

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

09-103610-852

Provincial and Territorial Deputy Ministers of Health
Canadian Veterinary Medical Association
Association des vétérinaires en industrie animale du Québec
Canadian Council on Animal Care
Canadian Animal Health Institute
College of Veterinarians of Ontario
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 1621 – Schedule F

The purpose of this letter is to provide an opportunity for comment on the proposed addition of 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.

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. Dirlotapide** is a microsomal triglyceride transfer protein inhibitor that is used to treat obesity in dogs. Direct supervision by a practitioner and routine laboratory monitoring are required. Dirlotapide has the potential for undesirable side effects at normal therapeutic doses.
- 2. Firocoxib** is a COX-2 (cyclooxygenase) inhibitor type of nonsteroidal anti-inflammatory drug (NSAID) that is used to control pain and inflammation associated with osteoarthritis in dogs. Firocoxib has the potential for undesirable side effects at normal therapeutic doses. There is a narrow margin of safety between the therapeutic and toxic dosages in younger and older dogs.
- 3. Ibfloxacin** is a fluoroquinolone antibiotic that is used to treat bacterial infections in dogs and cats. Ibfloxacin has the potential for undesirable side effects at normal therapeutic doses. A practitioner must provide individualized instructions and supervision. Ibfloxacin may contribute to the development of resistant strains of microorganisms.
- 4. Maripotent and its salts** is a selective neurokinin one (NK1) receptor antagonist that is used to treat and prevent acute vomiting in dogs. Individualized instructions, direct practitioner supervision and routine laboratory monitoring are required. Maripotent and its salts is used in serious disease states and its use may mask other ailments.

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 this amendment would need to be established through additional scientific information and clinical experience.

No other alternatives were considered.

Benefits and Costs

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

Any costs incurred by Canadians would be outweighed by the benefits of having the products used under the guidance and care of a practitioner. There would be no new costs to provinces as prescription drug products for veterinary use and practitioners' fees for veterinary services are not covered by provincial health care plans.

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.

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 22, 2005. The MOU is posted on the Health Canada Web site.

This letter is being sent by email to stakeholders and is also being posted on the Health Canada Web site and the *Consulting With Canadians* Web site.

Any comments regarding this proposed amendment should be sent as follows within **75** days following the date of posting of this letter on the Health Canada Web site. The policy analyst for this project, Carrie Harrison-Viau, may be contacted at:

Refer to Project Number: **1621**
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
1600 Scott Street, Holland Cross
Health Canada
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 this amendment will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately six to eight months from the date of posting of this letter on the Health Canada Web site. 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,

Meena Ballantyne
Assistant Deputy Minister