Quality Management Systems for non-laboratory settings – Toolkit

Regulation of IVDs: selection and national registration of RDTs marketing authorization

World Health Organization

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Access to good quality, affordable, and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations

A robust national regulatory system for In Vitro Diagnostics (IVDs), including RDTs, is essential for safeguarding public health. It ensures that only safe, effective, and quality-assured diagnostic products are introduced, used, and maintained within the health system. Regulation should span the entire lifecycle of IVDs, from product selection to marketing authorization, post-market surveillance, and ongoing performance monitoring.

An effective IVDs regulatory system serves several critical functions:

- **Protecting public health** by ensuring that diagnostic tools are quality-assured: accurate, reliable, and safe to use.
- **Promoting transparency and accountability** in the evaluation, selection, registration, and distribution of diagnostic products.
- **Facilitating rapid response** to safety concerns or performance issues through structured post-market surveillance (PMS) systems.
- **Supporting broader health system goals**, including progress toward Universal Health Coverage (UHC) and the delivery of high-quality care.

At the national level, the regulation of IVDs, especially rapid diagnostic tests (RDTs) – relies on four interdependent pillars (Read more: Guidance for procurement of in vitro diagnostics and related laboratory items and equipment):

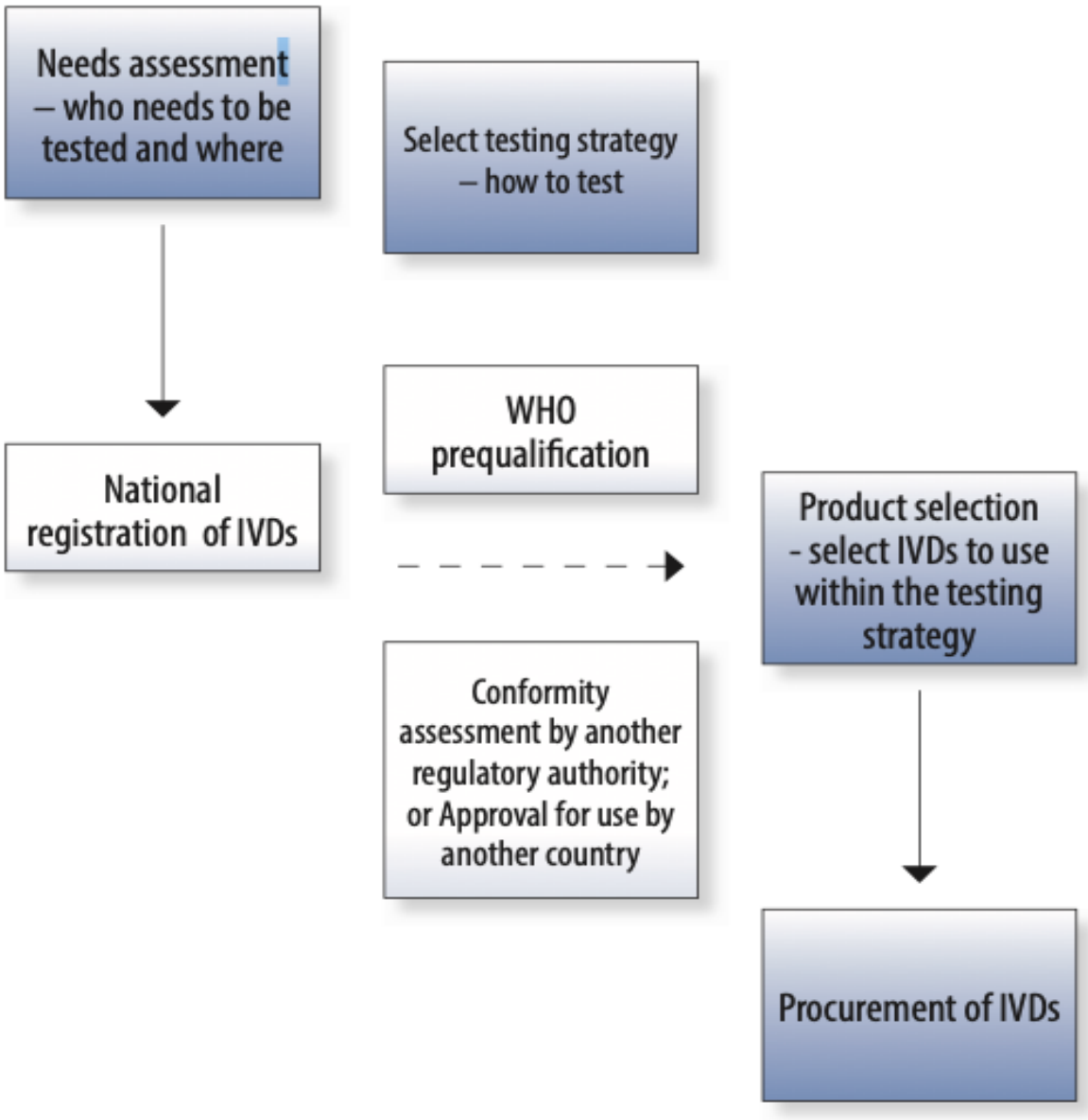
- Develop of national Essential Diagnostic list (EDL): Countries should assess their needs and develop tailored EDL which aim to Establish evidence-based standards for choosing appropriate diagnostics based on disease burden, epidemiology, and health system needs and resources at all stage of the health pyramid (who needs to be tested, where, and using which testing strategy). (Read more: The selection and use of essential in vitro diagnostics: report of the fourth meeting of the WHO
- Strategic Advisory Group of Experts on In Vitro Diagnostics, 2022)
- Validate assays selection Criteria – for each disease and each setting (laboratory and non-laboratory settings) country should select assays based on quality and product (performances and operational) specifications and cost (see figure 1).

National authorities and technical experts should be consulted to ensure that any proposed selection of specific products is harmonized with the relevant national policies and national testing strategies.

- National registration and market authorization – countries should implement structured and transparent national registration / market authorization systems and maintain a clear and updated list of approved IVDs through a structured product evaluation and registration process.
- Post-market surveillance (PMS) – Monitoring the ongoing use of diagnostics to detect and address issues related to performance, safety, or user error.

These areas of work must be supported by a comprehensive national regulatory framework, overseen by a competent authority, such as a National Regulatory Authority (NRA) or the Ministry of Health. This framework should be harmonized with international standards, including those set by WHO Prequalification department or other recognized regulatory authorities, to ensure global best practices are upheld. Building and maintaining such a regulatory system is not only vital for ensuring the quality of diagnostics but also foundational for trust, efficiency, and resilience in national health systems.

Figure 1: Product selection procedure:



The national assessment of applications for registration of IVDs is a key regulatory process that enables national regulatory authorities to evaluate and monitor the quality, safety and performance of IVDs.

It is important to note that for **some diseases** the diagnostic is based on a **testing strategy composed of several assays** (example for HIV testing for people >18 months old: read more: Consolidated guidelines on differentiated HIV testing services).

In these situations, it is crucial to ensure that each assay is selected in order to ensure appropriate testing algorithm performances. For HIV algorithm selection please refer to the WHO Toolkit to optimize HIV testing algorithms.

WHO prequalification of IVDs

The aim of WHO prequalification of in vitro diagnostics (IVDs) is to promote and facilitate access to safe, appropriate and affordable in vitro diagnostics of good quality in an equitable manner. The focus is on IVDs for priority diseases that are appropriate for use in resource-limited settings.

WHO IVD prequalification incorporates comprehensive assessment of individual IVDs through a standardized procedure, to determine whether the product meets WHO prequalification requirements. Assessment has three components:

- review of a product dossier
- laboratory evaluation of performance and operational characteristics
- manufacturing site(s) inspection

Following prequalification, post-market surveillance is undertaken. It includes reactive and proactive measures, through complaint reporting and post-shipment/pre-distribution lot testing. Post-qualification also includes mandatory manufacturer notification of changes to the product or the quality management system.

Read more: WHO Prequalification of medical products

WHO-collaborative registration procedure

Collaborative procedures have been developed and implemented with a view to accelerating the national registration and regulatory life-cycle of IVDs prequalified by WHO. Consideration of the outcomes/results of WHO prequalification dossier assessments, performance evaluations and manufacturing site inspections by NRAs during the national decision-making process is an example of a regulatory approach based on reliance. Such reliance on WHO prequalification outcomes/results contributes substantially to savings in regulatory resources and improvements in the quality of regulatory decisions, while retaining the prerogative of NRAs to conclude their assessment with sovereign decisions that reflect their own judgement of the risk–benefit balance in terms of their specific country situation and legislation.
Read more: Collaborative procedure between the WHO and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics

Additional useful tools for quantification:

The Procurement & Supply Management Toolbox is a comprehensive online platform developed by the WHO and its partners to support the effective management of health commodities, particularly in low-resource and emergency settings. Launched in 2007 by the WHO AIDS Medicines and Diagnostics Service (AMDS), it was created to improve access to practical tools for procurement and supply chain management. The toolbox provides a curated collection of validated tools, manuals, guidelines, and templates covering key functions such as procurement, stock management, forecasting, LMIS, and distribution.

Users can filter tools by health program (e.g., HIV, malaria, TB), product type (e.g., diagnostics, vaccines), language, and level of use (central, regional, facility). They can also build personalized toolkits, compare tools side by side, and access a downloadable offline version, ideal for field use where internet access is limited.

Tools are submitted and regularly updated by partners and reviewed based on objective criteria. While inclusion does not imply WHO endorsement, the PSM Toolbox remains a valuable resource for ensuring uninterrupted access to essential health products through efficient, sustainable supply systems.