NOTIFICATION

Addendum

The following communication, dated 15 May 2018, is being circulated at the request of the delegation of Canada.

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*Regulations Amending the Food and Drug Regulations (Vanessa’s Law)*

The proposed regulations notified in G/TBT/N/CAN/523 (dated 3 May 2017) were adopted and published on 2 May 2018 as the *Regulations Amending the Food and Drug Regulations and the Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drugs Act that are in Dosage Form)*.

The regulations make a number of amendments to the *Food and Drugs Regulations:*

* 1. Assessment and test and study orders made under Vanessa’s Law. In order to support the coming into force of new powers under the *Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)*,   new regulatory amendments  further define the scope of sections 21.31 and 21.32 of Vanessa’s Law. These amendments will come into force when these new legislative powers come into force. Together, the new amendments and legislation will create and establish the scope of the Minister’s new authorities to order drug manufacturers to conduct assessments or to conduct additional tests and studies. The amendments limit the scope of the new powers to drugs regulated under the *Food and Drug Regulations*.
  2. Notifying the Department of foreign actions regarding serious risk communications. Amendments will require the holder of an authorization (made through the assignment of a Drug Identification Number or the issuance of a Notice of Compliance), for a prescription drug or a drug sold without a prescription that is to be administered only under the supervision of practitioners, to provide the Minister of Health with information in respect of any serious injury to health the holder becomes aware of and that is relevant to the safety of the drug in Canada.
  3. Clinical case reports. The amendments repeal the requirement in paragraph C.08.005.1(1)(a) to provide clinical case reports when a new drug submission is filed with the Minister.

These regulatory amendments were registered on 20 April 2018.

The regulatory amendments in respect of the assessment and test and study order powers as well as the repeal of the requirement to provide clinical case reports came into force at the time these regulations were registered on 20 April 2018. The amendments respecting the notification of foreign action regarding serious risk come into force six months following registration on 20 October 2018 to allow stakeholders time to effectively implement the new requirements.

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

[<http://gazette.gc.ca/rp-pr/p2/2018/2018-05-02/pdf/g2-15209.pdf>](file:///C:\Users\rambla\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\XM685XFZ\%3ca%20class='document-link'%20target='_blank'%20href='http:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\pdf\g2-15209.pdf'%3ehttp:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\pdf\g2-15209.pdf%3c\a%3e)

[<http://gazette.gc.ca/rp-pr/p2/2018/2018-05-02/html/sor-dors84-eng.html>](file:///C:\Users\rambla\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\XM685XFZ\%3ca%20class='document-link'%20target='_blank'%20href='http:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors84-eng.html'%3ehttp:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors84-eng.html%3c\a%3e)

[<http://gazette.gc.ca/rp-pr/p2/2018/2018-05-02/html/sor-dors84-fra.html>](file:///C:\Users\rambla\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\XM685XFZ\%3ca%20class='document-link'%20target='_blank'%20href='http:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors84-fra.html'%3ehttp:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors84-fra.html%3c\a%3e)

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