WORLD TRADE ORGANIZATION

G/TBT/N/CAN/405/Rev.1/Add.1

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Committee on Technical Barriers to Trade

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NOTIFICATION

Addendum

The following communication, dated 18 November 2014, is being circulated at the request of the delegation of Canada.

Bill C-17, Amendments to the Food and Drugs Act, introduced as Protecting Canadians from Unsafe Drugs Act (Vanessa's Law).

This measure was previously notified under G/TBT/N/CAN/405/Rev.1 (dated 26 August 2014).

The new legislation updates the Food and Drugs Act and applies to drugs and medical devices in order to increase patient safety in key areas of concern. It does not apply to natural health products regulated under the Natural Health Product Regulations. The new legislation enables the Government to:
- Require strong surveillance including mandatory adverse drug reaction reporting by healthcare institutions;
- Recall unsafe products;
- Impose tough new penalties for unsafe products, including jail time and new fines of up to $5 million per day instead of the current $5,000;
- Provide the courts with discretion to impose even stronger fines if violations were caused intentionally;
- Compel drug companies to revise labels to clearly reflect health risk information, including potential updates for health warnings for children; and
- Compel drug companies to do further testing on a product, including when issues are identified with certain at-risk populations such as children.

The new legislation also:
- Places an obligation on the Minister to make label change, recall, test and studies and information orders publically available;
- Gives a new regulation-making authority permitting the Governor in Council to make regulations requiring the Minister to ensure that positive and negative regulatory decisions, and reasons for them, are publically available;
- Creates a new requirement for therapeutic product authorization holders to make publically available information about clinical trials;
- Gives a new regulation-making authority allowing the Governor in Council to make regulations concerning how, where, when and what information about clinical trials and investigational tests an authorization holder will have to make publically available;
- Gives a new section to make clear that the Minister may disclose confidential business information (CBI) for the purpose of identifying or responding to a serious risk of injury to the health of Canadians;
- Gives a new section that permits the Minister to share CBI with her regulatory counterparts, other federal departments, provinces and territories, and scientific and medical experts if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public; and
- Gives a new regulation-making authority allowing the Governor in Council to clarify what information obtained under the Act in relation to a therapeutic product authorization is not or ceases to be CBI.

Section 4, subsection 6(2) and section 10 and 11 of Bill C-17 were adopted on 5 November 2014.

Section 5 and subsection 6(3) and (4) of Bill C-17 will be adopted six months after the day on which subsequent regulatory amendments will be published in the Canada Gazette, Part II.

The full text of the measure can be downloaded from the Internet addresses below:

http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6767163&File=4&Col=1 (English)
http://www.parl.gc.ca/HousePublications/Publication.aspx?Mode=1&DocId=6767163&File=4&Col=1&Language=F (French)

or requested from:

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