

The Secretary of the 17th 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

December 12, 2008

Dear Committee Members:

We, the undersigned individuals and organizations, are writing this letter in support of Gynuity Health Project's application for misoprostol to be added to WHO's Model List of Essential Medicines for the indication of treatment of incomplete abortion and miscarriage. We request that the Expert Committee give serious consideration to this application.

Unsafe abortion contributes disproportionately to maternal morbidity and mortality in much of the developing world. Incomplete abortion is one the major clinical indications for which women present for care in settings where unsafe abortion is common. Medical evacuation of the uterus with misoprostol offers an alternative to surgical treatment, which is often either unavailable or associated with higher morbidity in some low-resource settings.

A wealth of scientific evidence, which includes numerous randomized and comparative clinical trials and several clinical guidelines, supports our view that misoprostol should be included in the Model List of Essential Medicines for this indication. These data document repeatedly the safety and effectiveness of misoprostol for treatment of incomplete abortion and miscarriage. Over 2,000 women with incomplete abortion or miscarriage have participated in clinical trials of the drug. The most recent of these trials show remarkably high success rates, in the range of 90 to 100%.¹⁻⁴ Of note, misoprostol is already included in the 14th and 15th editions of the *WHO's Model List of Essential Medicines (22.1 Oxytocic)* because of its proven safety and efficacy for medical abortion and labor induction.

Misoprostol's wide availability, low-cost, stability at room temperature and ease of use for both patient and clinician make it an ideal treatment in low-resource settings. Importantly, misoprostol is a very acceptable treatment to women in all types of settings. Research shows that many women prefer this non-invasive method of uterine evacuation to surgical methods.^{1,3,5}

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 particular important women's health indication. Likewise, UN agencies and agencies in emergency situations often cannot offer misoprostol because of its absence on the list. Listing misoprostol for incomplete abortion will break down one of the major barriers to use of this drug and facilitate access to safe and effective postabortion care in many settings throughout the world.

1. Bique C, Usta M, Debra 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.
2. 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.
3. 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.
4. 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.
5. Graziosi GC, Bruinse HW, Reuwer PJ, Mol BW. Women's preferences for misoprostol in case of early pregnancy failure. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2006; 124:184-6.

Complications from incomplete abortion and miscarriage constitute major health concerns for women world wide. We strongly urge the Expert Committee to prioritize women's lives and add misoprostol to the WHO's Model List of Essential Medicines for the indication of incomplete abortion and miscarriage. Thank you for your thorough consideration.

Sincerely,

Advocates for Youth

Association for Reproductive Health Professionals (ARHP)

Dr. André B. Lalonde, MD, FRCSC, FSOGC, FACS, MSc

Executive Vice-President, on behalf of the Society of Obstetricians and Gynaecologists of Canada

Dr Andrew Weeks, MD, MRCOG and

Dr. Christian Fiala, MD, PhD

Founders and editors, www.misoprostol.org

Dr. Asomba Asomba Tobias, MD

Executive Director, on behalf of Christian Community Health Care Foundation (COHECF) Cameroon

Center for Reproductive Rights

Elizabeth S. Maguire, MA, President & CEO and

Dr. Laura Castleman, MD, MPH, MBA, Medical Director

on behalf of Ipas

Engenderhealth

Family Care International

Ibis Reproductive Health

International Medical Corps

International Planned Parenthood Federation

Lindsey Fauss, Program Officer in International Programs, on behalf of the Buffet Foundation

Melanie Zurek, Executive Director, on behalf of Abortion Access Project

Pape Gaye, MBA

President & CEO, on behalf of IntraHealth International, Inc.

Population Services International (PSI)

Program for Appropriate Technology in Health (PATH)

Reproductive Health Technologies Project (RHTP)

Sexual Health and Family Planning Australia

Dr. Simon Nchifor, MD, OB/GYN

International Consultant in Reproductive Health

Women's Commission for Refugee Women and Children