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Contact
Regulatory Affairs

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07-110873-103

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 # 1575 – Schedule F

The purpose of this letter is to provide an opportunity for comment on the proposed addition of one medicinal ingredient to Schedule F, Part I 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:

Inhaled human insulin is used for the treatment of adult patients with diabetes for the control of high blood sugar. Inhaled human insulin is a rapid-acting form of insulin that may be used alone or in combination with oral antidiabetic agents and/or long or intermediate acting injectable insulins to optimize blood sugar control. Although injectable forms of insulin are not listed on Schedule F, it is recommended that the inhaled form be added to Schedule F. Inhaled human insulin has a rapid onset following administration. In addition, absorption of inhaled human insulin is dependant on adequate lung function in the patient. Lung function must be measured by a practitioner before beginning treatment and then monitored routinely thereafter. The starting and subsequent dosage must be determined individually by a practitioner and adjusted according to the patient's lung function and response to the drug dosage in relation to diet and activity level. The long-term effects of inhaled insulin are unknown at this time as there has not been a sufficient period of use to clarify the effects in humans.

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

Consideration was given to not listing inhaled human insulin on Schedule F, which would be consistent with the status of injectable insulins. Injectable insulins have a long history of use in Canada and are listed on provincial and territorial drug Schedule II by pharmacy regulatory authorities which means that they are kept "behind the counter" in the pharmacy but are available without a prescription. This availability of the injectable insulins from a pharmacist means that a diabetic is able to obtain insulin in situations where obtaining a prescription might be problematic or time-consuming, such as when traveling or when a supply of insulin has been damaged by lack of refrigeration. However, due to the unique route of administration of inhaled human insulin, many factors must be considered prior to initiation of therapy and while using this drug eg, adequate lung function and proper inhalation technique. It was therefore recommended that inhaled human insulin be added to Schedule F.

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.

- **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 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. 1575
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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