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Notice

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Regulations Amending the Food and Drug Regulations (1184 — Modafinil)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

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

Description

The Therapeutic Products Directorate (TPD) of Health Canada proposes to add the medicinal ingredient modafinil and its salts to Part I of Schedule F to the *Food and Drug Regulations*.

Modafinil is a non-amphetamine central nervous system stimulant that increases levels of alertness in patients whose level of alertness is below normal. It is used for the treatment of excessive daytime sleepiness in patients with narcolepsy, a medical condition in which there are recurrent, uncontrollable, brief episodes of sleep. Modafinil should not be used for the treatment of normal fatigue states. There is no evidence that normal levels of alertness can be heightened by modafinil.

Schedule F is a list of medicinal ingredients, the sale of which is controlled under sections C.01.041 to C.01.046 of the *Food and Drug Regulations*. Part I of Schedule F lists medicinal ingredients which require a prescription for both human and veterinary use.

The Drug Schedule Status Committee reviews the status of chemical entities proposed for marketing as medicinal ingredients in drug products. The decision regarding the necessity for prescription

versus non-prescription status was made on the basis of established and publicly available criteria. These criteria include, but are not limited to, concerns relating to toxicity, pharmacologic properties, and therapeutic applications. The recommended degree of regulatory control is based on the risk factors associated with each specific drug and each drug's potential for abuse. Prescription status will help to ensure that consumers receive adequate risk/benefit information from a medical practitioner before taking the medication.

Alternatives

Consideration was given to classifying modafinil as a controlled drug and recommending its addition to Schedule III to the *Controlled Drugs and Substances Act* (CDSA) and to Part I of the Schedule to Part G (Controlled Drugs) of the *Food and Drug Regulations*.

The CDSA limits the possession, import, export, production, distribution and sale of narcotics, controlled drugs, targeted substances and precursor chemicals that can result in harm when distributed or used without controls. The CDSA specifies restrictions and offences that apply to drugs that are subject to abuse and illicit activity. These more stringent limitations to access help to prevent the diversion of these substances for illegal purposes. The CDSA includes, but is not limited to, six schedules of controlled substances and precursor chemicals, each associated with different offences, penalties and controls. The CDSA is a tool used to implement Canada's obligations under the United Nations Drug Control Conventions.

The Schedule to Part G of the *Food and Drug Regulations* includes drugs that are generally listed on either Schedule III or IV of the CDSA. Part G defines and provides an appropriate level of control for controlled drugs, which are drugs that have a significant abuse potential. These Regulations require dealers to be licensed in order to produce, manufacture, distribute, import and export these drugs. Licensed dealers must meet security requirements and obtain permits to import and export controlled drugs. These Regulations restrict the distribution activities of pharmacists, hospitals and practitioners and outline the records which must be kept for these drugs.

Modafinil is not currently scheduled under the United Nations Drug Control Conventions and, therefore, Canada is not obligated to regulate it under the CDSA. In the absence of inclusion under these international schedules, scheduling under the CDSA is based on a number of criteria, including evidence of abuse within Canada. Some potential for abuse of modafinil was identified, based on its stimulant properties. However, evidence of actual abuse in Canada is currently lacking. There is not enough evidence of diversion of modafinil for illegal purposes to support a recommendation for the stricter security requirements of controlled drug status at this time.

Any alternatives to the degree of regulatory control recommended in this regulatory initiative would need to be established through additional scientific information and/or clinical experience.

Benefits and costs

The amendment would impact on the following sectors:

- Public

Prescription access to modafinil would benefit Canadians by decreasing the opportunities for improper use and by ensuring professional guidance and care.

- Health Insurance Plans

A drug, when assigned prescription status, may be covered by both provincial and private health care plans.

- Provincial Health Care Services

The provinces may incur costs to cover physicians' fees for services. However, the guidance and care provided by the physicians would reduce the need for health care services that may result from improper use of modafinil. The overall additional costs for health care services should therefore be minimal.

Consultation

A letter informing stakeholders of the initial proposal to add modafinil to Schedule III to the CDSA and to Part I of the Schedule to Part G of the *Food and Drug Regulations* was issued to the provincial ministries of health, medical and pharmacy licensing bodies, industry associations and the RCMP on July 5, 1999. Responses were received from five stakeholders. They proposed the addition of modafinil to Schedule F instead of adding it to the Schedule to Part G of the *Food and Drug Regulations*.

The Office of Controlled Substances, Healthy Environments and Consumer Safety Branch of Health Canada was consulted during the development of this proposal and has indicated that there is insufficient evidence of abuse in Canada at this time to recommend that modafinil be added to Schedule III to the CDSA nor to Part I of the Schedule to Part G of the *Food and Drug Regulations*.

Direct notice of this regulatory proposal is being provided to the 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 and other interested parties. This initiative is also being posted on the Therapeutic Products Directorate Web site.

A 75-day comment period will be provided upon prepublication in the *Canada Gazette*, Part I.

Compliance and enforcement

This amendment would 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

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PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) (see footnote a) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1184 — Modafinil)*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice and be addressed to Karen Ash, Policy Division, Policy Bureau, Therapeutic Products Directorate, Department of Health, Address Locator 3102C5, 1600 Scott Street, 2nd floor, Tower B, Ottawa, Ontario K1A 1B6 (tel: (613) 957-6455; fax:

(613) 941-6458; e-mail: karen_ash@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, March 21, 2005

EILEEN BOYD
Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1184 — MODAFINIL)

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:**

Modafinil and its salts
Modafinil et ses sels

COMING INTO FORCE

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

[13-1-o]

Footnote a

S.C. 1999, c. 33, s. 347

Footnote 1

C.R.C., c. 870

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