# Health Canada To Publish Regulations Implementing New Authorities under Vanessa's Law

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On June 18, 2016, the Federal Department of Health published a Notice of Intent to amend the *Food and Drug Regulations* and the *Medical Devices Regulations* to implement key authorities under Vanessa's Law (the "Notice of Intent").

Vanessa's Law received royal assent on November 6, 2014, and amended the *Food and Drugs Act* (the "Act") by substantially increasing Health Canada's pre and post-market authority over industry stakeholders and radically changing the consequences for violating the Act and its regulations. Vanessa's Law introduced the most significant amendments to the Act in 50 years, and represents a new chapter in Canadian drug and medical device regulatory enforcement.

Although most of the new authorities granted to Health Canada came into force immediately upon royal assent, several new authorities would not come into force until supporting regulations were established. With the publication of the Notice of Intent, Health Canada is now moving forward with the development and implementation of those supporting regulations.

According the the Notice of Intent, the supporting regulations will be implemented by way of amendment to the current *Food and Drug Regulations* and *Medical Devices Regulations*. The amendments to these regulations will be developed in phases, with the initial phase of implementation bringing forward the following proposals:

1. Amending the *Food and Drug Regulations* to:

- prescribe the conditions to which the Minister's power to make an order under sections 21.31 (assessments) and 21.32 (tests, studies and other activities) of the Act would be subject;
- pursuant to section 21.7 of the Act, authorize the Minister to impose or to amend terms and conditions on any therapeutic product authorization respecting a drug (including an authorization made through the assignment of a drug identification number [DIN], or the issuance of a notice of compliance [NOC] or of an establishment licence);
- pursuant to paragraph 30.1(1.2)(d) of the Act, require holders of a therapeutic product authorization respecting a prescription drug or a non-prescription drug that is administered under the supervision of a health care practitioner to report information

including risks communicated, changes to the labelling, recalls, reassessments, and suspensions or revocations of authorizations made outside of Canada; and
- require all DIN holders to report to the Minister when a label change or package modification has been made to mitigate a risk of injury to human health.

2. Amending the *Food and Drug Regulations* and the *Medical Devices Regulations* to

- require notification of a voluntary recall and the risk evaluation within 24 hours following the decision to recall;
- require a written report, which will include the recall strategy, within 72 hours of the initial recall notification; and
- clarify, in paragraph 44(2)(b) of the *Medical Devices Regulations*, that only a health care facility in respect of the medical device that is distributed for use within that facility or a hospital would be exempted from the requirement to hold an establishment licence.

Several of the proposed amendments will have a significant impact on drug and device manufacturers. Notably:

- Health Canada will have the power to order drug market authorization holders to conduct an assessment of a product and provide the Minister with the results. Health Canada will also have the authority to order a drug market authorization holder to compile information, conduct tests or studies or monitor experience in respect of a product and provide the Minister with the results. The conditions under which Health Canada can exercise these new powers will be established in the new regulations.
- Drug manufacturers will be required to report to Health Canada certain activities and events related to prescription and certain non-prescription drugs which occur outside of Canada. Specifically, risks communicated to foreign health agencies, changes to labelling, recalls, reassessment, and suspensions or revocations of market authorizations. This expanded reporting requirement will likely require the implementation of internal systems to ensure the timely communication of information from foreign affiliates for manufacturers who market drug products in Canada which are also available internationally.
- Drug and device manufacturers will be required to amend their recall procedures to incorporate the mandatory recall reporting timelines established by the new regulations.

The proposed regulations are expected to be pre-published in the Canada Gazette beginning in the Fall of 2016, at which time all interested stakeholders can provide comments. In the interim, Health Canada has stated that it will continue to engage certain industry stakeholders on the development of these regulatory proposals.