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Contact
Regulatory Affairs

This document is also available in PDF format [project_projet_1528_e.pdf]
Pages: 5, Size: 20 K, Date: 2007-07-06

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06-118498-725

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 # 1528 – Schedule F

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

Correction of one current Schedule F, Part I listing

The current listing in Schedule F, Part I :
Botulinum Toxin Type A
Antitoxine botulinique, Type A

is revised to:
Botulinum toxin Type A
Toxine botulinique, type A

Rationale:
Botulinum toxin Type A was added to Schedule F on September 5, 1991. An error in the French version of the listing has been noted and requires correction. The medicinal ingredient is a toxin, not an antitoxin.

Additions to Schedule F, Part I

Description of the medicinal ingredients:

1. **Alglucosidase alfa** is a synthetic protein produced by recombinant DNA technology that is used to treat individuals with Pompe disease. Pompe disease is a rare, but serious, genetic disorder in which a person's muscle and respiratory function are drastically reduced. Individualized instructions or direct supervision by a practitioner are required. Alglucosidase alfa may cause undesirable or severe side

effects at normal therapeutic dosage levels.

2. **Ciclesonide** is a corticosteroid for oral inhalation that can help to ease breathing problems in adult asthma patients. Asthma is a chronic inflammatory disease of the lungs. Ciclesonide relieves swelling and irritation in the small air passages in the lungs. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Ciclesonide may cause undesirable or severe side effects at normal therapeutic dosage levels.

3. **Darunavir** is a protease inhibitor that is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults. Darunavir is administered in combination with another anti-HIV medication. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Darunavir may cause undesirable or severe side effects at normal therapeutic dosage levels.

4. **Natalizumab** is a monoclonal antibody used to treat patients with the relapsing-remitting form of multiple sclerosis (MS), a disease of the central nervous system. Natalizumab is generally recommended in MS patients who have had an inadequate response to, or are unable to tolerate, other therapies for multiple sclerosis. Natalizumab should not be administered in combination with other immune system modifying drugs. Individualized instructions or direct supervision by a practitioner are required. Natalizumab may cause undesirable or severe side effects at normal therapeutic dosage levels.

5. **Rasagiline and its salts** is a monamine oxidase inhibitor (MAOI) used to treat the signs and symptoms of Parkinson's disease, a disorder of the central nervous system. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Rasagiline and its salts may cause undesirable or severe side effects at normal therapeutic dosage levels.

6. **Sorafenib and its salts** is used to treat advanced kidney cancer in adults for whom other anti-cancer therapies have failed or are considered unsuitable. Sorafenib acts by slowing down the rate of tumor growth and cutting off the blood supply that keeps tumors growing. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Sorafenib and its salts may cause undesirable or severe side effects at normal therapeutic dosage levels.

7. **Tigecycline** is an antibiotic that is administered intravenously to treat complicated infections of the skin and abdominal organs. Individualized instructions or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. Tigecycline 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 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:

Refer to Project No. 1528
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Therapeutic Products Directorate
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Tower 'B', 2nd Floor
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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 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 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: 2007-07-05  Important Notices

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