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FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1576 2014; Schedule F)

P.C. 2008-1607 September 5, 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 (1576 2014; Schedule F)*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1576 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:

Oxaliplatin
Oxaliplatine

Ranibizumab
Ranibizumab

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 two 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;**Oxaliplatin** is used to treat patients with advanced colorectal cancer. Oxaliplatin is used in combination with other medications and should be administered under the supervision of a practitioner experienced in the use of anti-cancer drugs. Oxaliplatin may cause undesirable or severe side effects at normal therapeutic dosage levels.

2.00A0;**Ranibizumab** is used to treat damage to the eye associated with abnormal blood vessel growth in the retina. This condition can occur in diseases such as age-related macular degeneration. Treatment with ranibizumab must be administered by a qualified ophthalmologist experienced in performing injections into the eye. Ranibizumab may have 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 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 was 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. This initiative was also posted on the Health Canada Web site and the 201C;Consulting With Canadians201D; Web site on October 3, 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. This project received one comment which was in support of the regulatory proposal.

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

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Footnote a
S.C. 2005, c. 42, s. 2

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

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