February 17, 2011

The Secretary of the 18th Expert Committee on the Selection and Use of Essential Medicines Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Pharmaceutical Policies (EMP)
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

Subject: Letter of Support for Revision of Oxytocin Formulation Specification

Dear Expert Committee on the Selection and Use of Essential Medicines:

PATH is writing to express support for a revision to the specifications for oxytocin formulation in the WHO Model List of Essential Medicines. The current listing specifies oxytocin injection as “10 IU in 1-ml ampoule.” It is our hope that the Expert Committee will consider the deletion of “in 1-ml ampoule” from the specification as requested by WHO’s Department of Child and Adolescent Health and Development and Department of Making Pregnancy Safer. The current specification may cause countries to believe that the 1-ml ampoule is the only allowable presentation for oxytocin and could thereby limit their ability to consider innovative presentations in compact, prefilled, autodisable devices such as the Unijec® device. Oxytocin in the Uniject device (oxytocin in Uniject) is currently being sold by manufacturers in Argentina and India. While we fully expect the ampoule presentation of oxytocin to continue playing an important role in countries’ essential medicines programs, countries are seeking innovative ways to deliver the lifesaving benefits of uterotonics such as oxytocin in an effort to reduce postpartum hemorrhage (PPH) and reach Millennium Development Goal 5. Changing the oxytocin specification by removing “10 IU in 1-ml ampoule” will allow for continued use of the 1-ml ampoule presentation and consideration of alternative oxytocin presentations.

**Oxytocin in Uniject for Preventing PPH**

PPH, or excessive bleeding occurring after childbirth, is the leading cause of maternal death worldwide, taking the lives of approximately 150,000 women a year. Most of these maternal deaths due to PPH occur in settings (both hospital and community) where there are no birth attendants or where birth attendants lack the necessary skills or equipment to prevent and manage PPH and shock. While prompt medical care in developed countries has reduced the rates of death from PPH, it continues to have a devastating impact on women in developing countries.

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2 Uniject is a registered trademark of BD.
Because many women give birth at home, an injection of oxytocin has to be simple enough for administration by a village health worker or midwife outside of hospital facilities. The Uniject autodisable injection device fits this description: the prefilled syringe ensures that an accurate dose of oxytocin is delivered to a patient with minimal preparation, minimum waste, and a guarantee that the syringe and needle will not be used again. A time-temperature indicator is included on the Uniject packaging so that health workers at the facility or community level can easily ensure that the oxytocin has not been damaged by heat exposure before administering it to women.

The simplicity of the device allows oxytocin to be delivered in emergency situations and remote locations. When given as part of a PPH-prevention strategy, oxytocin could help eliminate up to 60 percent of PPH cases, potentially saving thousands of women’s lives. These programs are tested and effective and need only to be scaled up to reach larger populations.

Experience to Date With Oxytocin in Uniject

Integrating oxytocin-filled Uniject devices into PPH-prevention strategies could achieve a significant, measurable impact on maternal deaths. In field trials in Vietnam and Angola, oxytocin in Uniject was used effectively in facility- and community-based settings by both skilled health workers and trained community members.iii,iv In Indonesia, village-based midwives successfully used oxytocin in Uniject during home deliveries.v In 2007, auxiliary midwives in Mali were trained and delivered oxytocin in Uniject to 15,000 women. A pilot introduction at the institutional level in Guatemala was completed in 2010. Providers and managers found Uniject highly acceptable for administering oxytocin during active management of the third stage of labor (AMTSL) as part of an effective PPH-prevention program.vi PATH is also supporting community-based trials in Ghana and India. The Ghana trial is expected to start in March 2011, and the India trial is currently under review by the relevant Research Ethics Committees. Additional field activities are planned for 2011 in Honduras.

We strongly urge the Expert Committee to prioritize women’s lives and support increased access to innovative presentations of oxytocin by revising the WHO List of Essential Medicines to delete “in 1-ml ampoule” from the oxytocin specification. Thank you for your thorough consideration.

Sincerely,

Christopher J. Elias, MD, MPH
President and CEO

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