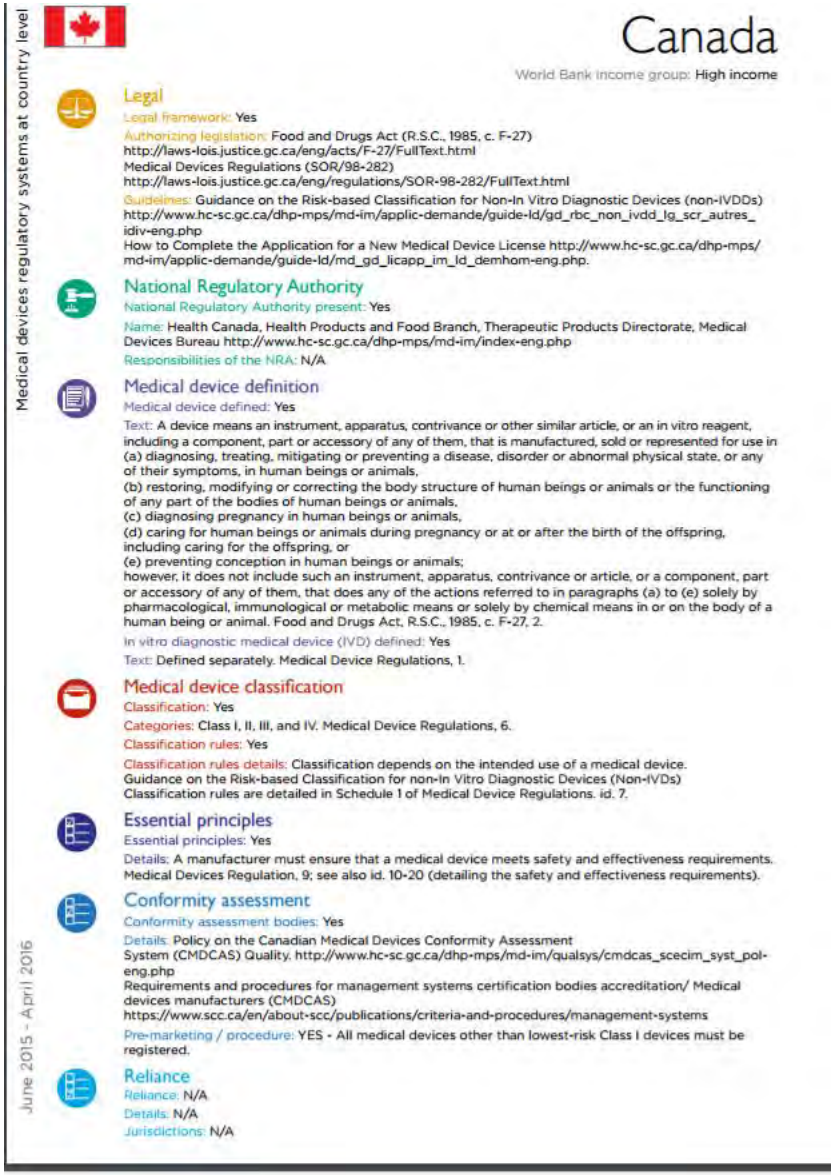






New country profiles on regulatory systems

http://who.int/medical_devices/countries/regulations/en//



Medical Devices nomenclature for the life cycle

Manufacturing → Regulators → Supply / procurers → Hospitals or patients

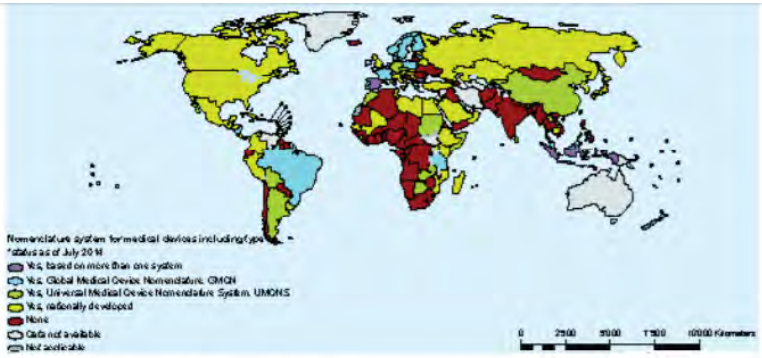


Fig. 3.5-1. Nomenclature systems for medical devices

About half of the responding member states, i.e. 90 countries (52%), use at least one official nomenclature system for medical devices. In contrast, 84 member states do not have any official national nomenclature (49%; see Fig. 3.5-2).

The 90 countries who have an official nomenclature system are using the following types: 26% have developed a system nationally, 12% use Universal Medical Device Nomenclature System (UMDNS) only, 10% use Global Medical Device Nomenclature (GMDN) only, and 3% more than one system.

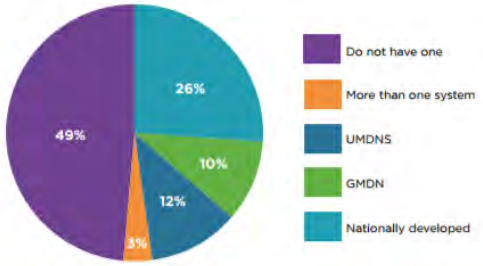


Fig. 3.5-2. Existence and type of the countries' official nomenclature system for medical devices

- WHO is searching for a global nomenclature
- Freely available for governments and users
- To be used with UDI
- With transparent process to assign codes.

http://who.int/medical_devices/priority/3_5.pdf?ua=1

WHO Medical Devices Inspections 2017

Types of Inspection	Number
Stage 1 desktop	5
Stage 1 onsite	2
Initial	2
Initial abridged	0
Follow up	1
Re-inspection	3
Supplier Inspection	0
Special	4
Total	17

WHO – MDSAP

- As an observer to the MDSAP, WHO is seeking to use the MDSAP audit outcomes

- For MDSAP to support a WHO Pre-qualification decision the MDSAP AO's report would need to have;
  - identified and sampled the WHO products.
  - provided evidence of the extent to which QMS requirements have been fulfilled by the manufacturer.

WHO – MDSAP

- WHO continues to support and promote MDSAP
- WHO is ready to assist the MDSAP Assessment program through:
  - The review of audit report samples for IVD manufacturers for MDSAP RA Surveillance Assessments.
  - The review of competence criteria, and the MDSAP AO's evaluation of competence, for MDSAP AO IVD auditors and technical experts
  - Participation in MDSAP assessments in Europe