



UNIVERSITY OF
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FACULTY OF LAW

September 7, 2007

Karen Wolfe
Executive Director
The National Association of Pharmacy Regulatory Authorities
#750-220 Laurier Ave W.
Ottawa, Ontario, Canada K1P 5Z9

Dear Ms. Wolfe:

Re: Request for changes to the scheduling status of levonorgestrel 0.75 mg from Schedule II to Schedule III

I am writing on behalf of the International Reproductive and Sexual Health Law Programme, Faculty of Law, University of Toronto to support the requested status change of levonorgestrel 0.75 mg, packaged and labelled for use as emergency contraception, from Schedule II to Schedule III.

The International Reproductive and Sexual Health Law Programme is an academic programme dedicated to improving the legal protection and promotion of reproductive and sexual health. The Programme has expertise in the application of equality and non-discrimination rights in the regulation of reproductive health care and has collaborated with government and international agencies, non-government organizations, and academic institutions to develop policies and scholarship on this subject.

The removal of required professional intervention from a pharmacist at the point of sale will significantly facilitate Canadian women's safe and effective access to emergency contraception. We therefore support the requested change to the scheduling status of emergency contraception as an important measure to ensure women's right to access health care on a basis of equality and free from discrimination as guaranteed by the *Canadian Charter of Rights and Freedoms* and the *Convention on the Elimination of All Forms of Discrimination against Women*.

Women's access to reproductive health care requires more than the mere availability of goods and services. Effective access requires that regulation of available reproductive health care, such as the conditions for sale of contraceptive products, address the needs of women in accessing care. Professional intervention from a pharmacist at the point of sale, as required by Schedule II status, fails to address important needs of women in accessing reproductive health care. It compromises women's privacy, increases out-of-pocket costs and may delay access as a result of pharmacists' exercise of conscientious objection. Schedule II status thereby restricts, if not prevents, women's access to available emergency contraception.

Pharmacist intervention requires the disclosure and collection of sensitive personal information, such as a woman's contraceptive practices. Respect for women's privacy is an essential component of effective access to reproductive health care. Many women, and especially adolescent women, are reluctant to disclose personal information when the need for collection is insufficiently demonstrated or where inadequate protection is provided. Most pharmacies, for example, do not have areas where pharmacists can hold private consultations. Women may be deterred from seeking emergency contraception where disclosure of personal information is a requirement of access to care.

Schedule II status also increases women's out-of-pocket costs for emergency contraception. Unlike physician consultations, pharmacist consultations are not routinely reimbursed by all public health insurance plans. In order to access emergency contraception directly in pharmacies, women must privately pay for pharmacist consultation fees in addition to dispensing fees and the cost of the medication itself. Affordability is an important component of accessible care. More than 1.5 million Canadian women lived in poverty.¹ Women also represent a disproportionate share of the Canadian population with low incomes.² Pharmacy regulation that increases the private costs of emergency contraception restricts access to valuable preventative care for poor and low income women.

Schedule II status may delay access to care as a result of pharmacists' exercise of conscientious objection. While pharmacists are protected from participating in the provision of healthcare to which they object on grounds of conscience, pharmacists who refuse to dispense emergency contraception on these grounds are obligated as a matter of professional ethics and law to refer women to another pharmacist or health facility where emergency contraception can be accessed.³ In circumstances where healthcare providers and facilities are limited, however, such as smaller towns or rural communities, the referral process may affect women's timely access to care. This is an especially important consideration in access to emergency contraception given that levonorgestrel exhibits a significant downward gradient in effectiveness as the time between intercourse and use increases.⁴ Even where alternative pharmacy services are conveniently available, the experience of a moral confrontation may affect women's capacity to make a free and informed decision about her reproductive health care needs. Women may also be deterred by the potential of moral judgment from even seeking care.

While the barriers to access imposed by Schedule II status are of serious concern, they may be justified if the safe and effective use of emergency contraception necessitates professional intervention from a pharmacist at the point of sale. Authoritative and widespread evidence demonstrates, however, that women can safely and effectively self-diagnose, self-select and self-administer emergency contraception. When assessed against the factors for Schedule II status, mandatory pharmacist intervention for emergency contraception proves unwarranted.

The initial need for emergency contraception, for example, is not normally identified by a health professional. Rather, health professionals rely on women to diagnose their need for emergency contraception. A woman is best positioned to know if she has had unprotected sexual intercourse. Although a pharmacist could dissuade a woman from using emergency contraception when she faces a low risk of pregnancy, there is no medical reason to do so. Even if the risk of pregnancy is low, a woman may wish to reduce her risk for non-medical reasons.⁵ Clinical guidelines of the Society of Obstetricians and Gynecologists of Canada recommend that emergency contraception “be considered for any woman wishing to avoid pregnancy, who presents within 5 days of unprotected or inadequately protected sexual intercourse.”⁶ The Regulatory Impact Assessment Analysis Statement (RIAS) that accompanied Health Canada’s deregulation of levonorgestrel as a prescription drug further states that “even regular postcoital use is associated with no serious or lasting adverse events other than reversible menstrual irregularities.”⁷ Emergency contraception, however, carries no abuse potential. This is in part because other contraceptive methods are more effective than the repeated use of emergency contraception and its side effects, although temporary and not serious, deter frequent repeated use.

Evidence demonstrates that the use of emergency contraception does not require reinforcement or expansion of directions for use through pharmacist-patient dialogue. Recent studies confirm that as long as credible information about emergency contraception use is provided on the product label, women can safely and effectively self-administer.⁸ In these studies, vulnerable groups, such as young or less-educated women, were not substantially less likely than others to use the product incorrectly. Individualized instruction is also unnecessary as the treatment is identical for all women.⁹ In this respect, emergency contraception is simpler to administer than many medications currently available over-the-counter, which require tailored dosages based on patient characteristics or therapeutic response.¹⁰ In addition, as stated by Health Canada, patient monitoring following use is generally not required unless there is a delay in the return of menstrual period.¹¹ Evidence indicates, however, that delay of menses and the need to seek follow-up care may also be adequately addressed in product labelling.

There is no evidence to support claims that a lack of professional intervention will lead to risk-taking in sexual activity or regular contraceptive use.¹² On the contrary, studies indicate that women who are most diligent about ongoing contraceptive use are most likely to seek emergency contraception.¹³ These claims are strongly influenced by sex discriminatory assumptions about women’s tendency toward promiscuous sexual behavior and the mismanagement of their reproductive health. Such assumptions should be strongly guarded against in regulatory decision-making. The use of emergency contraception represents an informed health care decision by women seeking to prevent unwanted pregnancy, and should be regulated as such.

Given the evidence that women can safely and effectively self-diagnose, self-select and self-administer emergency contraception, Schedule II status compromises women's access to valuable reproductive health care without furthering the objectives that lie behind pharmacy regulation. For this reason, we strongly support the requested change to the scheduling status of emergency contraception from Schedule II to Schedule III. By addressing the needs of women in accessing emergency contraception, the removal of required pharmacist intervention is an important measure to ensure Canadian women's access to reproductive health care.

Thank you kindly for your consideration of this letter.

Sincerely,

Joanna N. Erdman
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Director, Health Equity and Law Clinic
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Faculty of Law
University of Toronto

¹ M. Townson. *Poverty Issues for Canadian Women: Background Paper 3*. (2005).

² Statistics Canada. *Women in Canada: A Gender-Based Statistical Report*. 5th ed. (2006).

³ The Code of Ethics adopted by the College of Pharmacists of British Columbia, for example, requires that "[a] pharmacist ensure continuity of care in the event of ... conflict with moral beliefs." The 2006 Code of Ethics for Members of the Ontario College of Pharmacists provides that "No patient shall be deprived of access to pharmaceutical services because of the personal convictions or religious beliefs of a member. Where such circumstances occur, the member refers the patient to a pharmacist who can meet the patient's needs."

⁴ D.A. Grimes et al. "Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for Emergency Contraception" (1998) 352:9126 *Lancet* 428. See also C. Westhoff. "Emergency Contraception" (2003) 349(19) *N. Eng. J. Med.* 1830.

⁵ C. Ellerston et al. "Should Emergency Contraceptive Pills Be Available Without Prescription?" (1998) 53:5 *JAMWA* 226

⁶ S. Dunn & E. Guilbert. "SOCG Clinical Practice Guidelines: Emergency Contraception" (2003) 131 *J. Obstet. Gynaecol. Can.* 673.

⁷ Canada Gazette Part II. (2005). *Regulatory impact analysis statement*, SOR/2005-105, vol. 139(9): 857.

⁸ See E.G. Raymond, S.M. Dalebout & S.I. Camp. "Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product" (2002) 100(2) *Obstet. Gynecol.* 342; E.G. Raymond, P. Chen & S.M. Dalebout. "'Actual use' study of emergency contraceptive pills provided in a simulated over-the-counter manner" (2003) 102(1) *Obstet. Gynecol.* 17.

⁹ C. Ellerston et al. "Should Emergency Contraceptive Pills Be Available Without Prescription?" (1998) 53:5 *JAMWA* 226.

¹⁰ D. Grimes, E. Raymond & B. Scott Jones, "Emergency Contraception Over-The-Counter: The Medical and Legal Imperatives" (2001) 98:1 *Obstet. Gynecol.* 151.

¹¹ Canada Gazette Part II. (2005). *Regulatory impact analysis statement*, SOR/2005-105, vol. 139(9): 857.

¹² A. Glasier and D. Baird. "The effects of self-administering emergency contraception" (1998) 339:1 *N. Engl. J. Med.* 1.

¹³ E. Kosunen, S. Sihvo & E. Hemminki. "Knowledge and use of hormonal EC in Finland." (1997) 55 *Contraception* 153.