IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

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September 2021

1. WHO Emergency Use Listing Procedure for IVDs

WHO EUL: SARS-CoV-2 IVDs

- Priority categorization of applications for prequalification and Emergency Use Listing (EUL) assessment of IVDs

High priority:

- EUL applications for SARS-CoV-2 antigen detection tests
- EUL applications for SARS-CoV-2 nucleic acid detection tests intended to be used at a point of care.

Medium priority:

- prequalification applications
- EUL applications for SARS-CoV-2 nucleic acid detection tests.

- SARS-CoV-2 antibody tests are no longer eligible for WHO EUL assessment

WHO EUL update

	Total #	Test types		
		Nucleic acid	**Antigen**	**Antibodies**
Pre-submission interest	>200	*- no split available -*		
EOI	151	64	46	41
EUL listed	28	23	4	1
EUL not accepted	42	24	8	10
Active applications	81	17	34	30
Awaiting dossier		0	5	2
Dossier received		17	29	28
Pre-screening		3	4	
Pre-assessment (screening)		5	18	- on hold -
Under assessment		9	7	

SARS-CoV-2 IVDs

- Interim International Standard for SARS-CoV-2 antigen - exploratory study is ongoing (NIBSC/WHO)
- SARS-CoV-2 Serology Test Kit Evaluation - ongoing (NRL Australia/WHO)
- June 2021: 'Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities' (WHO interim guidance)

2. WHO Prequalification of IVDs

PQDx IVD product dossiers – ToC format

- For WHO PQ applications, product dossiers have been provided in, and reported against, **Summary Technical Documentation (STeD) format**
- In March 2020 WHO PQ Diagnostic Assessments began its transition to the **ToC format** for dossiers and review reports:
  - Dossier requirements, and dossier review documents have been updated to reflect ToC
  - Manufacturers are requested to provide product dossiers in either STeD or ToC format; dossier reviews will be reported using ToC report templates.
  - Training for assessors, and guidance for manufacturers will be provided.

Because of Covid-19 disruptions, transition will continue in 2021

In 2022:

- All product dossiers to be submitted in ToC format.

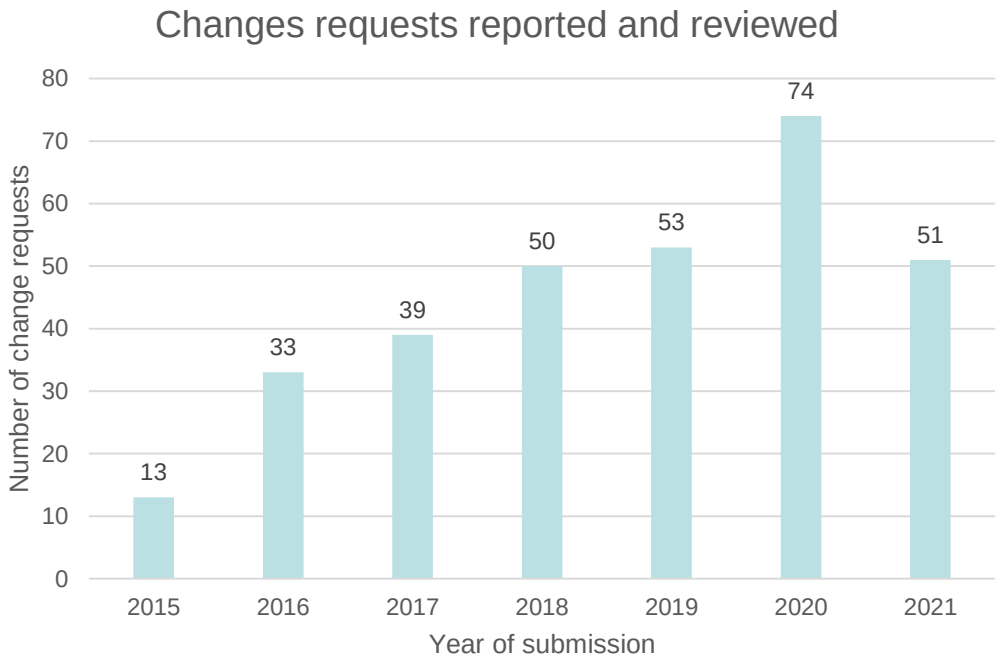
WHO PQ Inspection team activities

- **Inspections:**
  - All onsite inspections postponed (5 planned for Q3/4, 2021)
  - Desk assessments (1 completed, >10 planned for 2021)
- **Emergency Use Listing:**
  - NAT, Ab and Ag IVDs
  - Until July 2021 - 32 assessments completed.
- **Conference:**
  - ICDRA meeting, 20-24 Sept 2021 “Smart Regulation: Timely Delivery of Quality Assured Medical Products for All during the Global Pandemic” with workshop on EUL for IVDs

WHO PQ Changes to prequalified and EUL products

Guidance document to report changes under review to:

- Increase clarity for manufacturers on what is to be reported
- Provide descriptive generic examples of the changes to be reported
- Provide better overview of how to determine the severity of a change and the WHO change assessment process



PQ Workshops & Webinars

- Collaborative Registration Procedure

  Country specific workshops held to train NRAs in Uganda, Mozambique & Cameroon

- EUL Workshops

  Region specific workshops held in partnership with AFRO, EURO, PAHO & SEARO

- EUL-Facilitated Procedure

  Webinars conducted with manufacturers and NRAs to introduce the new procedure

- Prequalification Evaluation Laboratory Webinar

  Information session with reference laboratories in PAHO region

- PQ Workshop

  IVD Manufacturing Units in India

3. Regulatory strengthening

WHO Facilitated Procedure for accelerating national listing/authorization of WHO EUL SARS-CoV-2 IVDs

- Mechanism for accelerating national listing/ authorization of WHO EUL COVID-19 IVDs - **WHO-EUL-Facilitative procedure developed in May 2021**
- **Aim:** to provide a convenient means for NRAs wishing to enhance listing/authorization of IVDs by taking advantage of WHO EUL assessment outcome.
- Scope of products**: limited to COVID-19 IVDs**
- Similar principles to the WHO Collaborative Registration Procedure (CRP): **Participants, sameness of product and confidentiality of information.**
  Differences with CRP:
  Information to be shared with the NRAs; under the EUL-FP the **dossier and QMS (desk review) assessment reports are shared.**
  Timelines are shortened i.e., **5 days instead of 30 days for sharing reports and 15 days of regulatory decision instead of 90 days.**

Revision of the WHO Global Model Regulatory Framework for medical devices including invitro diagnostics

Why revise and update the GMRF

- The WHO GMRF was published in 2017, developed in 2015-2016
- Rapidly changing field
- Experience with implementation
- Member States will benefit from an update

What to emphasize and expand

- Good Regulatory Practice;
- Reliance and recognition
- Nomenclature system and UDI;
- Prioritization according to risk assessment in the jurisdiction concerned;
- Regulatory pathways for medical devices according to their risk class;
- Regulatory pathways for exemptions and emergency authorization;
- Regulatory pathways for borderline products;
- Regulatory pathways for donated medical devices;
- Policy and implementation of testing medical devices;
- Exchange of information amongst NRAs

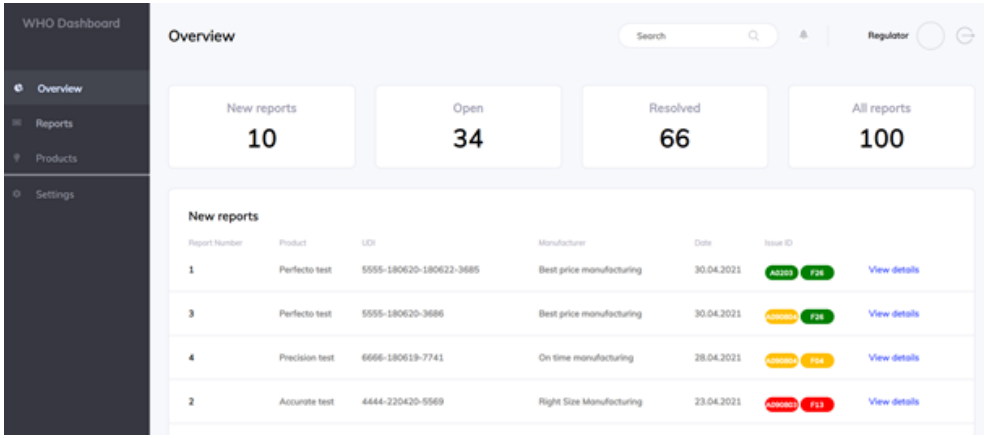
What to add (new)

- On risk assessment in priority-setting of the current situation regarding regulation of medical devices;
- Steps for implementation: e.g. how to prioritize;
- Start implementing regulatory controls;
- Guidance on developing a road map;
- New technologies such as software as a medical device (including cybersecurity);
- How to involve stakeholder i.e. industry and civil society
- Regulatory capacity building

4. Safety of medical devices

Substandard/falsified medical devices

- AER terminology adopted for all incidents of substandard/falsified IVDs notified to WHO (Global Surveillance and Monitoring System)
- Blockchain for user feedback and reporting incidents to NRAs
  - ➢ Minimum viable product complete
    - User reporting application
    - Dashboards for manufacturer and regulators



https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1

5. WHO standardization of medical devices nomenclature

WHO standardization of medical devices nomenclature

- 74 World Health Assembly in May 2021

- Requests by Member States

- Interventions by 21 Member States.
- Importance of nomenclature, coding and classification of medical device to support regulation, procurement, assessment
- Should be transparent, harmonized and evidence based, open systems to be accessible for all
- Requested WHO not to create a new nomenclature to avoid duplications
- Concerns of EMDN not harmonized with GMDN
- Request to: Map EMDN to GMDN to minimize impact,
- Costing study, Consultations with IMDRF, and industry.

- WHO response 31 of May

- Set of countries advocate for proprietary system (GMDN)
- Set of countries advocate for open existing systems (ie. EMDN)
- WHO confirms will not create a new nomenclature.
- Information and consultation sessions in 2021 to report to Executive Board 150, February 2022.
- WHO requires support by Member States to find agreements of nomenclature systems to map, have a transparent system to assign codes, and make information openly available, with no IP restrictions.

- Activities towards the 150 Executive Board in February 2022

Date	Activity	Expected outcome
May-June	WHA74 and EB149	----------
24 June	*IMDRF teleconference*	*Briefing of WHA and next steps*
16, 20 July	WHO HQ meetings	
19 July	WHO Regional advisors	Status, plan and their input
22 July	Medical devices industry	GMTA, DITTA,
28 July	UN agencies	Nomenclature and tech specs
July, August TBC	Nomenclature agencies	Willingness to map, WHO and agency
21-27 July	Biomedical and Clinical engineers, procurement and supply	Use of nomenclature in health care facilities
6,7,8,9,10, September	Regional regulators networks	Nomenclature uses and challenges
September, TBC	Member States information session	Report on the consultation sessions with various stakeholders
September	*IMDRF meeting*	*Briefing and next steps*
1 October	Report for EB150	Report sent for WHO internal clearance
1 February 2022	EB150.	Presentation to the Executive Board

Thank you