Notice

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Registration

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FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1575 2014; Schedule F)

P.C. 2008-1058 June 12, 2008

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) (see footnote a) of the *Food and Drugs Act* (see footnote b), hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1575 2014; Schedule F)*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1575 2014; SCHEDULE F)

AMENDMENT

1. Part I of Schedule F to the *Food and Drug Regulations* (see footnote 1) **is amended by adding the following in alphabetical order:**

Inhaled human insulin
Insuline humaine inhal00E9;e

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations*.)

Description

This amendment adds 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.

Description of the medicinal ingredient:

1.00A0;**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 patient2019;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

Any alternatives to the degree of regulatory control provided by this amendment would have to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and costs

The amendment impacts on the following sectors.

Public

Prescription access to drug products containing this medicinal ingredient will 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 practitioners2019; 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.

Consultation

The manufacturer affected by this amendment was made aware of the intent to recommend this medicinal ingredient for inclusion on Schedule F during the review of the drug submission.

Direct notice of the regulatory proposal was provided to provincial and territorial Ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations on September 17, 2007 with a 75-day comment period. This initiative was also posted on the Health Canada Web site and the 201C;Consulting With Canadians201D; Web site. No comments were received.

The process for this consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F. The MOU, signed by Health Canada, the Privy Council Office and the Department of International Trade on February 22, 2005, is posted on the Health Canada Web site.

Compliance and enforcement

This amendment does 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.

Contact

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Footnote a
2002;S.C. 1999, c. 33, s. 347

Footnote b
2002;R.S., c. F-27

Footnote 1
2002;C.R.C., c. 870

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NOTICE:
The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

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Important notices

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