Public Consultation on new financing model for prequalification of in vitro diagnostics

In line with modifications made to the fee system for WHO prequalification of vaccines and medicines introduced in 2017, WHO will be implementing a new fee system for the prequalification of in vitro diagnostics. The aim of the revision of the current system is to ensure a sustainable programme and increase its efficiency, but without compromising its quality.

The proposed new fee structure takes into consideration the type of assessment conducted (full or abridged), the cost of ensuring the maintenance of the prequalification status, including assessment of changes to prequalified products, mandatory re-inspections as well as the cost related to complaint handling. The proposed fee structure is now available for public consultation (until 30 April 2018). Manufacturers and partners are encouraged to provide their comments.

Recently WHO-prequalified IVDs

We are very pleased to announce the prequalification of the following product:

<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>INNOTEST HCV Ab IV</td>
<td>80068, 80330</td>
<td>Fujirebio Europe NV</td>
<td>15 February 2018</td>
</tr>
</tbody>
</table>

The INNOTEST HCV Ab IV is an enzyme immunoassay for the detection of antibodies to human Hepatitis C virus (HCV) in human serum or plasma. For more information on hepatitis C testing, please refer to the WHO guidelines on hepatitis testing.

Expansion of the scope of prequalification to include syphilis RDTs (rapid diagnostic tests)
On 13 March 2018, WHO announced that as of Q4 2018, WHO will start accepting applications for prequalification of syphilis RDTs. The decision, supported by a wide range of stakeholders, will support the implementation and achievement of the goals set out in the Global Guidance on Criteria and Processes for Validation: Elimination of mother-to-child transmission of HIV and Syphilis (EMTCT). The guidance calls for 95% coverage of syphilis screening during pregnancy and prompt treatment with benzathine penicillin of those women found to be positive. Syphilis RDTs are recommended in the recently released WHO guidelines on syphilis screening and treatment for pregnant women.

Additional guidance

**TSS-5 Rapid diagnostic tests (RDTs) used for surveillance and detection of an outbreak of cholera**

This document provides manufacturers of cholera IVDs with information on the minimum performance requirements for WHO prequalification to ensure that their product is safe and performs optimally. The document was developed with technical and programmatic input from the High Threat Pathogens team within the Department of Infectious Hazard Management, and Intervention, WHO as well as the Special Programme for Research and Training in Tropical Diseases (TDR).

**Update on WHO Prequalification Evaluating Laboratories**

The work to expand the network of WHO Prequalification Evaluating Laboratories continues. Sixteen institutions have submitted expressions of interest. Thirteen audits have been conducted and nine institutions listed. Two additional audits have been scheduled for Q2 2018.

Currently-listed laboratories have the capacity to
perform evaluations for most of the IVD analytes included in the scope of prequalification assessment including: HIV serology and NAT, CD4 enumeration technologies, hepatitis C serology and NAT, hepatitis B surface antigen, syphilis serology and HPV NAT.

An annual meeting to bring together all the laboratories in the network has been planned for Q2 2018 with the aim of providing laboratory staff with a deeper understanding of the performance evaluation processes, WHO prequalification requirements and communication procedures, and ensuring harmonized practices. The meeting will also provide a platform for laboratories to interact with each other and potentially facilitate specimen panel management.

The list of currently listed laboratories is available [here](http://www.who.int/diagnostics_laboratory/evaluations/en/).