



[Notice](#)

Quick Search  
 >>

Vol. 139, No. 11 — June 1, 2005

Registration  
SOR/2005-142 May 10, 2005

- [News and announcements](#)
- [Mandate](#)
- [Consultation](#)
- [Recent Canada Gazette publications](#)

FOOD AND DRUGS ACT

**Regulations Amending the Medical Devices Regulations (Developing Countries)**

P.C. 2005-860 May 10, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 30 ([see footnote a](#)) of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Medical Devices Regulations (Developing Countries)*.

- [Part I: Notices and proposed regulations](#)
- [Part II: Official regulations](#)
- [Part III: Acts of Parliament](#)

**REGULATIONS AMENDING THE MEDICAL DEVICES REGULATIONS (DEVELOPING COUNTRIES)**

AMENDMENTS

- [Learn more about the Canada Gazette](#)
- [Publishing information](#)

**1. Section 1 of the *Medical Devices Regulations* ([see footnote 1](#)) is amended by adding the following in alphabetical order:**

"Commissioner of Patents" means the Commissioner of Patents appointed under subsection 4(1) of the *Patent Act*. (*commissaire aux brevets*)

"General Council Decision" has the meaning assigned by subsection 30(6) of the Act. (*décision du Conseil général*)

- [Publishing requirements](#)
- [Deadline schedule](#)
- [Insertion rates](#)
- [Request for insertion form](#)
- [Subscription information](#)

**2. The Regulations are amended by adding the following after section 43.1:**

*Medical Devices to Be Sold for the Purposes of Implementing the General Council Decision*

Application

- [Useful links](#)
- [Archives \(1998-2004\)](#)

**43.2** Sections 43.3 to 43.6 apply to a medical device in respect of which a manufacturer has applied to the Commissioner of Patents for an authorization under section 21.04 of the *Patent Act* for the purposes of implementing the General Council Decision.

Notices to Commissioner of Patents

**43.3** The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the manufacturer's medical device meets the requirements of the Act and these Regulations if

(a) the manufacturer holds a medical device licence in respect of the device issued in accordance with section 36;

(b) the Minister is satisfied that the manufacturer and the device comply with the Act and these Regulations;

(c) the manufacturer has submitted to the Minister a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the *Patent Act*;

(d) the manufacturer has submitted to the Minister information regarding the manner in which the mark referred to in paragraph 43.5(1)(a) is applied to all permanent components of the device; and

(e) the manufacturer has submitted to the Minister a sample of the label for the device that includes the information required by paragraph 43.5(1)(b).

**43.4** The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(b) of the *Patent Act* in the event that the Minister is of the opinion that the manufacturer's medical device referred to in section 43.2 has ceased to meet the requirements of the Act and these Regulations.

#### Marking and Labelling

**43.5** (1) No person shall sell a medical device referred to in section 43.2 unless

(a) the mark "XCL" is displayed on all permanent components of the device; and

(b) the label of the device displays the mark "XCL" followed by the control number referred to in paragraph 21(1)(d) and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA.".

(2) The information required by subsection (1) shall be expressed in a legible, permanent and prominent manner.

#### Notice to Minister

**43.6** The manufacturer of a medical device referred to in section 43.2 shall notify the Minister in writing not less than 15 days prior to commencing the manufacture of the device.

#### COMING INTO FORCE

**3. These Regulations come into force on the day on which *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, being chapter 23 of the Statutes of Canada, 2004, comes into force.**

**N.B. The Regulatory Impact Analysis Statement for these Regulations appears following SOR/2005-141, Regulations Amending the Food and Drug Regulations (1402 — Drugs for Developing Countries).**

[Footnote a](#)

S.C. 2004, c. 23, s. 2

[Footnote 1](#)

SOR/98-282

#### 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.



[Top of page](#)

Maintained by the [Canada Gazette Directorate](#)  
Updated: 2005-06-01

[Important Notices](#)