Notice

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Registration

SOR/2008-204 June 12, 2008

FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1536 and 1550 2014; Schedule F)

P.C. 2008-1057 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 (1536 and 1550 2014; Schedule F)*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1536 AND 1550 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:**

Acamprosate and its salts
Acamprosate et ses sels

Micafungin and its salts
Micafungine et ses sels

Sitaxentan and its salts
Sitaxentan et ses sels

Varenicline and its salts
Var00E9;nicline et ses sels

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 four 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:

1.00A0;Acamprosate and its salts is indicated for the maintenance of abstinence from alcohol in patients with alcohol dependence. The safe and effective use of this drug requires that a practitioner evaluate the warnings and precautions associated with acamprosate use, particularly in patients with kidney or liver disease. The patient may also require continuous follow-up and support by a practitioner. Acamprosate may have undesirable or severe side effects at normal therapeutic dosage levels. (Project 1550)

2.00A0;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. (Project 1536)

3.00A0;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. (Project 1536)

4.00A0;Varenicline and its salts is indicated as a smoking

cessation aid in adults. The safe and effective use of this drug requires that a practitioner evaluate the warnings and precautions associated with varenicline use, particularly in patients who might also use other nicotine replacement therapies, and in patients with a serious illness such as epilepsy or heart disease. (Project 1550)

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 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 these medicinal ingredients 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 may 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 manufacturers affected by this amendment were made aware of the intent to recommend these medicinal ingredients for inclusion on Schedule F during the review of the drug submission.

Direct notice of the regulatory proposals were provided to provincial and territorial ministers of health, medical and pharmacy licensing bodies, and industry, consumer and professional associations with a 75-day comment period. These initiatives were also posted on the Health Canada Web site and the 201C;Consulting With Canadians201D; Web site: Project 1536 on September 14, 2007 and Project 1550 on September 17, 2007. The process for these consultations 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.

One comment was received regarding the proposed two amendments; the stakeholder had no objection to the regulatory proposals.

Compliance and enforcement

This amendment does not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act* and *Food and Drug Regulations* enforced by the Health Products and Food Branch Inspectorate.

Contact

Refer to Project Nos. 1536 and 1550
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Footnote a
S.C. 1999, c. 33, s. 347

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

Footnote 1
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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