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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
Canadian Food Inspection Agency, Industry Canada, Standards Council of Canada
Other Interested Parties

Dear Sir/Madam:

Re: *Food and Drug Regulations* - Project # 1434 - Schedule F

This letter is to provide an opportunity for comment on the proposed addition of 10 medicinal ingredients to Part I of Schedule F to the *Food and Drug Regulations*.

- Public Involvement & Consultations
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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 determines 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. **Agalsidase alfa** is an enzyme indicated for long-term replacement therapy in patients with a confirmed diagnosis of Fabry Disease (a deficiency of the enzyme alpha-galactosidase A). Individualized instructions and/or direct supervision by a practitioner are required for treatment with agalsidase alfa. The patient may also require treatment with other drugs or routine laboratory monitoring. This drug may have undesirable or severe side effects at normal therapeutic dosage levels.

2. **Botulinum toxin, Type B** is a paralytic agent which blocks the release of acetylcholine (Ach) at the point of contact between nerve and muscle tissue. Botulinum type B is indicated for the treatment of adult patients with cervical dystonia and for the management of adult patients with cervical dystonia who are resistant to Type A toxin. Cervical dystonia is a neurological movement disorder characterized by involuntary muscle contractions of the neck that can cause abnormal posture and movement of the head and neck. Botulinum type B should be administered intramuscularly by a physician experienced in the assessment and management of patients with cervical dystonia and the use of botulinum toxin preparations. The patient may also require treatment with other drugs or routine laboratory monitoring.

3. **Laronidase** is an enzyme used to treat the inherited metabolic disorder Mucopolysaccharidosis I (MPS I) which is characterized by a deficiency of the enzyme α-L-iduronidase. Reduced or absent α-L-iduronidase activity results in the accumulation of glycosaminoglycans substrates throughout the body and leads to widespread cellular, tissue, and organ dysfunction including stunted growth in children and reduced joint movement; e.g., Hurler syndrome. Laronidase is indicated for long term enzyme replacement therapy in patients with MPS I to treat manifestations of the disease except those related to the central nervous system. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs or routine laboratory monitoring.

4. **Miglustat** is indicated for the treatment of adult patients with mild to moderate Type 1 Gaucher disease (a rare genetic disease involving a specific enzyme deficiency) for whom enzyme replacement therapy is not a therapeutic option. Individualized instructions and/or direct supervision by a practitioner are required for treatment with miglustat. The patient may also require treatment with other drugs or routine laboratory monitoring. Miglustat may have undesirable or severe side effects at normal therapeutic dosage levels. This drug has not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans. It possesses a high level of risk relative to expected benefits.

5. **Muromonab-CD3** suppresses a patient's immune system to aid in preventing tissue rejection after transplants. It is specifically indicated for the treatment of acute kidney, cardiac or liver transplant rejection, where conventional anti-rejection therapy is not effective or when conventional therapy is not recommended. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs or routine laboratory monitoring. This drug may have undesirable or severe side effects at normal therapeutic dosage levels.

6. **Pegfilgrastim** stimulates the growth of white blood cells and

is indicated for use in adult and pediatric patients with cancer who are receiving chemotherapy which suppresses bone marrow activity, resulting in low levels of circulating white blood cells. Pegfilgrastim also can reduce the incidence of infection in patients with some malignancies. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs or routine laboratory monitoring. This drug may have undesirable or severe side effects at normal therapeutic dosage levels.

7. **Pemetrexed and its salts** is a treatment for cancer. It inhibits the growth or development of malignant cancerous cells by disrupting crucial metabolic processes that are essential for cells to multiply. In combination with the drug, cisplatin, pemetrexed disodium is indicated for the first-line treatment of patients with specific malignant tumours. Individualized instructions and/or direct supervision by a practitioner are required for treatment with pemetrexed. The patient may also require treatment with other drugs or routine laboratory monitoring. There is a narrow margin of safety between the therapeutic and toxic doses, especially in populations such as the elderly, children and pregnant women or nursing mothers. Pemetrexed may have undesirable or severe side effects at normal therapeutic dosage levels. This drug has not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans.

8. **Rasburicase** is a strong uricolytic agent that speeds up the enzymatic oxidation of uric acid into an inactive and soluble metabolite. Rasburicase is indicated for the treatment and prevention of excess uric acid in the blood in pediatric and adult cancer patients. Rasburicase should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents. The patient may also require treatment with other drugs or routine laboratory monitoring. This drug may have undesirable or severe side effects at normal therapeutic dosage levels.

9. **Teriparatide and its salts** helps to stimulate bone formation and is indicated for the treatment of men or women with

severe osteoporosis. Teriparatide acts in the regulation of bone metabolism and on the reabsorption of calcium and phosphate in the kidneys. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs or routine laboratory monitoring. This drug possesses a high level of risk relative to expected benefits.

10. **Vardenafil and its salts** is indicated for treatment of erectile dysfunction. Individualized instructions and/or direct supervision by a practitioner are required. There is a narrow margin of safety between the therapeutic and toxic doses and there may be undesirable or severe side effects at normal therapeutic dosage levels. This drug has not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans. This drug also possesses an abuse potential that is likely to lead to harmful non-medical use.

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 submissions.

A letter dated December 3, 2004 outlining this regulatory proposal

was sent by email to provincial and territorial Ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations with a 30-day comment period. The letter was also posted on the Therapeutic Products Directorate website. One response was received from a stakeholder who supported the proposed amendment.

The process for this further 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.

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

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

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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 6 to 8 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. The amendment would come into force on the date of registration.

Yours sincerely,

Original signed by

Neil Yeates
Assistant Deputy Minister

Last Updated: 2006-05-31

Important Notices