Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of in vitro diagnostics, vaccines, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products

The meeting took place at UN City, Copenhagen, Denmark from 17 to 21 September 2017 and was attended by around 450 participants, the highest attendance rate for these meetings to date.

Building on feedback from the 2015 meeting survey requesting additional materials and presentations for IVDs, this year’s meeting provided more information on IVD markets and a special session on Stimulating introduction of new innovative in vitro diagnostics. The session was chaired by Ms Jessica Jones from the Bill & Melinda Gates Foundation with presentations from Theodoor Visser from the Clinton Health Access Initiative (CHAI) and Gonzalo Domingo from the Program for Appropriate Technology in Health (PATH) and Dr Melanie Taylor, from WHO's Department of Reproductive Health and Research, Sexually-transmitted Infections (STI) Programme and seconded from the U.S. Centers for Disease Control and Prevention. Presentations focused on the challenges around research and development of innovative IVDs, regulatory considerations and international, donor-funded market access. A special message on the need for additional prequalified HIV/syphilis assays and benzathine penicillin for the treatment of syphilis was also directed at manufacturers present.

Presentations were followed by a panel discussion featuring the session speakers and Mr Walter Zhang, Head of International Business at Shanghai ZJ Bio-Tech Co., Ltd., who provided input from the manufacturer’s perspective.

The meeting also included a detailed presentations on the prequalification process and requirements for IVDs aimed at manufacturers new to prequalification, an update session discussing newly-developed guidance documents and latest highlights, as well as a specific session on IVD inspections.

In addition, the Diagnostics Assessment group and an IVD inspector conducted face-to-face meetings with 15 manufacturers. These meetings provide a special forum that allows manufacturers and the
The prequalification team was tasked with addressing any outstanding issues from ongoing prequalification applications, changes or complaints in an efficient way, as well as a means for manufacturers new to prequalification to better understand the process.

Other IVD sessions included a session on Technical Assistance and face-to-face meetings with the Technical Assistance and Laboratory Services team and an update on the status of the collaborative registration procedure, which offers manufacturers a means of getting their prequalified products onto markets promptly and efficiently.

An open forum for feedback on prequalification also took place during the meeting. As part of its improvement process the WHO Prequalification Team sought feedback from all stakeholders during this session where attendees were encouraged to provide constructive comments on the prequalification process and pinpoint any major issues and challenges encountered.

The meeting featured, for the second time, a mobile app allowing attendees to easily navigate the agenda and venue, to communicate directly with other attendees and to ask questions during plenary sessions. Seventy-four percent of attendees were active on the app during the course of the meeting. Initial feedback obtained through our polls indicated that the app was well received and was perceived as useful by a majority of attendees. For those who attended the meeting, we remind you that the meeting app is still active and all presentations are available in it under each session in the agenda.

A meeting survey has been sent to all participants in order to obtain feedback from the meeting. We encourage attendees to complete it so that their needs can be addressed in future meetings.

IVD related presentations are available [here](#).

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**Recently WHO-prequalified IVDs**

For more information on these recently prequalified products, click on the product of interest in the table below.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product code(s)</th>
<th>Manufacturer</th>
<th>Date of Prequalification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xpert® HIV-1 Viral Load</td>
<td>GXHIV-VL-CE-10</td>
<td>Cepheid AB</td>
<td>20 July 2017</td>
</tr>
<tr>
<td>OraQuick HIV Self-Test</td>
<td>5X4-1000, 5X4-1001</td>
<td>OraSure Technologies, Inc.</td>
<td>20 July 2017</td>
</tr>
</tbody>
</table>

See [our story](#) on the first HIV self-test prequalified.

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

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**Additional guidance**
Following our call for public comment, the following Technical Guidance Series documents have now been finalized and published on our website:

- **TGS 3 Principles of performance studies**: this document identifies the key principles that apply when conducting and reporting the study design, results, and conclusion of analytical and clinical performance studies that support performance claims for IVDs undergoing assessment for WHO prequalification.

- **TGS 4 Test method validation for an in vitro diagnostic medical device**: this document provides guidance for manufacturers on the validation of the test methods used in establishing the design, the development and manufacturing of an IVD.

We would also like to remind you that the Annex to TGS 2 (Establishing component stability for an IVD. Case study: single-use buffer vials for rapid diagnostic tests) is still available for public comment. This annex describes a specific case study of single-use buffer vials for rapid diagnostic tests and the recommendations for establishing the stability of these components for IVDs. More specifically, emphasis and examples are provided on the change from establishing stability for multi-use dropper bottles to that for single-use vials.

Comments will be taken into consideration if submitted to diagnostics@who.int no later than 30 November 2017 using the comments table.

To subscribe or unsubscribe to the Prequalification of In Vitro Diagnostics mailing list, send an email to diagnostics@who.int with subscribe or unsubscribe in the subject.

http://www.who.int/diagnostics_laboratory/evaluations/en/