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ADDITIONAL GUIDANCE AVAILABLE

Continuing its efforts to support manufacturers of IVDs intending to submit a product for prequalification assessment, WHO prequalification have published the following finalized guidance documents under its Technical Specifications and Technical Guidance Series. The technical specifications document “TSS-6 Syphilis Rapid diagnostic tests” has been developed for manufacturers of rapid diagnostic tests to detect syphilis infections interested in applying for WHO prequalification assessment. The technical guidance document “Annex to TGS-2: Establishing component stability for in vitro diagnostic medical devices” provides recommendations for establishing the stability of components for IVDs.

The public comment period for the following draft documents has been closed.

TSS-7 Rapid diagnostic tests to detect hepatitis C antibody or antigen, and TSS-8 Immunoassays to detect hepatitis C antibody and/or antigen. Anticipated publishing date is in Q2 2019. Both these working documents have been drafted with the WHO Global Hepatitis Programme based on the outcome of several discussions, external reviews and a technical consultation with external stakeholders. These technical specifications document outlines the minimum performance studies necessary to meet for WHO prequalification requirements.

NEW ABRIDGED ASSESSMENT PROCEDURE UNDER DEVELOPMENT

The abridged prequalification assessment pathway for IVDs has been in place since 2014. The rationale for abridged prequalification assessment is that a prior regulatory approval provides a level of assurance relating to the product’s quality, safety and performance in countries where it is approved, but it cannot always provide the same assurance when the product is used in other jurisdictions, including resource-limited settings. The aim of abridged prequalification assessment is to avoid duplication of effort and reduce the time taken to prequalify a product by focusing on aspects where WHO prequalification assessment brings added value. Products that do not qualify for abridged prequalification assessment undergo a full prequalification assessment.
WHO initiated the revision of the current abridged assessment guidance in order to amend it to reflect changes to regulations in jurisdictions for which the procedure applies. In addition, WHO is exploring options for expanding the procedure to regulatory approvals which have not yet been leveraged. The amended abridged assessment procedure for IVDs should be developed by the end of 2019 and implemented in 2020.

To access the current abridged assessment guidance click [here](#).

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**ELIGIBILITY FOR PREQUALIFICATION OF IVDs**

WHO hosted an online consultation to gather input from key stakeholders to determine the types of IVDs for which prequalification is most needed and will have the greatest benefit. The feedback gathered during the consultation was assessed and presented during the SAGE – IVD meeting held on 18 to 22 March 2019. To access the preliminary report on the consultation click [here](#). WHO will communicate the final decision on the addition of new IVDs to the current list of eligible IVDs in Q2 2019.

For more information on the recent SAGE – IVD meeting click [here](#).

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**CALL FOR APPLICATIONS: Syphilis RDTs and malaria RDTs**

In 2014, WHO launched the [Global Guidance on Criteria and Processes for Validation: Elimination of mother-to-child transmission of HIV and Syphilis (EMTCT)](https://www.who.int/hiv/pub/mtct/en/) (updated December 2017). This was preceded in 2007, by the WHO Global Congenital Syphilis Elimination Strategy. These initiatives call for 95% coverage of syphilis screening during pregnancy and prompt treatment with benzathine penicillin of those women found to be positive. Congenital syphilis is the second leading cause of stillbirth globally; efforts to secure syphilis screening among pregnant women are needed to prevent this and other adverse birth outcomes of vertically transmitted syphilis (neonatal death, low birth weight, prematurity, congenital defects). Syphilis RDTs are recommended in the [WHO guidelines on syphilis screening and treatment for pregnant women](https://www.who.int/hiv/pub/mtct/en/).

As of 20 March 2019, WHO expanded the prequalification of IVDs eligibility to include syphilis rapid diagnostic tests (RDTs). Manufacturers are encouraged to review the [Technical Specifications document for syphilis RDTs](https://www.who.int/hiv/pub/mtct/en/) before submitting an application.

In addition, WHO continues accepting malaria RDTs applications from manufacturers. Manufacturers are encouraged to contact the Prequalification Team – Diagnostics assessment at [diagnostics@who.int](mailto:diagnostics@who.int) for information on the process and requirements.

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**COLLABORATIVE PROCEDURE FOR IVDs**

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 Member States. Repetitive performance evaluations,
unclear pre-market registration processes and lengthy procedures result in a delayed market entry of products which have been assessed and found compliant with WHO prequalification requirements.

The Collaborative Registration Procedure (CRP) for finished pharmaceutical products was launched in 2013 and has since been expanded to 34 countries. The CRP builds on the collaboration among WHO, national regulatory authorities and manufacturers, reducing duplication and facilitating in-country registration of quality assured products. WHO will be implementing a one-year pilot project for collaborative registration of Medical Devices including in vitro diagnostics. More information will be provided in due course.

JOINT UNFPA–UNICEF WHO MEETING WITH MANUFACTURERS AND SUPPLIERS OF IN VITRO DIAGNOSTIC PRODUCTS

The next joint UNICEF-UNFPA-WHO meeting with manufacturers and suppliers will take place from 2 to 5 December 2019 at UN City in Copenhagen, Denmark. More details will be communicated in due course.

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