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07-114037-363

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 # 1536 - Schedule F**

The purpose of this letter is to provide an opportunity for comment on the proposed addition of two 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.

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. **Micafungin and its salts** is an antifungal drug that is indicated for the treatment and prevention of fungal infections of the esophagus in patients undergoing stem cell transplantation. Direct supervision by a practitioner is required. Micafungin and its salts is known to have undesirable or severe side effects at normal therapeutic dosage levels. Frequent laboratory monitoring is required while using micafungin and its salts.

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2. **Sitaxentan and its salts** is indicated for the treatment of pulmonary arterial hypertension (PAH), a rare progressive disease that is characterized by high blood pressure in the blood vessels leading to the lungs. Diagnosis by a specialist in the area of PAH is required. Close medical supervision and routine laboratory monitoring are required due to the potential for adverse effects involving the liver. Sitaxentan and its salts may have undesirable 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 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 submissions.

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 sent 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. 1536  
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Policy Bureau  
Therapeutic Products Directorate  
1600 Scott Street, Holland Cross  
Tower 'B', 2<sup>nd</sup> Floor  
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Telephone: 613-948-4623  
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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

Meena Ballantyne  
Acting Assistant Deputy Minister