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Contact
Regulatory Affairs

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Pages: 04, Size: 18 K, Date: 2006-08-22

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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 #1512 - Schedule F**

The purpose of this letter is to provide an opportunity for comments 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*

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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 ingredient:

1. Abatacept is a synthetic protein produced by recombinant DNA technology that is used to treat rheumatoid arthritis. It is used alone or in combination with other medications to treat adults with moderate to severe rheumatoid arthritis who have not been helped by other arthritis medications. Abatacept is given by intravenous infusion and acts on the immune system to prevent activation of the cells that cause the destruction of joint tissue and cause the signs and symptoms of rheumatiod arthritis. Because abatacept depresses the immune system, it can reduce a patient's ability to fight both infection and cancer. Individualized instructions and direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring.

2. Entecavir is a nucleoside analogue used to treat chronic hepatitis B virus infection in adults with evidence of active disease or liver damage. Administration of entecavir requires direct practitioner supervision and routine laboratory monitoring and may require individualized instructions or possible additional therapy with other drugs. There are potential or known undesirable or severe side effects at normal therapeutic dosage levels, such as liver damage and a build-up of lactic acid in the blood.

3. Sunitinib and its salts is a highly selective, multi-targeted tyrosine kinase inhibitor. It is used to treat patients with gastrointestinal stromal tumors, a rare type of stomach cancer, where other treatments have not worked. It is also used to treat

patients with advanced kidney cancer. Individualized instructions and direct supervision by a practitioner are required. The patient may also require treatment with other drugs and routine laboratory monitoring. 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 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 inclusions 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. 1512
Bureau of Policy, Science and International Programs

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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 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