In late 2018, a series of news articles took aim at Canada's regulation of medical devices, alleging that Health Canada's medical device approval and adverse event monitoring systems were severely lacking. This article will provide an update regarding steps Health Canada has now taken to tighten up regulation of medical devices.

Reports of Regulation Gaps

As part of a larger international investigation, the Toronto Star and CBC reported in late November 2018 that there were significant gaps in medical device regulation in Canada. These gaps included the following:

- Medical devices implanted into patients may only have been tested on animals or cadavers;

- Once a device was available on the market, legislation permitted regulators to rely on manufacturers and importers alone to provide updates, alerts, and recalls.(compared to the United States, where reporting by hospitals and health clinics is mandatory); and,

- Some medical devices withdrawn from the market in other countries continued to be implanted into uninformed Canadians.
The investigation highlighted the limited access Canadians have to information about devices. Most notably, the articles alleged that the lack of a patient registry in Canada resulted in medical device patients having less recall information than purchasers of other products such as vehicles. The system for medical device recalls has long been contrasted with that of automobiles, appreciating that health information is much more sensitive.

As explained in the series of articles, applications by manufacturers for new medical devices sometimes relied heavily on data from old versions of devices. Additional information about new versions only became available after the device was on the market and used "under 'real life' conditions."

**Health Canada Vows to Respond**

Four days after the articles were published, Canada's Health Minister responded by announcing three new goals:

- **To strengthen processes for the pre-market approvals of medical devices**: This will include a review of the policies and scientific requirements governing the approval of higher-risk medical devices, including requirements for clinical data. The Minister also directed Health Canada to enable more medical device research by health professionals. Specifically, the Minister suggested expanding the use of outside medical and scientific experts to advise the Department on medical device issues.

- **To enhance post-market surveillance of medical devices**: Health Canada will take steps to improve the reporting of medical device incidents by industry, health professionals and Canadians and make these reports publicly available. Specifically, Health Canada will propose new rules requiring companies to inform Health Canada promptly when foreign regulators issue warnings about a device.

- **To make the system for medical device approvals and surveillance more transparent**: The Department will provide summaries of regulatory decisions when it approves more complex medical devices (known as Class III and Class IV devices). Health Canada will also work to improve access to the clinical data.

The Medical Devices Regulations separate medical devices into the following 4 risk categories:

- Class I: Low risk devices such as wound care and non-surgically invasive devices.
- Class II: Low-to-medium risk devices including contact lenses and the majority of surgically invasive devices (e.g., surgical gloves, needles, magnetic resonance imaging equipment).

- Class III: Medium-to-high risk devices such as hip implants, glucose monitors, ultrasound diagnostic imaging equipment, and surgically invasive devices that are intended to be absorbed into the body or that are intended to remain in the body for at least 30 consecutive days.

- Class IV: High-risk devices such as pacemakers and surgically invasive devices that diagnose, control, or correct a defect in the central cardiovascular system. The device manufacturer, importer, or distributor is responsible for classifying the device.

As noted in the World Health Innovatin Network whitepaper entitled, Transforming Canada into a Global Centre for Medical Device Innovation and Adoption, Class I devices are exempt from licensing and do not need to obtain Health Canada approval to market. Class II devices require that applicants assert the safety and efficacy of their device without having to submit evidence to support this conclusion. Class III and IV devices require more documentation and provision of evidence proving the safety and effectiveness of their device.

Health Canada Publishes its Action Plan on Medical Devices

On December 20, 2018, Health Canada published the Action Plan on Medical Devices: Continuously Improving Safety, Effectiveness, and Quality, in which it acknowledged that more can be done to improve the safety and effectiveness of medical devices under Canada’s regulatory regime. The Action Plan outlines a three-part strategy to optimizing health outcomes for Canadian patients:

- **Part I: Improve how devices get on the market:**
  - Health Canada will increase research by allowing health professionals and other researchers to file an application for authorization to conduct investigational tests. Currently, only manufacturers (not independent researchers or healthcare professionals) can apply to undertake investigational testing for medical devices.

  - Health Canada will form a new expert advisory committee on women’s health issues for drugs and medical devices in collaboration with the Canadian Institute of Health Research. Health Canada will also review its evidence requirements for higher-risk medical devices...
with a view to strengthening the evidence required for new devices based on previously authorized versions.

- **Part II: Strengthen monitoring and follow-up:**
  - The proposed Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law) intends to amend the Food and Drugs Act to include new rules that strengthen the regulation of therapeutic products and improve the reporting of adverse reactions by healthcare institutions. These measures are intended to improve Health Canada’s ability to collect post-market safety information and take appropriate action when a serious health risk is identified. Pursuant to Vanessa’s Law, in January 2018, Health Canada published proposed regulations in the Canada Gazette, Part I to amend the Food and Drug Regulations and Medical Devices Regulations to require hospitals to report serious adverse drug reactions and medical device incidents. The proposed regulations have not yet been published.

  In tandem with new regulations being developed under the proposed Vanessa’s Law, Health Canada will implement new regulations requiring mandatory reporting from Canadian hospitals on medical device incidents. Health Canada will also work to improve reporting from healthcare facilities other than hospitals (such as long-term care facilities, clinics, etc.).

  - Proposed regulations under Vanessa’s Law will seek to compel manufacturers to conduct further assessments, tests and studies on medical devices. Manufacturers will be required to inform Health Canada within 72 hours if selected foreign regulatory agencies issue warnings about serious risks related to their medical device. Manufacturers will also be required to submit information regarding label changes or license suspensions.

  - Health Canada has also committed to further supporting investigation and enforcement efforts in the Department by expanding the role of inspectors in promoting the compliance of manufacturers, importers, distributors and healthcare professionals. This will include mandatory requirements to report issues with medical devices to investigators.

- **Part III: Provide more information to Canadians:**
  - Health Canada will implement new regulations to release clinical trial data provided in medical device submissions.

  - Health Canada will also publish summaries of decisions made by the Department when it
approves licence applications for Class III and Class IV medical devices. Previously, only Class IV licence applications were published by Health Canada. The proposed change will increase published summaries from fewer than 100 per year to well over 1,000.

**Proposed Changes Will Take Time**

Although the Action Plan commits to major changes in the regulation of medical devices, Health Canada has yet to implement the majority of the suggested modifications.

The Action Plan outlines specific 2019 Milestones for each element of the three-part strategy. Thus far, Health Canada has successfully delivered on the following Milestones:


- **Scientific Advisory Committee on Medical Devices Used in the Cardiovascular System – announcement of meeting, 1 March 2019:** Pursuant to Part II of the Action Plan, on February 1, 2019, Health Canada announced an upcoming meeting of Health Canada’s Scientific Advisory Committee on Medical Devices used in the Cardiovascular System. The advice received from this meeting will be used to facilitate and enhance the review process for medical devices used in the cardiovascular system.

- **Scientific Advisory Committee on Health Products for Women (SAC-HPW): nomination call for members:** In accordance with Part II of the Action Plan, on January 30, 2019, Health Canada published a nomination call for members for the proposed SAC-HPW. The SAC-HPW will provide Health Canada with advice on current and emerging issues regarding women’s health and the regulation of medical devices and drugs.

- **Consultation on Draft Guidance Document for Software as a Medical Device:** Pursuant to Part II of the Action Plan, Health Canada has developed the Draft Guidance Document – Software as a Medical Device to better define regulatory compliance requirements for emerging technologies. Consultation on the draft guidance document will be open until March 29, 2019.

**Implications for Medical Device Manufacturers**
Canada is not alone in its response to this international investigation. Germany, Italy and Denmark have also taken steps to review how their countries regulate implantable devices. Despite the findings of the investigation, Health Canada maintains that Canada’s medical device regulatory regime is one of the most stringent in the world.

The Action Plan’s proposed changes will alter the medical device approval process in Canada. They will also require manufacturers to notify Canadian regulators about foreign recalls and warnings. New disclosure and transparency measures may change how options and risks are explained to device recipients if clinical data is more accessible. However, Health Canada has yet to implement the majority of its proposed modifications.
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