Health Canada Santé Canada

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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 # 1452 - Schedule F

This letter is to provide you with an opportunity to comment on the proposed addition of **Choriogonadotropin alfa** to Part I of Schedule F to the *Food and Drug Regulations* to the *Food and Drugs Act*.

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 determined the necessity for prescription status for the medicinal ingredient 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 ingredient:

Choriogonadotropin alfa is a recombinant human chorionic gonadotropin, a hormone that is involved in the reproduction process in women. It is used to trigger ovulation in women undergoing treatment for infertility disorders. It is also used to help eggs mature in the ovaries of women undergoing assisted reproductive technologies (ART), such as in vitro fertilization and embryo transfer. Choriogonadotropin alpha is administered subcutaneously. Individualized instructions and/or

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direct supervision by a practitioner are required. The patient may also require treatment with other drugs or routine laboratory monitoring. This drug may have undesirable or severe side effects at normal therapeutic dosage levels. This drug has not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans.

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 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 will impact on the following sectors:

- **Public**

Prescription access to drug products containing this medicinal ingredient would benefit Canadians by decreasing the opportunities for improper use and by ensuring the guidance and care of a practitioner.

- **Health Insurance Plans**

Drug products for human use containing medicinal ingredients listed on Schedule F may be 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 will not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act and Regulations* enforced by the Health Products and Food Branch Inspectorate.

Consultation

The manufacturer affected by this proposed amendment was made aware of the intent to recommend this medicinal ingredient 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 the Consulting Canadians website.

Any comments regarding this proposed amendment should be addressed to Vilma Laryea, Policy Division, Policy Bureau, Therapeutic Products Directorate, 1600 Scott Street, Holland Cross, Tower 'B', 2nd Floor, Address Locator 3102C5, Ottawa, Ontario, K1A 0K9, by facsimile at 613-941-6458 or by email to vilma_laryea@hc-sc.gc.ca within **75** days following the date of posting of this letter on the website.

Final Approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to final publication in the *Canada Gazette,* Part II, approximately 6 to 8 months from the date of posting of this letter on the website. The amendment will come into force on the date of registration.

Yours sincerely,

Original Signed by

Diane Gorman
Assistant Deputy Minister