Health Canada Santé Canada

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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 # 1451 - Schedule F

This letter is to provide you with an opportunity to comment on the proposed addition of 3 medicinal ingredients to Part I of Schedule F to the *Food and Drug Regulations* to the *Food and Drugs Act*.

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.

The Drug Schedule Status Committee determined the necessity for prescription status for each of the medicinal ingredients in this proposed amendment 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 applications.

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Description of the medicinal ingredients:

1) **Bortezomib** - is an antineoplastic agent for human use in the treatment of multiple myeloma. It belongs to a new pharmacological class called proteasome inhibitors. Bortezomib is administered intravenously for the treatment of recurring bone marrow tumours that are resistant to treatment. Individualized instructions and continuous supervision of therapy is required by a cancer specialist. There is a narrow margin of safety between the therapeutic and toxic doses. This medicinal ingredient may have undesirable or severe side effects at normal therapeutic dosage levels and it possesses a high level of risk relative to expected benefits.

2) **Memantine and its salts** - is an N-methyl-D-aspartate (NMDA) receptor antagonist. It is used for the symptomatic treatment of patients with moderate to severe dementia of the Alzheimer's type. Memantine is intended for use alone or in conjunction with other therapies and should only be prescribed by, or following consultation with, a practitioner who is experienced in the diagnosis and management of Alzheimer's disease. Therapy should only be started if a caregiver is available to monitor drug intake by the patient.

3) **Nicotinic acid and its salts and its derivatives** in an extended release formulation providing 500 mg or more per dosage form or per daily dose - a lipid metabolism regulating agent used for the treatment of patients with abnormally high levels of cholesterol in the blood. Diagnosis by a practitioner is required to rule out other causes of high blood cholesterol levels and to determine that other treatments have not been effective. Individualized instructions and direct supervision by a practitioner are required. This medicinal ingredient may have 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 adequate risk/benefit information is available 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.

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Benefits and Costs

The amendment will 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.

- **Health Insurance Plans**

Drug products for human use containing medicinal ingredients listed on Schedule F may be 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 will not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act and 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 website.

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This letter is being sent by email to stakeholders and is also being posted on the Health Canada website and the Consulting Canadians website.

Any comments regarding this proposed amendment should be addressed to Holly Hutchings, Policy Division, Policy Bureau, Therapeutic Products Directorate, 1600 Scott Street, Holland Cross, Tower 'B', 2nd Floor, Address Locator 3102C5, Ottawa, Ontario, K1A 0K9, by facsimile at 613-941-6458 or by email to holly_hutchings@hc-sc.gc.ca within **75** days following the date of publication on the TPD website.

Final Approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to final publication in the *Canada Gazette,* Part II, approximately 6 to 8 months from the date of posting of this letter on the TPD website. The amendment will come into force on the date of registration.

Yours sincerely,

Original Signed by

Diane Gorman
Assistant Deputy Minister