Collaborative registration procedure (CRP) for in vitro diagnostics (IVDs) – Information note

1. Background

The availability of quality assured IVDs is a core element of a functional healthcare system. National regulatory and product selection processes have been identified as one of the barriers slowing down access to priority quality assured IVDs in many WHO Member States. Although WHO prequalified IVDs are assessed according to international standards, unclear pre-market registration processes, repetitive performance evaluations and lengthy product selection procedures result in a delayed market entry of products which have been assessed and found compliant with WHO prequalification requirements.

WHO is committed to supporting National Regulatory Authorities in optimizing available resources, applying reliance principles where possible, and facilitating access to quality assured health products.

2. WHO prequalification of IVDs

WHO’s prequalification of IVDs is a service to assess the quality, safety and performance of IVDs and is intended to give UN, international procurement agencies and Member States the choice of a range of quality assured IVDs for bulk purchase, and to save money on otherwise expensive and lengthy evaluations.

The assessment follows a standardized procedure which is either a full or an abridged assessment, depending on available evidence of prior stringent assessment. The prequalification assessment of quality, safety and performance includes the review of a product dossier, a performance evaluation including operational characteristics, an inspection of manufacturing site(s) and labelling review based on internationally recognized standards and WHO guidance and specifications. Once evaluated, if the products are deemed compliant, they are listed as eligible for procurement on a public website.

3. The CRP: aim and principles

**Aim:** WHO launched the Collaborative Registration Procedure (CRP) for finished pharmaceutical products in 2013. Currently, the procedure involves more than 35 participating countries in various regions. The CRP for WHO prequalified products aims to accelerate registration through improved information sharing between the WHO Prequalification and national regulatory authorities (NRAs). The CRP builds on the collaboration between WHO, national regulatory authorities (NRAs), and manufacturers, by leveraging the work of WHO prequalification, and hence reducing duplication of work, facilitating in-country registration of quality assured products and making these products more widely available.

**Principles:**

- **Voluntary:** Under the CRP, manufacturers of prequalified products voluntarily express interest in applying the procedure to facilitate in-country registration of their product(s) in specific countries.
- **Product sameness:** The manufacturer must submit the same product version as the one prequalified to countries where the CRP is applied. Product sameness is a mandatory pre-requisite for applying the CRP.
- **Confidentiality:** The NRAs sign a participation agreement and confidentiality undertaking with WHO, whereby they adhere to the provisions of the procedure. Only countries with a signed agreement with WHO can participate in the CRP. The manufacturer, through written consent, authorizes WHO to share prequalification assessment reports for the specific product(s) with the NRAs of countries in which accelerated registration is sought.

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4. CRP: process and impact

Based on the CRP agreement, WHO shares confidential prequalification assessment reports (product dossier assessment report, performance evaluation report, and manufacturing site(s) inspection report) with the NRAs in countries identified by the manufacturer. The information is shared via a secure internet-based platform, subject to confidentiality undertakings, and agreed restrictions on use.

The NRA follows its internal procedures using WHO confidential and public reports in addition to the data submitted by the manufacturer directly to the NRA to accelerate their registration decision. WHO prequalification does not interfere with the national decision-making. At a minimum, the NRA verifies sameness of the product submitted for registration and the prequalified product to make a registration decision.

For medicines, where the CRP is well established, NRAs commit to taking a registration decision within 90 days from receipt of the full information package (manufacturer’s submission and all prequalification reports). In case of a suspension or delisting of the prequalified product WHO alerts all NRAs which registered the respective product based on the CRP.

**Impact:** The CRP contributes to shorter time to national registration, optimization of limited pre-market registration resources and product traceability and transparency for buyers (due to a verified sameness between the prequalified product and the product registered at national level).

5. CRP pilot for IVDs

A one-year pilot project aiming at introducing the CRP for IVDs has started in Q3 2019. Five countries have been selected to participate in the pilot project: Cameroon, Côte d’Ivoire, Ethiopia, Nigeria, and the United Republic of Tanzania. The product selected for the CRP-IVD pilot is the m-PIMA HIV-1/2 VL test with product code 27015-W50 using m-PIMA Analyser (product code 27030R001), manufactured by Alere Technologies GmbH (a wholly owned subsidiary of Abbott Laboratories), rest of the world regulatory version.

It is expected that, as part of the pilot CRP project, at least three of the five countries will register the product, and the CRP guideline will be finalized based on lessons from the pilot before expanding the procedure to other countries and regions. The pilot project will also assist Member States in unpacking their current national registration procedures for IVDs, understanding the existing regulatory burden and duplication, and optimizing opportunities for reliance on prequalification listing.

6. CRP and access

The CRP has the potential to contribute to improved access to priority IVDs of assured quality, safety, and performance. WHO will assess the information gathered throughout the pilot project to assist Member States in optimizing regulatory processes and procedure to better support timely access to quality assured IVDs.

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