

Key points from second Uterotonic Drugs and Devices Task Force meeting March 20, 2006

During the first hour of the meeting we discussed, as a group, broad issues that will impact global recognition and availability of new drugs and drug/device combinations such as oxytocin in the Uniject™ device and misoprostol. The remaining portion of the meeting was spent exchanging ideas with the other task forces (TFs) during 15- to 20-minute cross-TF sessions.

General discussions:

- According to experts from the World Health Organization's (WHO's) Essential Medicines Programme, since oxytocin is already listed as an essential medicine, there will be no need to apply for a separate essential medicines listing of oxytocin in Uniject™. The essential medicines list is silent as to the particular type of container or injection syringe for a drug, as these may vary to meet different needs.
- However, the same WHO experts pointed out that it will still be critical to educate, through evidence, various WHO groups about the particular benefits of oxytocin in the Uniject™ device compared to current practice of oxytocin in ampoule. For example, the Expert Committee on Essential Medicines should be provided with the stability data and other key elements of the registration dossier for oxytocin in the Uniject™ device. The appropriate committee within Reproductive Health should receive evidence of program feasibility and impact.
- The process of WHO prequalifying specific manufacturers to become approved suppliers to United Nations (UN) system procurement agencies originally only applied to vaccines. Over the past few years, this has been expanded to include antiretroviral drugs. Within the next 12 to 24 months, the Essential Medicines program will initiate the prequalification process for an additional number of key reproductive health drugs, including oxytocin. There will be formal announcements of the process so that pharmaceutical producers can then consider applying. The actual process leading to prequalification might take 12 to 24 months and depends on the strength of the producers' application dossier, etc.
- As it now stands, UN procurement agencies can determine individually from which oxytocin producers to buy. Once there is WHO prequalification for oxytocin producers, this will change. UN agencies such as United Nations Children's Fund and United Nations Population Fund will be required to purchase only from oxytocin producers who have been prequalified by WHO.

Discussions with other TFs:

- Training TF—discussed what level and scope of pharmaceutical product knowledge should or should not be included in the training. It will be important for the UDD TF to get up-to-date information on oxytocin storage and handling to the Training TF.
- First Interventions TF—discussed ways oxytocin stability might be improved (i.e., lyophilization) but came to realize that benefits of stability would be overshadowed by higher product costs and, more importantly, challenges and risks of reconstitution with diluents in the field.

- Community-based prevention of postpartum hemorrhage TF—expressed concern about the storage challenges for oxytocin and explained that some countries do not use oxytocin because they don't trust the cold chain.