World Health Organization Update

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15 September 2026

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75 HEALTH FOR ALL

Presentation outline

1. Prequalification of IVDs
2. Prequalification of medical devices
3. WHO Emergency Use Listing
4. Access to medical devices: EDL and Global Dx coalition

WHO PQ Key Developments

Strengthening Regulatory Pathways

- Implemented revised WHO PQ procedure for IVDs (effective 1 Jan 2026)
    - Increased reliance-based approach
    - Streamlined assessment pathways to improve efficiency
    - Continued efforts to reduce assessment timelines through regulatory reliance and collaborative mechanisms.

Expanded PQ eligibility

- Interferon-Gamma Release Assays (IGRAs) for tuberculosis
- Targeted Next Generation Sequencing (tNGS) assays for tuberculosis diagnostics

Capacity Building & Stakeholder Engagement

Building Assessment Capacity

- New IVD Assessor Training - WHO Academy, Lyon (21-24 April 2026): Hands-on training in dossier review and change request evaluation
    - Expected to strengthen AMD assessment capacity and accelerate access to quality IVDs
- MDs assessors identified Q3 2026

WHA79: Accelerating Access to Health Technologies

- Promoting the importance of regulation and QA-ed MDs
- Alignment of regulatory, guidance, and procurement processes

Manufacturer Engagement

- Delivered global workshop on WHO Prequalification of IVDs
    - Practical guidance on dossier preparation, common submission challenges
    - Reinforced transparency, collaboration, and submission readiness across the diagnostics ecosystem

Launch of WHO Prequalification of Medical Devices

WHO Medical Device Prequalification Programme Launch on 1 October

- Launch webinar: 25 September 2026

Initial Scope:

- Contraceptive devices: male and female condoms and IUDs
- CAD-TB products
- Male circumcision devices

Prequalification Process

- Product dossier review aligned with the ToC structure
- Manufacturing site inspections based on ISO 13485 requirements
- Assessment of product labelling and accompanying documentation

Supporting Resources available soon

Emergency Use Listing (EUL): Rapid Response to Ebola Bundibugyo Virus (BDBV)

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Supporting outbreak preparedness and response

Opened WHO EUL procedure for Ebola Bundibugyo virus (BDBV) diagnostics following the declared public health emergency.

- Published submission instructions and accelerated assessment pathways for manufacturers.
- As of 2 Sep : Listed 4 diagnostic test for Ebola Bundibugyo virus under the WHO EUL framework.

Broader EUL Activities and Global Health Impact

- Continued EUL activities for high-priority outbreak pathogens, including MPXV nucleic acid detection assays.
- Continued promotion of reliance-based approaches and regulatory convergence to improve global availability of quality-assured diagnostics.

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Medical devices and Assistive technology (MDA) Team update 1/2

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Global Diagnostics Coalition

- First members meeting held in May 2026.
- Fourteen organizations elected to the Steering Committee (2025–2027) from 38 members, and six working groups established.
- GDC members will host a side event at the 2026 World Health Summit to raise awareness of the need for coordinated action to close the diagnostic access gap.

Medical Devices Information System（MeDevIS)

- A global public survey seeking feedback on MeDevIS is underway.
- Over 350 people responded to an online survey, and key stakeholder interviews have begun.
- A revision and update of the MeDevIS platform will follow, aligned with feedback received.

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MDA Team update 2/2

Priority diagnostics for humanitarian and public health emergencies

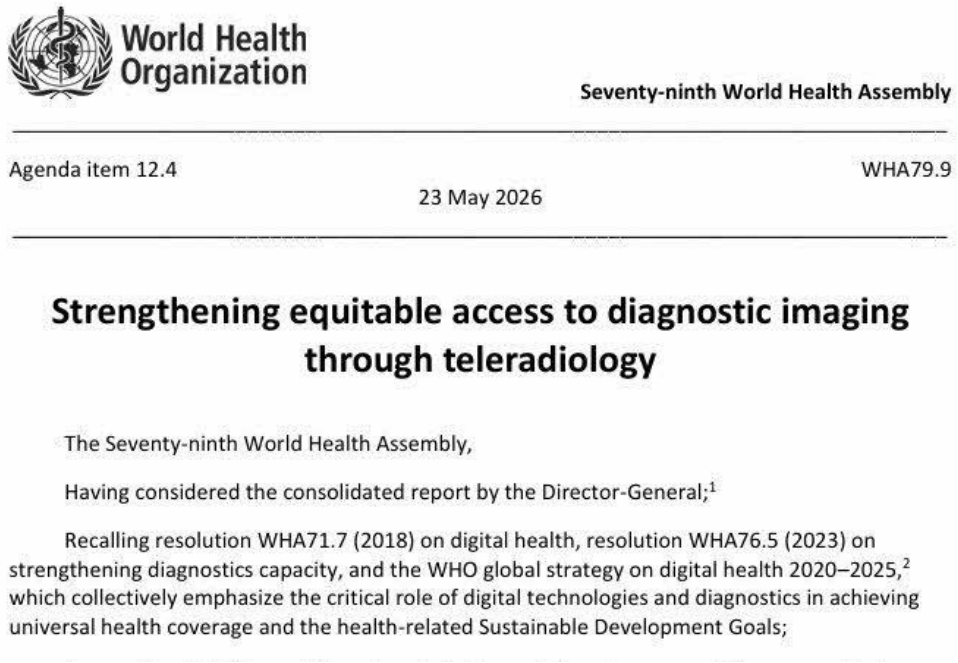
MDA in partnership with the Emergency team have progressed a list of diagnostic medical devices for emergency preparedness and response, including developing criteria for selection.

Resolution on strengthening equitable access to diagnostic imaging through teleradiology (WHA79.9)

Led by Egypt, the WHA79.9 resolution was tabled and adopted during WHA2026. MDA is working alongside colleagues in digital health to support implementation.

5th WHO Model List of Essential In Vitro Diagnostics (EDL 5)

EDL 5 is available in its electronic format; the report of the 5th SAGE IVD meeting is under final review. A review of the EDL process is underway, including a survey and consultation with stakeholders.



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Seventy-ninth World Health Assembly

Agenda item 12.4 — WHA79.9

23 May 2026

Strengthening equitable access to diagnostic imaging through teleradiology

The Seventy-ninth World Health Assembly,

Having considered the consolidated report by the Director-General;[1]

Recalling resolution WHA71.7 (2018) on digital health, resolution WHA76.5 (2023) on strengthening diagnostics capacity, and the WHO global strategy on digital health 2020–2025,[2] which collectively emphasize the critical role of digital technologies and diagnostics in achieving universal health coverage and the health-related Sustainable Development Goals;

EDL 5 link

Thank you!

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