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FURTHER DETAILS ON CHANGES TO PHARMACEUTICAL QUALITY ASSURANCE POLICY

In Issue 111, GFO reported briefly on a Global Fund Board decision in November 2009 to further modify its Quality Assurance Policy for Pharmaceutical Products. This article provides some background information and further details of the decision.

The Board had previously approved a revised Quality Assurance Policy at its meeting in November 2008. That revised policy came into effect on 1 July 2009.

As reported in GFO 111, under the revised policy, ARVs, anti-TB and anti-malaria pharmaceutical products are eligible for purchase with Global Fund money if (a) they are prequalified by the World Health Organisation (WHO) Prequalification Programme; OR (b) they are approved or authorised for use by a "stringent regulatory authority" (SRA); OR (c) they are not yet WHO-prequalified or SRA-authorised, but are recommended by the Global Fund's Expert Review Panel (ERP). ERP recommendations are valid for only 12 months.

For a finished pharmaceutical product (FPP) to be eligible for review by the ERP, the manufacturer of the FPP must have submitted an application for pre-qualification by the WHO, and the WHO must have accepted to review the application; OR the manufacturer of the FPP must have submitted an application for marketing authorisation to an SRA, and the SRA must have accepted to review the application. However, the Board agreed at its last meeting to allow an exception to this criterion. The Board said that certain multi-source FPPs for malaria and TB that do not meet the criterion will nevertheless be eligible for review by the ERP.

"Multi-source" means a pharmaceutical product for which the monograph of the finished dosage form was

published in the international, U.S. or U.K. Pharmacopeia before 10 October 2002.

When the Global Fund publishes its list of ERP-recommended FPPs in future, it will indicate which of these were deemed eligible for review as a result of the above exception.

As reported in GFO 111, the Board also decided that because it will take some time to organise submissions and reviews for products newly eligible as a result of the above exception, certain additional exceptions to the current policy will be allowed until 31 December 2010. Specifically, the Board said that grant funds may be used to procure certain multi-source FPPs for malaria and first-line tuberculosis treatment, provided that:

- there are no other FPPs for that product formulation available that are WHO-prequalified or SRA-authorized or ERP-recommended;
- the site at which such FPP is being manufactured is, at the time of the procurement, in compliance with the relevant GMP (Good Manufacturing Practices) standards as verified by the WHO Prequalification Program, or an SRA or a regulatory authority participating in Pharmaceutical Inspection Cooperation Scheme (PIC/S);
- the FPP has been selected for procurement by relevant UN procurement agencies; and
- the notification, confirmation and testing processes described in the Quality Assurance Policy will apply to such procurement.

The first set of ERP reviews of product dossiers submitted by manufacturers was conducted in May 2009, prior to the introduction of the revised Quality Assurance Policy. Of the 63 dossiers submitted, 29 FPPs were recommended by the ERP for procurement with Global Fund resources – 15 ARVs, 3 anti-malarial products and 10 anti-TB products. The manufacturers who submitted the other 35 dossiers were informed that they would be able to re-submit at the next set of reviews, which was scheduled for October 2009.

For more information on the Board decision, see Decision Point 13 in the Decision Points document at www.theglobalfund.org/en/board/meetings/twentieth.

Some of the information in this article was taken from “Procurement and Quality Assurance Matters,” a report prepared in September 2009 by the Global Fund Secretariat for the Portfolio and Implementation Committee of the Board.

More information on the revised Quality Assurance Policy is available on the Quality Assurance Information page on the Global Fund website at www.theglobalfund.org/en/procurement/quality . The information includes a copy of the revised policy; an information letter to manufacturers on the revised policy; a list of products recommended by the ERP; a list of countries considered as SRA; and a list of the countries participating in PIC/S.

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