Prequalification and Coalition Procurement

Effective Use of the WHO and UNFPA Prequalification Process for RH Supplies

The most widely used contraceptives and other reproductive health supplies are now off-patent and are being produced by generic and developing-country manufacturers at a lower cost than the innovator brand products. There is potential for these contraceptive manufacturers to help countries move closer to contraceptive supply security.

In 2006, WHO and UNFPA, with the assistance of PATH, developed and published a list of Essential Medicines for Reproductive Health.[1] A limited number of these products[1] were identified as priorities for inclusion in the prequalification program, including some primary treatment medicines for STIs, contraceptives, and medicines to facilitate safe pregnancy and delivery. UNFPA and WHO also are working on a mechanism to include medical devices (IUDs and condoms).

Previous presentations at RHSC meetings and discussion around prequalification have introduced Coalition members to the prequalification process and provided updates with regard to RH medicines. At the January 2006 MDA Working Group meeting in London, a number of procurers, such as UNFPA, ICON, and Crown Agents, agreed in principle to only purchase products that had been prequalified by WHO and to adopt a policy based on that used by the GFATM, which states: "…a product may be procured if:

Option A: it is approved by the pre-qualification program.

Option B: it is approved by a stringent regulatory authority, defined as a National Drug Regulatory Authority (NDRA) participating in the International Conference of Harmonization (ICH) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S)."

To catalyze movement toward prequalification of reproductive health supplies, WHO, UNFPA and PATH are implementing a series of workshops with three objectives: ensure engagement by manufacturers in the prequalification process, promote national-level procurement units' understanding of the prequalification process and how to incorporate it into their procurement framework, and discuss with donors whose funds support RH supplies procurement specific ways they can support the prequalification program and encourage its use. This effort is supported by a grant from the Bill & Melinda Gates Foundation.

The presentation and discussion on Day 2 of the RHSC meeting in April 2007 will address how to operationalize this thinking and will focus on key messages regarding use of prequalification to share with institutional and field-based colleagues

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[1] WHO has identified the following RH medicines and medical devices for inclusion in national essential medicines lists.

*azithromycin; *cefixime; **clotrimazole; **condoms; **ethinylestradiol + levonorgestrel; ethinylestradiol + norethisterone; **copper-bearing intrauterine contraceptive devices (IUD); **levonorgestrel for oral hormonal contraception; **levonorgestrel for emergency contraception; **magnesium sulfate; **medroxyprogesterone acetate (DMPA) depot injection: methyldopa; misoprostol; mifeprpistone with misoprostol; nifedipine; **oxytocin

* *Already in the WHO prequalification process in 2006*

** *Considered by WHO to be priorities for inclusion in the prequalification project beginning in 2007.*