IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

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Overview

1. WHO EUL
2. WHO Prequalification
3. Substandard and Falsified Medical Devices

WHO Emergency Use Listing Procedure for IVDs

SARS-CoV-2 IVDs continue to be a high priority

Focus is on antigen RDTs, particularly those for self testing

			Test Types			
	Total #		**Nucleic Acid**	**Antigen**	**Antigen Self-Test**	**Antibodies**
Pre-submission interest	>200		*no split available*			
EOI	**184**		**71**	**63**	**9**	**41**
EUL listed	**32**		20	10	1	1
EUL not accepted	**71**		27	34	0	10
Failed	*64*		*24*	*31*	*0*	*9*
Withdrawn	*7*		*3*	*3*	*0*	*1*
EUL Active Applications	**47**		**20**	**19**	**8**	**Hold (30)**
EUL Renewal Ongoing	**20**		17	2	0	1

WHO Prequalification: Eligibility expansion and new guidance for manufacturers

1. PQ Technical specifications have been published for IVDs used for the qualitative detection of **Mycobacterium tuberculosis complex DNA** and mutations associated with drug-resistant tuberculosis

- https://extranet.who.int/pqweb/sites/default/files/documents/220805_TSS17_MBTC-NAT.pdf
- WHO will be accepting applications for such products from 22 Sep 2022
- A The virtual workshop will take place on 21 September 2022 12:00 – 13:30 (UTC+2); register in advance:

  https://who.zoom.us/webinar/register/WN_Im4vSUC5SN24YQDPH1EgEQ

2. Technical Specifications for **glucose meters and HbA1c** POC IVDs are in development

PQDx IVD product dossiers – ToC format

WHO PQ continues its implementation of the ToC format for dossiers and review reports

- Because of Covid-19 disruptions, transition will continue in 2022
- Manufacturers may provide product dossiers in either STeD or ToC format
- Dossier requirements, and dossier review documents have been updated to reflect ToC
- Training for assessors, and guidance for manufacturers will be provided

In 2023, product dossiers must be submitted in ToC format

Upcoming events

1. The virtual workshop for TB NAT PQ applications will take place on 21 September 2022 12:00 – 13:30 (UTC+2); https://who.zoom.us/webinar/register/WN_Im4vSUC5SN24YQDPH1EgEQ

2. UN meeting with manufacturers and suppliers

Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Registration will start soon

Substandard and Falsified Medical Devices

AER terminology continues to bring value to WHO's Global Surveillance and Monitoring System for incidents related to WHO prequalified and emergency use listed IVDs

- WHO welcomes new work item on Common Dataset for AE Data Exchange

Support to WHO Member States to prevent, detect and respond to substandard/falsified medical devices is provided through:

- normative guidance on post-market surveillance and market surveillance
- updated WHO Global Model Regulatory Framework, and
- WHO's Global Benchmarking Tool+medical devices

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Thank you/Questions

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