Contact
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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 #1370 - Schedule F*

This Notice of Intent (NOI) is to provide an opportunity for comment on the proposal to amend Part I of Schedule F to the *Food and Drug Regulations* to the *Food and Drugs Act* to remove nicotine from Schedule F, when administered by an oral lozenge containing 4 mg or less of nicotine per lozenge. The nicotine 4 mg or less lozenge is an alternative to existing nicotine replacement therapies

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(NRTs), intended to assist in the cessation of smoking.

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.

Schedule F includes nicotine and its salts for human use as a medicinal ingredient with the following exceptions:

1. in natural substances
2. in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit
3. in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day; or
4. in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit

Products in gum, patch and inhaler form are commonly used in smoking cessation therapy to relieve nicotine withdrawal symptoms.

Rationale

- In 1997, the United Nations Focal Point on Tobacco or Health recommended that less hazardous nicotine devices should be as or more easily available than cigarettes.

- In 2000, the Tobacco Free Initiative, a World Health Organization cabinet project recommended increasing public access to the range of effective methods for treating tobacco dependence, including NRTs.

- When faced with the challenge of achieving a more rapid rate of decline of Canadians who smoke, the Government of Canada launched the Federal Tobacco Control Strategy in April of 2001. The Strategy emphasizes partnerships among

government departments, and between government and voluntary health agencies and non-governmental organizations.

- The ultimate objective of the Canadian Federal Tobacco Control Strategy is to reduce the number of tobacco-related deaths and illnesses. The four mutually reinforcing components of the strategy are protection, prevention, cessation and harm reduction.

- The proposal to remove nicotine lozenge 4 mg or less from Schedule F is based on a review of the clinical evidence and safety data provided in a New Drug Submission. A general review of the known pharmacological and toxicological properties of nicotine, reported adverse drug reactions, abuse potential studies and available literature has also been undertaken.

- Nicotine in a lozenge dosage form is available without prescription in the United States and the United Kingdom.

- There is no evidence from the post-market data that this product is being abused by either children or non-smokers. There have been no reports of inappropriate use, overdose or product dependence.

Alternative

Prescription Status

The alternative option would be to leave nicotine lozenge containing 4 mg or less of nicotine, on Schedule F. This option was not considered to be an appropriate risk management tool. Prescription status would unnecessarily restrict the availability of a safe and effective smoking cessation product. The benefits of having the nicotine 4 mg or less lozenges available as a nonprescription drug clearly outweigh the risks.

Benefits and Costs

The proposed amendment would impact on the following sectors:

- **Public**

  The availability of the nicotine 4 mg lozenge as a nonprescription product would provide consumers with the convenience of self-medication. It would also provide consumers with a greater choice of nonprescription aids for smoking cessation. This may encourage more Canadians to try to quit smoking.

  Product labels would be required to include directions for use and applicable cautionary statements. This would help to provide information to the public about safe and proper use of the product.

  The public would be required to pay directly for the product as nonprescription products are not usually covered by drug insurance plans.

- **Provincial Health Care Systems**

  There would be no anticipated cost to publicly funded drug benefit plans since most do not cover the cost of nonprescription drugs.

  An increased number of smokers quitting their use of tobacco products could lead to fewer patients with smoking-related diseases and reduced costs to the health care system.

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. Inspection mechanisms at both the federal and provincial levels would be maintained.

Consultation

Direct mailing of this regulatory proposal was sent on September 3, 2003 to the provincial Ministries of Health, medical and pharmacy

licensing bodies and pharmaceutical industry with a 30 day comment period. Responses were received from three external stakeholders. All respondents expressed support for this proposal.

The process for further 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 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 ON 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 Health Canada website.

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 6 to 8 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,

Original Signed by:

Diane Gorman
Assistant Deputy Minister

Last Updated: 2005-08-05  Important Notices