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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 Number 1597 – Schedule F

The purpose of this letter is to provide an opportunity for comment on the proposed addition of three 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. **Idebenone** is a benzoquinone derivative that is used to manage symptoms of Freidreich's Ataxia. Freidreich's Ataxia is an inherited disease that causes progressive damage to the nervous system, resulting in symptoms ranging from difficulty walking to speech problems and also frequently leads to heart disease. Idebenone should only be prescribed by, or following consultation with, practitioners who are experienced in the diagnosis and management of Freidreich's Ataxia. Direct supervision by a practitioner is required during treatment.
2. **Idursulfase** is an enzyme that is manufactured using recombinant deoxyribonucleic acid (DNA) technology. Idursulfase is used to treat deficiency of the enzyme, iduronate-2-sulfatase, in patients with Hunter syndrome, a serious progressive genetic disorder that can result in permanent damage such as vision and hearing loss, heart disease, breathing difficulties and joint stiffness. Direct supervision by a practitioner and routine laboratory monitoring are required.
3. **Nesiritide** belongs to a new drug class that is manufactured using recombinant deoxyribonucleic acid (DNA) technology. Nesiritide is used to treat patients in hospital who have symptoms of heart failure and have not responded to treatment with other drugs. Direct supervision by a practitioner is required. Nesiritide 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: **1597**
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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