February 18, 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
emlsecretariat@who.int.

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

Instituto Biológico Argentino S.A.I.C. (BIOL) 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 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.¹

The current specification may cause countries to believe that the 1-ml ampoule is the only allowable presentation for oxytocin and reduce their ability to consider innovative presentations for oxytocin such as compact prefilled, autodisable devices such as the Uniject² device.

As a manufacturer of oxytocin in ampoules and oxytocin in Uniject, BIOL is committed to expanding access to oxytocin. While we fully expect the ampoule presentation of oxytocin to continue to play an important role in countries essential medicines programs, countries are seeking innovative ways to deliver the lifesaving benefits of uterotonicics such as oxytocin in an effort to reduce postpartum hemorrhage. We have registered oxytocin in Uniject in a number of countries and expect to continue registration around the world as demand for this innovative product grows.

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

Sincerely,

[Signature]

Dr. Patricia López Biscayart
President
Instituto Biológico Argentino S.A.I.C.

² Uniject is a registered trademark of BD.