

Registration

SOR/2009-305 November 19, 2009

FOOD AND DRUGS ACT

## Regulations Amending the Food and Drug Regulations (1594 — Schedule F)

P.C. 2009-1872 November 19, 2009

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act* ([see footnote b](#)), hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1594 — Schedule F)*.

### REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1594 — SCHEDULE F)

#### AMENDMENT

##### 1. The reference to

**Fluconazole**

*Fluconazole*

in Part I of Schedule F to the *Food and Drug Regulations* ([see footnote 1](#)) is replaced by the following:

Fluconazole, except when sold in a concentration of 150 mg per oral dosage unit and indicated for the treatment of vaginal candidiasis

*Fluconazole, sauf s'il est vendu en une concentration de 150 mg par unité posologique orale pour le traitement des candidoses vaginales*

#### COMING INTO FORCE

2. These Regulations come into force 90 days after the day on which they are published in the *Canada Gazette* Part II.

#### REGULATORY IMPACT ANALYSIS STATEMENT

*(This statement is not part of the Regulations.)*

##### ***Issue and objectives***

This amendment to Part I of Schedule F to the *Food and Drug Regulations* provides an exemption to allow nonprescription status for fluconazole 150 mg for oral use for the treatment of vaginal candidiasis.

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.

Drugs can only be sold in Canada once Health Canada has assessed them for safety, efficacy and quality as required by the *Food and Drugs Act* and the *Food and Drug Regulations*.

### *Description and rationale*

Health Canada's Drug Schedule Status Committee (Committee) recommends prescription status or exemption from prescription status for medicinal ingredients on the basis of an assessment of the medicinal ingredient against a set of established and publicly available factors. These factors include, but are not limited to, toxicity, pharmacological properties and therapeutic uses of the medicinal ingredients.

The Committee assessed fluconazole 150 mg for oral use for the treatment of vaginal candidiasis against the factors for listing in Schedule F and recommended nonprescription status. All other strengths and dosage forms of fluconazole will still require a prescription in order to be sold.

Fluconazole, a triazole antifungal agent, is used to treat vaginal yeast infections due to *Candida*. Vaginal candidiasis is a common vaginal yeast infection affecting many women. Orally administered fluconazole 150 mg has been available in Canada as a prescription drug for treatment of vaginal candidiasis since 1994. It has been a nonprescription drug in the United Kingdom since 1995 and Australia and New Zealand since 2003.

A number of related antifungal products (e.g. clotrimazole, miconazole) that are administered vaginally have been available in Canada without a prescription since 1993. As with the labelling of the nonprescription vaginally administered antifungal products, labelling for 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 nonprescription fluconazole 150 mg will also 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.

Manufacturers can sell fluconazole 150 mg for oral use for the treatment of vaginal candidiasis as a nonprescription product only once the regulatory amendment has come into force and at that point can no longer sell their products with prescription labelling. Advance notice of the proposed change in regulatory status was communicated to the pharmaceutical industry through a Notice of Intent (NOI). This advance notice plus a delayed coming into force allows manufacturers of these products time to obtain approval of nonprescription labelling. In addition, draft labelling information was sent to manufacturers of prescription products affected by this regulatory amendment to assist them in beginning preparation of nonprescription labelling.

The availability of fluconazole 150 mg for oral use when sold as a nonprescription product will provide consumers with more convenient access to this treatment for vaginal candidiasis. The public may be required to pay directly for the product, as products which do not require a prescription are not usually covered by drug insurance plans.

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

### **Consultation**

Direct notice of this regulatory proposal was provided to external stakeholders, including provincial and territorial ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations in two NOIs. The first NOI was sent on December 29, 2008 and published in the *Canada Gazette*, Part I, on January 10, 2009, with a 75-day comment period. Modifications were required to the first NOI regarding the date of coming into force of the proposed amendment. Consequently, a second NOI was published in the *Canada Gazette*, Part I, on April 11, 2009, and sent to external stakeholders on April 14, 2009, with a 75-day comment period. The two NOIs were also posted on the Health Canada Web site and the *Consulting With Canadians* Web site. The process for this consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F. The MOU, signed by Health Canada, the Privy Council Office and the Department of International Trade on February 22, 2005, is posted on the Health Canada Web site.

Comments were received from seven respondents during the first consultation period. The applicant for this proposal submitted one comment of support. Six other respondents expressed support for the proposed amendment. No negative comments were received. No comments were received during the second consultation period.

### **Implementation, enforcement and service standards**

This amendment will come into force 90 days after publication in the *Canada Gazette*, Part II.

This amendment does 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.

### **Contact**

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### [Footnote a](#)

S.C. 2005, c. 42, s. 2

### [Footnote b](#)

R.S., c. F-27

### [Footnote 1](#)

C.R.C., c. 870

### **NOTICE:**

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

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