Changes in WHO’s prequalification assessment of in vitro diagnostics: Stakeholders briefing

Assessment of medical devices team (AMD)
Prequalification Unit

17 December 2025

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Housekeeping rules

- All microphones are muted
- Use the Q&A to share any questions
- Presentation will be followed by Q&A
- Webinar being recorded
- Recording will be posted on website

Content

- Context and background to changes
- Overview of changes to the performance evaluation and prequalification assessment procedure
- Updated guidance documents and resources
- Q and A

Context and background to changes

Irena Prat,
Team Lead AMD

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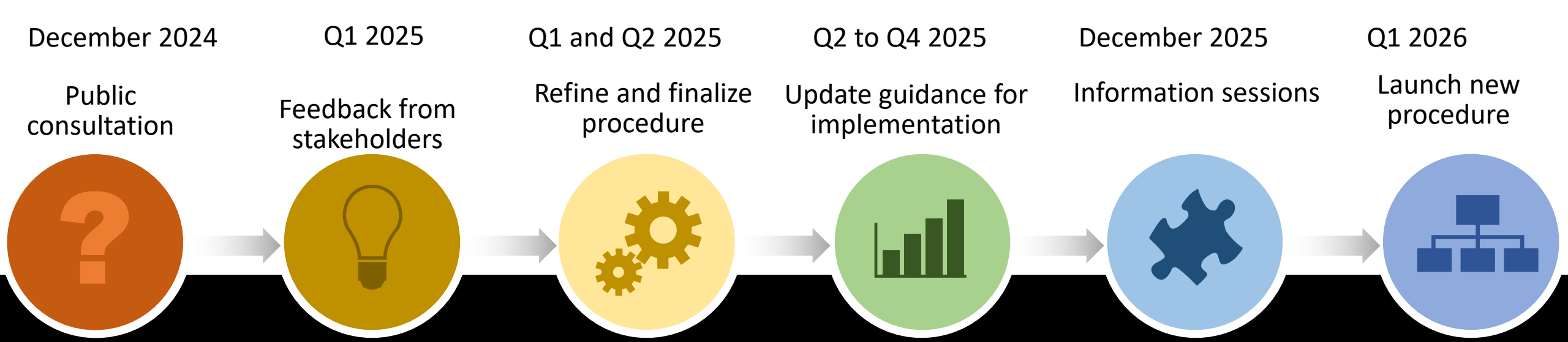
Background to WHO’s prequalification assessment

- In **1988**, WHO launched the **Test Kit Evaluation Programme** to support procurement of IVDs on the global market
- WHO’s **Prequalification Programme for In Vitro Diagnostics (IVDs)** was implemented in 2010 and shifted from performance-based programme to a regulatory-alike approach embracing quality, safety and performance
- Since **2010**, WHO’s prequalification assessments have expanded in scope and diversity, alongside growing global regulatory convergence
- **2014**, major revision of prequalification assessment, including the introduction of abridged assessment
- **2026**, a second major reform to be implemented

Context to changes to prequalification assessment procedure

- In 2024, WHO published a consultation with a new proposed assessment pathway for WHO's prequalification assessment of IVDs
- Aim of proposed pathway was to establish more consistency in meeting expected timelines for manufacturers, improve responsiveness and overall efficiency
- Rationale:
  - Increasing no. and diversity of IVD applications
  - Continuous alignment with regulatory convergence efforts (IMDRF and ISO)
  - Improve resource allocation, turnaround time, and more predictability for manufacturers
  - Implement a more agile approach



- Launched a public consultation to get feedback from stakeholders including manufacturers, partners, procurers
- Input sought on feasibility, clarity, implementation of proposed procedure

- PQ refined and finalized procedure based on the feedback received from NRAs, manufacturers and other stakeholders and updated PQ guidance documents
- Launching the updated prequalification assessment procedure **as of 1 January 2026**

Overview of changes to prequalification assessment

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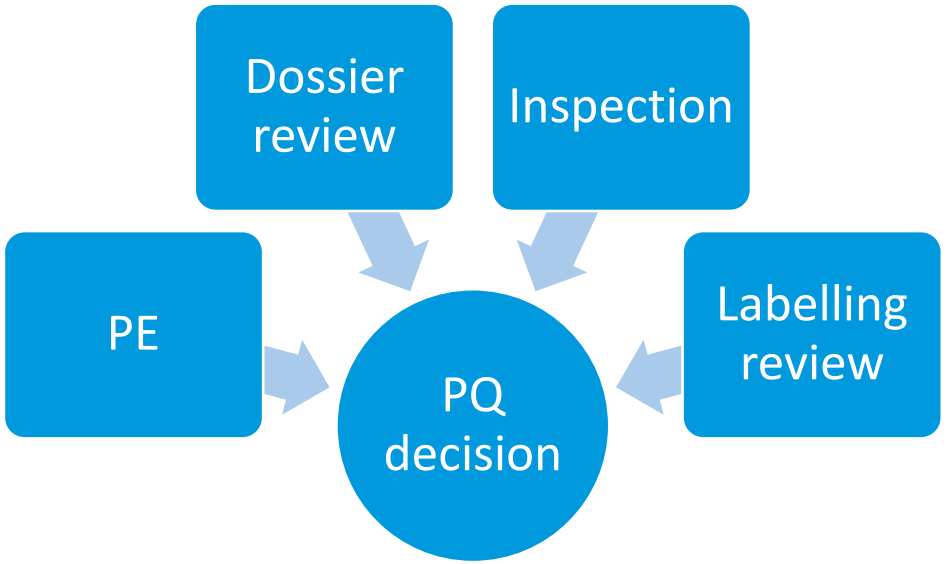
Current prequalification assessment model until end 2025

- Current model includes a comprehensive review of dossier, manufacturing sites, PE and labelling review



- PE is a PQ assessment component
- Predictability in timelines can vary depending on product type

New prequalification assessment procedure – 1 January 2026

Overall aim: Adopt a more modular, risk-based assessment framework and better integrate reliance

- Change 1: Performance evaluation becomes **a prerequisite and a separate step** to prequalification assessment
- Change 2: **Eligibility** for PE
- Change 3: PE options 1 and 2 become **options A and B**
- Change 4: WHO's prequalification assessment **components updated**
- Change 5: Expanded use of **reliance and recognition** pathways as part of the abridged prequalification assessment
- Change 6: Prequalification **fees** paid in one installment

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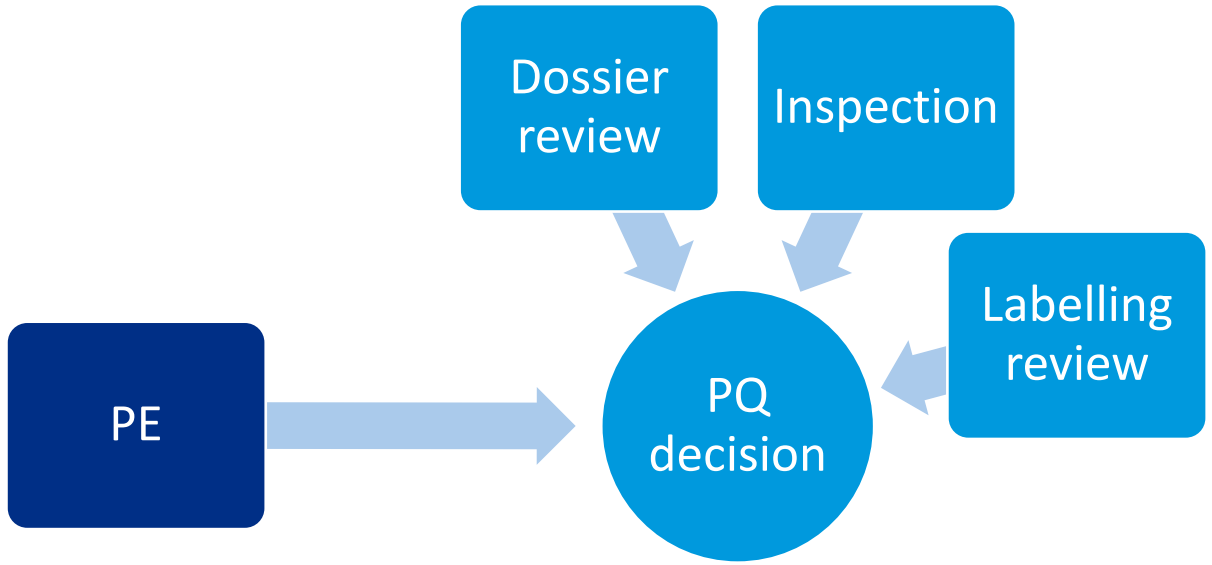
Change 1: Performance evaluation becomes a prerequisite and a separate step to prequalification assessment

Anne-Laure Page, Scientist

Change 1 : **Performance evaluation becomes a prerequisite and a separate step to prequalification assessment**

Performance evaluation will now be a **separate and mandatory step** before prequalification assessment and listing for specific IVDs



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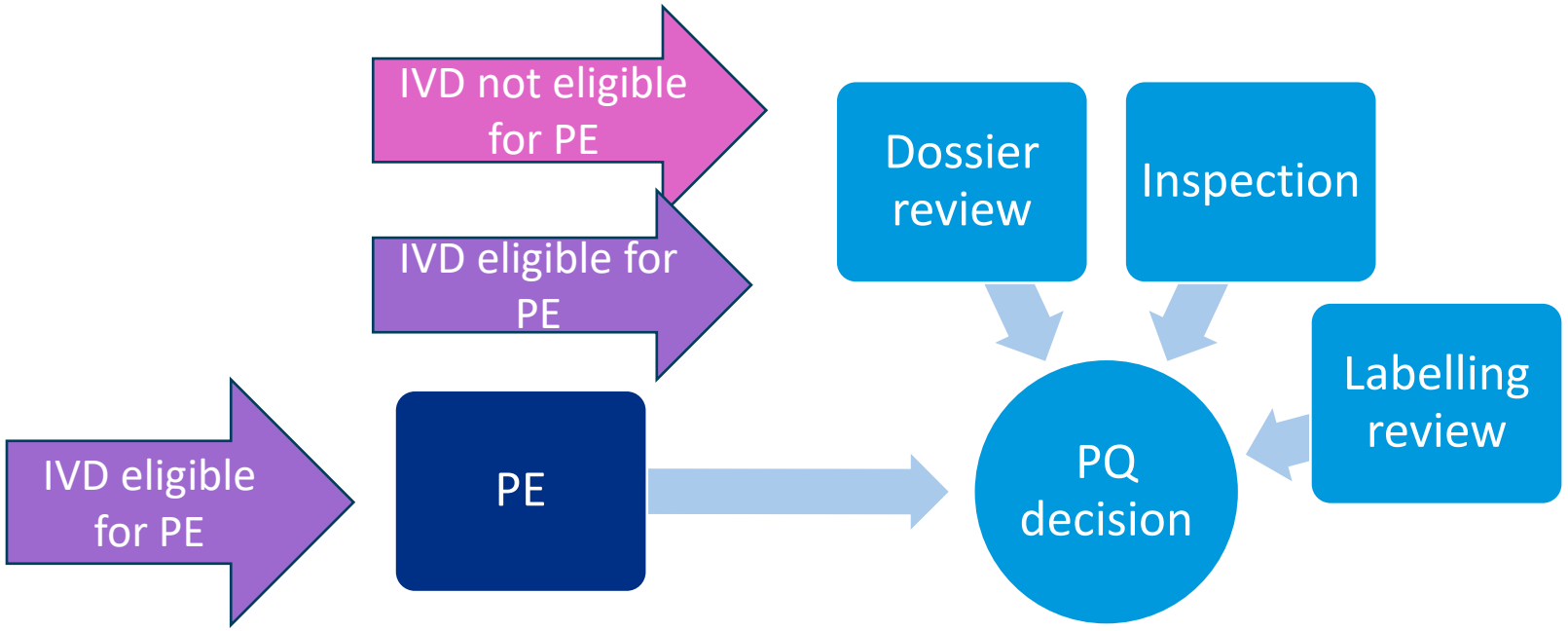


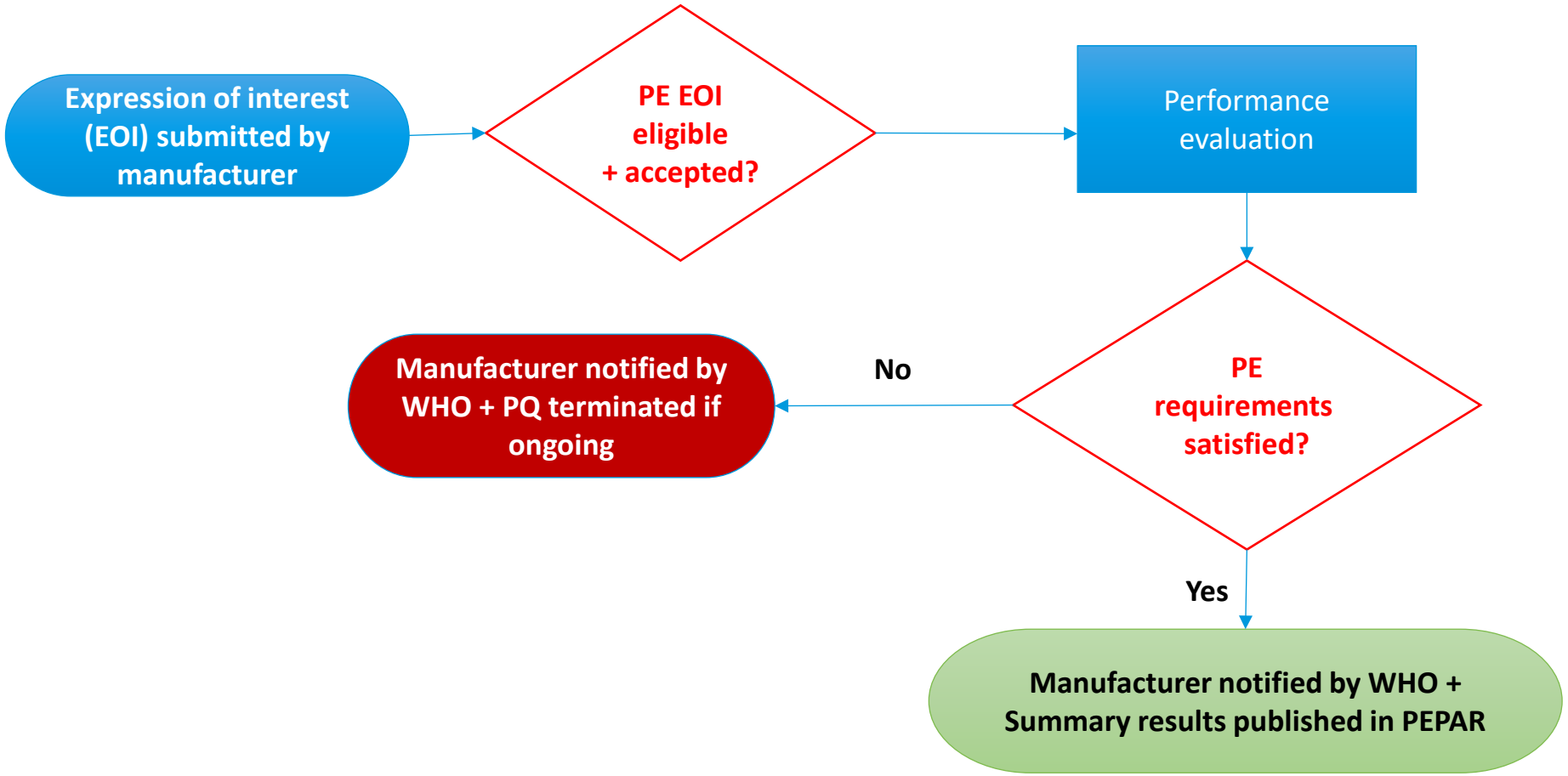
Change 1 : **WHO's performance evaluation assessment procedure**

- Manufacturers must first submit an Expression of Interest (EOI) for their IVD for a performance evaluation.
- If the EOI is accepted, the manufacturer must sign a Letter of Agreement with WHO and coordinate the performance evaluation directly with a WHO-listed Performance Evaluation Laboratory (PEL) and cover the PE costs.
- The performance evaluation will follow the relevant WHO PE protocol
  - Protocols revised to better reflect the risk-based approach and PE feasibility
- Results of the evaluation and the draft report will be shared with the manufacturer
- If the IVD meets the technical requirements of the PE, summary results will be published on the PQ website in a Performance Evaluation Public Assessment Report (PEPAR) report which will be published on the PQ website
- The PE outcomes inform the PQ decision

Change 1 : **WHO’s performance evaluation assessment procedure**

- WHO will continue to use the list of current PELs (adapted to the new list of IVDs required to undergo PE)
- WHO PELs are listed on the WHO website https://extranet.who.int/prequal/vitro-diagnostics/prequalified/performance-evaluation-laboratories

Process for performance evaluation



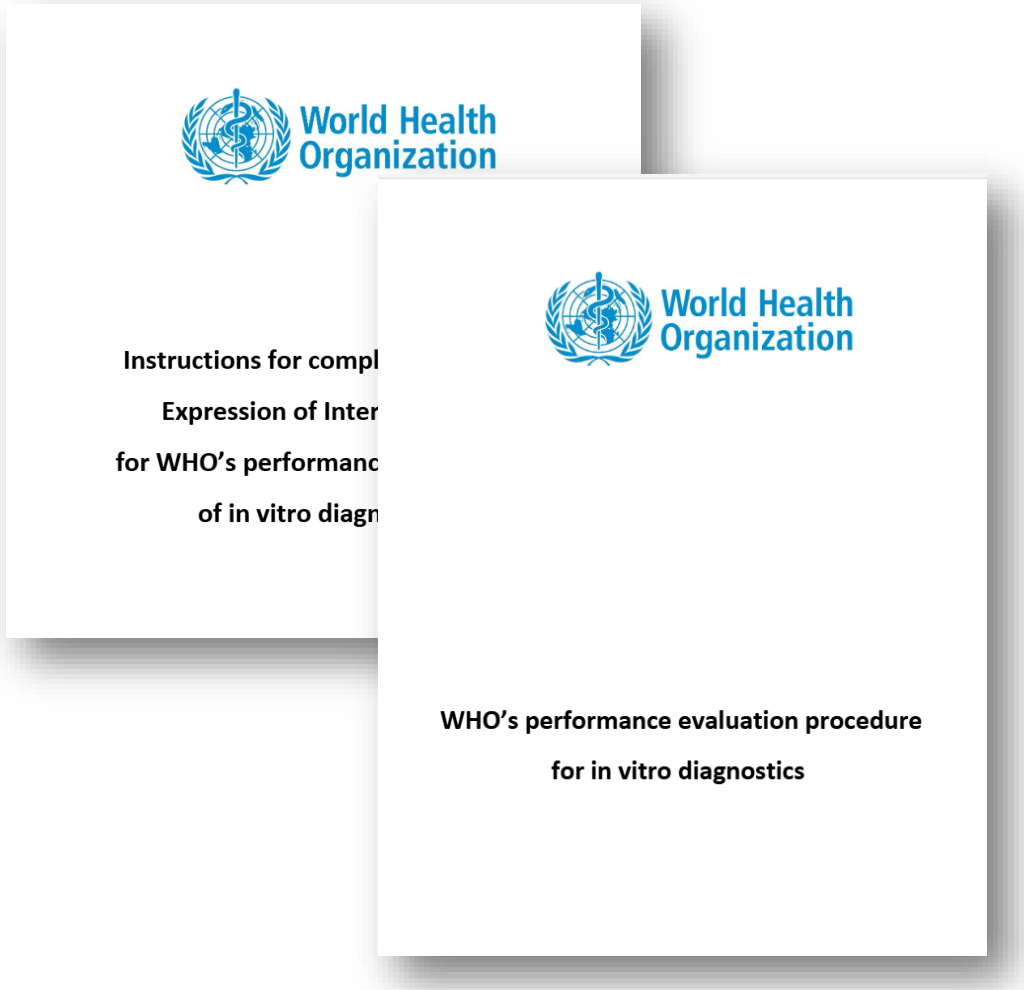
PE= WHO's performance evaluation
PQ = WHO's prequalification assessment
PEPAR = WHO's performance evaluation public assessment report

Change 1 : **Pathway for applying for WHO prequalification assessment as part of new procedure**

- Manufacturers can submit their application for WHO prequalification
  - once their IVD has been accepted for performance evaluation (PE assessment in **parallel** to PQ assessment), or
  - once the performance evaluation is complete (PQ assessment **sequential** to PE assessment).
- In all cases, the performance evaluation **must be finalized** before a final prequalification listing decision can be made.
- **IVD must meet the technical requirements of the PE to be eligible for PQ listing**

Change 1 : **Guidance and resources for performance evaluation**

- **New Performance evaluation website is live with guidance documents and instructions**
- https://extranet.who.int/prequal/ivd-performance-evaluation
  - WHO's Performance evaluation procedure
  - Eligibility criteria
  - EOI form and instructions
  - Fees
- Information on the IVDs undergoing PE assessment will be published on the PE website in a *"Status table"*



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Change 2: Eligibility for PE

Anne-Laure Page, Scientist

Change 2: Eligibility for PE

- Implementation of a strengthened risk-based approach, including to PE
- 2 lists of products based on risk and PE feasibility
  - Eligible for PE
  - Not eligible for PE
- PE design for eligible products: risk-based
  - Highest risk products: analytical and clinical part
  - Other products: analytical part only

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Manufacturers are expected to submit a robust product dossier, including independent data

IVDs eligible for PE

Analyte/pathogen	Technology
HIV	Rapid diagnostic tests
	Enzyme immunoassays
	Nucleic acid tests (early infant diagnosis)
Hepatitis C virus	Rapid diagnostic tests
	Enzyme immunoassays
	Nucleic acid tests
Hepatitis B virus	Rapid diagnostic tests
	Enzyme immunoassays
Malaria	Rapid diagnostic tests
Treponema pallidum (Syphilis)	Rapid diagnostic tests
Mycobacterium tuberculosis complex	Qualitative nucleic acid tests
	LF-LAM urinary tests

IVDs not eligible for PE

Analyte/pathogen	Technology
HIV	CD4 tests (quantitative or semi-quantitative) Nucleic acid tests for measuring viral load
Hepatitis B virus	Quantitative nucleic acid tests
Human papilloma virus	Nucleic acid tests (DNA or mRNA)[1]
Glucose-6-phosphate dehydrogenase (G6PD) enzyme	Technologies/formats to be used at or near the patient (quantitative or semi-quantitative or qualitative)
SARS-CoV-2	Rapid diagnostic tests Qualitative nucleic acid tests
Blood glucose	Point of care systems
HbA1c	Point of care systems
Haemoglobin	Point of care systems
Neisseria gonorrhoeae (NG), Chlamydia trachomatis (CT) and Trichomonas vaginalis (TV)	Nucleic acid tests (NG, CT, TV) Rapid diagnostic tests (NG) Rapid diagnostic tests (CT)

Change 3: PE options 1 and 2 become options A and B

Anne-Laure Page, Scientist

Change 3: PE options 1 and 2 become options A and B

- Currently, PE options 1 and 2 are in use:
  - Option 1 coordinated and paid by WHO
  - Option 2 coordinated and paid by the manufacturer
- As of 1.1.2026 commissioning options A and B will be implemented:
  - **Option A:** WHO's performance evaluation commissioned by the manufacturer and carried out by a PEL selected by the manufacturer (alike current option 2)
  - **Option B:** WHO's performance evaluation commissioned by WHO and carried out by a PEL selected by WHO.
- PE fees:
  - Option A: PE cost paid by the manufacturer to the PEL
  - Option B: PE cost paid by the manufacturer, through WHO, to the PEL, plus 13% PSC to WHO

Change 4: **WHO's prequalification assessment components updated**

Irena Prat,
Team Lead

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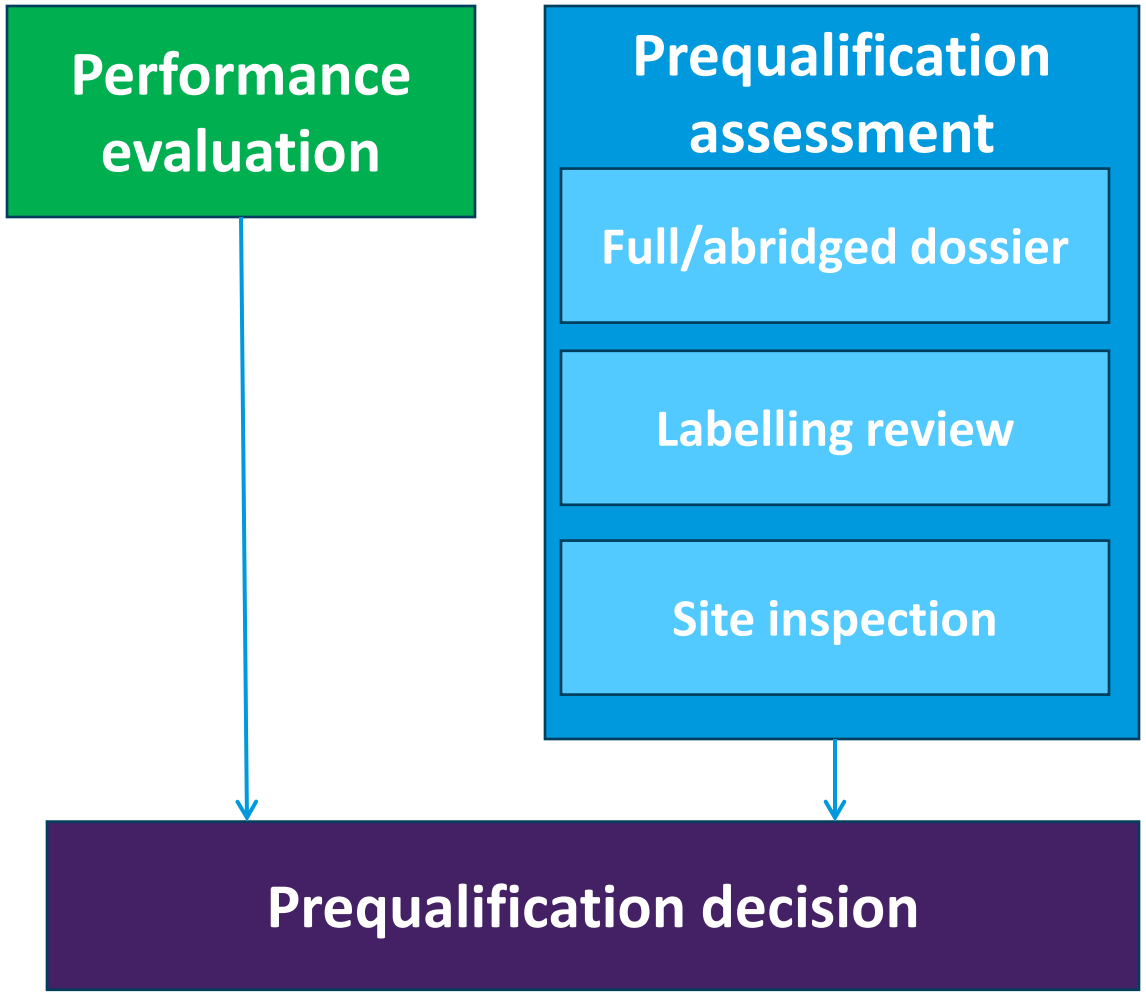
Change 4: **WHO's prequalification assessment components updated**

The PQ assessment procedure will change for applications received on or after 1st January 2026

- Prequalification assessment will consist of:
  - Full or abridged product dossier review
  - Site inspection
  - Labelling review



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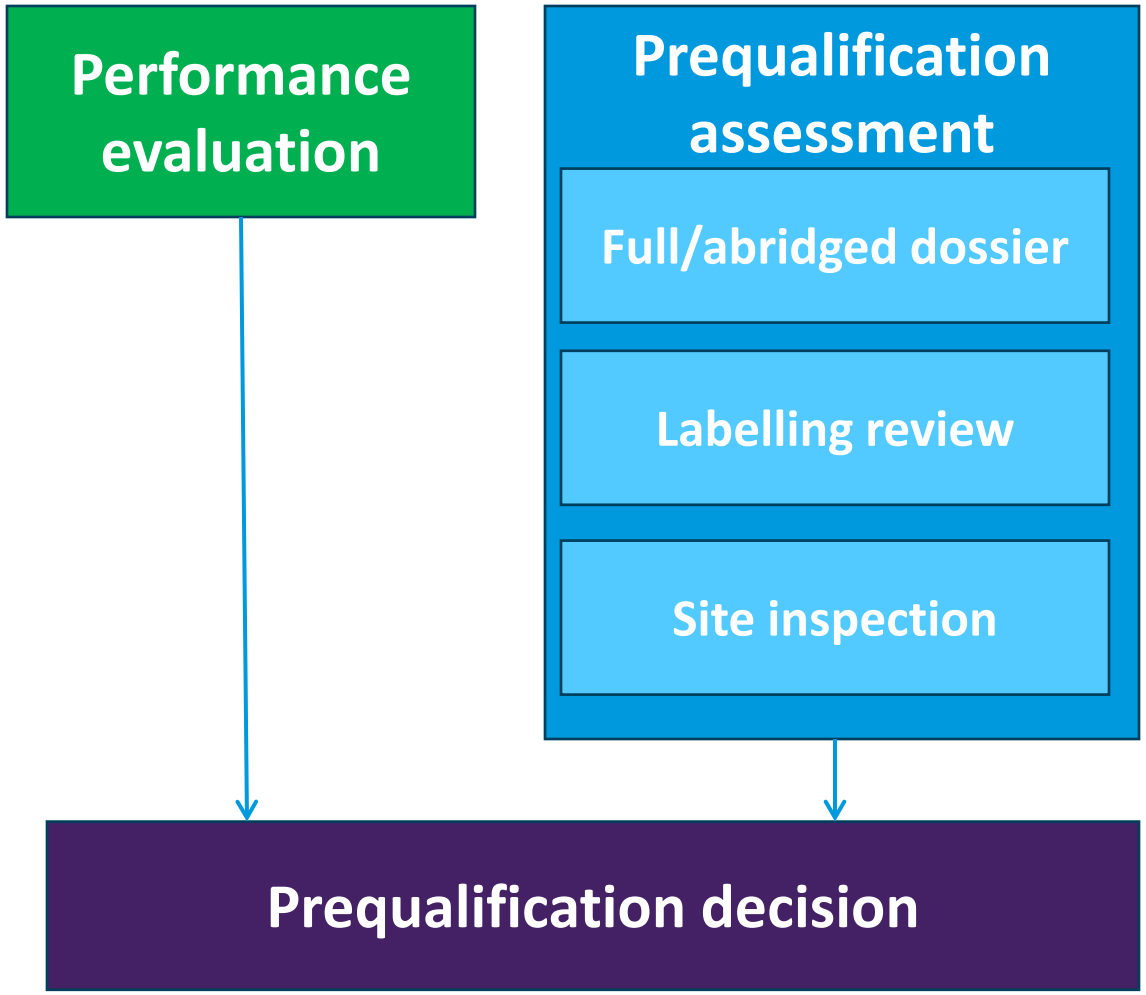
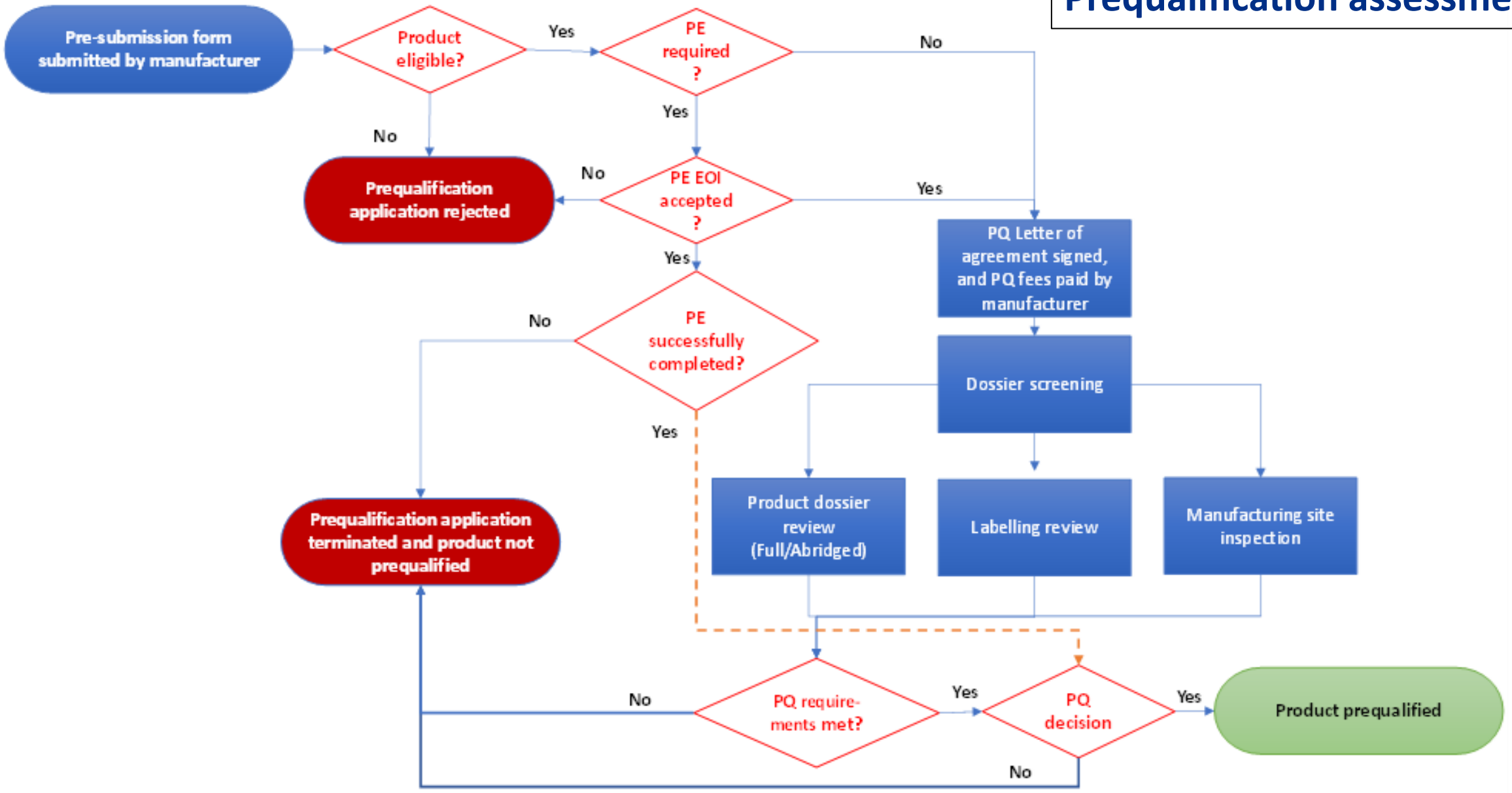
Change 4: **WHO's prequalification assessment components updated**

- IVD must meet the technical requirements of the PE **and** successfully completed all components of the PQ assessment to be eligible for PQ listing



Prequalification assessment



Change 4 : **Guidance and resources for prequalification assessment**

- **New guidance documents and instructions available on our website**

https://extranet.who.int/prequal/vitro-diagnostics

- *Overview of WHO's prequalification procedure for IVDs*
- *Eligibility criteria for WHO's prequalification assessment of in vitro diagnostics*
- *Pre-submission form*
- *Instructions for completion of the pre-submission form*

Change 4 : **Applications undergoing PQ assessment and accepted for assessment before 31 Dec 2025**

- This change in prequalification assessment procedure will **not** impact PQ applications that are
  - already under PQ assessment or
  - who have submitted **and accepted** for assessment before 31 December 2025.

  In these cases, WHO will continue assessing the applications using the current PQ assessment pathway
- The provisions of the updated *"Overview of WHO's prequalification procedure for IVDs"* **will apply will be implemented as of 1st January 2026**

NOTE: **ongoing compliance** with PQ requirements is a pre-requisite for maintaining PQ listing

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Change 5: Expanded use of reliance and recognition pathways as part of the abridged prequalification assessment

Susie Braniff, Scientist

Change 5: **Expanded use of reliance and recognition pathways as part of the abridged prequalification assessment new in yellow**

- The abridged PQ assessment has been strengthened to recognize a broader range of approvals issued by recognized regulatory authorities

Recognized Regulatory Authority	Risk classes undergoing stringent assessment
TGA, Australia	Class 3 and Class 4
Health Canada	Class III and Class IV
Notified bodies designated by EU Member States or other countries under specific agreement	Annex II List A and **List B (IVDD)** [1] Class C and Class D (IVDR)
MHLW, Japan	Class III
Singapore HSA	Class C and Class D
MHRA, United Kingdom	Annex II List A and **List B,** (Medical Device Regulations 2002)
US FDA	**Class II** and Class III

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[1] The validity of certificates during the transition period will be reviewed to verify compliance with the EU IVDR transitional conditions.

Change 5: **Update to dossier requirements for abridged assessment**

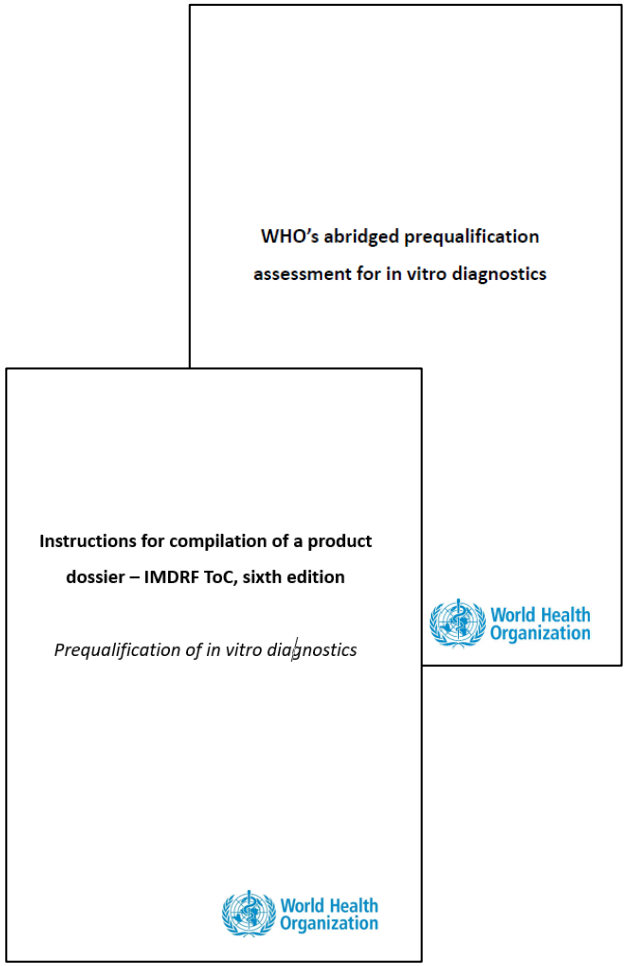
- Aim to further align and streamline dossier requirements for manufacturers with existing regulatory approval by a recognized regulatory authority
  - ➢ Reduced document submission for evidence of analytical performance

Administrative	Submission Context	Analytical Performance / Other	Labelling / Promotional materials

• Submission letter
• ToC & List of terms
• Application form
• Listing of device
• QMS & reg certificates
• Certificates of marketing
• User fees
• Statements/Declaration
	• Device description
	• Indications for use / Intended use
	• Global market history
	• Other submission context information
		• Risk management
		• Usability / human factors
		• Stability of the IVD
		  • Claimed shelf-life
		  • In-use stability
		  • Shipping stability
			• Product package labels
			• Package insert / Instructions for use
			• Technical / Operators manual
			• Other labelling and promotional materials

Change 5: **Guidance and resources for Abridged assessment**

- Updated guidance document are published on our website
- "*WHO's abridged prequalification assessment for in vitro diagnostics*"
  - ✓ Lists RRAs and risk classes that are considered eligible for abridged assessment
  - ✓ Lists the evidence of regulatory approval to be provided by manufacturers as part of the PQ abridged dossier submission
- "*Instruction for compilation of a product dossier*"
  - ✓ New annex with the revised list of documents required to be submitted as part of an abridged dossier
- Update to the Timelines webpage of the PQ website to include timelines for abridged dossier assessment
  - https://extranet.who.int/prequal/vitro-diagnostics/timelines



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Change 6: Prequalification fees paid in one installment

Irena Prat,
Team Lead

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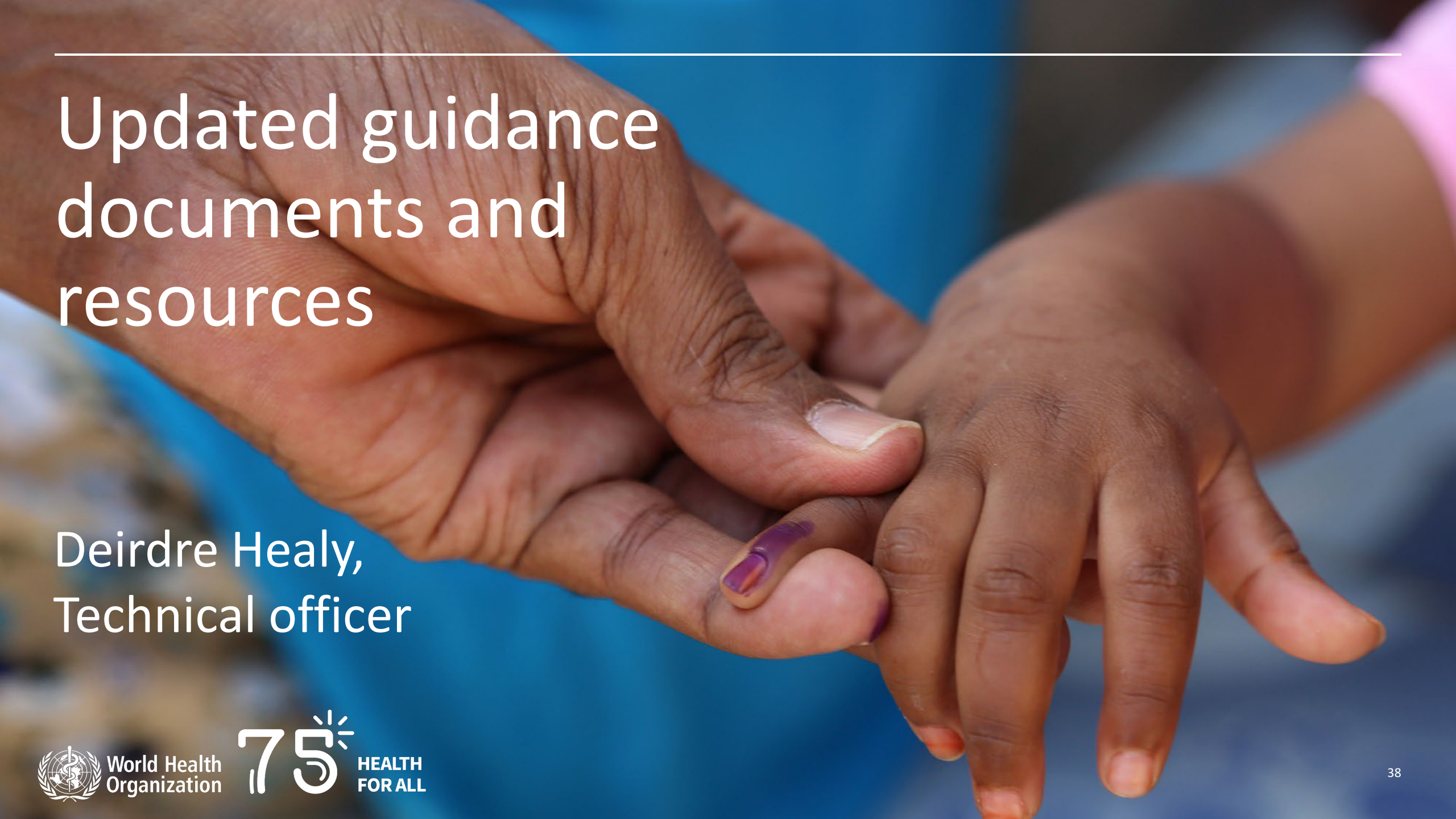
Change 6: **Prequalification fees paid in one installment**

- WHO prequalification fees – unchanged in amount – will now be payable in one installment for both full and abridged PQ assessment.
- All fees will be invoiced to manufacturers once the product has been prioritized for assessment
- Full assessment fee: US$ 17,000
- Abridged assessment fee: US$ 8,000 USD

- Updated guidance *“WHO’s prequalification assessment fees”* is available on our website

Updated guidance documents and resources



Deirdre Healy,
Technical officer

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Website and resources

Performance evaluation website and resources

https://extranet.who.int/prequal/ivd-performance-evaluation

Guidance documents for manufacturers

- *WHO's performance evaluation procedure for in vitro diagnostics*
- *Eligibility criteria for performance evaluation*
- *Expression of interest form for performance evaluation*
- *Instructions for completion the Expression of interest form*
- *Performance evaluation fees*

List of PELs https://extranet.who.int/prequal/vitro-diagnostics/prequalified/performance-evaluation-laboratories

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- *Instruction for compilation of a product dossier*

Conclusion

Irena Prat,
Team Lead

Conclusion

- The changes aim to introduce a more agile approach, allowing to best handle overall assessment timelines, and further streamline processes under an enhanced reliance framework.
- Focus on efficiency, regulatory alignment, and stakeholder trust.
- Continue to monitor and assess trends to improve the assessment process.
- Continued collaboration essential for successful implementation.

Q and A

Post your questions in the chat

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Thank you for participating to this webinar

The recording will be posted on our webpages

Contact our team:
diagnostics@who.int

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