

250 Lanark Avenue
Graham Spry Building
Address Locator 2005D
OTTAWA, Ontario
K1A 0K9

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Provincial and Territorial Deputy Ministers of Health
Provincial and Territorial Drug Program Managers
Deans of Faculties of Pharmacy
Registrars of Provincial Medical and Pharmacy Associations
Industry and Consumer Associations
Regulatory and Health Professional Associations
Other Interested Parties

Dear Sir/Madam:

Re: *Food and Drug Regulations* - Project Number 1658 - Schedule F

The purpose of this letter is to provide an opportunity to comment on the proposal to add to Part I of Schedule F to the *Food and Drug Regulations* six medicinal ingredients.

Sections C.01.041 to C.01.049 of the *Food and Drug Regulations* control the sale of medicinal ingredients that are listed in Schedule F. Part I of Schedule F lists medicinal ingredients that require a prescription for human use and for veterinary use. 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.

Health Canada's Drug Schedule Status Committee recommends the necessity for prescription status or exemption from prescription status for medicinal ingredients on the basis of an assessment of the medicinal ingredients against a set of established and publicly available factors. These factors include, but are not limited to, toxicity, pharmacological properties and therapeutic uses of the medicinal ingredients.

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Description of the medicinal ingredients:

1. **Alitretinoin, its salts and derivatives** is a retinoid drug that is related to Vitamin A. Alitretinoin, its salts and derivatives are used to treat severe chronic eczema of the hand that has not responded to topical treatment with corticosteroids. Because alitretinoin, its salts and derivatives can cause severe birth defects, its use requires specific and effective pregnancy prevention measures for women of childbearing potential. Individualized instructions, direct supervision by a practitioner and routine laboratory monitoring are required during treatment.
2. **Aripiprazole and its salts** belong to a group of medicines called atypical antipsychotic drugs. Aripiprazole and its salts are used to treat schizophrenia and bipolar disorder. Aripiprazole and its salts should be prescribed by a practitioner who is experienced in the diagnosis of psychiatric disorders. Due to the potential for undesirable or severe side effects from aripiprazole and its salts at normal therapeutic dosage levels, individualized instructions, direct supervision by a practitioner and routine laboratory monitoring are required during treatment.
3. **Besifloxacin and its salts** is an antibiotic used for the treatment of inflammation of the eye caused by bacteria. The use of besifloxacin and its salts requires direct supervision by a practitioner as there may be undesirable or severe side effects at normal therapeutic dosage levels.
4. **Doripenem, its salts and derivatives** is a broad-spectrum antibiotic used for the treatment of pneumonia that occurs in a hospital or similar setting. Individualized instructions, direct practitioner supervision and routine laboratory monitoring are required. Doripenem, its salts and derivatives may have undesirable or severe side effects at normal therapeutic dosage.
5. **Saxagliptin and its salts** are used to improve blood sugar levels in adult patients with type 2 diabetes. Saxagliptin and its salts are used in combination with other drugs used to treat diabetes when diet and exercise and other drugs have failed to adequately control blood sugar levels. Saxagliptin and its salts should be used under the supervision of a physician as it is indicated for use in combination with other prescribed drugs and requires routine laboratory monitoring. Saxagliptin and its salts may also have undesirable or severe side effects at normal therapeutic dosage levels.

6. **Sevoflurane** is a halogenated inhalation anesthetic that is used for general anesthesia during surgery. Individualized instructions, direct practitioner supervision and routine laboratory monitoring are required. There is a narrow margin of safety between the therapeutic and toxic dosages.

The degree of regulatory control afforded by Schedule F (prescription drug) status coincides with the risk factors associated with each medicinal ingredient. Oversight by a practitioner is necessary to ensure that appropriate risk/benefit information is considered before the drug containing the medicinal ingredient is administered and that the drug therapy is properly monitored.

Alternatives

Any alternatives to the degree of regulatory control recommended in these amendments would need to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and Costs

These amendments would impact on the following sectors:

- **Public**

Prescription access to drug products containing these medicinal ingredients would benefit Canadians by decreasing the opportunities for improper use and by ensuring the guidance and care of a practitioner.

Another benefit would be that drug products for human use containing medicinal ingredients listed on Schedule F may be covered by both provincial and private health care plans.

- **Health Insurance Plans**

Drug products for human use containing medicinal ingredients listed in Schedule F may be a cost covered by both provincial and private health care plans.

- **Provincial Health Care Services**

The provinces may incur costs to cover practitioners' fees for services. However, the guidance and care provided by the practitioners would reduce the need for health care services that may result from improper use of drug products for human use that contain medicinal ingredients listed in Schedule F. The overall additional costs for health care services should therefore be minimal.

Compliance and Enforcement

These amendments 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.

Consultation

The manufacturers affected by these proposed amendments were made aware of the intent to recommend these medicinal ingredients for inclusion on Schedule F during the review of the drug submission.

The process for this consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F, which came into effect on February 23, 2005. The MOU is posted on the Health Canada website.

Health Canada will send the letter by email to stakeholders. The letter will also be posted on the Health Canada and the *Consulting with Canadians* websites.

Any comments regarding these proposed amendments should be sent within **75** days following the date of posting of this letter on the Health Canada website. The policy analyst for this project, Ginette Chalifoux, may be contacted at:

Refer to Project Number: **1658**
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street, Holland Cross
Tower 'B', Second Floor
Address Locator: 3102C5
Ottawa, Ontario
K1A 0K9

Telephone: 613-948-4623
Facsimile: 613-941-6458
Email: regaff-affreg@hc-sc.gc.ca

Final Approval

In accordance with the MOU process, it is anticipated that the proposed Schedule F amendments will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately eight to ten months from the date of posting of this letter on the Health Canada website. If approved by the Governor in Council, publication in the *Canada Gazette*, Part II, would follow. These amendments would come into force on the date of registration.

Sincerely,

Paul Glover
Assistant Deputy Minister