WHO Prequalification Financing Model – Public consultation on fees for in vitro diagnostics

What is WHO prequalification?

WHO prequalification assesses the quality, safety and efficacy/performance of health products for priority diseases for UN and other international procurers of such products to developing countries. The programme evaluates in vitro diagnostics (IVDs), vaccines, medicines, active pharmaceutical products, some medical devices and vector control products for several high-burden diseases.

The Global Fund to fight AIDS, TB and Malaria, UNICEF, GAVI and Unitaid, among others, rely on WHO prequalification to ensure a quality supply of health products to countries. Many low- and middle-income countries also use WHO’s lists of prequalified products to guide national procurement of health products and/or facilitate national registration.

Prequalification fee structure

WHO began to charge fees for vaccine prequalification in 1999, in 2008 for IVDs and in 2013 for medicines. In 2015 the fee structure was upgraded. The introduction of the new model was motivated by the need for financial sustainability in order to continue to provide this vital service.

Based on the number of overall submissions to WHO prequalification (i.e. all product streams) between 2013 and 2015, the new fee model is expected to generate about US$ 20 million annually. Those funds will be used to cover a significant portion of the programme’s operating costs. It is expected that the fee structure will secure the financial sustainability and maintain the quality of the programme.

The development of the fee model, which was funded by the Bill & Melinda Gates Foundation (BMGF), was guided by the following principles:

- it should not introduce inequity among manufacturers;
- it must not represent a financial burden for manufacturers, restricting their ability to enter a market (and especially not those where public health need is critical);
- it should be financially and administratively easy to execute and monitor.

What’s changing for IVDs?

In vitro diagnostics (IVDs) prequalification began with the assessment of rapid HIV assays in 2008 and soon expanded to include rapid malaria tests. Today, the diagnostics team also works on emergency-prone pathogens for which few or no medical products exist, such as Ebola and Zika.

The proposed new fee structure for IVDs represents a fine-tuning of the previous financial model to include considerations of:

- The type of assessment: whether a full or abridged assessment of a new application, or assessment of changes;
- an annual maintenance fee.

What are the proposed fees for IVDs?
What will WHO do to further streamline prequalification assessments of IVDs?

Since 2014, prequalification of IVDs has introduced a number of measures to increase efficiency and transparency. As part of a continuous improvement process, WHO will establish new measures to facilitate reliance and harmonization mechanisms. These will include:

- MDSAP audit reports: for abridged prequalification assessments the current site inspections will be replaced by reliance on MDSAP audit reports and review of specific technical documents; and
- the alternative performance evaluation pathways\(^1\),\(^2\).

These measures aim to ensure a more efficient use of resources, streamlined assessments and shorter timeframes.

When does the new financing model start?

The new fee structure has been applied to assessments of medicines and vaccines since January 2017. WHO expects to begin to apply the new fee structure for IVDs on 1 July 2018.

What will WHO do to support prequalification activities for products that generate only small profits?

Applicants of such products are encouraged to approach the WHO prequalification team in a proactive manner to discuss options.

How will this new fee structure be evaluated?

Implementation of the new model is expected to start on 1 July 2018. As well as enabling many prequalification services to be continued, the fees will be used to further improve those services. This will include working towards compliance with (and public disclosure of) the recently published key performance indicators \(\text{(http://www.who.int/entity/diagnostics_laboratory/key-performance-indicators/en/index.html)}\) relating to: review time for full assessment, review time for abridged assessments, and review time for assessment of changes. Discussion with industry associations about performance targets and indicators will be continuous.

\(^1\) For more information on the alternative performance evaluation please refer to \(\text{http://www.who.int/diagnostics_laboratory/evaluations/alternative/en/}\)

\(^2\) In the future the uptake of performance evaluations coordinated by manufacturers is expected; a cost recovery mechanism for performance evaluations coordinated by WHO may be considered.
It is intended that the impact of the model will undergo a review after three years of implementation. Prior to that, regular assessment of model impact will be undertaken.

**Who can I contact to provide feedback on proposed fees?**

Comments on the proposed fees for IVDs should be sent by email to diagnostics@who.int before 30 April 2018.