GOWLING WLG

BILL C-17: PROTECTING CANADIANS FROM UNSAFE DRUGS ACT (VANESSA'S LAW) IS NOW LAW

25 February 2015

The Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) ("Vanessa's Law") received royal assent on Nov. 6, 2014 and is now law. Vanessa's Law strengthens oversight of "therapeutic products" and paves the way for an orphan drug framework in Canada.

Vanessa's Law amended the Food and Drugs Act regarding therapeutic products in order to improve safety by introducing measures to, among other things:

- strengthen safety oversight of therapeutic products throughout their life cycle;
- improve reporting by certain health care institutions of serious adverse drug reaction and medical device incidents that involve therapeutic products, and
- promote greater confidence in the oversight of therapeutic products by increasing transparency.

The new measures outlined in Vanessa's Law will come into force in different manners and timelines. A number of the above Ministerial powers came into force immediately upon royal assent, including the product recall and labelling modification powers. The orphan drug authorization framework and healthcare institution adverse reaction reporting requirements will require the development of regulations.

What products will be impacted?

The definition of "therapeutic products" is broad, encompassing any drug, device or drug-device combination. The definition specifically excludes NHPs regulated under the Natural Health Products Regulations; however, it does not exclude over-the-counter (non-prescription) products regulated as drugs ("OTCs").

New regulations

Vanessa's Law provides for new regulations concerning therapeutic product authorizations, including requiring authorization holders to provide the Minister with information on risks communicated outside of Canada, as well as any labelling changes, recalls, reassessments and suspensions/revocations of authorizations outside Canada. These regulations are expected to be released for public comment in 2015. We expect that the comment period will last for 75 days.

What will Vanessa's Law enable the Minister to order?

- post-approval assessments, tests, studies, monitoring or compilation of information on therapeutic products, including submitting results to the Minster;
- submission of additional information post-approval if the Minister believes there is a serious risk of injury;
- label or packaging modifications if the Minister believes it is necessary to prevent injury; and,
- product recalls, stop-sales or corrective action if the Minister believes there is a serious or imminent risk of injury to health.

Additional details

Recall:

- The Minister may order that a product be recalled that presents a serious or imminent risk of injury to health. The Minister may also authorize a person to continue to sell a product, with or without additional conditions of sale. A person cannot be convicted for selling a recalled product unless it can be proven that they were notified of the recall or reasonable steps were taken to notify them of the recall.
- While the Minister's recall power will come into force immediately upon assent, Health Canada is currently developing internal processes for recall orders that will be reflected in future regulations.

Modification of replacement-labelling or packaging:

- If necessary to prevent injury to human health, the Minister may order a therapeutic

product authorization holder modify the product's label or modify or replace its package. This power will come into force immediately upon assent.

Reporting:

- This measure aims to improve adverse-reaction reporting by requiring "prescribed" health care institutions to report serious adverse reactions involving therapeutic products. Regulations will be required prior to this measure coming into force.

Injunction:

- On application by the Minister, the court may order an injunction if a person is, is about or is likely to do anything that constitutes an offence under the Food and Drugs Act in respect of a therapeutic product. Prior to issuing an injunction, the named party must be given 48 hours notice. This power will come into force immediately upon assent.

Orphan Drugs:

- The development of an orphan drug framework has been enabled by Vanessa's Law but will require regulations. The framework is expected to reflect the Government's 2012 discussion document[1] and will provide specific orphan drug designation status, priority review, and linkages to market exclusivity provisions.

Offences and Penalties:

- Contravention of any provision of Vanessa's Law or regulations may be subject to penalty maximum fine of $5,000,000 per day of contravention and/or up to two years imprisonment, having regard to the nature of the contravention, the harm or risk that resulted, the vulnerability of affected consumers, and the existence of a due diligence defence.
- Where contravention of Vanessa's Law is known or undertaken recklessly, a fine determined at the discretion of the court and/or up to five years imprisonment may be imposed. Importantly, even if not prosecuted directly, directors, officers, or agents may be liable for the same punishment as their company if found to have directed, authorized, or participated in the commission of the offence.

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[1] Office of Legislative and Regulatory Modernization, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, "Initial Draft Discussion Document for a Canadian Orphan Drug Regulatory Framework", Ottawa: Government of Canada (Dec 13, 2012).

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