Contact
Regulatory Affairs

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Graham Spry Building
250 Lanark Avenue
A.L. 2005D
Ottawa, ON K1A 0K9

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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 #1405 - Schedule F**

This letter is to provide an opportunity for comment on the proposed addition of 7 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

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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 determined the necessity for prescription status for each of the medicinal ingredients in this proposed amendment 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 applications.

Description of the medicinal ingredients:

1. **Atazanavir and its salts** - is a protease inhibitor indicated for the treatment of human immunodeficiency virus (HIV), a serious and potentially life-threatening illness. Individualized instructions are necessary in all potential use settings for atazanavir. It is to be used only in combination with other Schedule F HIV drugs. Routine lab and clinical monitoring are essential to adequate therapy. Specialized knowledge is required to treat HIV disease and its potential complications.

2. **Fulvestrant** - is an estrogen receptor antagonist. It is used in the hormonal treatment of locally advanced or metastatic breast cancer in postmenopausal women in whom the disease has spread in spite of previous endocrine therapy. Treatment with fulvestrant requires intramuscular administration by a physician and regular medical assessments.

3. **Gefitinib** - is an enzyme inhibitor that affects the rate at which cells grow (divide) and die. It is used to treat specific types of lung cancer in patients who have not responded to other types of chemotherapy. Gefitinib belongs to a new therapeutic class of drugs called epidermal growth factor receptor tyrosine kinase inhibitors. Treatment with this drug requires continuous supervision by a cancer specialist.

4. **Gemifloxacin and its salts** - is a synthetic broad-spectrum antibacterial agent that belongs to the fluoroquinolone class of antibiotics. Gemifloxacin is used to treat chronic bronchitis when caused by susceptible strains of microorganisms. Gemifloxacin and its salts, like other fluoroquinolone antibiotics, have the potential to cause serious adverse reactions in some patients. It must therefore be administered under the supervision of a medical practitioner.

5. **Hetastarch and its derivatives** - is a plasma volume expander administered by intravenous infusion to treat low blood plasma volume. Treatment with hetastarch requires individualized instructions and direct supervision by a specialist experienced with the appropriate use and the side effects of hetastarch and its derivatives, adjunctive therapy with other blood products as well as laboratory monitoring.

6. **Ibandronic acid and its salts** - is a bisphosphonate that acts on bone tissue to reduce bone resorption with no direct effect on bone formation. Ibandronic acid is used to treat and prevent osteoporosis (thinning or weakening of the bones) in postmenopausal women. Direct supervision by a physician is required for proper diagnosis, individualized instructions and monitoring for potential side effects.

7. **Ponazuril** - is an antiprotozoal treatment for horses. It is used to treat equine protozoal myeloencephalitis (EPM), a progressive, degenerative disease of the central nervous system of horses caused by the protozoal parasite, Sarcocystis neurona. A veterinarian must perform the testing required to diagnose the disease and to monitor the safe use of the drug.

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 adequate risk/benefit information is available 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 this amendment would need to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and Costs

The amendment 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 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 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 on Schedule F. The overall additional costs for health care services should therefore be minimal.

Compliance and Enforcement

This amendment 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 this proposed 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 this regulatory proposal was provided to provincial and territorial ministers of health, medical and pharmacy licensing bodies, and industry, consumer and professional associations on June 22, 2004 with a 30-day comment period. This initiative was also posted on the Therapeutic Products Directorate website. One supportive response was received from stakeholders.

The process for this further consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F, which came into effect on February 22, 2005. The MOU is posted on the Health Canada website.

This letter is being sent by email to stakeholders and is also being posted on the Health Canada website and the Consulting Canadians website.

Any comments regarding this proposed amendment should be sent within **75** days following the date of posting of this letter on the Health Canada website.

Project No.1405
Policy Division
Policy Bureau
Therapeutic Products Directorate
1600 Scott Street, Holland Cross
Tower 'B', 2nd Floor
Address Locator 3102C5
Ottawa, Ontario K1A 0K9

telephone: 613-948-4623 (refer to Project No. 1405)
facsimile: 613-941-6458
email: RegAff_Access@hc-sc.gc.ca

Final Approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately 6 to 8 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. The amendment would come into force on the date of registration.

Yours sincerely,

Original signed by

Diane Gorman
Assistant Deputy Minister