A 2016 retrospective

Prequalified IVDs

A total of 15 IVDs were prequalified in 2016, including two IVDs intended for the early diagnosis (EID) of HIV in infants under 18 months at or near the point-of-care (POC), contributing to ongoing efforts to increase access to testing and reducing infant mortality linked to HIV. Additionally, the first rapid diagnostic test intended for the diagnosis of hepatitis C was prequalified. PQT hopes that this result will assist in current efforts to curb the trend in viral hepatitis infections and provide accurate diagnosis to facilitate cure of affected populations. An additional rapid diagnostic test for hepatitis C has since been prequalified in 2017 (see Error! Reference source not found. in the last section of this newsletter for details).

Scope of WHO Prequalification

G6PD IVDs

The scope of IVD prequalification was expanded in Q4 2016 to cover IVDs intended to identify glucose-6-phosphate dehydrogenase (G6PD) enzyme deficiency in the context of treatment of infection with malaria parasite Plasmodium vivax (P. vivax) with a high dose of primaquine. Administration of primaquine may result in the death of patients with G6PD deficiency. These assays are considered a critical tool in current efforts to obtain a radical cure, eliminating residual parasites and therefore preventing relapse in patients that have been infected.

We therefore invite all manufacturers of G6PD IVDs that can be used at or near to POC, including commercially-available qualitative rapid diagnostic tests and quantitative biosensor assays, to submit an application for assessment.

HIV IVDs intended for self-testing

Following publication of the WHO WHO Guidelines on HIV self-testing and partner notification in December 2016, WHO would also like to reiterate its invitation to manufacturers of IVDs intended for self-testing of HIV to submit an application for assessment.

Guidance

A technical guidance series was developed to assist manufacturers in the process of manufacturing, validation and verification of their products. These documents are expected to result in better-quality dossiers but most importantly, in better quality products by providing a more targeted approach to implementation of best practice and evidence
gathering that is more suitable for resource-limited settings. The documents can be found here.

A technical specifications series (TSS) for submission to WHO prequalification have been developed and set out appropriate performance criteria to meet prequalification requirements. Each TSS document provides information on the minimum performance requirements for WHO prequalification that must met by a manufacturer in order to demonstrate that the IVD in question is safe and performs optimally.

The following two documents have been finalized and published:

**TSS-1: Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional and/or self-testing.**

**TSS-2: In vitro diagnostic medical devices (IVDs) to identify Glucose-6-phosphate dehydrogenase (G6PD) activity.**

A webinar to launch Technical specifications for malaria rapid diagnostic tests submitted for WHO Prequalification, currently in draft form, will be held on Thursday, 20 April 2017 at 12:00 PM Europe Summer Time (Paris, GMT+02:00). Please join using this link using meeting number (access code): 843 924 025. Alternatively, join from a video system or application: 843924025@who-meeting.webex.com or by phone, using Global call-in number.

**Post-market Surveillance**

Workshops to support the roll-out of post-market surveillance (PMS) guidance published in 2015 were held in the second part of 2016. Subsequently, PQT has noted increased interest and requests for assistance in PMS from WHO Member States. It is anticipated that continued efforts to training relevant health professionals in PMS will contribute to better-regulated IVD markets.

A survey carried out during the WHO workshop on post-market surveillance of in vitro diagnostics (IVDs) for testing providers and regulators held in Arusha, United Republic of Tanzania on 23–24 November 2016 showed that although 70% of respondent countries have a national laboratory strategic plan mentioning post-market surveillance, only 54% of those countries have a unit within the national regulatory agency that is responsible for post-market surveillance.

WHO will continue to roll out the guidance and
advocate for establishment of post-market surveillance systems in WHO Member States. A French version of the guidance is expected to be available in Q2 2017.

Shift in WHO recommendations for procurement of malaria RDTs

A shift in WHO recommendations for procurement of malaria RDTs has been initiated following internal and external discussion. WHO prequalification will become the sole procurement requirement for this type of IVD in 2018. Manufacturers were notified of the new requirements and given a timeline and conditions for retaining or acquiring eligibility for procurement by WHO and UN agencies. The timelines for the transition period were decided as follows:

1. For products currently eligible for WHO procurement, manufacturers to submit a WHO prequalification pre-submission form to WHO PQT by 31 July 2016.
2. For products new to WHO processes, or for products due for compulsory resubmission for product testing, manufacturers to make a submission under the revised Invitation to manufacturers to submit and expression of interest for product evaluation (EOI) for Round 8, in quarter 4 of 2016.
3. Manufacturers to have submitted a complete dossier for each product to WHO PQT by 31 December, 2016.
4. Manufacturers to complete full prequalification by 31 December 2017. Beyond this date, only prequalified products will be recommended and eligible for WHO procurement.

WHO guidance on Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device

The guidance includes a non-exhaustive list of generic examples. The document can be downloaded here.

We would like to remind manufacturers that in 2016 WHO published guidance on reporting of changes made to WHO prequalified IVDs. The document provides manufacturers with information on when and how to report:

- other reportable administrative changes.
- changes to the quality management system under which the product was designed and manufactured under

Update: Alternative Performance Evaluation Mechanism
In June 2016, WHO announced the introduction of an alternative performance evaluation mechanism and invited laboratories to submit an expression of interest (EOI) to become a WHO Prequalification Evaluating Laboratory.

Eleven laboratories have now expressed interest, six have been audited and three have been listed. The list of laboratories is available here. In addition, protocols used for the evaluations in the laboratories listed have now been published. You will find these protocols here.

**WHO Prequalified IVDs**

The following IVDs have been added to the list of prequalified products in 2017.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product code(s)</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geenius™ HIV 1/2 Confirmatory Assay with Geenius™ HIV1/2 Confirmatory Controls</td>
<td>72460, 72329</td>
<td>Bio-Rad</td>
</tr>
<tr>
<td>OraQuick HCV Rapid Antibody Test Kit</td>
<td>1001-0270, 1001-0274</td>
<td>OraSure Technologies, Inc.</td>
</tr>
</tbody>
</table>

For the complete list of prequalified in vitro diagnostics, please refer to: http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

For the complete list of prequalified male circumcision devices, please refer to: http://www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/index.html