Publication of updated Guidance and Application Form for Reportable changes to WHO prequalified and emergency use listed in vitro diagnostics

WHO is pleased to announce the publication of the **revised guidance** **and** **application form** for reporting changes to WHO prequalified and emergency use listed in vitro diagnostic (IVD) products. These updates are part of WHO's continued commitment to ensuring the quality, safety and performance of prequalified IVDs throughout their lifecycle.

Key Updates

Changes to WHO prequalified and emergency use listed in vitro diagnostics—such as modifications to components, manufacturing processes, or quality management systems—must be reported to WHO and approved prior to implementation. The newly released guidance introduces several improvements to streamline the review process and support manufacturers in meeting reporting requirements:

- **Changes are now categorized by impact level**:
  - *Medium to High Impact changes* will continue to undergo a full technical review, following the same evaluation process currently used by the WHO PQ team.
  - *Low Impact changes* will be subject to a risk-based categorization check, requiring reduced documentation. If appropriately categorized, these changes will be approved upon screening.
- **Updated application form** has been aligned with the new categorization system and include additional instructions and checklists.
- A **list of required documents** by change category is included to promote transparency and consistency in submissions.

These updates aim to enhance regulatory clarity, minimize delays in implementation, and reinforce WHO's commitment to ensuring access to quality-assured products in line with global health priorities.

Implementation

WHO is implementing a **4-week transition period**. During this time, manufacturers may submit change notifications using either the previous or the updated version of the guidance and forms.

The **new guidance** **and** **application form** **will become mandatory as of [1 June 2025]**. After this date, only submissions using the revised versions will be accepted. To allow stakeholders time to adapt to the new process.

Next Steps and Stakeholder Support

1. **Access the New Documents**:
   The updated guidance and forms are available on the WHO website here: Post-prequalification Procedures and Fees: Prequalified IVDs | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)
2. **Register for the Informational Webinar**:
   WHO will host a webinar on **[19 May 2025]** to introduce the changes, walk through the new forms, and respond to stakeholder questions. Further details and registration information will be shared shortly.