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Registration

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FOOD AND DRUGS ACT

**Regulations Amending the Food and Drug Regulations  
(1541 — Schedule F)**

P.C. 2008-613 April 3, 2008

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 (1541 — Schedule F)*.

**REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1541 — SCHEDULE F)**

**AMENDMENT**

**1. The reference to**

**Diclofenac and its salts**

***Diclofénac et ses sels***

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

Diclofenac and its salts, except when sold as a single medicinal ingredient in a concentration equivalent to 1% or less diclofenac in preparations for topical use on the skin

*Diclofénac et ses sels sauf s'ils sont vendus comme ingrédient médicinal unique en une concentration maximale de 1 % dans les préparations pour usage topique sur la peau*

## **COMING INTO FORCE**

**2. These Regulations come into force on the day on which they are registered.**

## **REGULATORY IMPACT ANALYSIS STATEMENT**

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

### ***Description***

This amendment to Part I of Schedule F to the *Food and Drug Regulations* provides an exemption to allow non-prescription status for diclofenac and its salts when sold as a single medicinal ingredient in a concentration equivalent to 1% or less diclofenac in preparations for topical use on the skin.

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.

Diclofenac and its salts is a non-steroidal anti-inflammatory analgesic drug (NSAID) that is available in Canada as a prescription drug to reduce inflammation and pain in conditions such as arthritis, acute injury and kidney stones. Prescription drug products containing diclofenac are available as oral dosage forms, suppositories and topical products containing more than 1% diclofenac.

Diclofenac as a 1% topical preparation is intended to be applied to the skin for the relief of pain due to muscle and joint injuries such as sprains, strains and sports injuries. Although there is currently no diclofenac 1% topical product on the market in Canada, it has been approved for marketing in over 100 countries world-wide since 1985.

A non-prescription 1% topical strength will provide a route and dose option to those who wish to use a topical treatment for the acute pain of a sprain or strain type injury to a muscle or joint. The product should be applied three to four times a day. The duration of use should not exceed seven days of continuous treatment without consulting a practitioner.

Post-marketing experience indicates that the 1% dosage strength of diclofenac for topical use is not associated with significant adverse effects. There are no dose-related or age-related adverse effects and no special population is at risk. The likelihood of diclofenac use masking the symptoms of a serious condition is very low. In addition to its large safety margin, side effects are minor and transient in nature. The use of the non-prescription product in other countries has revealed no indication that the drug product poses generalized safety problems that will be incompatible with self-care use by Canadians.

### ***Alternatives***

The alternative option was to leave diclofenac and its salts on Schedule F without any exemption for 1% or less concentrations for topical use on the skin. As measured

against the factors for listing drugs on Schedule F, it was determined that maintaining diclofenac and its salts on Schedule F without any exemption is not appropriate. The availability of a non-prescription 1% diclofenac for topical use will provide a treatment option for those suffering from pain associated with a muscle or joint injury.

### ***Benefits and costs***

The amendment impacts on the following sectors:

#### **Public**

The availability of diclofenac 1% as a non-prescription product will provide consumers with more convenient access to this topical treatment for muscle or joint injury.

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

The public will 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 is no anticipated cost for privately funded drug benefit plans since most do not cover the cost of non-prescription drugs.

#### **Provincial health care services**

There is no anticipated cost to provincial drug benefit plans since most do not cover the cost of non-prescription drugs.

#### ***Consultation***

Direct notice of the regulatory proposal was provided to

provincial and territorial ministers of health, medical and pharmacy licensing bodies, and industry, consumer and professional associations on July 9, 2007 with a 75-day comment period. This initiative was published as a Notice of Intent in the *Canada Gazette*, Part I, on July 7, 2007. It was 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.

Two responses were received with comments on the proposed regulatory amendment; both stakeholders supported the proposal. One stakeholder provided an additional comment regarding the product labelling. As this additional comment does not affect the proposed regulatory amendment, a direct response was provided to the stakeholder.

### ***Compliance and enforcement***

This amendment does not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act* and *Food and Drug Regulations* enforced by the Health Products and Food Branch Inspectorate.

### ***Contact***

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**[Footnote a](#)**

S.C. 1999, c. 33, s. 347

**[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 hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

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**Updated: 2008-04-16**