



IMDRF

International Medical
Device Regulators Forum

WHO Update

Mike Ward

Department of Essential Medicines and Health Products



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No withdrawn		23	9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



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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

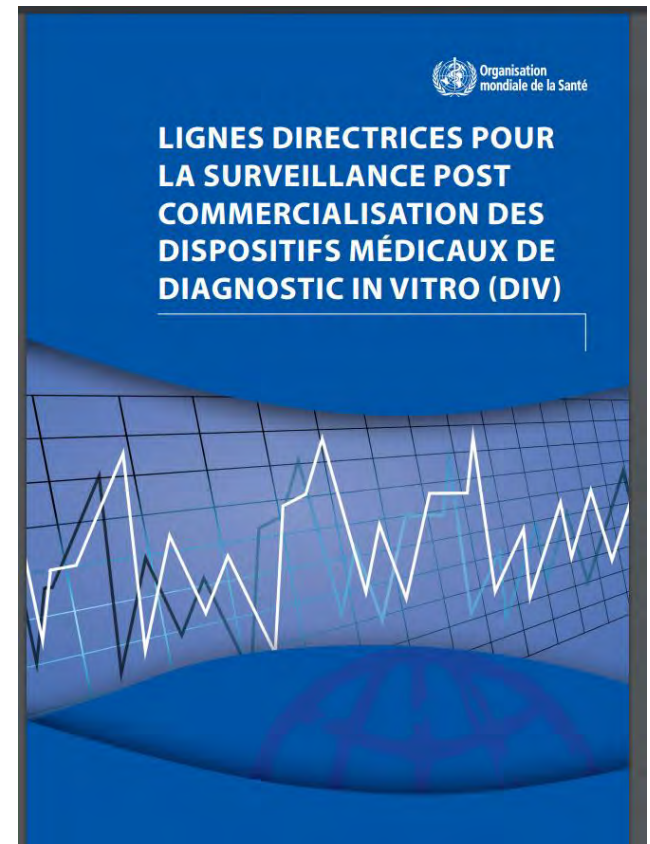
SUPPORT FOR DOSSIER ASSESSORS FOR WHO PREQUALIFICATION

Activity	Outcome
Improved guidance on good regulatory reporting practice (under development)	<ul style="list-style-type: none">• Great transparency in assessors decision making
Improved reporting templates that mirror the requirements of each TSS (under development)	<ul style="list-style-type: none">• 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

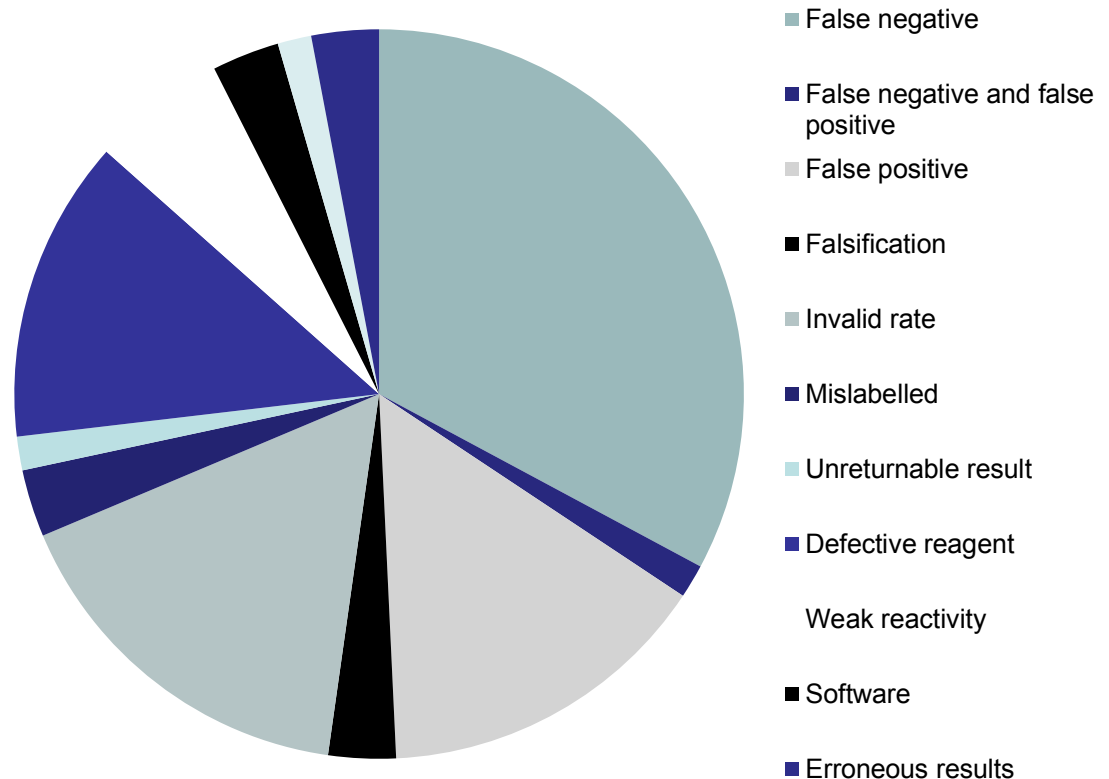




WHO complaint handling (n=67)

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

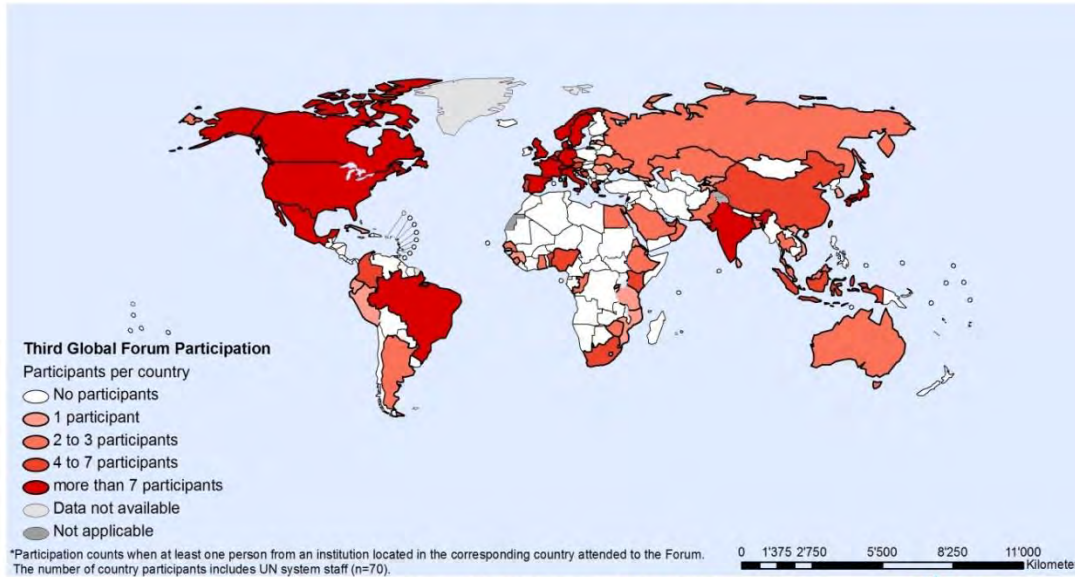
Type of complaint





Report of the 3rd Global Forum on Medical Devices

*Participants to the Third Global Forum of Medical Devices by country: n=571 (10-12 May 2017, Geneva, Switzerland).



The boundaries and names shown, and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: Third Global Forum Registration, 20 May 2017 update
Map Production: Policy, Access, and Use (PAU unit)
World Health Organization



Numeralia of 3rd Global Forum on Medical Devices

Participants	571
Oral session presentations	130
Posters	104
Plenary presentations	64
Workshops	46
Exhibitions	42
Videos	7



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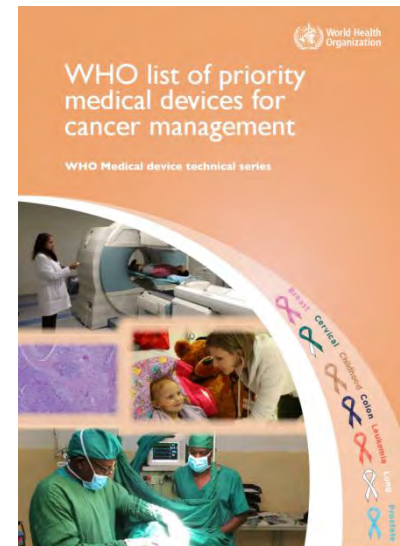
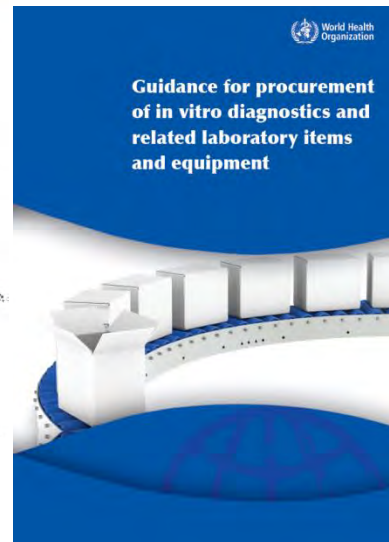
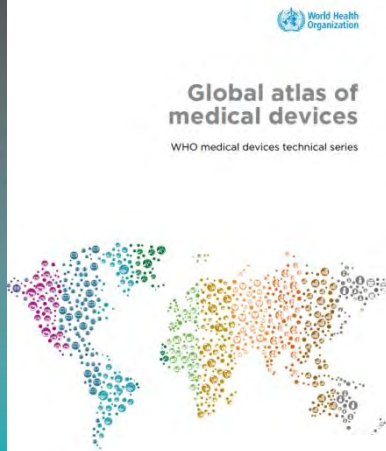
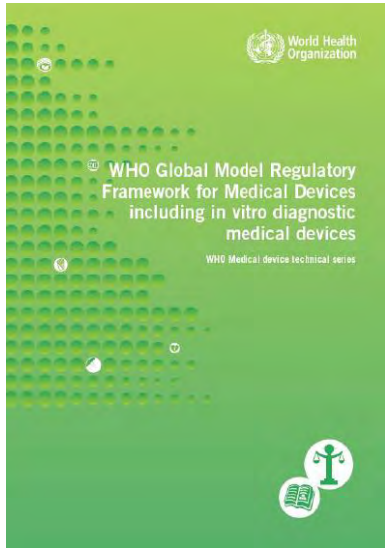
New WHO Books, launched at 3rd Global Forum May 2017



Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health



http://who.int/medical_devices/publications/en/





IMDRF International Medical Device Regulators Forum

New country profiles on regulatory systems

The screenshot shows the WHO website's 'Medical devices' section. The main heading is 'Medical devices regulatory systems at country level'. Below this, it states: 'Data was collected on the medical devices regulatory systems at country level through a desk survey during 2015-2016. These country profiles are a result. Related links: - Country profiles - Global atlas of medical devices - Medical devices regulations web page'. A list of countries is provided under the letter 'A', including Afghanistan, Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, and Azerbaijan. On the right side, there is a section for 'ESSENTIAL MEDICINES AND HEALTH PRODUCTS' with links to 'EMIP home page' and 'Policy, Access and Use'. There are also 'Publications and other resources' listed, such as WHO publications, information in French, and biomedical engineering resources.

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

Medical devices regulatory systems at country level



Canada

World Bank income group: High income



Legal

Legal framework: Yes
Authorizing legislation: Food and Drugs Act (R.S.C., 1985, c. F-27) <http://laws-lois.justice.gc.ca/eng/acts/F-27/FullText.html>
 Medical Devices Regulations (SOR/98-282) <http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/FullText.html>
Guidelines: Guidance on the Risk-based Classification for Non-In Vitro Diagnostic Devices (non-IVDDs) http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-id/gd_rbc_non_ivdd_ld_scr_autres_idiv-eng.php
 How to Complete the Application for a New Medical Device License http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-id/md_gd_licapp_im_ld_demhom-eng.php.



National Regulatory Authority

National Regulatory Authority present: Yes
Name: Health Canada, Health Products and Food Branch, Therapeutic Products Directorate, Medical Devices Bureau <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>
Responsibilities of the NRA: N/A



Medical device definition

Medical device defined: Yes
Text: A device means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals, (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals, (c) diagnosing pregnancy in human beings or animals, (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or (e) preventing conception in human beings or animals; however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal. Food and Drugs Act, R.S.C., 1985, c. F-27, 2.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined separately. Medical Device Regulations, 1.



Medical device classification

Classification: Yes
Categories: Class I, II, III, and IV. Medical Device Regulations, 6.
Classification rules: Yes
Classification rules details: Classification depends on the intended use of a medical device. Guidance on the Risk-based Classification for Non-In Vitro Diagnostic Devices (Non-IVDDs) Classification rules are detailed in Schedule 1 of Medical Device Regulations. id. 7.



Essential principles

Essential principles: Yes
Details: A manufacturer must ensure that a medical device meets safety and effectiveness requirements. Medical Devices Regulation, 9; see also id. 10-20 (detailing the safety and effectiveness requirements).



Conformity assessment

Conformity assessment bodies: Yes
Details: Policy on the Canadian Medical Devices Conformity Assessment System (CMDCAS) Quality. http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/cmdcas/scemim_syst_pol-eng.php
 Requirements and procedures for management systems certification bodies accreditation/ Medical devices manufacturers (CMDCAS) <https://www.scc.ca/en/about-scc/publications/criteria-and-procedures/management-systems>
Pre-marketing / procedure: YES - All medical devices other than lowest-risk Class I devices must be registered.



Reliance

Reliance: N/A
Details: N/A
Jurisdictions: N/A

June 2015 - April 2016



Medical Devices nomenclature for the life cycle

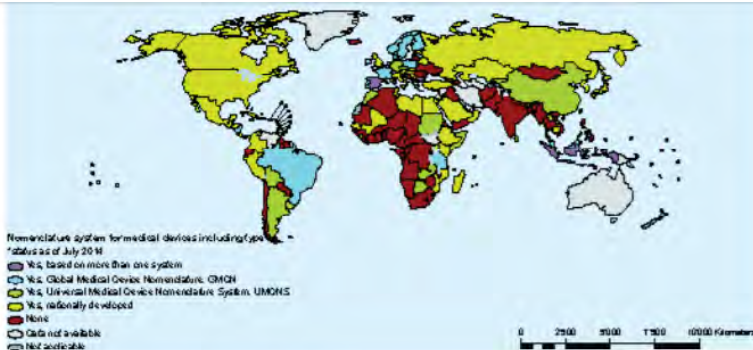


Fig. 3.5-1. Nomenclature systems for medical devices

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.

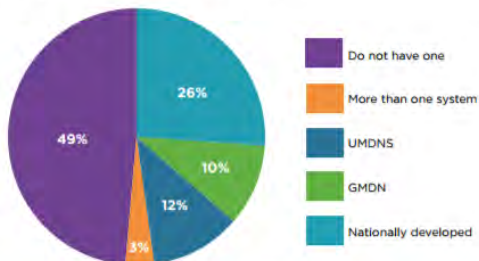


Fig. 3.5-2. Existence and type of the countries' official nomenclature system for medical devices

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



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