

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

07-110914-171

Provincial and Territorial Deputy Ministers of Health  
Canadian Veterinary Medical Association  
Association des vétérinaires en industrie animale du Québec  
Canadian Animal Health Institute  
Canadian Council on Animal Care  
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 # 1554 Schedule F***

The purpose of this Notice of Intent (NOI) is to provide an opportunity for comment on a proposed change in status of the medicinal ingredient, progesterone, in 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.

Progesterone is currently included in Part II of Schedule F in the group listing for sex hormones, which means that a prescription is required for progesterone for human use

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but not for veterinary use. The proposed change in status means that progesterone would require a prescription for both human and veterinary use except when sold in an implant for veterinary use for growth promotion.

The proposed change would require two amendments to Schedule F:

- progesterone would be added to Part I of Schedule F as,  
*Progesterone and its derivatives except when sold in an implant for veterinary use for growth promotion.*
- progesterone would be removed from Part II of Schedule F by listing it as an exception under the group listing for sex hormones.

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 ingredient:

**Progesterone** is a hormone that is used in veterinary medicine to treat conditions of the reproductive system in both farm animals and domestic pets. Examination and diagnosis by a veterinarian are required to determine that treatment with progesterone is appropriate. Treatment with progesterone may also involve the use of other reproductive hormones that are prescription drugs. Direction and oversight by a veterinarian are required because improper use or handling of progesterone in drugs intended for large animals may result in adverse reproductive effects in humans.

An exception from prescription status is proposed for growth implants for veterinary use because they are not intended for use in breeding animals and individual examinations are not required. In addition, implant devices are packaged in cartridges and administered with implant guns, therefore the risk of human exposure is significantly reduced.

### ***Alternatives***

The alternative option would be the status quo; that is, all veterinary products containing progesterone would continue to have nonprescription status. This option was not considered to be appropriate given the risks associated with unsupervised use of progesterone except when sold in implants for growth promotion. The degree of

regulatory control afforded by Schedule F (prescription drug) status coincides with the risk factors associated with progesterone. Oversight by a practitioner is necessary to ensure that appropriate risk/benefit information is considered before the drug containing progesterone is administered and that the drug therapy is properly monitored.

### ***Benefits and Costs***

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

Prescription access to veterinary drug products containing progesterone 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.

### ***Consultation***

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

Any comments regarding this proposed amendment should be addressed as follows within **75** days following the date of publication in *Canada Gazette*, Part I. The policy analyst for this project, Karen Ash, may be contacted at:

Refer to Project No. 1554  
Bureau of Policy, Science and International Programs  
Therapeutic Products Directorate  
1600 Scott Street, Holland Cross  
Tower 'B', 2<sup>nd</sup> Floor  
A.L. 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 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,

Meena Ballantyne  
Assistant Deputy Minister