Mechanism to guide procurement of diagnostics not yet in receipt of stringent regulatory approval

**Expert Review Panel for Diagnostics**

Diagnostics for the prevention, diagnosis or management of AIDS, TB or malaria are procured with international donor funds and in significant quantities for use in low- and middle-income countries. The Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund) and UNITAID each operates a quality assurance policy to guide such procurement. This stipulates that procured diagnostics must be quality assured: for example, they have undergone stringent assessment by a regulatory authority. But quality-assured diagnostics are not always available. In their absence, treatment may be delayed or not administered at all. Modelling itself on the Expert Review Panel for medicines (ERP),¹ the recently piloted Expert Review Panel for Diagnostics (ERPD) aims to provide guidance to procurers who find themselves in this situation.

ERPD has been designed to assess the risks associated with procurement of diagnostic products that have high public health impact, but that have not yet undergone assessment by WHO or a stringent national regulatory authority (NRA). It is not intended to replace WHO prequalification or stringent regulatory assessment. Rather, it provides an interim assessment decision, valid for a time-limited period, in anticipation of completion of stringent regulatory review. It is hosted by WHO, as requested by Global Fund’s Board, while the Global Fund leads ERPD technical implementation.

ERPD, processes and procedures were piloted earlier this year, using point-of-care HIV early infant diagnosis (POC HIV EID) technologies. The pilot covered selection of experts to conduct product reviews, identification of potential product-related quality assurance risks and their grouping into risk categories,² and development and testing of ERPD operating procedures and documents. Thereafter, in February 2014, an invitation to manufacturers to submit an expression of interest for product evaluation (EoI) was issued by the Global Fund and UNITAID. Manufacturers were given two months in which to submit their product information to the Global Fund. After review for completeness, it was forwarded to ERPD members for assessment. In June 2014, the assessment results were presented to the applicant manufacturers and implementation of the ERPD process—which is designed to take no longer than 6 months, from issue of the EoI to informing the applicant manufacturers of the assessment results — reviewed.

This first ERPD meeting facilitated the adoption of the ERPD panel members of a risk–benefit approach to assessment, based on sufficient satisfactory evidence, to make a decision regarding acceptability for procurement, for a time-limited period. This differs from full-scale, stringent review, as carried out for WHO prequalification or by a stringent NRA, which is based on a full product data set.

Key lessons learned during this pilot ERPD related to:

1. **Product range for assessment.** Initially it was intended that each ERPD EoI concern only one particular diagnostic product type: for example, POC HIV EID assays, or CD4 technologies. Given the dynamic of the market for HIV related diagnostic products, however, this approach is now thought too slow, and not adapted to either the number of new products arriving on the

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market or the testing capacities of recipient countries. Therefore, the current EoI for ERPD review (issued in June 2014) is open to a wider range of diagnostic products, including POC CD4 technologies, HIV viral load tests and HIV early infant diagnosis assays. HIV molecular tests that use dried blood spots are also accepted for review. The product scope for upcoming EoIs will be defined according to market demand and product availability.

2. **The information requested from the manufacturers, and its format has been revised.** Following a meeting with key stakeholders the format for an ERPD submission has been revised to better meet their needs. In addition manufacturers will be invited to grant access to information that they have already submitted to WHO for prequalification purposes or to stringent NRAs when seeking registration, thus limiting duplication of effort.

3. **The importance of maintaining an open dialogue with product manufacturers:** The pilot demonstrated that technical guidance, not only on the ERPD mechanism but also on quality management systems, and the quality assurance policies and practices of major procurers such as the Global Fund, should be provided to manufacturers to help them to meet international procurement and quality-assurance requirements. (Participating manufacturers were asked to provide feedback on ERPD outcomes, so that their suggestions and findings could be included in the review of the pilot ERPD.)

4. **Understanding of the readiness for market entry of new diagnostic products:** The ERPD pilot indicated that this mechanism will promote understanding and transparency regarding the stage of development of new diagnostics.

5. **The ERPD calendar:** In order to accommodate the progressive arrival to market of new products of interest to the Global Fund and UNITAID, EoIs for a wide range of diagnostic products, should be published at regular intervals. This will allow manufacturers to submit completed product questionnaires to ERPD as and when their product is ready to enter the market.

In summary, although the ERPD pilot did not lead to a positive procurement decision for any products — since required performance evidence was still being gathered by the manufacturers concerned — it proved to be an informative exercise that demonstrated ERPD’s validity as a mechanism for assisting procurement in the absence of stringently assessed diagnostic products.

**Further information:**

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