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09-132418-439

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 Number 1652 – Schedule F**

The purpose of this Notice of Intent (NOI) is to provide an opportunity for comment on the proposal to amend the current listing for l-asparaginase (also known, as asparaginase) in Part I of Schedule F to the *Food and Drug Regulations* to maintain prescription status for injectable dosage forms while providing an exemption from prescription status for other dosage forms.

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.

***Description***

**L-asparaginase** is an enzyme that breaks down the amino acid, asparagine, in the body and is used as an injectable drug to treat some forms of cancer. L-asparaginase is not given orally to treat cancer because it is broken down in the stomach and therefore not absorbed by the body. Available information indicates that l-asparaginase is used therapeutically as an injectable drug but not in any other dosage forms. Therefore prescription status is required only for the injectable dosage form.

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The enzyme, asparaginase, can also act on food to reduce the amount of the amino acid, asparagine. Adding asparaginase to food to reduce the amount of asparagine can reduce the risk of formation of the chemical acrylamide which occurs during processing. Any residual asparaginase in the food would be broken down in the stomach and consequently would not be absorbed by the body.

The Joint Food and Agriculture Organization and World Health Organization Expert Committee on Food Additives and Contaminants, has determined that acrylamide in food may be a human health concern. Health Canada agrees with this assessment. This proposed amendment to the listing of l-asparaginase in Schedule F would remove prescription restrictions from asparaginase when used orally. This would then allow asparaginase to be proposed for use as a food additive under the *Food and Drug Regulations* for the reduction of acrylamide in prepared and packaged foods. Information on the proposal to use asparaginase in certain food products can be found in the consultation section of the Food and Nutrition part of the Health Canada Web site. Requests for information on the proposal can also be sent by email to the Food Directorate at [sche-ann@hc-sc.gc.ca](mailto:sche-ann@hc-sc.gc.ca).

### ***Alternatives***

The alternative option would be to leave l-asparaginase in Schedule F for all strengths, dosages, dosage forms and conditions of use. As measured against the factors for listing drugs in Schedule F, it has been determined that maintaining the current listing in Schedule F for l-asparaginase is not appropriate.

As well, any alternatives to the degree of regulatory control recommended in this amendment would need to be established through additional scientific information and clinical experience.

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

- **Public**  
The public would benefit from continued prescription status and oversight by a practitioner for injectable dosage forms of l-asparaginase, which are used in the treatment of cancer.

The public would benefit from exemption from prescription status for oral forms of l-asparaginase as this would allow it to be proposed for use as a food additive under the *Food and Drug Regulations* to reduce the amount of acrylamide produced in the processing of some foods.

- **Manufacturers**

There would be no immediate impact on manufacturers as there are currently no products on the market in Canada for the dosage forms proposed for exemption from Schedule F. The status of currently marketed prescription drugs containing l-asparaginase would not change.

Food manufacturers would benefit from a proposal to allow asparaginase as a food additive under the *Food and Drug Regulations* to reduce the amount of acrylamide produced in the processing of some foods.

- **Health Insurance Plans**

There would be no change in costs to drug benefit plans for prescription drugs containing this medicinal ingredient as their status would not change.

- **Provincial Health Care Services**

There would be no change in costs to drug benefit plans for prescription drugs containing this medicinal ingredient as their status would not change.

### ***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*.

### ***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 Web site.

This NOI 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 publication in *Canada Gazette*, Part I. The policy analyst for this project, Karen Ash, may be contacted at:

Refer to Project Number: **1652**  
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Therapeutic Products Directorate  
Health Canada  
1600 Scott Street, Holland Cross  
Tower 'B', Second Floor  
Address Locator: 3102C5  
Ottawa, Ontario K1A 0K9  
Telephone: 613-948-7542  
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Email: [regaff-affreg@hc-sc.gc.ca](mailto: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 publication of this NOI in the *Canada Gazette*, Part I. 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