Health Canada Santé Canada

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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 # 1530 - Schedule F**

The purpose of this letter is to provide an opportunity for comment on the proposed addition of two medicinal ingredients to Schedule F, Part I 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.

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Description of the medicinal ingredients:

1. **Pimobendan** is a cardiovascular drug for use in dogs. It is indicated for the treatment of congestive heart failure associated with a weakened heart and heart valves. Direct supervision by a veterinarian is required to diagnose congestive heart failure and identify the underlying disease. The animal may also require treatment with other drugs. Pimobendan is known to have undesirable or severe side effects at normal therapeutic dosage levels.

2. **Pirlimycin and its salts** is an antimicrobial indicated for the treatment of mammary gland infection in lactating dairy cows caused by the bacteria, *Staphylococcus aureus*. Diagnosis by a veterinarian is required prior to use because pirlimycin and its salts should not be used in animals with mastitis caused by other bacterial strains. Individualized instruction by a veterinarian is required to demonstrate the correct use of the drug because incorrect use may result in more severe mastitis.

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 veterinarian 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

The amendment would have the following impact on the public sector:

Prescription access to drug products containing these medicinal ingredients would benefit Canadians by decreasing the opportunities for improper use. The products would be used under the supervision of a veterinarian.

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.

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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 website.

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

Any comments regarding this proposed amendment should be addressed as follows within **75** days following the date of posting of this letter on the Health Canada website. The policy analyst for this project, Karen Ash, may be contacted at:

Refer to Project No. 1530
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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 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

Meena Ballantyne
Acting Assistant Deputy Minister