

Secretary of the 17th Expert Committee on the Selection and Use of Essential Medicines
Medicine Access and Rational Use
Department of Essential Medicines and Pharmaceutical Policies
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

December 22, 2008

Dear Committee Members:

This letter is to offer my support of the application to include misoprostol for the treatment of incomplete abortion and miscarriage on the World Health Organization's (WHO) Model List of Essential Medicines.

Throughout the developing world, unsafe abortion contributes disproportionately to maternal morbidity and mortality. Where abortion is highly restricted and unsafe abortion common, incomplete abortion is one of the major clinical indications for which women present for care. Year 2000 estimates indicate that of 210 million pregnancies globally, 32 million ended in miscarriage or still birth and an additional 46 million ended in induced abortion—many of which were conducted under unhygienic conditions, by an unskilled provider, or both.^{1,2} Between 1995 and 2003, the proportion of abortions worldwide that were unsafe increased from 44 to 48 percent.³ Tackling treatment of incomplete abortion will alleviate the unacceptably high levels of maternal death and disability due to increasing unsafe abortions globally.

Medical evacuation of the uterus with misoprostol offers an alternative to surgical treatment for incomplete abortion, which is often either unavailable or associated with higher morbidity in some low-resource settings. The published literature, including

¹ Alan Guttmacher Institute (AGI). Sharing responsibility: women, society and abortion worldwide. New York: AGI; 1999. p. 7.

² Ahman E, Shah I. Unsafe abortion: global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000. 4th ed. Geneva: World Health Organization; 2004. p. 13.

³ Cohen S. New Data on Abortion Incidence, Safety Illuminate Key Aspects of Worldwide Abortion Data. Guttmacher Policy review. Fall 2007; 10(4).

numerous randomized and comparative clinical trials enrolling over 2,000 women and several clinical guidelines, supports the view that misoprostol is an evidenced-based approach to the treatment of incomplete abortion and miscarriage. Clinical drug trials of misoprostol for incomplete abortion have demonstrated an efficacy rate of 90-100% and high acceptability among women.^{4,5,6,7} Moreover, misoprostol is already included on the 14th and 15th editions of the *WHO's Model List of Essential Medicines (22.1 Oxytocics)* because of its proven safety and efficacy for labor induction and medication abortion.

Our nonprofit organization, Venture Strategies for Health and Development, strongly supports the inclusion of misoprostol into the WHO's Model List of Essential Medicines for the treatment of incomplete abortion and miscarriage as it is directly in line with our work to save women's lives. Misoprostol for the treatment of incomplete abortion and miscarriage is a low cost, simple to administer and safe tablet with the potential to have a greater reach in resource-poor settings than surgical treatment.

In our policy work with leaders within ministries of health, presidents of national obstetrics and gynecology societies, and national safe motherhood coordinators, we witness daily the groundswell of support for misoprostol in the countries where we work. In several countries, ministries of health and local partners are specifically interested in integrating misoprostol for post-abortion care. The Expert Committee's support of misoprostol for this indication will have significant implications for successful public sector integration and implementation of misoprostol for safe motherhood programs that include the treatment of incomplete abortion and miscarriage.

At present, some ministries of health are unable to provide misoprostol for incomplete abortion via standard drug registries because the product is not listed on the Model List of Essential Medicines for this important women's health indication. Likewise, United

⁴ Bique C, Usta M, Debora B, Chong E, Westheimer E, Winikoff B. Comparison of misoprostol and manual vacuum aspiration for the treatment of incomplete abortion. *International Journal of Gynaecology & Obstetrics* 2007;98:222-6.

⁵ Shwekerela B, Kalumuna R, Kipingili R, et al. Misoprostol for treatment of incomplete abortion at the regional hospital level: results from Tanzania.[see comment]. *BJOG: An International Journal of Obstetrics & Gynaecology* 2007;114:1363-7.

⁶ Dao B, Blum J, Thieba B, et al. Is misoprostol a safe, effective and acceptable alternative to manual vacuum aspiration for postabortion care? Results from a randomised trial in Burkina Faso, West Africa.[see comment]. *BJOG: An International Journal of Obstetrics & Gynaecology* 2007;114:1368-75.

⁷ Weeks A, Alia G, Blum J, et al. A randomized trial of misoprostol compared with manual vacuum aspiration for incomplete abortion. *Obstetrics & Gynecology* 2005;106:540-7.

Nations agencies and organizations working in emergency situations often cannot offer misoprostol because of its absence from the list. Adding misoprostol to the model list will remove a significant obstacle to use of a safe and effective non-surgical treatment for incomplete abortion and miscarriage where it is urgently needed. Governments are looking to the WHO and the published Model List of Essential Medicines to guide their policies. The addition—or omission—of misoprostol for the treatment of incomplete abortion and miscarriage has far-reaching implications for millions of women’s lives. I strongly urge the Expert Committee to prioritize women’s lives and add this crucially important medication to the WHO Model List of Essential Medicines for the treatment of incomplete abortion and miscarriage. I thank you for your time and consideration.

Sincerely,



Melodie Holden, MS, MPH
Vice President/ COO