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Registration

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FOOD AND DRUGS ACT

Regulations Amending the Food and Drug Regulations (1530 2014; Schedule F)

P.C. 2008-1059 June 12, 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 (1530 2014; Schedule F)*.

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1530 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:**

Pimobendan
Pimobendan

Pirlimycin and its salts
Pirlimycine et ses sels

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;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.**00A0;**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 this 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 public sector.

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

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 submissions.

Direct notice of the regulatory proposal was provided to provincial and territorial Ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations on October 3, 2007 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.

One comment was received regarding the proposed amendment; the stakeholder had no objections to the regulatory proposal.

The process for this consultation 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.

Compliance and enforcement

This amendment does 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.

Contact

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Footnote a
S.C. 1999, c. 33, s. 347

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

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

00A0;

NOTICE:
The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

Top of page

Important notices

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