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Essential Medicines List Secretariat  
Medicines Policy, Access and Use Team (PAU)  
Department of Essential Medicines and Pharmaceutical Policies (EMP)  
World Health Organization  
20 Avenue Appia  
CH-1211 Geneva 27  
Switzerland  
Email: emlsecretariat@who.int

Dear Committee Members:

We are pleased to submit an application for the inclusion of misoprostol on the WHO’s Model List of Essential Medicines (EML), in section 22.01.00.00 “Oxytocics”, for the treatment of postpartum hemorrhage (PPH). Hemorrhage accounts for approximately one quarter of maternal deaths globally, with the greatest burden of maternal mortality falling most heavily on low income countries. Prompt administration of uterotonics is a critical first-line treatment measure to help minimize severe outcomes, complications, and deaths resulting from PPH.

Misoprostol, a prostaglandin E1 analogue, induces strong uterine contractions and has been shown to be safe and effective in treating PPH attributable to uterine atony. While intravenous oxytocin is the standard drug for treatment of PPH, its therapeutic use is complicated by the need for cool storage and sterile equipment. Several studies have highlighted persisting barriers to offering high quality oxytocin products in resource-poor settings,i,ii and even where oxytocin is available, health care personnel are often faced with equipment shortages.iii Results from two large, multi-country studies comparing the efficacy of misoprostol to intravenous oxytocin confirmed that first-line treatment with 800 mcg sublingual misoprostol stops post-partum bleeding within 20 minutes of its administration for nine out of ten women suffering a hemorrhageiv. A recent Cochrane review on the treatment of primary PPH concluded that while oxytocin infusion works better than misoprostol, misoprostol can be used in settings where refrigeration and infusions are not readily availablev.

Several large international bodies, including the World Health Organization, the International Federation of Gynecologists and Obstetricians, and the International Confederation of Midwives, have updated their guidelines to reflect the evidence, and now recommend misoprostol as an option to treat PPH in the event that oxytocin is unavailablevi,vii,viii. Moreover, in January 2014, the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA), in accordance with Article 58 of Regulation (EC) No. 726/2004, approved 800 mcg sublingual misoprostol (Hemoprostol) for the treatment of PPH due to uterine atonyvii.

While efforts must continue to improve access to intravenous oxytocin for treating PPH, misoprostol may be the only treatment option in some delivery situations. Indeed, in the absence of oxytocin, providers have sought alternative and additional ways to treat PPH, including the use of misoprostol. An inclusion on the EML will help institutions, ministries of health and providers to clarify the role of misoprostol for the treatment of PPH in hospital protocols, training curricula, and national guidelines.
Reductions in maternal deaths and morbidity due to PPH can only be achieved if providers have access to a range of treatment options for all delivery scenarios across the globe. We believe that the inclusion of misoprostol for the treatment of PPH on the EML will help expand access to these treatment options.

Please note that grade tables showing comparative safety and efficacy are included in the ‘Cochrane Review on Treatment for Primary Postpartum Hemorrhage’. We have included a PDF copy of those tables to this application.

We thank you for considering the addition of misoprostol to the Model List of Essential Medicines for this indication.

Sincerely,

Dina Abbas, MPH  Jill Durocher               Beverly Winikoff, MD, MPH
Program Associate  Senior Program Associate President

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