

WHO/UN Prequalification programme for RH medicines

General: The "Prequalification" programme is coordinated by WHO on behalf of UNICEF, UNAIDS and UNFPA and supported by the World Bank. Based on a voluntary expression of interest by innovator and generic companies to offer medicines for procurement or funding by UN agencies, products dossiers are assessed and manufacturing sites of pharmaceutical active ingredients (APIs) and finished products, and Contract Research Organizations (CROs), are inspected by international teams of assessors and inspectors. If approved, products are listed as prequalified for UN procurement. This service is free of charge and independent of patent status. The standard requirements and procedures, the list of prequalified products, the WHO Public Assessment Reports (WHOPIRs) and the WHO Public Assessment Reports (WHOPARs) are published on the WHO Prequalification web site (www.who.int/medicines). The list of prequalified products is increasingly used by the World Bank, the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), national programmes and NGOs to guide their procurement and funding decisions. The prequalification programme also includes the prequalification of diagnostics for HIV/AIDS. In 2005, prequalification of medicine control laboratories in Africa was added and in July 2006 funding was received to start prequalification of priority medicines for Reproductive Health.

Prequalification of medicines for Reproductive Health: The RHSC meeting of April 2006 decided to focus on injectable (IC) and oral contraceptives (OCs), and oxytocics (ergometrine, oxytocin). An early analysis of about 30 manufacturers of OCs revealed that only 5-7 may be prequalified in the immediate and medium term; most others have serious problems with production quality. In 2006 a call for an Expression of Interest was issued. Dossier assessment may start before the end of the year, and site inspections in the course of 2007.

Expected input from RHSC members:

1. Further feedback on the selection of priority RH items to be included in the prequalification programme
2. Acceptance of the list of prequalified products for procurement, following the general approach of the Global Fund (obligatory use of prequalified products as soon as two or more prequalified products are available; in case one or no prequalified products are available, use of manufacturers who have been prequalified for other products, or have passed WHO/GMP inspections).
3. Feed-back on any supply or quality problems encountered with prequalified products
4. Global advocacy and promotion of the prequalification programme among partners and country programmes

Interagency lists of Essential Medicines and Commodities for Reproductive Health

In 2006 the revised Interagency List of Essential Medicines for Reproductive Health (RH) was issued by WHO on behalf of WHO, UNFPA and several international NGOs. This sub-set of the 14th WHO Model List of Essential Medicines (2005) reflects the global consensus of all major agencies. Work is now in progress on a similar list of RH non-drug commodities, with strong input from UNICEF and NGOs. Special emphasis is put on international agreement and standardization of product specifications, in order to promote economies of scale and price comparisons, and simplify inventory systems and stock reporting. It is anticipated that the Interagency List of RH commodities will be finalized and approved before the end of 2006. Both lists will be updated every two years; selected items of these lists will be chosen for inclusion in the RH prequalification programme.

Expected input from RHSC partners:

1. Contributing to finalizing and updating the interagency list
2. When invited to do so by WHO, confirm their official endorsement of and commitment to the list by allowing the partner's logo to be put on interagency document to be issued by WHO
3. Focusing procurement programmes on items on the list, using the same specifications

Potential areas of further WHO activity:

- Expansion of WHO/UN prequalification programme, with methodological advice to UNFPA and WHO/RHR on prequalification of condoms and IUDs, and with other priority RH medicines;
- Publication of sources and prices of prequalified products
- Promoting the rights-based approach to access to essential RH items