Join us in:

Improving Access to Emergency Contraception

A call to action

Access to emergency contraception, popularly known as “the morning after pill” is a key element in any comprehensive program addressing women’s reproductive and sexual health. It is of particular importance to the health of teenaged girls and young women, the age group at greatest risk, relative to the general population of women, of unintended pregnancy. Effective access to emergency contraception requires that it be readily available, quickly, regardless of a woman’s age. It must be accessible to rural as well as urban women and to women of limited financial means. Finally, it must be accessible in a way that respects women’s right to privacy, as well as their right to freely make informed health care choices. The use of emergency contraception represents a responsible and informed decision by a woman seeking to prevent an unintended pregnancy and must be respected as such.

There is currently available in Canada a safe, effective, and easy-to-use emergency contraceptive pill. It is sold under the brand name Plan B and its active ingredient is levonorgestrel, a progestin with a long and positive track record, commonly-used in birth control pills.¹

Women and Health Protection (WHP) and the Canadian Women’s Health Network (CWHN) want access to emergency contraception to be improved. A lack of awareness about emergency contraception, the costs of obtaining it, and existing regulations unnecessarily restrict this access. As a first step in improving access, we are submitting a request to Canadian regulatory authorities for Plan B to become an “off-schedule” medication, available for sale at any retail outlet.

We invite and encourage you to give your support to this position.

¹ Throughout this paper, the emergency contraceptive pill (ECP) referred to is Plan B.
**Context: how drugs are regulated**
The Food and Drugs Act regulates the use of therapeutic drugs and medical devices in Canada. Schedule F of the Act’s regulations lists products that require a prescription from a licensed health practitioner. Individual provinces decide whether the licensed practitioner must be a medical doctor, a pharmacist, a nurse practitioner, or other.

For drugs that are not federally controlled, individual provinces decide how and to what extent to regulate them. Most provinces look to the National Association of Pharmacy Regulatory Authorities (NAPRA) for guidance in deciding what regulations to impose. NAPRA is an association that represents registrars of provincial colleges of pharmacy across Canada. It is a self-regulating body that appoints, from among its members, the National Drug Scheduling Advisory Committee (NDSAC). The role of NDSAC is to establish national standards by assigning drugs to one of three schedules. They may also determine that a drug is an “off-schedule” product. The following table lists the regulatory options. Detailed guidelines for inclusion of a product in each schedule are set out in Appendix A.

<table>
<thead>
<tr>
<th>NDSAC Schedules</th>
<th>Associated regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>The product is available only when prescribed by a physician.</td>
</tr>
<tr>
<td>II</td>
<td>The product is available without a physician’s prescription, but is kept “behind the counter” in pharmacies and is only available by request to the pharmacist. This essentially amounts to prescription by pharmacist.</td>
</tr>
<tr>
<td>III</td>
<td>The product is available “over the counter”, but in an area of a pharmacy that can be supervised by a pharmacist; consumers can purchase the product without any consultation.</td>
</tr>
<tr>
<td>Off-schedule</td>
<td>The product is available for sale at any retail outlet, with no health professional oversight.</td>
</tr>
</tbody>
</table>

In Manitoba, Ontario, New Brunswick, Nova Scotia and Saskatchewan, provincial legislation delegates regulatory power to the respective Colleges of Pharmacy. Scheduling amendments made by NDSAC are effective immediately in these Provinces. Prince Edward Island has plans to adopt similar regulations in the near future. Although British Columbia, Newfoundland and the Northwest Territories have not completely delegated regulatory authority, each has regulations or systems in place to automatically review and (generally) adopt NDSAC recommendations. Alberta has not adopted the national drug scheduling system, but generally follows NDSAC’s recommendations as well. ¹ The Yukon and Nunavut are not yet part of NAPRA. (See Appendix B for more detail.) In Quebec, which is not a member of NAPRA, decisions on the regulatory status of therapeutic drugs are made by the Department of Strategic Planning, Evaluation and Information Management.
within the Ministry of Health and Social Services.

**Current status of the Emergency Contraception Pill (ECP) in Canada**

As of April 19, 2005, Plan B has been removed from Schedule F of the Food and Drugs Act; this means it is no longer federally mandated as a prescription drug. This decision is supported by the Society of Obstetricians and Gynaecologists of Canada, Planned Parenthood Federation of Canada, the Canadian Pharmacists’ Association, the CWHN and the Women’s Capital Corporation. Many organizations within the Canadian women’s health community also support Plan B having non-prescription status.

NDSAC has acted immediately to classify Plan B as a Schedule II drug, making it a behind-the-counter product with access controlled by pharmacists. As a result, in most Canadian provinces women and girls have to make a request to a pharmacist to purchase ECP.

Schedule II status for ECP is an important first step. However, we are concerned that this behind-the-counter status is unnecessarily restrictive and will cause needless delays in access. We want ECP to be easily available to women at any retail outlet. We also want to see programs put in place that ensure access for low income women. Awareness of ECP remains limited. Programs that urge sexually active young women to have a “back up” to their birth control method remain few and far between.

**ECP: the facts**

**What it is:** ECP is a hormonal product, taken orally, to prevent pregnancy after unprotected intercourse. This same hormone is used in some birth control pills.

**Effectiveness:** ECP has been shown to have an overall 89% rate of effectiveness if used within 72 hours of unprotected intercourse. The rate climbs to 95% if the medication is taken within 24 hours of intercourse, but it drops to only 58% if taken more than 49 hours after intercourse. Some experts have noted that ECP can provide benefit if taken up to 5 days after intercourse.

**Safety record:** ECP is safe. There have been no reports of deaths or other serious consequences from taking Plan B. Pregnancy is listed as a contraindication only because, like all contraceptives, ECP will not work if a woman is already pregnant. If a woman takes ECP while pregnant, it will not affect her pregnancy and it will not harm the foetus. ECP does not cause an abortion.

**Side effects:** Women using Plan B may have side effects like nausea, diarrhoea and spotting. Their period may come early or late and look a little different.

**Ease of use:** No individualized instruction is needed when taking ECP because the dose is identical for all women. Explanations for use are simple and easy to follow.

**Other jurisdictions:** Women have direct access to ECP in a growing number of countries, including Brazil, Dominican Republic, France, Israel, Kenya, Madagascar, Malaysia, Netherlands, South Africa, Sweden, Thailand, UK, and Vietnam.

**Access behind-the-counter**

Increasing access to ECP can help reduce unintended pregnancy. Given that this is a safe, effective and easy to use medication, a key consideration is the need for timeliness in its use. ECP is most likely to prevent a pregnancy if taken within 24 hours of intercourse. As
more time passes, the effectiveness rate decreases. It is clear that timely access to the medication is crucial and the determination of its scheduling status must take this into account. ECP must be available to women and adolescent girls in a location that is accessible daily, including on weekends and holidays, and that is accessible to rural as well as urban consumers. It should be easy to find and purchase.

Behind-the-counter (Schedule II) status means that only pharmacies can carry ECP — a significant limitation in small towns and rural communities. Some pharmacists, due to religious or other convictions, have already declared their unwillingness to dispense ECP. This is likely to continue to be an issue and could pose substantial problems for timely and equitable availability, particularly in small towns and rural areas where there may be only one local pharmacy.

The right to privacy
Current guidelines for pharmacists require a “consultation” with a woman before providing ECP. This is, in our view, an unnecessary intervention that interferes with women’s right to privacy. Women should not be treated as patients when there is no evidence of medical necessity. Women and teenagers are able to diagnose their need, understand the labelling and directions, and use ECP safely and effectively without medical intervention.

The need for ECP is a private matter and it must be available in a manner that respects an individual’s privacy to the greatest extent possible. If ECP is only available by consultation with a pharmacist, the purchaser may well find herself having this consultation at a very public prescription counter. While pharmacists are encouraged to provide a private area for consultations, a private room away from the retail area frequently does not exist.

Complete privacy is obviously impossible because of the need to purchase ECP in a public place. However, being able to take a product off the shelf and directly to the checkout counter provides a greater degree of privacy than having a discussion at a prescription counter. Even greater privacy can be achieved if the consumer has a number of options available for purchasing the product. Imagine a woman or an adolescent girl having to purchase her ECP on a Sunday at the only pharmacy in town open at that time. On arriving at the pharmacy, she discovers that a family friend is working at the cash register. Having another option of where to purchase the medication would greatly enhance her privacy and, therefore, increase the likelihood of her making the purchase and taking the pills within the optimal time frame.

Costs behind the counter
Finally, there is the question of cost. Government and private drug insurance plans do not generally cover non-prescription drugs or pharmacists’ “consultation” services. Therefore, it is likely that the cost of ECP will increase as provinces remove emergency contraception from provincial formularies, with the result that low-income women and women with drug plans will have to cover the cost themselves. As pointed out by Joanna Erdman and Rebecca Cook, behind-the-counter status for ECP may result in women having to pay the cost of the medication, plus a dispensing fee, plus a pharmacist consultation fee. Consultation fees range from $15 to $45.

If ECP is available over-the-counter, no dispensing fee is involved and there is no
consultation fee, resulting in a more affordable cost. In addition to looking at the cost to the consumer, it is worth considering that more widespread availability of ECP could result in savings to the healthcare system. The average cost of an unintended pregnancy in Canada is $1,289 — just for medical services. The average cost of an abortion is $618. Although not the responsibility of those regulating the schedule, provincial governments should see ECP as an essential drug to which all women can have access, no matter what their income level.

**Access and adolescents**
The particular needs of adolescent girls must receive special consideration in determining to what extent ECP is regulated. While statistics show that teen pregnancy rates have been dropping, with teenagers using birth control more consistently than ever, there is still evidence that girls aged 15 to 19 are more likely than older women to engage in unplanned intercourse and to use contraception intermittently or not at all. Therefore we must ensure that ECP is accessible to adolescents. Adolescents, like adult women, can understand the instructions provided in the package. Adolescents have the ability to purchase condoms, aspirin and other drugs; ECP should be no different. Regardless of whether unprotected intercourse was unplanned, the result of a method failure, or the result of an assault, adolescents’ strong need for privacy can prevent them from seeking assistance from any health professional. They fear a lack of confidentiality and are not willing to risk having their parents notified. Requiring contact with a pharmacist creates a barrier – one that sexually active teens may not cross.

In addition, pharmacists may not be adequately prepared to meet adolescent needs. In a survey of pharmacists trained to provide ECP, many still reported that they were inadequately trained to deal with parents’ inquiries about provision of ECP to their daughters.

**Why not Schedule III?**
Schedule III “over-the-counter” drugs are found on shelves within a pharmacy in an area that can be supervised by a pharmacist, but where consumers can help themselves. When purchasing an over-the-counter product, the consumer can choose whether or not to seek advice from the supervising pharmacist.

Introducing the element of choice is certainly preferable to a situation of mandated advice; surely women and girls purchasing ECP can decide for themselves whether they need or want advice. If the goal, however, is to maximize equitable and speedy access, Schedule III status poses many of the same problems as Schedule II. If ECP can only be purchased in an area supervised by a pharmacist, there may be more limited hours of access, especially on evenings and weekends. While a large drugstore may have extended hours, the hours during which there is a pharmacist on duty may not be as extensive. When there is no pharmacist on duty, Schedule III products are not available.

Concerns about the growing number of pharmacists who are unwilling to sell ECP for religious or other reasons are also not addressed by Schedule III status.

Most importantly, Schedule III status does not address the situation of women in small towns and rural areas, where there may be only one local pharmacy, with limited hours, and where privacy concerns are more likely to arise.
Does increasing access increase promiscuity?
There has been some debate about whether increased availability of ECP may lead to increased sexual promiscuity. A recent University of California study indicates that this is not the case:

“Young, urban women showed no reduction in their use of contraceptives, nor any other changes in their sexual behavior when provided with easier access to the so-called ‘morning after pill’, also known as emergency contraception (EC), according to UCSF researchers. Rates of pregnancy and sexually transmitted infections (STIs) were the same at the end of the six-month study regardless of whether women had increased access to EC.”¹¹

The results of this study are consistent with previous findings: increased access to emergency contraception does not result in women abandoning traditional contraception methods,¹² nor does it encourage adolescents to engage in promiscuous sex.¹³

Increasing Access and Reducing Unintended pregnancy
The inherent value of ECP is that it eliminates the need for women and adolescent girls to choose between abortion and unwanted pregnancy by providing a third option. The safety record of Plan B, as well as clear indications for use and ease of use, make it an obvious candidate for sale as an unscheduled product available at any retail outlet. The risks of making ECP widely available are negligible; the benefits are significant. “ACOG [the American College of Obstetricians and Gynecologists] and other organizations have estimated that the greater access to Emergency Contraception could cut the US unintended pregnancy and abortion rates in half.”¹⁴ There is every reason to think that the same would be true in Canada.

Please join us in improving the reproductive health of Canadian women by endorsing our call for “off-schedule” status for the emergency contraception pill. If you wish to have the name of your organization or group, or your own name added to the joint CWHN/WHP brief to the National Drug Scheduling Advisory Committee, please send us your contact information by email at cwhn@cwhn.ca, by fax at 204-989-2355 or by phone, toll free, at 1-888-818-9172.

As stated in a recent editorial in the Journal of the Canadian Medical Association, “Health Canada's reclassification of the levonorgestrel "morning-after pill" as a nonprescription drug . . . is welcome news. Less welcome is the "behind the counter" classification . . .”¹⁵

By building a strong coalition, we can work toward the goal of fully accessible emergency contraception for all Canadian women.
11 Carol Hyman, UCSF, “Sex habits of young women unchanged by morning after pill” from “Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs: A Randomized Controlled Trial”, Tina R. Raine; Cynthia C. Harper; Corinne H. Rocca; Richard Fischer; Nancy Padian; Jeffrey D. Klausner; Philip D. Daney, JAMA 2005;293 54-62, http://jama.ama-assn.org/cgi/content/abstract/293/1/54?etoc
Appendix A

Outline of the Scheduling Process

Factors for Schedule I

1. Indications for use of the drug are identifiable only by the practitioner.
   Diagnosis of the indication requires intervention by the practitioner before the drug is used.
2. Use of the drug requires adjunctive therapy or evaluation.
   Adjunctive therapy could include other drugs, non-pharmacologic measures, or specialized drug delivery devices. Evaluation could include indicated laboratory or clinical assessments.
3. Use of the drug may produce dependency.
   The drug may cause addiction or become habit forming. Control of access and duration of therapy by a health care professional is required.
4. Serious adverse reactions to the drug are known to occur or have a recognized potential to occur at normal therapeutic dosage levels.
   Adverse experiences require special monitoring or intervention by a health care professional.
5. There exists a narrow margin of safety between the therapeutic and toxic dosages of the drug, either in the general population, or in identified subpopulations, or in patients with multiple medical problems.
   Safe use requires the involvement and intervention of a health care professional.
6. Serious interactions of the drug are known to occur.
   Such interactions (drug-drug, drug-food, drug-disease) require special monitoring or intervention by a health care professional.
7. Use of the drug has contributed to, or is likely to contribute to, the development of resistant strains of microorganisms.
   Appropriate use, and/or the decision to continue treatment, requires evaluation by the practitioner.
8. The mechanism of action of the drug is known but the consequences of widespread use are not adequately established.
   Unexpected effects of the drug must be evaluated and reported by a health care professional.
9. The therapeutic effects of a newly released drug are based on new or unknown mechanisms of action, but the consequences of widespread use are not adequately established.
   Close monitoring of the patient is required by a health care professional for unanticipated effects.

Factors for Schedule II

1. The initial need for a drug is normally identified by the practitioner, in addition chronic, recurrent, or subsequent therapy must be monitored by the pharmacist.
   A prescription should not be required to obtain a drug if the patient can understand directions for continued use through the intervention of the pharmacist. Therefore, the patient should have access to the drug for subsequent treatment and use following the first diagnosis and prescription by the practitioner. This collaborative approach enhances patient care. 11/98
2. The drug must be readily available under exceptional circumstances when a prescription is not practical.
   Such a drug might be required for a serious medical situation and the patient should have access to it to prevent a possible health emergency. An example of such an exceptional
circumstance is availability of injectable epinephrine for anaphylactic reactions.

3. The drug is intended for administration in a health care setting or under direction of a health care professional, or is in an injectable dosage form and is not otherwise included in Schedule I. Examples include preoperative or diagnostic agents and products used for immunization or desensitization.

4. Evidence of abuse of the drug has been reported, due to its inherent pharmacological action which has the potential for abuse. Monitoring by a health care professional is necessary. 11/98

5. The selection of the drug requires intervention by the pharmacist to confirm that an appropriate self-assessment has been made by the patient. Dosage form, for example, may be an important consideration.

6. Use of the drug may delay recognition or mask the symptoms of serious disease. Intervention by the pharmacist is necessary to ensure appropriate referral to the practitioner.

7. The drug may cause important adverse reactions, including allergies, or interacts with other drugs, foods, or disease states that cannot be adequately addressed through product labelling. Intervention by the pharmacist is necessary to assess patient risk to prevent such problems for an individual patient through interpretation and clarification of labelling.

8. Use of the drug requires reinforcement or an expansion of the directions for use, through pharmacist - patient dialogue. Such reinforcement and expansion may include the explanation of the use of a drug delivery system.

9. The drug is a new ingredient for self-medication and monitoring by the pharmacist is necessary to facilitate observation and reporting of any unexpected event.

10. The maximum labelled dosage directions exceed the generally accepted or usual limits for Schedule III status. 11/98

Factors for Schedule III

1. The initial need for a drug is normally identified by the patient, physician, or pharmacist, but chronic, recurrent, or subsequent therapy can be monitored by the pharmacist. 11/98

2. The maximum recommended duration of use of the drug is limited and specified on the product label. The pharmacist is available to explain that the consequences of not following the period of use may be serious and that persistence of symptoms may suggest an underlying ailment.

3. The maximum recommended duration of use of the drug is not specified on the label, but continued use may delay recognition or mask the symptoms of serious disease. The pharmacist is available to help in interpretation of symptoms, to assist in selection of alternative therapy, or to provide appropriate referral.

4. The drug is used to treat a persistent, chronic or recurring condition and the availability of the pharmacist to provide advice can promote appropriate use. The pharmacist should be available to direct the patient to a practitioner for assessment if the treatment period has been inappropriate or the therapy has been ineffective.

5. The drug is used for self-treatment of self-limiting ailments; however, where product selection has been identified as likely to cause patient confusion and the availability of the pharmacist to provide advice can promote appropriate use. Many product selections may be confusing for the patient. These choices are further complicated by the different forms of available therapy or dosage forms. 11/98

6. The drug demonstrates adverse effects, including allergies, or interacts with other drugs,
foods, or disease states that can be identified in product labelling, but appropriate product selection and explanation of risk may require the advice of the pharmacist. For example, individuals taking a traditional monoamine oxidase inhibitor are aware that certain drugs should be avoided (e.g., cold products) but might require assistance in selecting a safe product to use.

7. The drug is a new ingredient for self-selected self-medication and the availability of the pharmacist to provide advice can promote appropriate use.

The pharmacist is available to answer questions about this new ingredient.

8. The drug has inherent pharmacologic action which has the potential for non-medical use which may result in adverse patient outcomes.

9. The maximum labelled dosage direction exceeds the generally accepted or usual limits for unscheduled status. 11/98

Appendix B

Implementation of the National Drug Schedule Model Across Canada
(as of February 2004)

Alberta
In most cases, Alberta follows the recommendations of the National Drug Scheduling Advisory Committee (NDSAC). There are only limited differences between Alberta’s schedule I and II and the national model. However, the number of drugs listed in schedule III in Alberta is substantively less than in the national model. This is because many of the products listed in schedule III nationally were available in non-pharmacy outlets prior to the adoption of the national process. Alberta will follow the future recommendations of the NDSAC. In most cases, scheduling changes will be made immediately upon the recommendations of NDSAC becoming effective. Due to the aforementioned differences, Alberta does maintain a list of its drug schedules on its website at www.altapharm.org

British Columbia
The National Drug Scheduling System was adopted in March 1998. However, scheduling decision must first be approved by the College of Pharmacists of BC (CPBC) and the BC government, and this causes a waiting period before scheduling decisions can be implemented in that province. The CPBC has submitted a request to the government for a By-law change to allow scheduling decisions to be adopted directly. Provincial implementation time: 3 months.

Manitoba
Manitoba was the first province to adopt the National Drug Scheduling System model as the provincial model (“scheduling by reference” to the national model). This was done in September 1998. Scheduling amendments made to the National Drug Scheduling System are immediately effective in Manitoba.

New Brunswick
New Brunswick was the second province to adopt the National Drug Scheduling System model as the provincial model (“scheduling by reference”). This was done in January 1999. Scheduling amendments made to the National Drug Scheduling System are immediately effective in New Brunswick.
Newfoundland and Labrador
The National Drug Scheduling System was adopted in May 2001. No plans at the moment to adopt scheduling by reference.
Provincial implementation time: 1 - 2 months.

Nova Scotia
In July 2001, Nova Scotia became the fourth province to adopt the National Drug Scheduling System model as the provincial model (“scheduling by reference”). Scheduling amendments made to the National Drug Scheduling System are immediately effective in Nova Scotia.

Ontario
Ontario was the third province to adopt the National Drug Scheduling System model as the provincial model (“scheduling by reference”). This was done in April 1999. Scheduling amendments made to the National Drug Scheduling System are immediately effective in Ontario.

Prince Edward Island
Provincial Act was recently changed to accommodate the National Drug Scheduling system by reference. Enabling Regulations are expected to be passed by government by the end of March 2004.

Quebec
No plans are underway for provincial adoption of the national model.

Saskatchewan
The National Drug Scheduling System was adopted by the Saskatchewan Council in January 1998. Direct scheduling by reference to the National System is supported by the Saskatchewan College of Pharmacists. Government approval in principle has been received informally, and the formal process to obtain approval is in progress.
Provincial implementation time: minimum 6 weeks.
This document was jointly prepared by the Women and Health Protection working group and the Canadian Women's Health Network. We wish to thank Joanne Erdman and Rebecca Cook, whose work provided much of the background information for this paper. Thanks go as well to Lyba Spring, Joanne Erdman and Nathalie Parent for their feedback and input.

Permission to duplicate is granted provided credit is given and the materials are made available free of charge.

Women and Health Protection is financially supported by the Women’s Health Contribution Program, Bureau of Women’s Health and Gender Analysis, Health Canada. The views expressed herein do not necessarily represent the views of the Bureau of Women's Health and Gender Analysis, Health Canada.

Également disponible en français.

May 2005