

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

09-118361-538

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 Consumer Associations  
Regulatory and Health Professional Associations  
Other Interested Parties

Dear Sir/Madam:

**Re: *Food and Drug Regulations* – Project Number 1623 – Schedule F**

The purpose of this letter is to provide an opportunity for comment on the proposed addition of four medicinal ingredients to Part I of Schedule F to the *Food and Drug Regulations*.

Schedule F is a list of medicinal ingredients, the sale of which is controlled under sections C.01.041 to C.01.049 of the *Food and Drug Regulations*. Part I of Schedule F lists ingredients that require a prescription for human use and for veterinary use. Part II of Schedule F lists 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 for medicinal ingredients on the basis of established and publicly available criteria. These criteria include, but are not limited to, concerns related to toxicity, pharmacological properties and therapeutic uses of the ingredients.

Description of the medicinal ingredients:

1. **Desvenlafaxine and its salts** is a serotonin and norepinephrine reuptake inhibitor that is used to treat major depression. Individualized instructions and direct supervision by a practitioner are required during treatment. Desvenlafaxine and its salts may cause undesirable or severe side effects at normal therapeutic dosage levels.
2. **Eplerenone** is a newer aldosterone antagonist that is used to treat heart failure in patients who have recently had a heart attack. Individualized instructions and direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Eplerenone may cause undesirable or severe side effects at normal therapeutic dosage levels.
3. **Fosaprepitant and its salts** is a pro-drug form of aprepitant and, once administered, is rapidly converted to aprepitant in the body. Fosaprepitant and its salts is used for the prevention of nausea and vomiting associated with cancer treatment. Fosaprepitant and its salts should be administered under the supervision of a practitioner experienced in cancer therapy. The patient may require treatment with other drugs and routine laboratory monitoring. Fosaprepitant and its salts may cause undesirable or severe side effects at normal therapeutic dosage levels.
4. **Moclobemide** is a short-acting reversible inhibitor of monoamine oxidase type A that is used to treat the symptoms of depression. Individualized instructions and direct supervision by a practitioner are required during treatment. Moclobemide may cause undesirable or severe side effects at normal therapeutic dosage levels.

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 this amendment would need to be established through additional scientific information and clinical experience.

No other alternatives were considered.

### ***Benefits and Costs***

The amendment 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 is 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 on 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 on Schedule F. The overall additional costs for health care services should therefore be minimal.

### ***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.

### ***Consultation***

The manufacturers affected by this proposed amendment 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 22, 2005. The MOU is posted on the Health Canada Web site.

This letter is being sent by email to stakeholders and is also being posted on the Health Canada Web site and the *Consulting with Canadians* Web site.

Any comments regarding this proposed amendment should be sent as follows within **75** days following the date of posting of this letter on the Health Canada Web site. The policy analyst for this project, Karen Ash, may be contacted at:

Refer to Project Number: **1623**  
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](mailto:regaff-affreg@hc-sc.gc.ca)

***Final Approval***

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

Yours sincerely,

Meena Ballantyne  
Assistant Deputy Minister