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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 # 1594 - Schedule F**

This revised 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 revise the listing for fluconazole to allow nonprescription status for fluconazole 150 mg for oral use for the treatment of vaginal candidiasis.

An initial NOI was published in the *Canada Gazette*, Part I on January 10, 2009 that requires modification. The January 10, 2009 NOI stated that the amendment would come into force on the date of registration. As there are multiple manufacturers of products containing fluconazole 150 mg for the treatment of vaginal candidiasis, a coming into force at a date later than the date of publication of the amendment in *Canada Gazette*, Part II is needed to allow these manufacturers the opportunity to have nonprescription labelling approved for their products. This revised NOI reflects these considerations.

Fluconazole is currently listed in Part I of Schedule F without any qualifying phrases or exceptions. This means that all strengths of fluconazole currently require a prescription in order to be sold in Canada.

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.

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Description

Fluconazole is a triazole antifungal agent indicated for the treatment of vaginal yeast infections due to *Candida*. Vaginal candidiasis is a common vaginal yeast infection affecting many women. The proposed nonprescription fluconazole 150 mg would have exactly the same indications for use as the currently available prescription fluconazole 150 mg. Single dose orally administered fluconazole 150 mg has been available in Canada as a prescription drug for treatment of vaginal candidiasis since 1994.

A number of related antifungal products (e.g., clotrimazole, miconazole) that are administered vaginally have been available in Canada without a prescription since 1993. The risk benefit profile of single dose orally administered fluconazole 150 mg is comparable to that of nonprescription vaginally administered antifungal products. As with the labelling of the nonprescription vaginally administered antifungal products, labelling for the proposed nonprescription fluconazole 150 mg will advise women experiencing a first vaginal infection to see their doctor to confirm the diagnosis of a yeast infection. Similarly, the product labelling for the proposed nonprescription fluconazole 150 mg will include a list of symptoms that are not associated with yeast infections; patients will be advised to contact their physician immediately if any of these symptoms are present.

Alternatives

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

Single dose orally administered fluconazole 150 mg is intended to be used as a stand-alone therapeutic. No adjunctive therapy with scheduled drugs or routine laboratory monitoring are required for the safe use of this drug.

Post marketing experience has shown that single dose orally administered fluconazole 150 mg is not associated with significant adverse effects. There are no dose-related or age-related adverse effects, no special populations at risk and no clinically significant drug or food interactions. In addition to its large safety margin, side effects associated with the use of single dose orally administered fluconazole 150 mg are minor and transient in nature, with incidence and severity being equivalent to that observed in placebo-treated groups.

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Benefits and Costs

The proposed amendment would impact on the following sectors:

- **Public**

  The availability of a nonprescription single dose orally administered fluconazole 150 mg would provide consumers with another option for the treatment of vaginal candidiasis.

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

  The public would be required to pay directly for the product as products which do not require a prescription are not usually covered by drug insurance plans.

- **Health Insurance Plans**

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

- **Provincial Health Care Services**

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

- **Pharmaceutical Industry**

  Following implementation of this initiative, fluconazole 150 mg for oral use for the treatment of vaginal candidiasis could no longer be sold with prescription labelling. Notice of this change in regulatory status is being communicated to the pharmaceutical industry through this NOI. This advance notice plus a delayed coming into force would allow manufacturers of these products sufficient time to obtain approval of nonprescription labelling. Draft guidance will be sent to manufacturers affected by this proposed regulatory amendment which may assist them in beginning preparation of nonprescription labelling.

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.

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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 within **75** days following the date of publication in *Canada Gazette,* Part I. Please note that any comments received during the first consultation period will be addressed along with comments received during this second comment period. The policy analyst for this project, Karen Ash, may be contacted at:

Refer to Project No. **1594**
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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 will come into force 90 days after the date of publication in the *Canada Gazette*, Part II.

Yours sincerely,

Meena Ballantyne
Assistant Deputy Minister