ILF roundtable

# Rapid access to new technology and reaching the unreached

Tuesday, 24 July 2018, 18:00 – 21:30

Room F002-004, RAI Amsterdam, the Netherland

# Next steps

Outcomes of this meeting will form the basis of a statement on accelerated access to new diagnostic technologies.

The paper will be submitted for publication in a peer-reviewed journal, adding to other ILF publications in the area of diagnostics.

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VIEWPOINTS

## The Manufacturers' Perspective on World Health Organization Prequalification of In Vitro Diagnostics

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In vitro diagnostic devices (IVDs) help clinicians determine specific conditions, monitor therapeutic efficacy, and prevent drug resistance development. While stringent regulatory authorities (SRAs) regulate IVDs in most high-income countries, regulatory authorities in many low- and middle-income countries (LMICs) are nonexistent or do not enforce rigorous standards. In 2010, the World Health Organization established its Prequalification of In Vitro Diagnostics (PQDx) program to ensure "access to safe, appropriate and affordable" IVDs, especially in LMICs with little or no domestic regulatory frameworks, thereby reaching underserved populations. However, challenges in PQDx policies and procedures include an overloaded pipeline, timelines not publicly available, confusion about which products PQDx focuses on, perceived burden for documenting changes to prequalified products, overlap with SRA approvals, and uncertainty around long-term financing. PQDx can maximize its impact by considering the perspective of IVD manufacturers; similarly, IVD manufacturers should exercise adequate quality control over their submissions and associated processes.

**Keywords.** World Health Organization; prequalification; in vitro diagnostics; regulatory environment; low- and middle-income countries.

The United Nations (UN) Sustainable Development Goal 3 is to "ensure healthy lives and promote well-being for all at all ages" [1]. Achieving this goal requires quality-assured in vitro diagnostic devices (IVDs) that facilitate timely patient access to drug regimens (when clinically relevant), to treat patients, prevent onward transmission of infections, and monitor therapeutic responses (thereby reducing the risk of drug resistance emerging due to suboptimal treatment) [2]. IVDs must be reliable, robust (ie, functional in the intended settings of use, which sometimes include extreme operating conditions, such as dust or excessive temperature), and with acceptable sensitivity and specificity [3]. In low- and middle-income countries (LMICs), additional issues must be considered when choosing IVDs for use in national programs (eg, shortage of skilled laboratory personnel, unstable electricity supply, scarcity of laboratory equipment, and costs for equipment and consumables).

### Risks of Regulatory Control Absence

Stringent regulatory authorities (SRAs; including US Food and Drug Administration [FDA] and Conformité Européenne [CE] Marking) regulate IVDs in developed countries. Unfortunately, regulatory authorities in many LMICs are nonexistent or do not enforce rigorous standards for IVDs [2, 4]. This lack of regulatory control can lead to insufficient access to quality-assured and appropriate IVDs, resulting in the use of poor-quality tests potentially producing inaccurate or misleading results, inadequate monitoring of responses to therapy, and incorrect treatments, with potential consequences on the health of patients [4].

Antigen-detecting rapid diagnostic tests (RDTs) for malaria provide an example of the risks of using IVDs not properly evaluated. These RDTs have been available for >15 years, but quality assurance is still not universally enforced; nonvalidated RDTs with suboptimal performance are widely available despite little evidence of their functionality [4–6]. In response to this situation, companies that manufacture malaria RDTs were invited to submit products for the World Health Organization (WHO)/Foundation for Innovative New Diagnostics (FIND) malaria RDT evaluation program; since 2006, 247 products have been tested [7]. After December 2017, only antigen-detecting RDTs that meet WHO Prequalification of In Vitro Diagnostics (PQDx) requirements will be eligible for procurement by WHO [8]. Unfortunately, substandard malaria RDTs will remain available since a significant proportion are purchased through the private sector (and not procured by national programs). National regulatory authorities might benefit from WHO support to help address this issue.

### WHO Prequalification of In Vitro Diagnostics Program

WHO established its PQDx program to ensure "access to safe, appropriate and affordable [IVDs] of good quality," especially in resource-limited settings with little or no domestic regulatory

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