Launch of WHO Prequalification of Medical Devices

Quality-assured medical devices for better health outcomes

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Housekeeping rules

- All microphones muted
- Webinar being recorded
- Slides and recording will be posted on WHO's website
- Q&A : Use of Q&A function

Webinar outline

1. Introduction to Prequalification of MDs
2. Contraceptive devices: transition from UNFPA and way forward
3. PQMD: Product dossier assessment and labelling review
4. PQMD: Site inspection
5. Q&A

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Welcoming remarks

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1. Introduction to prequalification of medical devices

A Major Milestone for WHO Prequalification

WHO expands prequalification to medical devices

Initial scope:

- Male latex condoms
- Female condoms
- Intrauterine devices (IUDs)
- CAD software for TB screening (CAD-TB)
- Male circumcision devices

Why this matters

- Supports access to safe, quality-assured and effective medical devices
  - Strengthens procurement decisions
  - Promotes regulatory convergence
  - Supports countries and UN agencies in resource-limited settings

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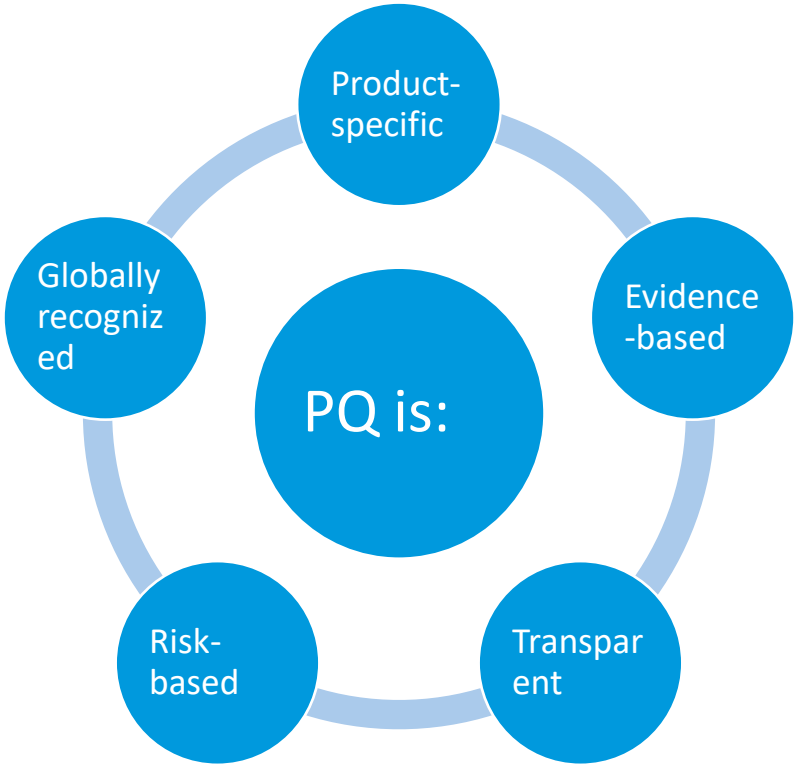
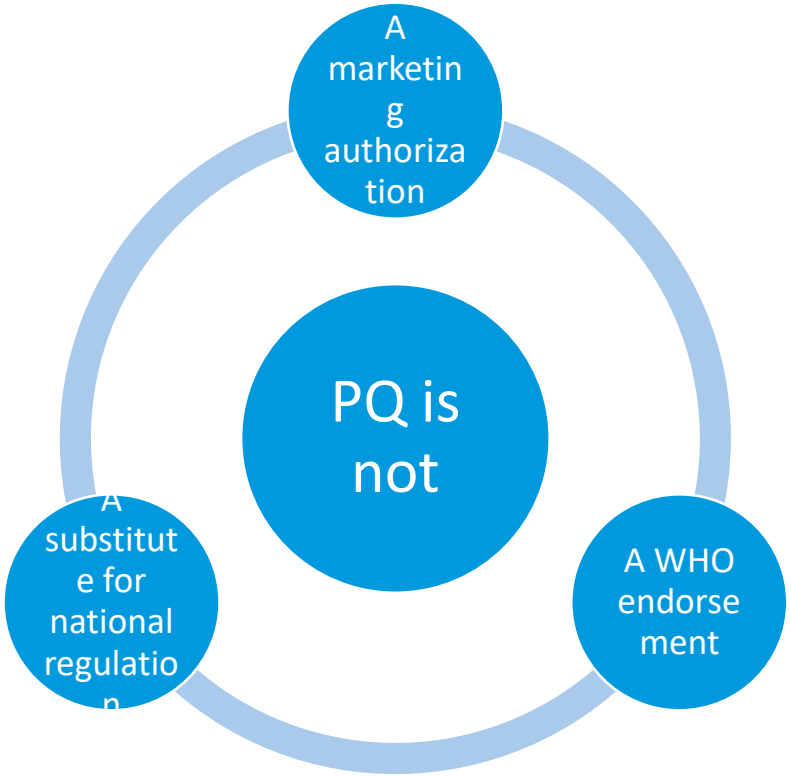
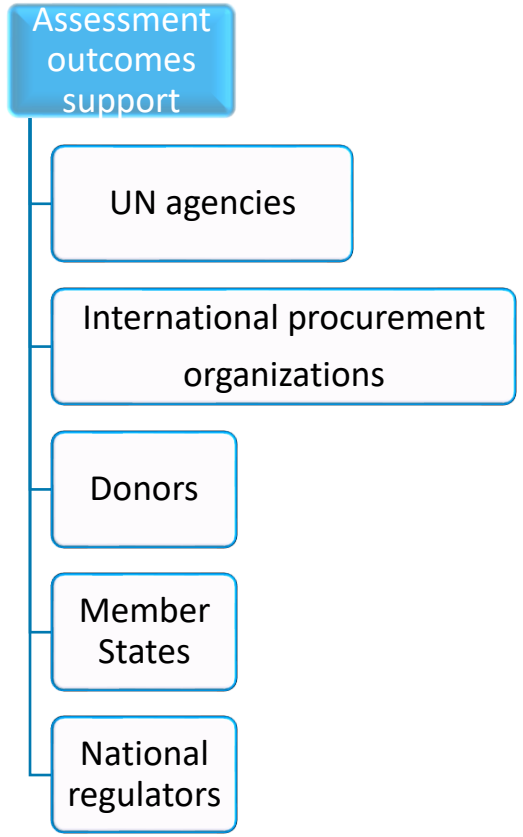
Prequalification of MDs: why now?

- Growing importance of medical devices in achieving health outcomes
- Increasing procurement of complex technologies, including software
- Continued need for trusted quality assurance mechanisms in resource-limited settings
- Building on 20+ years of success of WHO medicines, vaccines and IVD prequalification
- Supporting universal health coverage and access to quality-assured products

What is WHO Prequalification?







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Why WHO Prequalification Matters

WHO prequalification provides:

- Independent assessment
- Inspection of manufacturing quality systems
- Public assessment reports
- Post-listing oversight

Supporting:

- Procurement confidence
- Access to quality products
- Better use of donor resources
- Stronger supply chains

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Built on International Best Practices

The PQMD framework reflects globally recognized standards and approach:

TLCA, risk-based assessment

- IMDRF Essential Principles
- ISO 13485 Quality Management Systems
- ISO 14971 Risk Management

Reliance on recognized regulatory assessments

Goal: **Global convergence, not duplication**

WHO PQMD Assessment Pathways

Full assessment

- Full product dossier
- Manufacturing site inspection
- Labelling review

Abridged assessment

- Available for selected products already assessed by recognized regulatory authorities
- Benefits:
  - Avoid duplication
  - More efficient review
  - Continued focus on WHO-specific considerations

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PQ vs RRA approvals

Common elements

- Risk-based assessment of the product
- Review of safety, performance and quality evidence
- Assessment of manufacturer quality management systems (e.g. ISO 13485)
- Lifecycle oversight, including management of reportable changes

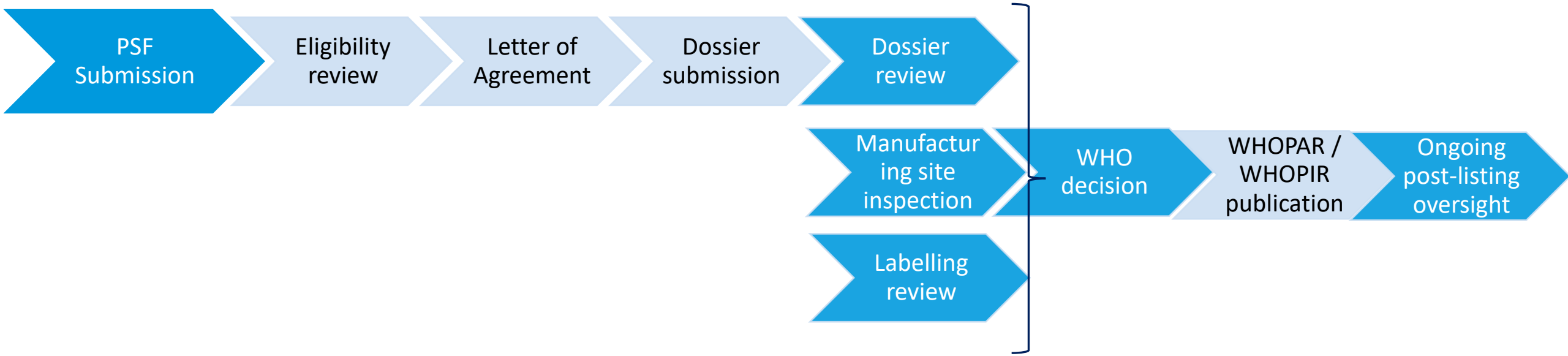
What is different?

- Supports global procurement decisions rather than market authorization
- Focus on suitability for WHO priority settings and resource-limited environments
- Outcomes support UN agencies, global health procurers, donors and Member States
- Does not replace national regulatory requirements or approvals

Abridged assessment: RRAs

Recognized Regulatory Authority	MD Risk classes undergoing stringent assessment
Therapeutic Goods Administration, Australia	Class IIb and Class III
Health Canada	Class III and Class IV
Notified bodies designated by European Union Member States or other countries under specific agreement	Class III (MDD)* Class IIb and Class III (MDR)
Ministry of Health, Labour and Welfare, Japan	Class III and Class IV
Singapore Health Sciences Authority	Class C and Class D
Medicines and Healthcare products Regulatory Agency, United Kingdom (UKCA)	Class III
Food and Drug Administration of the United States of America	Class II and Class III

The prequalification process: Overview



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What Does WHO Assess – Product Dossier Review

WHO reviews evidence supporting:

- Product design
- Safety
- Performance
- Intended use
- Risk management
- Suitability for intended settings

Focus

- "Does the evidence support the manufacturer's claims?"

Manufacturing Site Inspection

Inspection objectives

Assessment of:

- ISO 13485 implementation
- Manufacturing controls
- Supplier controls
- CAPA systems
- Risk management
- Post-market processes

Key message

- Quality products require quality systems.

Fees for PQ of medical devices

Year	Full prequalification assessment	Abridged prequalification assessment	Change assessment	Annual fee
2026	18 700 US$ per product	8 800 US$ per product	3 300 US$ per application	4 440 US$ per product
2027	20 570 US$ per product	9 680 US$ per product	3 630 US$ per application	4 840 US$ per product

Timelines for assessment

Assessment Type	WHO Target Review Time
Full Assessment	**270** calendar days

DOSSIER REVIEW

90d review

60d CAP1 review

60d CAP2 review

60d Amendments Review

SITE INSPECTION

30d Stage 1 Review

30d Additional Information Review

30d Inspection Report

30d CAP Review

LABELLING REVIEW

60d Review

30d Revised Labelling Review

Up to 180d Stage 2 Scheduling Window

▼

✅ DECISION & LISTING
10 DAYS

Timelines for assessment

Assessment Type	WHO Target Review Time
Abridged Assessment	**100** calendar days

DOSSIER REVIEW

60d review

30d CAP/Amendments Review

SITE INSPECTION

30d Information Package Review

30d Additional Information Review

30d Inspection Report

30d CAP Review

LABELLING REVIEW

30d Review

30d Revised Labelling Review

Up to 180d Stage 2 Scheduling Window

▼

✅ DECISION & LISTING
10 DAYS

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Timelines for assessment

Post-Prequalification Reportable Change Assessment

SCREENING

30d Change Request Screening
30d Screening of Additional Information

APPLICANT RESPONSES

30d Additional Information Submission

30d Response to R1 Review

30d Final Response to R2 Review

WHO ASSESSMENT

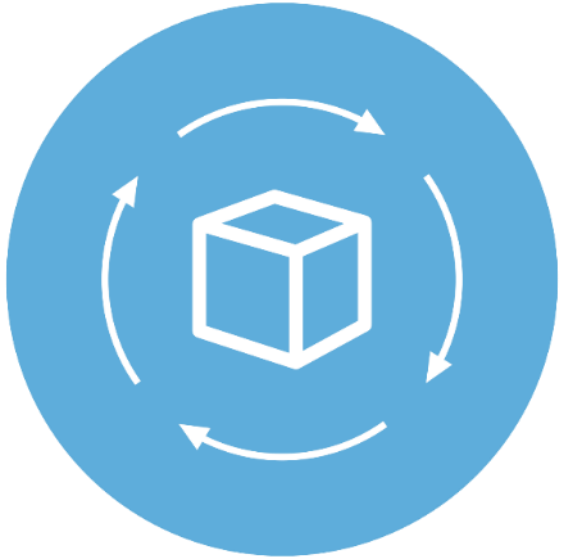
60d R1 Review

60d R2 Review

60d R3 Review (if applicable)

Maintaining PQ Listing: obligations

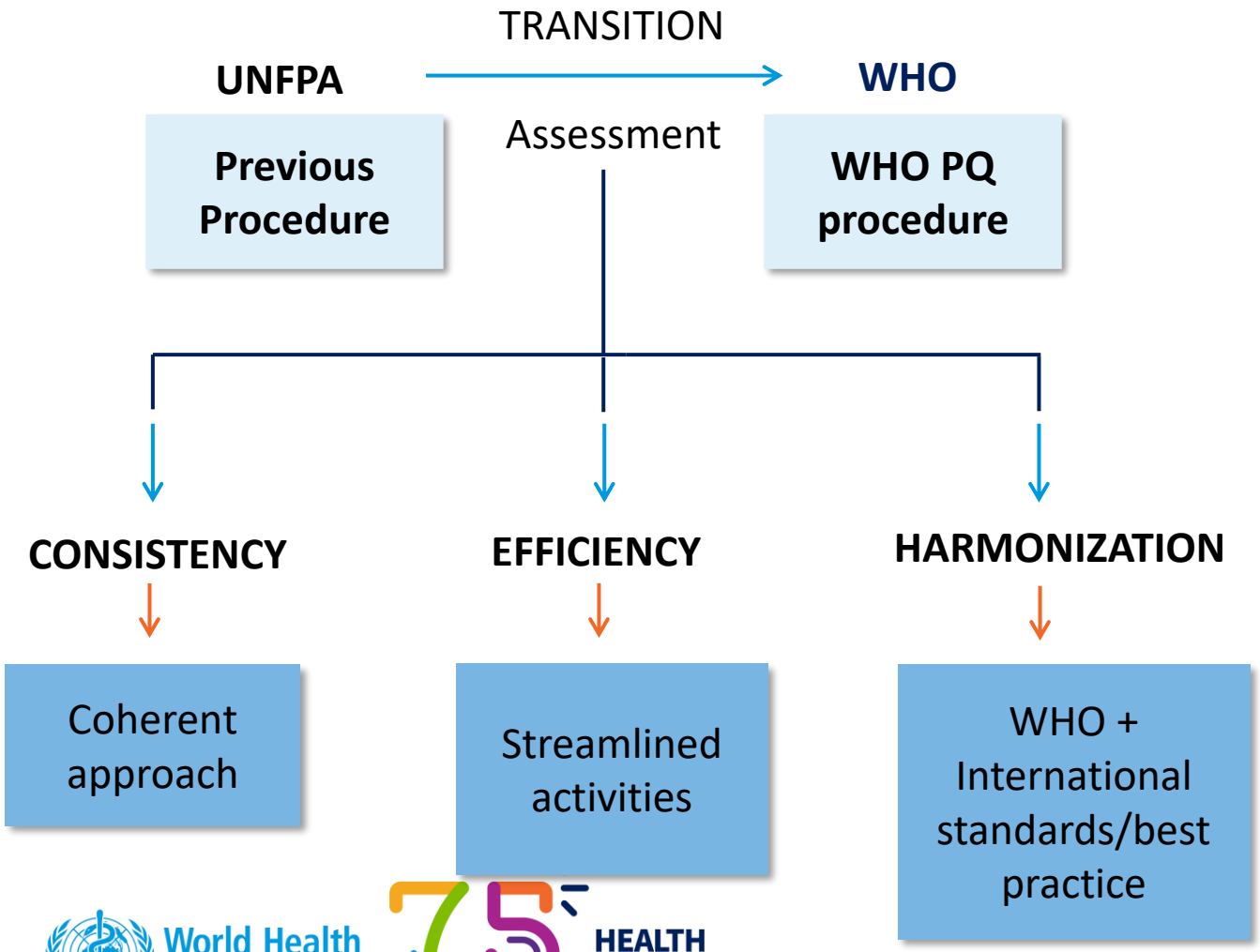
- Commitments to PQ
- Change reporting
- Post market surveillance obligations
- Ongoing compliance with TSS/TRS
- Routine/for cause site inspections
- Maintain quality system compliance
- Payment of the annual fee



Throughout product lifecycle

2. Contraceptive devices: transition from UNFPA and way forward

Transition of prequalification of contraceptive devices to WHO PQ



Background: Objective to centralize and harmonize the procedure for prequalification by transferring responsibility for contraceptive devices to WHO Prequalification from UNFPA

Aim: to ensure a consistent, transparent and efficient approach to medical device assessment

- Lifecycle management
- Focus on needs in RLS
- Regulatory convergence and reliance

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Transitional arrangements for UNFPA-Listed devices

WHO will acknowledge contraceptive devices currently included in UNFPA prequalification lists during a transitional period ending: 30 September 2030

Products will be acknowledged during the transition on the condition that manufacturers:

① Sign & Comply

Sign the applicable WHO Letter of Agreement indicating that they agree with the applicable conditions in the WHO Prequalification Procedure for Medical Devices.

② Report Changes

Notify WHO of reportable changes in accordance with WHO requirements.

③ Maintain Compliance

Fulfil all WHO post-qualification obligations throughout the transition period.

④ Apply for WHO PQ

Agree to submit a new WHO prequalification application by 30 September 2028 following the new procedure.

Important: No WHO application by September 2028 → acknowledgement ends

Changes to note for manufacturers of UNFPA-Listed devices

Main Differences for Existing UNFPA PQ Manufacturers
New post-PQ change management and reporting: Reportable changes to components, manufacturing processes or the QMS must be reported to and approved by WHO prior to implementation.
Annual fee: Annual fee is payable for each product that has been listed on WHO's list of PQ medical devices for ≥12 months.
Enhanced lifecycle oversight: Manufacturers must maintain PMS activities (WHO guidance), support routine and non-routine inspections, and demonstrate continued compliance with WHO prequalification requirements.
New application required under WHO PQ guidance and procedures by 30 September 2028: Applications must follow the new WHO process, including pre-submission eligibility review, product dossier compilation according to PQDx_468, and assessment under either the Full or Abridged prequalification pathway.

Next steps for UNFPA-listed manufacturers

1. Review new WHO procedure
2. Review conditions in WHO's Letter of Agreement and sign/return within 30 days of receipt
3. Ensure ongoing compliance with WHO post qualification obligations
4. Prepare a new WHO PQ application
5. Submit by 30 September 2028

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Applications previously submitted to UNFPA for assessment

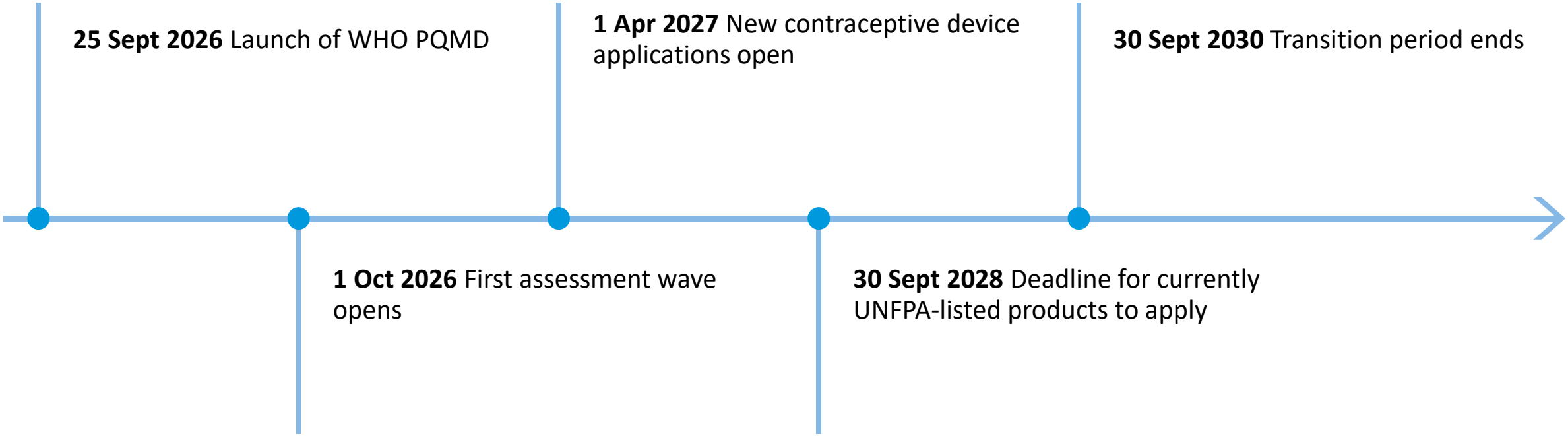
Steps for applying to WHO Prequalification :

1. Manufacturers to submit a new application form
2. If eligible for review and accepted, you will be requested to submit
   - Evidence of previous fees paid to UNFPA
   - A new product dossier following WHO prequalification instructions. The TRS requirements published by WHO/UNFPA related to product specifications, stability studies are still applicable
3. WHO will conduct dossier assessment, labelling review and manufacturing site inspection and send a response for each component
4. WHO will reach WHO prequalification decision and if accepted, publish the product in the WHO list of PQ'd medical devices

Changes from UNFPA application

1. IMDRF Table of Contents dossier structure instead of the previous STED-based submission format
2. Product sampling/testing is no longer a component of the assessment. Instead the new WHO PQ procedure consists of product dossier review, manufacturing site inspection and labelling review
3. Assessment pathways and timelines: Introduction of a pre-submission eligibility review and two assessment pathways (Full or Abridged prequalification assessment)
4. Instructions/Guidance: Mandatory compliance with WHO guidance and technical specifications

Looking ahead



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Transitional Scenarios for Manufacturers

Scenario	Pathway
Currently listed by UNFPA	WHO acknowledgement + transition to WHO PQ
Submitted to UNFPA but not yet listed	Eligible from 1 Oct 2026
CAD-TB products	Eligible from 1 Oct 2026
Male circumcision devices	Eligible from 1 Oct 2026
New contraceptive device submissions	Eligible from 1 Apr 2027
Changes to UNFPA-listed products	Submit to WHO from 1 Oct 2026

Fee benefit

WHO assessment fees waived for products already submitted to UNFPA and fully paid.

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Transitional Scenarios for Manufacturers

Scenario	Pathway
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Webinar on changes in Oct 2026

Fee benefit

WHO assessment fees waived for products already submitted to UNFPA and fully paid.

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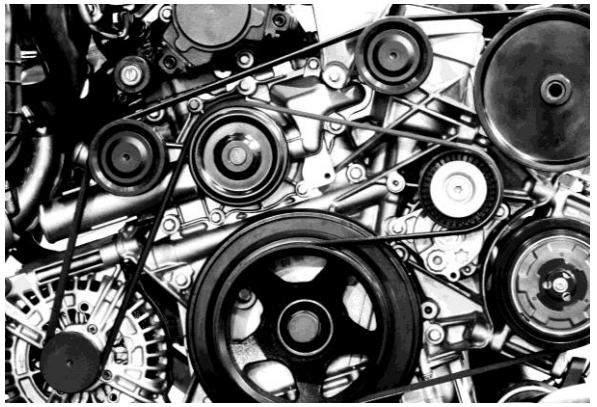
3. PQMD: Product Dossier assessment and Labelling review

Purpose of a product dossier



- Clearly identifies the product under assessment
  - product number/s, version, different configurations
- Shows how the device is designed, developed, validated, and manufactured
  - covers complete product lifecycle
- A collection of existing technical documentation and records to provide evidence that a MD conforms to quality, safety and performance principles
- WHO reviews the product dossier with the purpose of:
  - Assessing if the device's safety, performance, benefit-risk profile, and conformity with the applicable requirements has been demonstrated
  - Determining if the manufacturer’s QMS is sufficient to warrant a WHO site inspection

Dossier Assessment

Technical review of manufacturer's evidence of product design, safety & performance

- Assessment conducted by subject matter experts
  - Analysis of the relevance of the data in the dossier and if performance claims are based on appropriate evidence
  - Review completeness, accuracy and consistency of data from design, validation, manufacture, QC and release
  - Evaluate if the risks associated with the product identified by the manufacturer and appropriate mitigation measures have been implemented
  - Evaluate if there is a functional QMS implemented
  - Evaluate if WHO requirements are met
  - Determine if the manufacturer has considered use in likely settings of use in WHO Member States

Preparing for Dossier Assessment

Guidance documents on our website

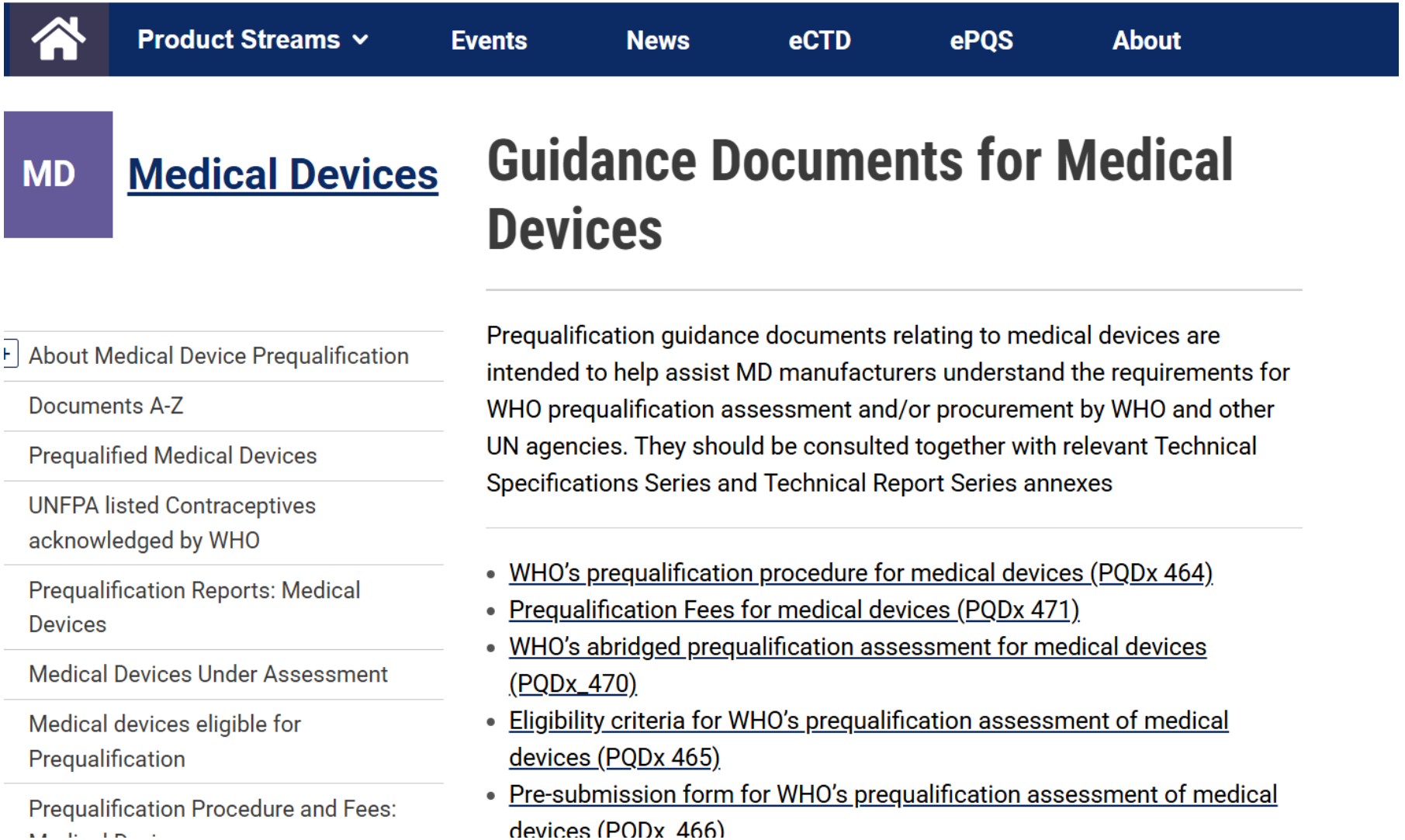
- https://extranet.who.int/prequal/medical-devices/guidance-documents-medical-devices

Types of guidance documents

General guidance: intended to assist MD manufactures to understand the process for PQ

Specific guidance: intended to assist in understanding requirements

Aim: prepare a ready for review dossier

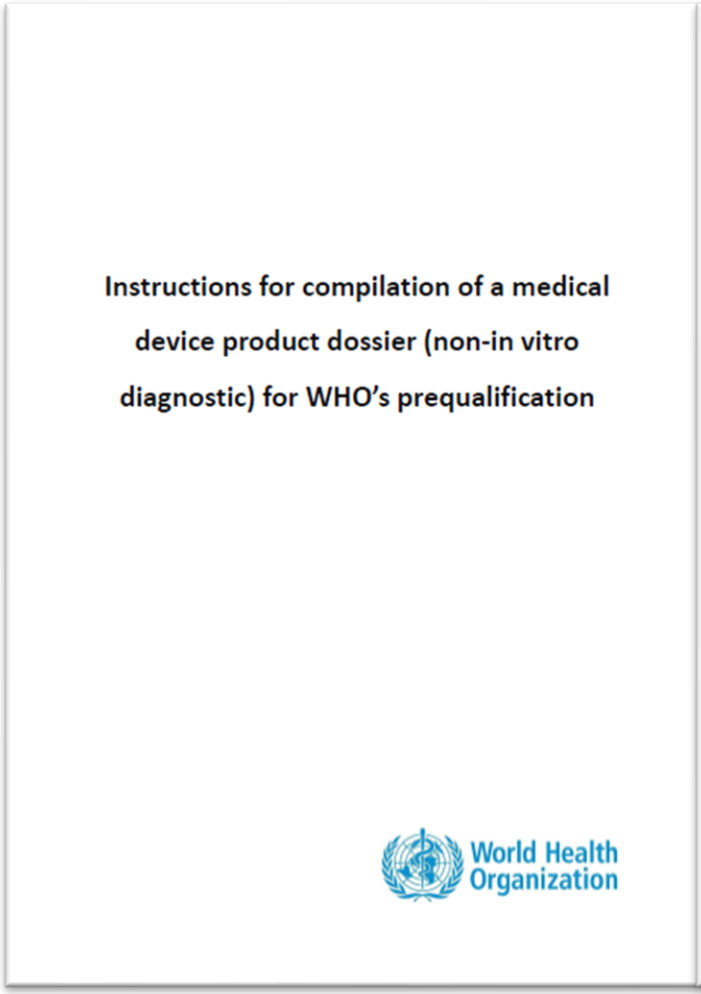


PQ instructions for compiling a dossier to demonstrate safety, performance, benefit-risk profile

Key document when preparing a product dossier

- Follows **IMDRF Table of Contents** format
- Requirements for full/abridged dossier
- Outlines what information is required for each section
- Applies to all eligible MDs: i.e. some sections may not be applicable to your MD

Dossier Instructions (PQDx_468)



Instructions for compilation of a medical device product dossier (non-in vitro diagnostic) for WHO's prequalification

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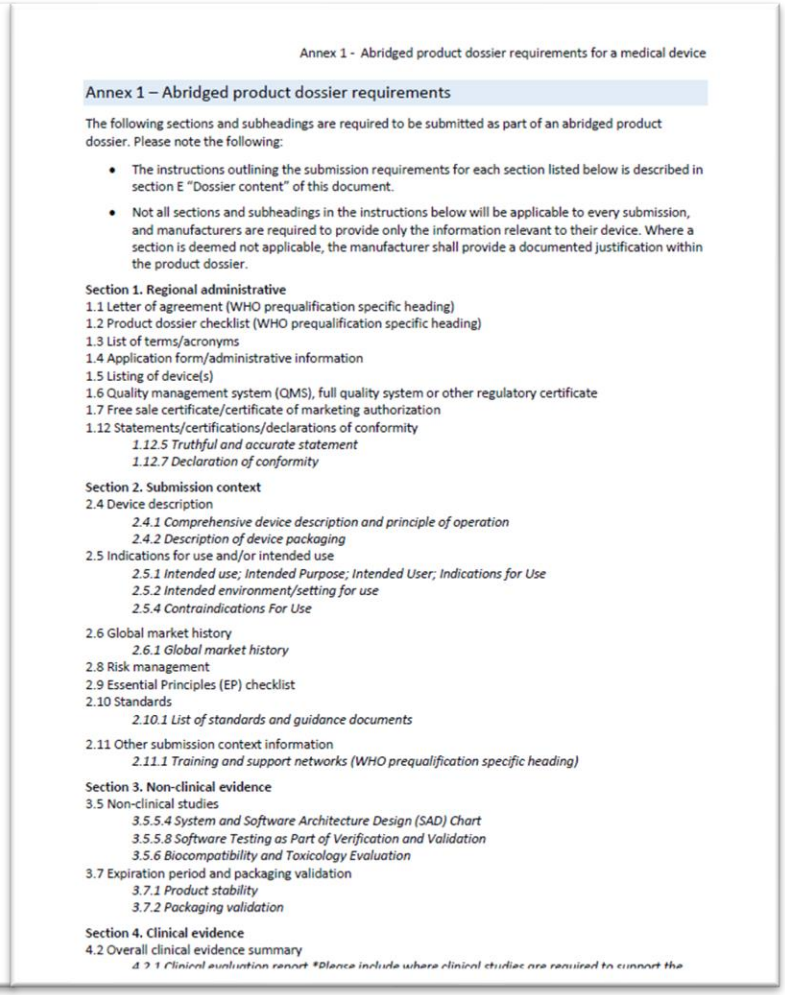
Annex 1 of dossier instructions outline requirements for an abridged dossier



Annex 1 - Abridged product dossier requirements for a medical device

Annex 1 – Abridged product dossier requirements

The following sections and subheadings are required to be submitted as part of an abridged product dossier. Please note the following:

- The instructions outlining the submission requirements for each section listed below is described in section E "Dossier content" of this document.
- Not all sections and subheadings in the instructions below will be applicable to every submission, and manufacturers are required to provide only the information relevant to their device. Where a section is deemed not applicable, the manufacturer shall provide a documented justification within the product dossier.

Section 1. Regional administrative
1.1 Letter of agreement (WHO prequalification specific heading)
1.2 Product dossier checklist (WHO prequalification specific heading)
1.3 List of terms/acronyms
1.4 Application form/administrative information
1.5 Listing of device(s)
1.6 Quality management system (QMS), full quality system or other regulatory certificate
1.7 Free sale certificate/certificate of marketing authorization
1.12 Statements/certifications/declarations of conformity
1.12.5 Truthful and accurate statement
1.12.7 Declaration of conformity

Section 2. Submission context
2.4 Device description
2.4.1 Comprehensive device description and principle of operation
2.4.2 Description of device packaging
2.5 Indications for use and/or intended use
2.5.1 Intended use; Intended Purpose; Intended User; Indications for Use
2.5.2 Intended environment/setting for use
2.5.4 Contraindications For Use
2.6 Global market history
2.6.1 Global market history
2.8 Risk management
2.9 Essential Principles (EP) checklist
2.10 Standards
2.10.1 List of standards and guidance documents
2.11 Other submission context information
2.11.1 Training and support networks (WHO prequalification specific heading)

Section 3. Non-clinical evidence
3.5 Non-clinical studies
3.5.5.4 System and Software Architecture Design (SAD) Chart
3.5.5.8 Software Testing as Part of Verification and Validation
3.5.6 Biocompatibility and Toxicology Evaluation
3.7 Expiration period and packaging validation
3.7.1 Product stability
3.7.2 Packaging validation

Section 4. Clinical evidence
4.2 Overall clinical evidence summary
*4.2.1 Clinical evaluation report *Please include where clinical studies are required to support the*

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WHO TSS/TRS and Framework documents for MDs

Computer-aided detection software for TB Screening

WHO policy recommendations published in 2021

Technical specifications (TSS) published in 2025 sets out the performance evaluation criteria for meeting PQ requirements

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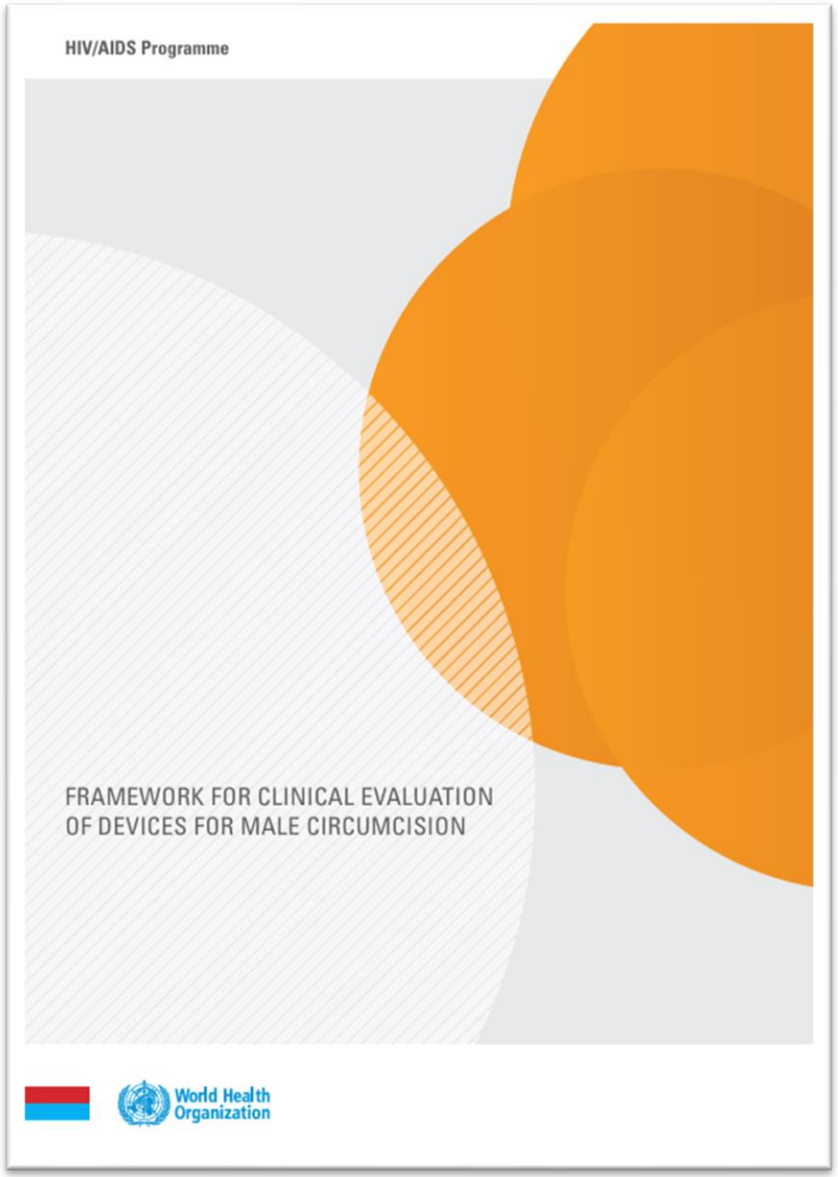
WHO TSS/TRS and MCD Framework for MDs

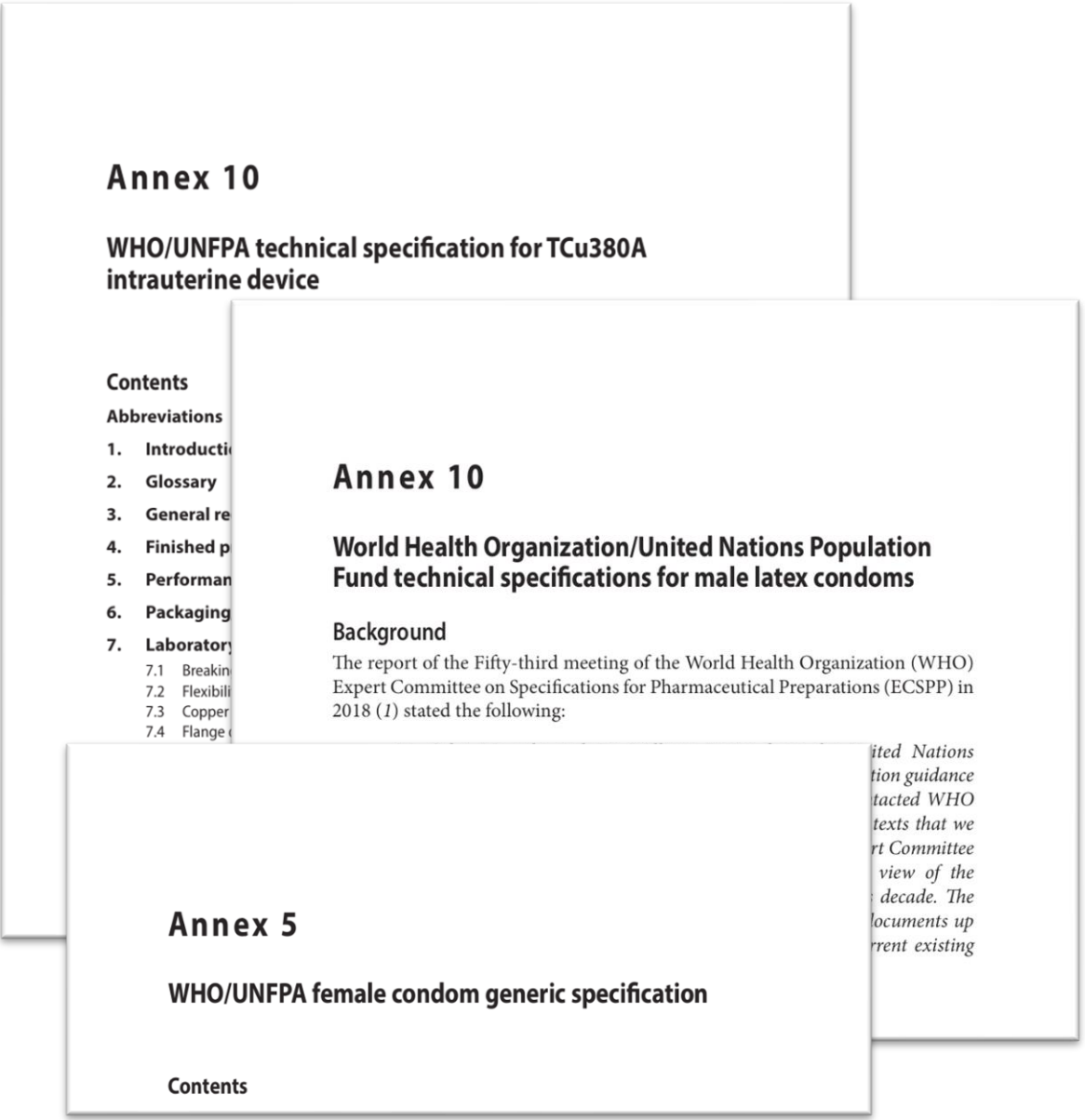


PQ of male circumcision devices (MCDs)

From 2026 onward, PQ of MCDs to be integrated into Medical Devices Procedure

Oversight from the Technical Advisory Group on Innovations in Male Circumcision remains an integral step

WHO TSS/TRS and MCD Framework for MDs


Annex 10

WHO/UNFPA technical specification for TCu380A intrauterine device

Contents

Abbreviations

1. Introducti
2. Glossary
3. General re
4. Finished p
5. Performan
6. Packaging
7. Laboratory

7.1 Breakin
7.2 Flexibili
7.3 Copper
7.4 Flange

Annex 10

World Health Organization/United Nations Population Fund technical specifications for male latex condoms

Background

The report of the Fifty-third meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in 2018 (*1*) stated the following:

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Annex 5

WHO/UNFPA female condom generic specification

Contents

WHO Technical Report Series requirements for contraceptives

WHO TRS 1025, 2020: Annex 10 World Health Organization/United Nations Population Fund technical specifications for male latex condoms.

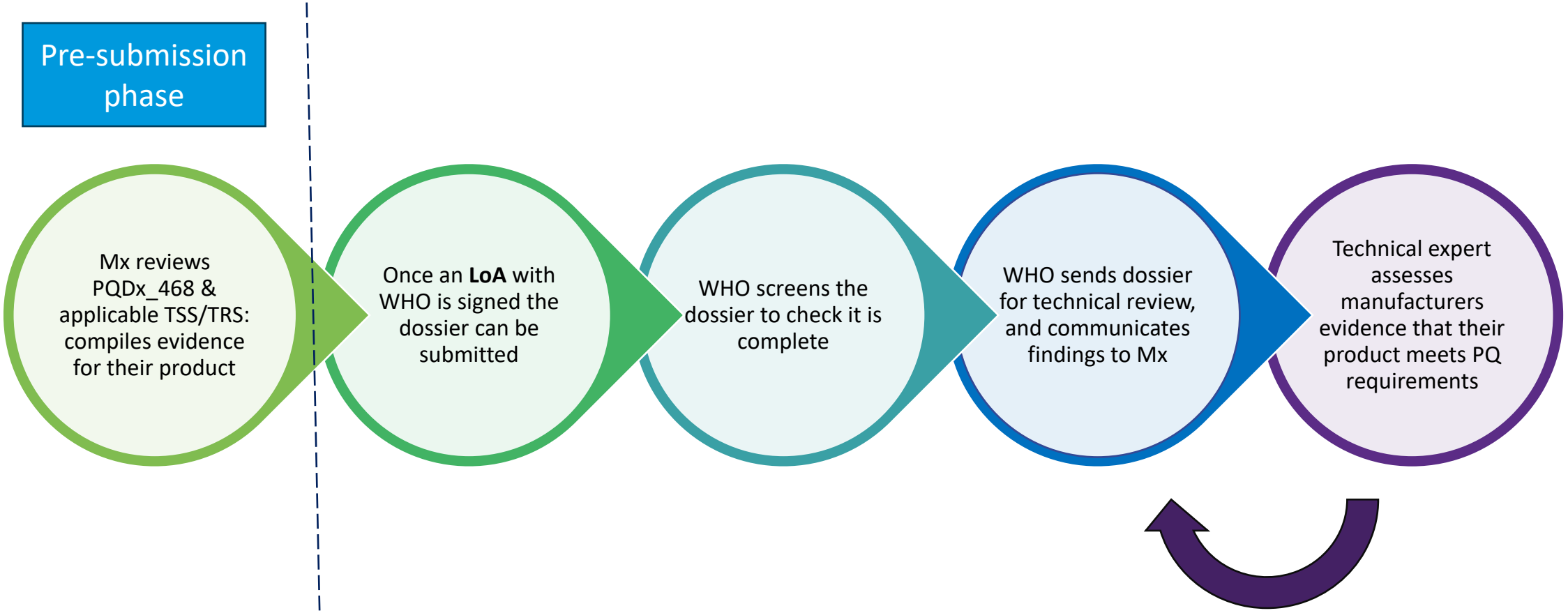
WHO TRS 1044, 2022: Annex 9 WHO/UNFPA guidance on natural rubber latex male condom stability studies **and Annex 10** WHO/UNFPA technical specification for TCu380A intrauterine device.

WHO TRS 1052, 2024: Annex 5 WHO/UNFPA female condom generic specification.

WHO TRS 1033, 2021: Annex 5 World Health Organization/United Nations Population Fund Recommendations for condom storage and shipping temperatures.

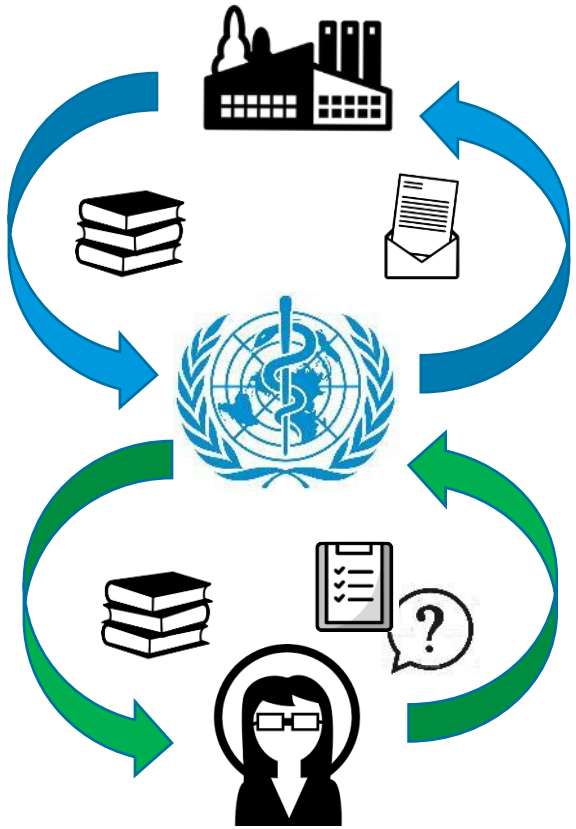
WHO TRS 1067, 2025: Annex 6 World Health Organization/United Nations Population Fund specifications for personal lubricants.

Assessment of a product dossier

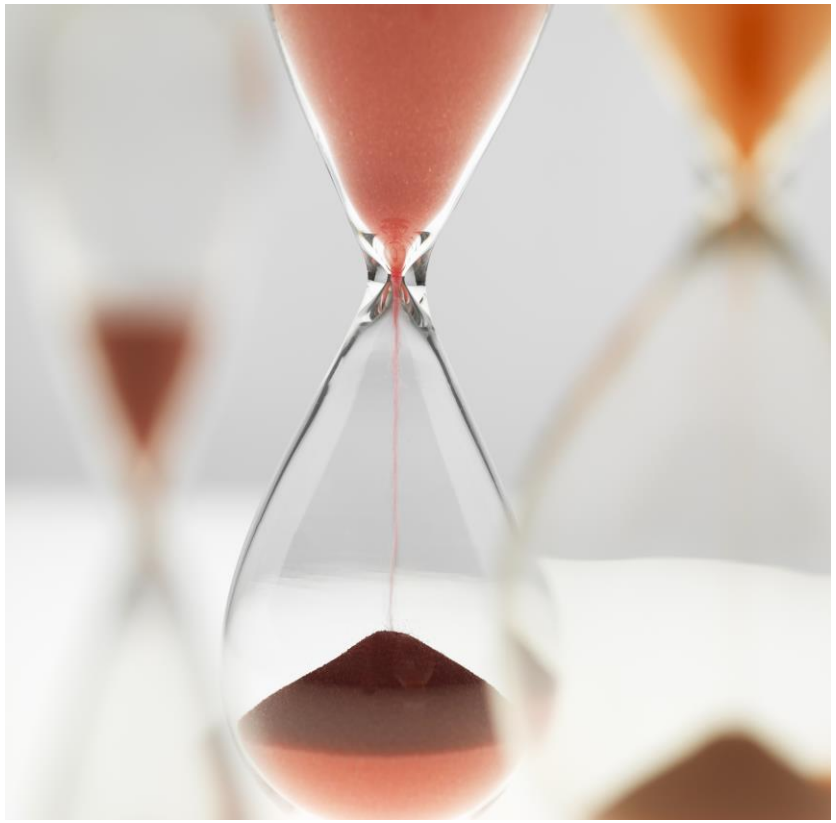


Dossier Review Process

- Dossier sent to subject matter expert for technical review
- Expert provides completed dossier review report and notes any deficiencies in the dossier
- WHO prepares dossier review letter for manufacturer requesting additional information and/or clarifications
- Manufacturer submits a corrective action plan (CAP) – Round 1
- Expert reviews new information and amends the dossier review report for WHO
- Further clarification by the manufacturer (CAP) may be required to address any additional requests – Round 2



Invest time to prepare a detailed product dossier



- Clearly address the PQ requirements
  - General (PQDx_468) & product specific (TSS, TRS, MCD Framework)
  - Clarify with the PQ team on the pre-submission call
- A dossier that lacks detail will lead to a lot of requests for clarification
  - Only 2 opportunities to supplement the product dossier during technical assessment
  - 1 month to provide a corrective action plan
  - Maximum of 6 months time extension available during assessment phase

Labelling Review

All labelling is reviewed (labels, IFU, healthcare professional labelling, patient labelling, promotional materials)

Verification that claims made in the labelling are supported by evidence submitted in the technical documentation (dossier)

Ensure labelling follows international harmonized regulatory best practice

Resources for applicants

All guidance documents, forms and instructions are available on the PQ MD website https://extranet.who.int/prequal/medical-devices

Prequalification of medical devices website	Prequalification procedure for MDs	Eligibility criteria	Timelines guidance	Fees guidance
Application forms	Report changes guidance	Technical report series for contraceptive devices	Technical specification series for CAD-TB	Pre-submission meetings

Contact team at diagnostics@who.int with questions

4. PQMD: Site inspection

Ensuring quality and compliance in medical device manufacturing

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Objectives and Scope of Inspections

Inspection Objectives

- **verify compliance** with WHO and international guidelines and standards
- **verify data** supporting product claims

Scope of Inspections

Manufacturing sites, emphasizing the robustness and effectiveness of the implemented **QMS**.

Inspection Criteria

- ISO 13485
- WHO-specific requirements
- Company's own QMS.

Focus on Resource-Limited Settings

Unique challenges specific to resource-limited environments requiring tailored compliance.

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Inspection Categories and Focus Areas

Initial Inspections

Focus on **QMS implementation** and accuracy of **dossier data**

Follow-Up Inspections

Verify **CAPA implementation and effectiveness**.

Routine Inspections

Verify **ongoing compliance**

For-Cause Inspections

Address **specific issues**

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Initiation of Inspection

Inspection Triggers

- **New** applications, new sites
- **Changes** (e.g., to processes, infrastructure)
- **Post-market signals**

Trigger Assessment

Risk-based evaluation determines inspection necessity and modality

Stage 1 documentation review

Offline review of high-level documentation to ensure **readiness** of the site and inform **scope**

Scope and Objectives

To prepare for a thorough inspection process

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Scheduling of Inspection

Timely Scheduling Requirement

Three months after the inspection need is identified to ensure **timely decision**.

Logistical Factors

Location, staff availability, and production schedules **influence the planning** of inspection dates and times.

Effective communication between Inspection Services and manufacturers is vital for finalizing inspection schedules and preparing resources.

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Inspection Team Composition

WHO Lead Inspector

To ensure **adherence to WHO procedures**.

Co-inspector/s

To bring the necessary **technical expertise**.

Observers

Members of the NRA may observe the inspection for **transparency** and to **build capacity**.

Legal context

- **Confidentiality agreements**
- **Declarations of conflicts of interest**.

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On-site Activities

Opening meeting

Facility tour

up to one full day, to observe production and QC activities

Quality Management System Assessment

Any applicable areas **selected based on risk**

Data Verification and Traceability

Data supporting product dossiers verified for **accuracy and traceability**

Daily debriefings

Any findings are discussed to ensure they are **true and accurate**.

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Inspection Report

Report Compilation and Delivery

Approved by inspection team, peer-reviewed internally, and sent to the manufacturer within **30 calendar days**

Regulatory Use of Report

The inspection report **guides prequalification decisions** and further actions

Findings and Non-conformities

The report outlines inspection findings, highlights **non-conformities**, and indicates their **severity rating**

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CAPA Response

Timely Submission Requirement

CAPA response within **30 calendar days** after receiving the inspection report

Addressing Inspection Findings

The CAPA response should outline **root-cause** analyses as well as **CAPA**

CAPA Evaluation

Inspection Services evaluate CAPA responses to ensure **adequacy and effectiveness**

Importance of CAPA

Essential for **compliance and progression** in the prequalification process.

Finalization and Consequences of Noncompliance

Timely Closure

Within six months to ensure **timely access** to quality-assured medical products.

Compliance Reporting

WHO Public Inspection Report for **transparency and trust**.

Consequences of Noncompliance

Noncompliant sites face **Notices of Concern** that may lead to product suspension or delisting

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Key takeaways

Less breadth, more depth

WHO inspections do not aim to be comprehensive but to **thoroughly assess key aspects** of the QMS relevant to the **specific context** of use of prequalified medical devices.

Transparent and objective process

The inspection process is guided by **published procedures** and guidelines followed by **trained inspectors** to ensure timely delivery of quality inspection outputs.

Risk-based approach

The scheduling of inspections, their scope, duration, objective, closure, and follow-up are all supported by **risk analyses** to maintain process effectiveness.

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Thank you!

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Key takeaway messages

- WHO has launched prequalification of medical devices.
- Initial scope covers contraceptive devices, CAD-TB and male circumcision devices.
- Applications open 1 October 2026.
- Reliance and abridged pathways reduce duplication.
- WHO will support manufacturers throughout implementation and transition.
- This is an important step toward greater access to quality-assured medical devices globally.

5. Q&A

Please use the Q&A function

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