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* (Opioids)

The proposed regulations notified in G/TBT/N/CAN/528 (dated 19 June 2017) were adopted and published on 2 May 2018 as the *Regulations Amending the Food and Drug Regulations (Opioids).*

Given the potential for harm associated with opioid drugs and the related public health crisis, the Government of Canada has identified the need for strengthened post-market oversight of opioids and the need to better inform patients about the safe use of opioids and their associated risks.

The regulations make two amendments to the *Food and Drugs Regulations:*

* 1. The amendments expressly permit the Minister of Health to add or amend terms and conditions to an authorization for the sale of an opioid. This authority is intended to be used by the Minister to compel opioid authorization holders to develop and implement a risk management plan to appropriately monitor, quantify, characterize and mitigate the risks associated with post-market use of these products.
  2. The amendments also require that a warning sticker and patient information handout accompany prescription opioids at the time of sale. The warning sticker and patient information handout will provide key information to patients about the safe use of opioids and their associated risks of dependency, addiction and overdose. The sticker and handout will not be required when the opioid is administered to the patient under the supervision of a practitioner, as risks associated with the drug are mitigated in those circumstances.

The regulatory amendments in respect of terms and conditions to increase post-market oversight of opioids came into force when the regulations were registered on 20 April 2018, to address an urgent public health crisis.

The regulatory amendments in respect of the patient information handout and warning sticker will come into force on 2 November 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://www.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\ITGQ451P\%3ca%20class='document-link'%20target='_blank'%20href='http:\www.gazette.gc.ca\rp-pr\p2\2018\2018-05-02\pdf\g2-15209.pdf'%3ehttp:\www.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-dors77-eng.html>](file:///C:\Users\rambla\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\ITGQ451P\%3ca%20class='document-link'%20target='_blank'%20href='http:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors77-eng.html'%3ehttp:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors77-eng.html%3c\a%3e)

[<http://gazette.gc.ca/rp-pr/p2/2018/2018-05-02/html/sor-dors77-fra.html>](file:///C:\Users\rambla\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\ITGQ451P\%3ca%20class='document-link'%20target='_blank'%20href='http:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors77-fra.html'%3ehttp:\gazette.gc.ca\rp-pr\p2\2018\2018-05-02\html\sor-dors77-fra.html%3c\a%3e)

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