Dear Committee Members,

The International Federation of Gynecology and Obstetrics (FIGO), and numerous international colleagues write to you in support of the application to include misoprostol on the World Health Organization (WHO) Model List of Essential Medicines (EML) for treatment of post-partum hemorrhage (PPH) submitted by Gynuity Health Projects.

Misoprostol is already included on the WHO EML (22.1 “Oxytocics”) because of its proven safety and efficacy for a number of obstetric indications including the prevention of PPH. Gynuity has proposed that the medicine be specifically listed for its PPH treatment indication as well, under section 22.01.00.00 “Oxytocics” of the WHO EML list.

We, the undersigned, strongly support the listing of misoprostol (800mcg sublingual) for its PPH treatment indication for the following reasons.

1: Persistent high rates of maternal mortality and morbidity are unacceptable

PPH remains the single largest contributor to maternal morbidity and mortality in the world.\(^1\) Despite some progress made in reducing maternal deaths throughout the Millennium Development Goal years, two thirds of maternal deaths are still due to hemorrhage.\(^2\)

Improvements have been slow or almost absent in Sub-Saharan Africa, where women face the greatest lifetime risk of dying during pregnancy and childbirth. As PPH can affect any woman, and will continue to affect up to 16% of women even following prophylaxis,\(^3,4\) rapid treatment options are essential. Women can die within two hours from onset of PPH\(^5\) making prompt initiation of treatment imperative for preventing death and reducing global maternal mortality. Misoprostol offers such a treatment.

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2: Current lack of life-saving interventions available in low-resource settings

One reason for the slow progress towards reductions in mortality and morbidity from PPH is that the primary focus has been on increasing access to skilled birth attendants and emergency obstetric care, which cannot bring benefit to the large numbers of women delivering outside of health facilities. A second reason is that the recommended PPH treatment of oxytocin is often not available even inside many health facilities in low-resource settings, and there may not be the appropriate storage or personnel trained in its administration. Expanding treatment options for women and providers in all delivery contexts, and most importantly, in settings where no other treatment is available, is essential. Misoprostol offers such a treatment.

3. Role of misoprostol for treatment of PPH is already well known

International agencies and governing bodies, given the wealth of scientific evidence, have recognized the important role that misoprostol can play in the treatment of PPH. This is reflected in guidelines by WHO, FIGO and ICM on the management of PPH and the recent approval of the use of misoprostol for treatment of hemorrhage due to uterine atony by the European Medicines Agency. It is important that misoprostol is included on the EML for its PPH treatment indication to further harmonize guidelines, which will assist countries in adopting and following standardized guidelines as well as to further prioritize misoprostol and empower organizations to advocate and ensure its availability.

In summary, we believe that 800mcg sublingual misoprostol is an easy-to-use, low-cost, evidence-based regimen that can be used in situations in which intravenous oxytocin is not feasible. It is an ideal medicine to add to the package of interventions available to providers at all levels to treat PPH, and making misoprostol more available will help to advance efforts to bring to scale interventions to reduce maternal mortality and morbidity, particularly in low-resource settings.

We thank you for considering the addition of misoprostol to the WHO’s EML for the treatment of PPH.

Yours respectfully, the undersigned

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