

# WORLD TRADE ORGANIZATION

G/TBT/N/CAN/5  
11 May 2001

(01-2447)

Committee on Technical Barriers to Trade

Original: English/  
French

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	<b>Member to Agreement notifying:</b> <u>CANADA</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Department of Health <b>Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> National Enquiry Point
3.	<b>Notified under Article 2.9.2 [ X ], 2.10.1 [    ], 5.6.2 [    ], 5.7.1 [    ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> medical devices
5.	<b>Title, number of pages and language(s) of the notified document:</b> Proposed Amendment to the Medical Devices Regulations (pages 1625-1631; English and French)
6.	<p><b>Description of content:</b> The <i>Medical Devices Regulations</i> (the Regulations) set out the requirements governing the sale, importation and advertisement of medical devices in Canada. The goal of the Regulations is to ensure that medical devices distributed in Canada are both safe and effective. The Regulations were revised in 1998 to reflect contemporary regulatory philosophy.</p> <p>Following final publication of the revised <i>Medical Devices Regulations</i> in 1998, several oversights were noted. Some of the oversights may have caused difficulty in understanding the intent of the Regulations. Other oversights imposed an unnecessary burden on industry.</p> <p>Therefore, amendments are required in order to:</p> <ul style="list-style-type: none"><li>— correct lack of clarity or inconsistencies in the wording between the <i>Food and Drugs Act</i> and the <i>Medical Devices Regulations</i>;</li><li>— enhance compliance with the <i>Official Languages Act</i>; and</li><li>— remove unnecessary words as identified by the Standing Joint Committee for the Scrutiny of Regulations.</li></ul> <p>In addition, the amendments reduce unnecessary paper work while maintaining appropriate regulatory controls for devices sold in Canada. This maintains consistency with TPP regulatory philosophy to intervene no more than necessary to enhance the safety and efficacy of products sold in Canada.</p>
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> protection of human safety

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<b>8.</b>	<b>Relevant documents:</b> Canada Gazette, Part 1, 5 May 2001
<b>9.</b>	<b>Proposed date of adoption:</b> not stated <b>Proposed date of entry into force:</b> not stated
<b>10.</b>	<b>Final date for comments:</b> 4 June 2001
<b>11.</b>	<b>Texts available from: National enquiry point [ X ] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b> The electronic version of the Canada Gazette Part 1 can be downloaded at:  <a href="http://canada.gc.ca/gazette/part1/pdf/g1-13518.pdf">http://canada.gc.ca/gazette/part1/pdf/g1-13518.pdf</a>