Health Canada Santé Canada

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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 # 1590 – Schedule F

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

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Description of the medicinal ingredient:

1. Lenalidomide is used in the treatment of patients with certain types of myelodysplastic syndromes (MDS) who require red blood cell transfusions to manage low red blood cell counts (anemia). MDSs are a group of diseases of the blood and bone marrow in which the bone marrow does not make enough healthy blood cells. Individualized instructions or direct supervision by a practitioner is required. The patient may also require routine laboratory monitoring. Lenalidomide 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 this 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 this medicinal ingredient 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.

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- **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 manufacturer affected by this proposed amendment was made aware of the intent to recommend this medicinal ingredient 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 sent 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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Refer to Project No. **1590**
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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
Assistant Deputy Minister