



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Graham Spry Building
250 Lanark Avenue
Address Locator: 2005D
Ottawa, Ontario K1A 0K9

File # OF15-57-12-84
MECS # 09-133780-296

JUN 22 2011

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 Number 1659 –
Schedule F**

The purpose of this letter is to provide an opportunity to comment on the proposal to add six medicinal ingredients to Part I of Schedule F to the *Food and Drug Regulations*.

Sections C.01.041 to C.01.049 of the *Food and Drug Regulations* control the sale of medicinal ingredients that are listed in Schedule F. 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.

Health Canada's Drug Schedule Status Committee recommends prescription status or exemption from prescription status for medicinal ingredients on the basis of an assessment of the medicinal ingredients against a set of established and publicly available factors. These factors include, but are not limited to, toxicity, pharmacological properties and therapeutic uses of the medicinal ingredients.

Description of the medicinal ingredients:

1. The current listing for ‘amiodarone and its salts’ is revised to **‘amiodarone, its salts and derivatives’**. The revised listing is necessary to include the new medicinal ingredient, dronedarone, a derivative of amiodarone. Amiodarone, its salts and derivatives are used to treat irregular heartbeat. Direct supervision by a practitioner with routine laboratory monitoring is required. There may be a narrow margin of safety between the therapeutic and toxic doses of amiodarone, its salts and derivatives.
2. **Azacitidine, its salts and derivatives** are used to treat patients with blood diseases related to abnormal production of blood cells in the bone marrow but who are not eligible for stem cell transplantation. Individualized instructions, direct supervision by a practitioner and laboratory monitoring are required. There may be a narrow margin of safety between the therapeutic and toxic doses of azacitidine, its salts and derivatives.
3. **Certolizumab pegol** is a human monoclonal antibody used to treat active forms of rheumatoid arthritis, an inflammatory disorder that affects tissues and organs. Individualized instructions or direct supervision by a practitioner and routine laboratory monitoring are required. There may be a narrow margin of safety between the therapeutic and toxic doses of certolizumab pegol.
4. The current listing for ‘cladribine and its salts’ is revised to **‘cladribine, its salts and derivatives’**. The revised listing is necessary to include the new medicinal ingredient, clofarabine, a derivative of cladribine. Cladribine, its salts and derivatives are used to treat leukemia. Individualized instructions, direct supervision by a practitioner and laboratory monitoring are required. There may be a narrow margin of safety between the therapeutic and toxic doses of cladribine, its salts and derivatives.
5. **Degarelix, its salts and derivatives** are used to treat advanced prostate cancer by reducing levels of the hormone testosterone. Individualized instructions or direct supervision by a practitioner is required. There are potential undesirable and severe side effects at normal therapeutic dosage levels of degarelix, its salts and derivatives.

6. **Urokinase** is an enzyme that is used to treat patients with severe blood clotting in the lungs (pulmonary emboli) or heart (coronary artery thrombosis). Individualized instructions or direct supervision by a practitioner is required along with monitoring against sudden and serious bleeding or infection. There are potential undesirable and severe side effects at normal therapeutic dosage levels of urokinase.

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 recommended in these amendments would need to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and Costs

These amendments would impact on the following sectors:

- **Public**

Prescription access to drug products containing these medicinal ingredients would benefit Canadians by decreasing the opportunities for improper use and by ensuring the guidance and care of a practitioner.

Another benefit would be 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 in 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 in Schedule F. The overall additional costs for health care services should therefore be minimal.

Compliance and Enforcement

These amendments 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 manufacturers affected by these proposed amendments were made aware of the intent to recommend these medicinal ingredients for inclusion on Schedule F during the review of the drug submissions.

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 23, 2005. The MOU is posted on the Health Canada website.

Health Canada will send the letter by email to stakeholders. The letter will also be posted on the Health Canada and the *Consulting with Canadians* websites.

Any comments regarding these proposed amendments should be sent within **75** days following the date of posting of this letter on the Health Canada website. The policy analyst for this project, Susan Marthaler, may be contacted at:

Refer to Project Number: **1659**
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street, Holland Cross
Tower 'B', Second Floor
Address Locator: 3102C5
Ottawa, Ontario K1A 0K9
Telephone: 613-948-4623
Facsimile: 613-941-6458
Email: regaff-affreg@hc-sc.gc.ca

Final Approval

In accordance with the MOU process, it is anticipated that the proposed Schedule F amendments will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately eight to ten 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. These amendments would come into force on the date of registration.

Yours sincerely,

Original signed by

Paul Glover
Assistant Deputy Minister