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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 # 1481 - Schedule F

This letter is to provide an opportunity for comment on the proposed addition of eleven 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

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- Special Access to Drugs & Health Products
- Substances: Problematic Use
- Veterinary Drugs
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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. **Alemtuzumab** is used for the treatment of B-cell chronic lymphocytic leukemia in patients who have been treated with other drugs and who have remission (less than 6 months). Alemtuzumab should be administered under the supervision of a practitioner experienced in cancer therapy. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring.

2. **Azelaic acid** is used in a topical gel for the treatment of mild to moderate inflammatory acne and mild to moderate rosacea, a chronic inflammatory skin disorder. Azelaic acid helps the skin to renew itself more quickly and therefore reduces pimple and blackhead formation. It also helps to kill the bacteria that cause acne and rosacea. The safe and effective use of azelaic acid requires that an accurate diagnosis of the condition be made by a practitioner, who must then select an appropriate treatment. Rosecea is not a straightforward clinical diagnosis to make and may be easily confused with other conditions. Close medical supervision and patient follow-up during treatment are needed to monitor for potential adverse effects from azelaic acid.

3. **Bevacizumab** is a recombinant humanized monoclonal antibody that is used to treat cancer. Bevacizumab slows the growth and spread of cancer cells in the body. Bevacizumab

should only be administered under the supervision of a practitioner experienced in the use of cancer chemotherapeutic agents. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring.

4. **Cetuximab** is a recombinant, chimeric monoclonal antibody that is used to treat patients with some types of cancer of the large intestine or rectum that have spread to other parts of the body. Individualized instructions and/or direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring.

5. **Darifenacin and its salts** is used for the treatment of overactive bladder associated with symptoms of urinary frequency, urinary urgency, and urinary incontinence. Darifenacin relieves spasms of the bladder. There is a potential for darifenacin to cause side effects; therefore, individualized instructions and continuous supervision of treatment by a practitioner are required.

6. **Efalizumab** is a recombinant humanized monoclonal antibody that acts as an immunosuppressant, decreasing the activity of the body's immune system. Efalizumab may relieve the signs and symptoms of moderate to severe chronic plaque psoriasis in adult patients. Efalizumab is intended for use under the guidance and supervision of a practitioner. Blood tests and other medical evaluations may be required during treatment. Patients may self-inject efalizumab under the skin following proper training.

7. **Emtricitabine** is an antiviral medication used to treat the human immunodeficiency virus (HIV), which causes the acquired immunodeficiency syndrome (AIDS). Emtricitabine is to be used in combination with other antiretroviral drugs in the treatment of HIV infection and therefore requires direct practitioner supervision and routine laboratory monitoring.

8. **Nitric Oxide** is used to dilate blood vessels in the lungs to treat critically ill newborn infants suffering from low levels of

oxygen in respiratory failure associated with high blood pressure in the lungs, a serious/life-threatening condition. Nitric oxide is used in conjuction with breathing support and other appropriate treatment and is administered in the neonatal intensive care unit under the supervision of a practitioner.

9. **Palifermin** is a human keratinocyte growth factor produced by recombinant DNA technology. Palifermin is used to reduce the chance of developing sores and ulcers in the mouth and to shorten the time with sores or ulcers in patients with blood cancers who receive high doses of chemotherapy and radiation therapy before bone marrow transplants. Palifermin is administered by intravenous injection under the supervision of a practitioner.

10. **Pegvisomant** is a manufactured protein similar to human growth hormone that blocks the effects of growth hormone. Pegvisomant is used to treat acromegaly, a growth disorder caused by too much growth hormone, in patients who have had inadequate response to surgery, and/or radiation therapy, and other medical therapies, or for whom these therapies are not appropriate. Blood tests and/or other medical evaluations are required during treatment with pegvisomant to monitor progress and side effects.

11. **Tipranavir and its salts** is a protease inhibitor used to treat the human immunodeficiency virus (HIV) which causes acquired immunodeficiency syndrome (AIDS). Tipranavir must be used in combination with ritonavir and at least two other anti-HIV drugs and therefore requires direct practitioner supervision and routine laboratory monitoring.

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.

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, Ginette Chalifoux, 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