WORLD TRADE ORGANIZATION

G/TBT/N/CAN/525

8 May 2017

(17-2471)

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**Committee on Technical Barriers to Trade**

Original: English/French

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** CANADA<br><br>**If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Department of Health<br><br>**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above**:<br><br>Canada's Notification Authority and Enquiry Point<br>Global Affairs Canada<br>Technical Barriers and Regulations Division<br>111 Sussex Drive, Ottawa, ON K1A 0G2<br>Canada<br>Telephone: (343)203-4273<br>Fax: (613)943-0346<br>E-mail: enquirypoint@international.gc.ca |
| **3.** | **Notified under Article 2.9.2 [ ], 2.10.1 [X], 5.6.2 [ ], 5.7.1 [ ], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Drug Products (ICS: 11.040, 11.120). Medical equipment (ICS 11.040), Pharmaceutics (ICS 11.120). |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need) (17 pages, in English; 17 pages, in French) |
| **6.** | **Description of content:** The Government of Canada is committed to making treatment options available to patients who require them in situations where this is an urgent public health need, including the current the opioid crisis. The Government is taking action in a number of areas to address the impacts of problematic substance use, including supporting better treatment options for patients.<br><br>To help respond to this need, Health Canada is proposing to allow the importation and use of medications that have been authorized for sale in the United States, the European Union or Switzerland, but are not yet authorized in Canada.<br><br>Once this process is implemented, the most immediate need is expected to be for drugs to treat opioid use disorder (addiction); however, drugs for other urgent public health needs (e.g., pandemics) could also be approved for importation through this new process.<br><br>Health Canada will work with provincial, territorial and federal Chief Medical Officers of Health ("public health officials") to explain the process for requesting access to a drug. To access a drug through this new process, public health officials would send a notification to Health Canada and provide key information on the drug, the urgent public health need, and how the drug is expected to help those in need in their jurisdiction. Once approved, the name and other details of the drug, such as the countries from which the drug could be imported, would be published on Health Canada's website. |

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| | The drug would remain active on the list for one year, after which it would be removed unless Health Canada received a request for continued access. As with any drug sold in Canada, Health Canada would be able to issue a recall or take other necessary actions to protect the health and safety of Canadians should a safety concern arise. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** To address urgent public health needs, such as the growing opioid crisis, Health Canada is allowing the importation of medications that have been authorized for sale in the United States, European Union or Switzerland, but that are not yet authorized in Canada. |
| **8.** | **Relevant documents:** *Canada Gazette,* Part I, 22 April 2017, pages 1732-1748 (available in English and French) |
| **9.** | **Proposed date of adoption:** On the date the amendments are registered, Notification of registration will occur through publication in Canada Gazette, Part II, which is anticipated to be 28 June 2017.<br><br>**Proposed date of entry into force:** As this proposal would result in an enabling regulation meant to address a serious and ongoing public health crisis, it is proposed that the new regulations would be brought into force immediately upon registration by the Clerk of the Privy Council. At the same time, an Order in Council would bring into force the sections of Vanessa's Law necessary to implement requirements for serious adverse drug reaction reporting by health care institutions. |
| **10.** | **Final date for comments:** 7 May 2017 |
| **11.** | **Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**<br><br>The electronic version of the regulatory text can be downloaded at:<br><br>http://www.gazette.gc.ca/rp-pr/p1/2017/2017-04-22/html/reg3-eng.php (English)<br><br>http://www.gazette.gc.ca/rp-pr/p1/2017/2017-04-22/html/reg3-fra.php (French) |