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FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1272 — Levonorgestrel)

P.C. 2005-614 April 19, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1272 — Levonorgestrel)*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1272 — LEVONORGESTREL)

AMENDMENT

1. The drug description "Sex hormones" in Part II of Schedule F to the *Food and Drug Regulations* ([see footnote 1](#)) is amended by adding to its list of exceptions the following, in alphabetical order:

Levonorgestrel, when sold in concentrations of 0.75 mg per oral dosage unit *Lévonorgestrel, s'il est vendu en une concentration de 0,75 mg par unité posologique orale*

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

- [News and announcements](#)
- [Mandate](#)
- [Consultation](#)
- [Recent *Canada Gazette* publications](#)
- [Part I: Notices and proposed regulations](#)
- [Part II: Official regulations](#)
- [Part III: Acts of Parliament](#)
- [Learn more about the *Canada Gazette*](#)
- [Publishing information](#)
- [Publishing requirements](#)
- [Deadline schedule](#)
- [Insertion rates](#)
- [Request for insertion form](#)
- [Subscription information](#)
- [Useful links](#)
- [Archives \(1998–2003\)](#)

This amendment excludes from Part II of Schedule F to the *Food and Drug Regulations*, levonorgestrel, when sold in a concentration of 0.75 mg per oral dosage unit. This is the dosage strength of levonorgestrel recommended for use as an emergency contraceptive (EC).

Part II of Schedule F lists medicinal ingredients that require a prescription for human use, but do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use. Presently all dosage strengths of levonorgestrel are included in Schedule F, Part II in the group listing for sex hormones.

The term "emergency contraceptive" has been used internationally for many years to describe contraceptive methods that can be used by women within a few days after unprotected intercourse or contraceptive failure to prevent an unwanted pregnancy. Some forms of ECs have been available for almost thirty years.

Timely access to levonorgestrel 0.75 mg is important for it to be effective as an EC. It can prevent pregnancy if the first dose is taken within 72 hours following unprotected intercourse, and the second dose is taken 12 hours after the first dose. Efficacy is greatest when treatment commences within the first 24-hour period. Currently, because a prescription is required from a practitioner, levonorgestrel 0.75 mg is not always available within the recommended time period, especially during weekends and holidays.

Levonorgestrel 0.75 mg is the only EC that has been approved for use in Canada. It acts as an EC by preventing the release of an egg from the ovary, preventing fertilization of the egg or preventing the fertilized egg from attaching to the wall of the uterus. Levonorgestrel 0.75 mg has been available to Canadian women as a prescription drug for EC use since February, 2000. Its explicit listing on Schedule F did not require a regulatory amendment as it was automatically included in the Part II group listing for sex hormones.

The federal *Food and Drug Regulations* (Regulations) define a practitioner as a person authorized by the law of a province of Canada to treat patients with any drug listed or described in Schedule F to the Regulations. The provincial laws regarding practitioners and authority to prescribe drugs vary from province to province. For example, British Columbia, Quebec and Saskatchewan enacted legislative changes in 2000, 2001 and 2003, respectively, allowing pharmacists in those provinces to prescribe levonorgestrel 0.75 mg as an EC. Other provinces and territories have not done so. Therefore, levonorgestrel 0.75 mg for EC use is not equally available to women across the country.

An article, *Provision of emergency contraceptives by pharmacists* by Judith A. Soon et al, was published in the *Canadian Pharmaceutical Journal* in July, 2004. This paper described the results of a study of pharmacist-prescribed levonorgestrel 0.75 mg in British Columbia since 2001. It concluded that specially trained community pharmacists improved access to ECs in all regions of the province. More than half of the ECs were provided on weeknights, weekends and holidays when most physician offices and clinics were closed. Fifty-seven percent (57%) of women were able to access ECs within 24 hours of unprotected intercourse and eighty-seven percent (87%) within 48 hours.

The results of a year-long pharmacist prescribing pilot project in Ontario has also been published. Pharmacists participating in the project received training on the use of ECs. The 2001-2002 pilot project involved almost 7,000 doses of EC. Fifty-four percent (54%) of the women accessed EC within 24 hours of

intercourse. The majority of women were very satisfied with the service, and 21.1% indicated that had they not obtained EC in this way, they would not have obtained it elsewhere.

Levonorgestrel as a component of daily oral contraceptive products has been widely used as a prescription drug in women for several decades. There is therefore a large amount of post-market data available regarding the long-term effects of daily use of levonorgestrel by women.

There is also a long history of safe and effective use of levonorgestrel 0.75 mg as an EC. The first clinical trials using levonorgestrel 0.75 mg as an EC were conducted in the 1970's. Post-marketing surveillance by pharmacovigilance agencies indicates no safety problems. There have been no adverse drug reaction reports in Canada for levonorgestrel 0.75 mg as an EC during the time that it has been available as a prescription drug.

The World Health Organization (WHO) supports the use of ECs and their ready availability. Levonorgestrel 0.75 mg for emergency contraception is available without a doctor's prescription in 28 countries including the United Kingdom, France, Denmark and Norway. The WHO has concluded that ECs are appropriate for general use and do not have a clinical effect on pre-existing conditions such as heart or liver disease. It has also concluded that there is unlikely to be an increased risk of heart attack and stroke with the short duration use of levonorgestrel 0.75 mg for emergency contraception.

Levonorgestrel 0.75 mg, when used occasionally as an EC, does not increase either the absolute risk of ectopic (tubal) pregnancy or the chance that a pregnancy following its use will be ectopic. There is no known increased risk of birth defects in women who have inadvertently taken levonorgestrel when pregnant.

Experience in other countries shows that easier access to ECs does not lead to excessive use. Excessive use or use of levonorgestrel 0.75 mg as a form of regular contraception is unlikely to occur. There are several reasons why levonorgestrel 0.75 mg is not a logical choice for ongoing contraception:

- any method of ongoing contraception is more effective than repeated use of an EC;
- long-term overuse can cause prolonged menstrual bleeding;
- the possible side-effects of nausea and vomiting associated with the use of levonorgestrel 0.75 mg would deter its routine use.

The place of sale for a drug once it is removed from Schedule F is determined by provincial and territorial pharmacy regulatory authorities. However, the National Drug Scheduling Advisory Committee (NDSAC) of the National Association of Pharmacy Regulatory Authorities (NAPRA) makes recommendations to the provincial and territorial pharmacy regulatory authorities on the appropriate conditions and place of sale of drugs in Canada. NDSAC evaluates a drug and then recommends its placement on an appropriate schedule. NDSAC Schedule II drugs require professional intervention from the pharmacist at the point of sale and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection. NDSAC has recommended that provinces and territories adopt Schedule II status for levonorgestrel 0.75 mg as an EC.

Given their expertise and accessibility when access to other health professionals is limited, pharmacists are well-positioned to play a major role in increasing women's access to emergency contraception and in providing counselling about contraceptive options. Wider availability and use of levonorgestrel 0.75 mg as an EC could significantly reduce the number of unwanted pregnancies. A number of professional pharmacy organizations including the Canadian Pharmacists Association (CPhA) have developed guidelines and extensive training for pharmacists who would be dispensing levonorgestrel 0.75 mg to ensure that women are appropriately screened and counselled before receiving it.

Alternatives

Status quo

The alternative option would be to leave levonorgestrel 0.75 mg on Schedule F. The decision by Health Canada to remove levonorgestrel 0.75 mg from Schedule F was made following a review of clinical evidence and safety data. The review included an assessment of levonorgestrel 0.75 mg against the following set of factors that must be met to warrant prescription status: (The rationale why each factor does not apply to levonorgestrel 0.75 mg is also given.)

(a) Individualized instructions and/or direct practitioner supervision, adjunctive therapy with scheduled drugs or routine laboratory monitoring are required.

Rationale Individualized instructions are not necessary for use of levonorgestrel 0.75 mg as an EC. All instructions for use are printed on the package. Dose-tailoring is not required because the same dose is applicable to all women. Use of levonorgestrel 0.75 mg for emergency contraception does not require adjunctive therapy, nor is it necessary for a physician to perform any clinical evaluation (such as pelvic examination) or laboratory assessments. The labelling includes circumstances under which a physician should be consulted but general follow up of patients is usually not required.

(b) There is a narrow margin of safety between the therapeutic and toxic doses, especially in populations such as geriatrics, children and pregnant or nursing mothers.

Rationale There is a wide margin of safety between the therapeutic dosage of levonorgestrel (2 doses of 0.75 mg each) and toxic dosages. There is a long history of safe and effective use of levonorgestrel 0.75 mg as an EC and as a component in conventional oral contraceptives. Levonorgestrel 0.75 mg as an EC will not cause the abortion of, or affect in any way, an already established pregnancy.

(c) There are potential or known undesirable or severe side effects at normal therapeutic dosage levels.

Rationale Special monitoring for adverse effects by a physician is not required. There are no long term or serious side effects from using levonorgestrel 0.75 mg as an EC. Adverse experiences such as nausea and vomiting are usually mild, transitory and do not require professional management.

(d) The drug is known by experimental data to induce toxicity in animals but has not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans.

Rationale The clinical toxicology of levonorgestrel has been extensively studied during the course of development of products for use as an oral and implantable contraceptive and there are no toxicology issues for its use as an EC.

(e) The drug is used in treatment of a serious disease easily misdiagnosed by the public.

Rationale The need for an EC can be self-diagnosed.

(f) Use of this drug may mask other ailments.

Rationale The dosing regimen of levonorgestrel 0.75 mg as an EC is short and has no potential to delay recognition or mask the symptoms of another serious disease. Taking an EC does not provide protection against STDs, and this will be indicated in a black box warning in the labelling.

(g) The drug has contributed to, or is likely to contribute to, the development of resistant strains of micro-organisms in humans.

Rationale Not applicable: levonorgestrel has no anti-microbial activity.

(h) The drug possesses a dependence or abuse potential that is likely to lead to harmful non-medical use.

Rationale Levonorgestrel is not addictive. Repeated use studies do not show the development of drug dependence.

As measured against these factors for listing drugs on Schedule F, it has been determined that maintaining levonorgestrel 0.75 mg on Schedule F is not appropriate. The benefits of more timely access to levonorgestrel 0.75 mg as an EC outweigh any theoretical risks. It has been determined that any potential risks can be managed by appropriate labelling and additional information provided when the product is requested.

Benefits and Costs

The amendment impacts on the following sectors:

1. Public

The availability of levonorgestrel 0.75 mg as a non-prescription product would provide women with more convenient access to emergency contraception.

Women may be required to pay directly for the product as nonprescription products are not usually covered by drug insurance

plans. However, coverage is decided on a case-by-case basis by each drug plan. Strong support for continued coverage of levonorgestrel 0.75 mg has been expressed.

There may be an additional cost to women for a pharmacist's counselling fee. The current cost for a physician visit is covered by provincial and territorial health plans. Coverage for the pharmacist's counselling fee under provincial and territorial health plans is not under federal jurisdiction and would be negotiated at the provincial/territorial level.

2. **Provincial Health Care Systems**

Most public drug benefit plans do not cover the cost of nonprescription drugs. However, there is strong interest in having the cost of levonorgestrel 0.75 mg covered under these plans.

The provincial health care system presently pays the cost of a physician visit for women requiring a prescription for levonorgestrel 0.75 mg. There would be negligible impact on the system if a similar fee were paid to pharmacists.

3. **Private Drug Benefit Plans**

These plans do not usually cover the cost of nonprescription drugs. Coverage is determined on a case-by-case basis by each drug plan.

Consultation

A letter dated June 16, 2003 proposing this regulatory amendment was sent by e-mail to provincial and territorial Deputy Ministers of Health, provincial and territorial Drug Program Managers, Deans of Pharmacy, Registrars of Provincial Medical and Pharmacy Associations, Industry and Regulatory Associations, Professional Health and Consumer Associations, Canadian Food Inspection Agency, Industry Canada, Standards Council of Canada and other interested parties with a 30-day comment period. The letter was also posted on the TPD website at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_regulations_e.html#notices. Responses were received from 64 stakeholders.

The proposal was then pre-published in the *Canada Gazette*, Part I, on May 22, 2004 with a 75-day comment period. The proposal included the Regulatory Impact Analysis Summary (RIAS) which summarized the comments received from stakeholders in the earlier consultation and provided Health Canada's responses to the issues raised. The proposed amendment and RIAS were also sent to stakeholders and posted on the website as above. The comments received in response to the *Canada Gazette*, Part I, consultation are summarized below with Health Canada's responses.

Support the amendment

One hundred and forty-five (145) respondents (95 individuals and 50 associations/organizations) expressed support for the amendment. The 50 associations/organizations include district health organizations, women's health groups and provincial and national associations representing physicians, nurses and pharmacists.

Many of these respondents indicated that they support the amendment because timely access to EC is key to its effectiveness. Some respondents suggested that the amendment would result in reduced costs to the health care system

with the removal of the requirement for a physician visit and may also help to significantly reduce the social, emotional and economic consequences of unintended pregnancy, a major health issue for women. Twenty-nine (29) respondents indicated support for provincial/territorial Schedule II status because of the safety measures provided through patient counselling by a pharmacist.

The respondents that supported the amendment also raised the following issues, summarized with Health Canada's responses:

1. Prior to the change from prescription to nonprescription status taking place, a commitment should be received from the NDSAC that EC will be given Schedule II status.

Response: In a meeting held on November 3, 2001 NDSAC agreed that levonorgestrel in a 1.5 mg per course dosing (two doses of 0.75 mg each), packaged and labelled for emergency contraception, would meet the requirements for Schedule II status. NDSAC also noted that final confirmation of Schedule II status would be reserved until such time as the federal government's intention to de-regulate is published and final labelling is confirmed. Information on the NAPRA decision regarding Schedule II status is available on the NAPRA website at <http://napra.ca/docs/0/92/116/122/128.asp>.

2. Patient and pharmacist's information packages should state that recurrent use is inappropriate for contraceptive purposes.

Response: The product labelling will include a section that addresses recurrent use.

3. Two respondents provided a detailed list of information that should be included in the labelling and advertisements for levonorgestrel 0.75 mg. Many of the items listed will be included on the label or package insert. However the list also included recommendations for multilingual labelling, advertising and website information and that the labels include resource phone numbers.

Response: The *Food and Drug Regulations* define the information that is required on the labeling of drug products in the English and French languages. The manufacturer may decide to include non-required information on the label or package insert. Additional information such as community resources, websites or third-party phone numbers may also be made available by parties other than the manufacturer through means other than the product label.

4. It is essential that there be an increase in awareness of ECs with the help of health professionals and intermediaries, such as teachers and social workers.

Response: Health Canada has communicated broadly with stakeholders such as health professional associations as part of the consultation stage of the regulatory amendment process. The proposed amendment was also publicly available on the Health Canada and *Canada Gazette* websites.

accessibility to EC by removing levonorgestrel 0.75 mg from Schedule F also raised concerns about cost coverage by private and public drug plans.

Response: Cost is an important accessibility issue and Health Canada is aware of concerns about this issue. It should be noted that prescription status for a drug does not guarantee its coverage on all drug plans. Likewise, nonprescription status does not automatically exclude it from coverage on all drug plans. Cost coverage for drugs including professional fees is determined on a case-by-case basis by private and public drug programs in collaboration with provincial associations representing pharmacists.

6. Five respondents supported the removal of levonorgestrel 0.75 mg from Schedule F but strongly opposed the NDSAC recommendation for Schedule II status. They recommend access to EC without the intervention of a pharmacist being required.

Response: The place of sale for drugs not listed on Schedule F is determined by provincial and territorial pharmacy licensing bodies following a recommendation by NDSAC. The recommendation for Schedule II status will be addressed by provincial and territorial regulatory authorities and NDSAC. Information on the NDSAC decision is available on the NAPRA website at <http://napra.ca/docs/0/92/116/122/128.asp>.

7. A number of respondents raised issues related to the practice of pharmacy:

- an implementation strategy re screening, counselling, referrals and follow-up must be in place;
- there should be consistent education and training of pharmacists to pre-determined standards of care with ongoing evaluation and a plan for addressing gaps in knowledge or care;
- there is a need to ensure that all provinces and territories have policies to ensure that pharmacists who refuse to dispense the medication for moral reasons are expected to (as stated in the RIAS in CGI) "as a standard of care, to refer the woman to another pharmacist, physician or health facility where the medication can be readily obtained.";
- there is a need to ensure the privacy and confidentiality of patient information. Patient consent should be required before sharing information between professions.

Response: The practice of pharmacy falls under provincial and territorial jurisdiction. Provincial and territorial pharmacy regulatory authorities and professional associations have established standards of practice, codes of ethics and education requirements for pharmacists.

8. Guidelines developed for pharmacists should be available to physicians and health care providers.

Response: Guidelines and other supporting documents have been developed

by a number of different organizations and are available on websites or directly from associations such as the CPhA.

Object to the amendment

One hundred and fifty-two respondents (141 individuals and eleven organizations or associations) objected to the amendment. The eleven organizations/associations consist of nine right-to-life groups and two associations representing pharmacists. The individual respondents and the right-to-life groups expressed the concerns summarized below:

1. Health Canada should conduct studies on the effects of the morning after pill (MAP) on women because long term testing on the MAP has not been sufficient.

Response: Health Canada has examined the information available on the use of levonorgestrel 0.75 mg as an EC and does not require further studies to support a recommendation of nonprescription status for this drug in Canada. The use of levonorgestrel 0.75 mg as an EC has been extensively studied internationally for many years before Health Canada's review and approval for nonprescription use. Its safety will continue to be monitored once levonorgestrel 0.75 mg has been approved for nonprescription use as an EC. In Canada, levonorgestrel 0.75 mg as an EC has been available as a prescription drug since 2000. It has been available from pharmacists without a physician's prescription in British Columbia since December 2000 with a 2-year follow-up study, in Quebec since December 2001 and in Saskatchewan since September 2003. The results of a pilot project conducted in Ontario in 2001-2002 have been studied and published. No safety-related issues were raised in any of these studies.

2. Concerns were expressed about overuse and repeat use as a regular contraceptive. The experience in the United Kingdom (UK) has shown that easier accessibility to the MAP has increased repeated usage. Will frequent use generate long term health effects?

Response: ECs have been available without a prescription in the UK since 2001. The UK Office of National Statistics released a report in October 2004 on the use of emergency contraception in 2003-2004 that showed low incidence of repeat use and that most women who used ECs were using some other form of birth control. Studies have shown that repeat use results in no serious or lasting adverse events other than menstrual irregularities. The most common side effects, nausea and vomiting, make regular use of ECs undesirable for most women. Information that emergency contraception is not for repeated use is included in both the product labelling and the pharmacists' counselling material.

3. Concern was expressed about side effects and health risks such as cancer, heart attack, deep-vein thrombosis, ectopic pregnancy, migraine, nausea and vomiting.

Response: Health risks - No serious adverse events have been reported since levonorgestrel was first approved for EC use in Europe in 1980. Since ECs are used for such a short period of time, the

contraindications associated with regular use of oral contraceptives do not apply. Studies sponsored by the manufacturer in the 1970s and 1980s and by the WHO in the late 1980s and early 1990s, covering approximately 3,700 women, demonstrated that even regular postcoital use is associated with no serious or lasting adverse events other than reversible menstrual irregularities. No substantial increased risk for developing deep-vein thrombosis has been found with use of an EC. Nausea and vomiting are a predictable side effect and can be controlled by the administration of anti-nausea medication with the dose of EC.

Ectopic pregnancies (pregnancies outside of the uterus) occur more often in women who use daily progestin only contraceptives (10% vs 2% in general population). The reasons for this are unclear. However, levonorgestrel 0.75 mg used as EC does not have this increased risk. Therefore, ECs could be used even in women who had previous ectopic pregnancy. The levonorgestrel 0.75 mg label advises women to contact their doctor if their menstrual period does not occur within 21 days after using levonorgestrel 0.75 mg. Further, the label instructs women to call their doctor immediately if they experience cramping or severe pain in their stomach or belly prior to their next normal period, since that can be a warning sign of an ectopic pregnancy.

4. Sexually transmitted diseases may go unnoticed and left untreated. Making the MAP available over the counter will exacerbate the already epidemic levels of certain sexually transmitted infections (STIs).

Response: None of the regular birth control methods, with the exception of condoms, prevent STI's. The labelling for levonorgestrel 0.75 mg will clearly state that it does not provide any protection against contracting STI's. However, counselling associated with the provision of ECs has been identified as an opportunity to address STI prevention.

5. The MAP is used to prevent the implantation of a fertilized egg. Women may not be aware of the abortion action of the MAP and those who strongly oppose abortion may be devastated when they find out its potential as an abortifacient. Women should be aware of this information before they give their consent. The common description of the MAP as an emergency contraceptive is misleading to the public with respect to its possible abortifacient action. Will the mechanism of action be clearly indicated on the label?

Response: The ways in which levonorgestrel 0.75 mg may work as an EC are described on the product labelling. The information is also included in the recommended counselling information to be provided by pharmacists. Canadian women will have the information needed to make a personal, informed choice. The term "emergency contraceptive" (EC) has been used internationally for many years to refer to all methods of contraception that are used after intercourse and before implantation. It is the term used by the WHO for levonorgestrel at this dosage strength.

6. The United States FDA rejected over-the-counter access to levonorgestrel 0.75 mg in May, 2004. Why is Health Canada proposing to do the opposite?

Response: The proposed switch in the United States would have allowed levonorgestrel 0.75 mg to be sold as an EC in the self-selection area of pharmacies without professional intervention. The FDA's initial decision was based on the lack of data concerning the public access use in teens under 16 years. The issue is again under review by the FDA. In Canada, behind-the-counter status would give timely access and professional advice. As a drug, levonorgestrel is approved for use in daily oral contraceptives by those 14 years and older. No outstanding concerns on its safety in younger teens has yet been identified. There is no reason to delay timely access to other women. A number of European countries and several US states have already granted access to emergency contraceptives via pharmacist-controlled sales. This is what is being proposed for Canada.

7. The MAP has been available over the counter (OTC) since January 1, 2004 in Australia. The Australia Medical Association is already questioning the wisdom of making this risky drug so easily available without restriction.

Response: Levonorgestrel 0.75 mg as an EC has been available in Australia from pharmacists without a prescription for more than a year. There is no evidence at this time to indicate a change in status.

8. Progestin-only contraceptives for regular use require a prescription, so why make the same drug in higher doses for the purpose of MAP available without a prescription? The progestin-only hormonal contraceptive in Canada's morning after pill is the same active ingredient found in Norplant, which is no longer available for use in the United States because it is so dangerous.

Response: Daily-use, ongoing contraceptives provide a larger dose of hormones overall than ECs and have been associated with side effects and adverse events. Since ECs are used for a short period of time (2 days) the contraindications associated with regular use of oral contraceptives do not apply. It is important to note that ECs are not meant for regular use but only on occasions when the regular methods of contraception have failed or not been used appropriately. Norplant, a long-acting implantable contraceptive containing 36 mg of levonorgestrel, was removed from the North American market in 2002 by its manufacturer, Wyeth-Ayerst.

9. Several respondents raised concerns about moral issues and the use of ECs, especially by teens.

Response: Forms of birth control such as condoms and spermicides are widely available to minors without parental notification or consent. Provincial laws guide health care professionals in providing medications for minors in the absence of consent from their parents or legal guardians.

10. ECs have a failure (pregnancy) rate of 11-25%

Response: A number of factors can impact on the effectiveness of levonorgestrel 0.75 mg in preventing pregnancy. Timing is a key factor and that is why improved access is so important. Studies have shown that levonorgestrel 0.75 mg can be 95% effective if

taken within the first 24 hours after unprotected intercourse.

11. One respondent disagrees that an objecting pharmacist should have to make a referral to another pharmacist to provide EC.

Response: Licensed pharmacists are expected to follow the standards of practice established by their professional associations. Concerns about this issue should be directed to an individual pharmacist's professional association.

12. Concerns were expressed about the ability of pharmacists to counsel and the lack of medical supervision and counselling.

Response: National and provincial pharmacy associations have been actively providing training to pharmacists to counsel women on the provision of ECs. The circumstances which might lead to a request for an EC do not require medical diagnosis. The labelling and counselling material describe situations and conditions for which medical intervention or follow-up are recommended.

Two organizations representing the pharmacy sector objected to the amendment as follows:

13. One organization representing pharmacy businesses and one provincial pharmacy organization indicated support for ready access to emergency contraception. However, rather than supporting a Schedule F amendment, they expressed support for legislative changes at the provincial and territorial level to allow pharmacists to prescribe EC such as is the case in British Columbia, Quebec and Saskatchewan. They expressed concerns related to cost coverage under public and private drug plans. They also raised pharmacy practice issues including provincial drug scheduling, training, a pharmacist's ability to opt out of providing EC and payment for pharmacists' services.

Response: The changes required to give pharmacists prescribing authority in the remaining provinces and territories vary in complexity with each jurisdiction. Relying on such changes could extend significantly the period in which levonorgestrel 0.75 mg for EC use would not be equally available to women across the country. Health Canada recognizes the shared responsibility between the federal and provincial/territorial jurisdictions to provide Canadians with access to safe and effective, quality drugs. To this end, Health Canada has reviewed the use of levonorgestrel 0.75 mg as an EC and has determined that, with appropriate labelling, it no longer meets the criteria for listing a drug on Schedule F. The provinces and territories, either independently or coordinated through NAPRA, will make risk benefit scheduling decisions based on specific criteria and principles. The issue of drug plan coverage has been discussed in other responses above. The management and legal issues regarding pharmacists selling Schedule II drugs will be a matter of discussion by provincial or territorial pharmacy regulatory authorities.

Compliance and Enforcement

This amendment would not alter existing compliance mechanisms under the

provisions of the *Food and Drugs Act* and the *Food and Drug Regulations*, enforced by the Health Products and Food Branch Inspectorate.

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[Footnote a](#)

S.C. 1999, c. 33, s. 347

[Footnote 1](#)

C.R.C., c. 870

NOTICE:

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



[Top of page](#)

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