# Canada Gazette, Part I, Volume 153, Number 24: Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Post-market Surveillance of Medical Devices)

June 15, 2019

**Statutory authority**
*Food and Drugs Act*

**Sponsoring department**
Department of Health

## REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

### Issues

Health Canada has the authority to regulate the safety, efficacy and quality of drugs and the safety, effectiveness and quality of medical devices. Health Canada's authority is derived from the *Food and Drugs Act* (FDA), and its associated regulations, the *Food and Drug Regulations* (FDR) and the *Medical Devices Regulations* (MDR).

Health Canada increasingly regulates drugs and medical devices from a life cycle approach whereby evaluation occurs throughout the life cycle (i.e. both before and after products reach the market). Regulatory agencies worldwide have adopted this approach in recognition that important information about the safety and effectiveness of drugs and medical devices can be learned only after a product is marketed and more people use it. However, Health Canada is currently limited in what it can require from medical device authorization holders once their products are approved for sale in Canada.

In 2014, the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* [Vanessa's Law] amended the FDA to improve the safety of therapeutic products (drugs and medical devices) by introducing measures to, among other things,

(a) allow the Minister of Health (the Minister) the power to compel an assessment of a marketed therapeutic product;

(b) allow the Minister the power to compel additional tests and studies regarding a marketed therapeutic product; and

(c) require product authorization holders to provide information about foreign risk actions for their products.

Regulations regarding these provisions were introduced by Health Canada in 2017 and came into force in 2018 with respect to drugs; the regulations now being proposed would bring these provisions into effect for medical devices.

To appropriately implement a life cycle approach for medical devices, additional authorities are required to monitor devices once they are on the market. The proposed regulations would also

(a) require medical device manufacturers to prepare annual summary reports; and

(b) provide the Minister with the power to request that medical device manufacturers provide an analysis of the safety and effectiveness of their product for the purpose of conducting a post-market safety review.

Similar post-market regulations were introduced for drugs in 2011.

Finally, these regulations will change the reference to the International Organisation for Standardization (ISO) standard for Quality Systems Management of medical devices, included in the MDR, to an ambulatory reference, thereby facilitating international harmonization and allowing certainty for medical device manufacturers.

# Background

## Vanessa’s Law provisions that require supporting regulations

### Power to issue orders

The amendments to the FDA through Vanessa’s Law strengthen Health Canada’s ability to collect post-market safety information and take appropriate action in situations where a serious risk to health is identified. While several amendments came into force immediately (e.g. the power to recall unsafe therapeutic products, the power to compel label changes and the possibility of tougher fines and penalties for contraventions), other powers require regulations to clarify their scope. These include the Minister’s power to

- order the holder of a therapeutic product authorization to conduct an assessment and provide the Minister with the results of the assessment (under section 21.31); and
- order the holder of a therapeutic product authorization to compile information, conduct tests or studies or monitor experience and provide the Minister with the information or the results (under section 21.32).

These order powers are intended to be used to gather information to resolve uncertainties that may arise respecting the benefits and harms associated with a therapeutic product, in this case, medical devices. The power to order an "assessment" requires that an authorization holder determine the risk/benefit profile of a product by considering all the information that it currently holds. The power to order tests and studies or the monitoring of experience allows the Minister to require the authorization holder to create or compile new information in order to resolve uncertainties about safety and effectiveness. Uncertainties could be identified in new information that was not previously available to the Minister, such as a post-market safety signal obtained through a review of adverse medical device incident reports. Without additional information to resolve the uncertainties, the Minister could not reasonably decide whether there was a significant change to the safety and effectiveness of the device that would constitute an elevated risk to patients and that could warrant further action to mitigate the risk. Regulations are required to clarify the circumstances and scope of the power that the Minister would exercise in orders made pursuant to sections 21.31 and 21.32.

### Notifying Health Canada of foreign risk actions

Amendments to the MDR are necessary to support the receipt of more targeted and timely safety information regarding devices on the market in foreign jurisdictions and in Canada. Currently, Health Canada monitors the safety of medical devices for sale in Canada through the receipt of reports of incidents involving medical devices. The MDR require manufacturers and importers to submit reports of incidents that have occurred inside and outside Canada (subsection 59(1)). Subsection 59(2) specifies that incidents that occur outside Canada must only be reported if the regulatory agency of the country in which the incident occurred has required the manufacturer to take corrective action or if the manufacturer has indicated their intent to do so to the regulatory agency. The same reporting requirements apply to all classes of medical devices, from the lowest risk (Class I) to the most invasive devices (Class IV). [1]

The current information received by Health Canada on medical device foreign risk actions pursuant to section 59 does not meet Health Canada's needs as it is not timely, nor does it contain the most relevant information. Paragraph 60(1)(b) specifies that preliminary reports for incidents occurring outside Canada must be reported by the manufacturer or importer to Health Canada "as soon as possible" instead of specifying a clear timeline. Further, the MDR does not impose a timeline for the submission of a final report. Information submitted to Health Canada by manufacturers or importers focuses on the incident rather than the actions taken in response to the incident. Without timely and relevant information, Health Canada is hampered in its ability to act quickly if there is a serious risk to Canadian patients from a medical device.

Amendments made to the FDA as part of Vanessa's Law allow for the development of regulations requiring holders of medical device authorizations to provide the Minister with information on actions taken outside Canada relevant to medical devices marketed in Canada. Paragraph 30(1.2)(d) allows for regulations requiring the reporting of the following actions to Health Canada:

- risks that have been communicated outside Canada;
- changes that have taken place to labelling outside Canada; and
- recalls, reassessments and suspensions or revocations of authorizations, including licences, that have taken place outside of Canada.

These regulations would provide Health Canada with more targeted and pertinent information about actions taken in other countries in respect of serious risks of injury to human health for medical devices that are marketed in Canada. This is particularly important for actions that are typically not made public, such as reassessments, and that are therefore less likely to come to Health Canada's attention.

Having better information would permit Health Canada to follow up appropriately with either the medical device authorization holder or the foreign regulatory jurisdiction. It would also enable Health Canada to act sooner if there is a serious risk posed by the device. To implement the proposed amendments, other sections of the MDR which require similar information (i.e. section 59 of the MDR) would be modified to ensure that there is no duplication.

## Regulations to improve post-market surveillance

### Annual summary reports

Amendments to the MDR are necessary to implement a post-market vigilance tool that is lacking for medical devices: annual summary reports (ASRs). ASR requirements have been present in the FDR for drugs since 2011 (FDR C.01.018) and are a requirement of the 2017 European Commission regulations for medical devices that will be fully implemented for most devices [2] by 2020. The addition of ASR requirements to the MDR would align the requirements for medical devices with those of drugs and would reflect international standards that support the post-market surveillance of medical devices.

### Issue-related analysis of safety and effectiveness

Existing information-request provisions in the MDR, sections 25 and 39, allow Health Canada to request information or samples to determine whether the device meets the applicable safety and effectiveness requirements. The ability to require manufacturers to analyze these elements in light of specific real world situations would facilitate better tracking and reporting of issues that can have an impact on the safety of devices for Canadians. Such requirements exist in the FDR (C.01.019), which allow Health Canada to request a critical analysis of a drug product for the purpose of post-market assessment.

## *Provisions to remove unnecessary burden*

### *Revising the reference to quality standards*

The MDR require that medical device manufacturers provide copies of a quality management certificate to certify that they comply with the specified International Organization for Standardization (ISO) standard set out in the application section of the regulations (section 32). Because the ISO standard is specifically mentioned in the regulations by name, the regulations must be amended each time the ISO standard changes. Given the global nature of medical device manufacturing and widespread use of the standard, manufacturers of medical devices undertake to revise their manufacturing processes once a change to the ISO standard is released; however, an amendment to the MDR is required in order to refer to the changed standard in Canada. Failure to amend the regulation in a timely fashion would result in Canada continuing to refer to an outdated standard while other countries have adopted the new ISO standard. This could lead to uncertainty for manufacturers and potential delay in medical devices being brought to the Canadian market. Section 30.5 of the FDA allows for regulations that reference a document that is amended from time to time (i.e. ambulatory reference).

## Objectives

The objectives of the proposed regulatory amendments are to

- operationalize the powers included in Vanessa's Law to require assessments, tests and studies by establishing the rules needed to structure the exercise of those powers for medical devices;
- further support post-market medical device safety by creating
    - new rules for reporting actions in foreign jurisdictions for the highest risk medical devices, which will provide timely and targeted information, and
    - a requirement for medical device manufacturers to annually review risk information about their products and notify Health Canada when there has been a change in the risk/benefit profile;
- create a transactional tool by which Health Canada can ask medical device authorization holders to analyze the safety and effectiveness of their products in response to a post-market signal; and
- provide greater certainty for medical device manufacturers about the standards they must meet regarding quality management for medical devices.

Together, the proposed regulatory amendments are intended to enable Health Canada to regulate medical devices more efficiently and effectively, based on a life cycle approach.

## Description

### *Vanessa's Law provisions that require supporting regulations*

This proposal includes regulatory amendments to support sections 21.31 and 21.32 of Vanessa's Law so as to fully operationalize the Minister's authority to order medical device licence holders to conduct an assessment, collect information, conduct additional tests and studies, and/or monitor experience. The proposed regulations would apply to medical device licence holders for Class II, III and IV medical devices. [3] They would not apply to establishment licence holders for Class I medical devices, as these products are not licensed and establishment licence holders who import or distribute these products may not have access to the information required to conduct an assessment or carry out tests and studies.

This proposal also includes amendments to the *Food and Drug Regulations* (FDR) to clarify the regulations currently in place with respect to the assessment power and the authority to require tests and studies for drugs. By amending the FDR, any potential inconsistencies or conflict in interpretation between the regulatory provisions for therapeutic products that are drugs and therapeutic products that are medical devices will be eliminated.

### *Assessments ordered under section 21.31 of the Act:*

An order under section 21.31 would be issued by the Minister when new information has surfaced and the Minister wants a new assessment of the risk/benefit profile of the product considering both the old and new information. The proposed regulations would establish the following with respect to an order made under section 21.31 of the Act:

- The order must relate to a Class II, III or IV medical device;

- The person to whom the order relates must be the holder of the authorization (i.e. the medical device licence) for that device;
- The Minister must have reasonable grounds to believe that the benefits or risk of injury to health associated with the medical device are significantly different than they were when the licence was issued;
- The Minister shall, after examining the results of an assessment, inform the medical device licence holder of the results of the examination;
- The Minister shall publish on the Government of Canada website a summary of the results of the examination along with a description of the action that the Minister has taken or may take as a consequence of the examination; and
- If the licence holder fails to comply with the order or if the results of the assessment are inadequate, the Minister may suspend the medical device licence.

### Tests, studies and other activities ordered under section 21.32 of the Act

Orders for tests and studies would be used when the Minister deems that it is necessary for the medical device licence holder to monitor the benefits, harms and uncertainties of a device through conducting tests or studies, monitoring experience with the device or compiling information. The tests and studies order could be used to monitor benefits and harms associated with a device, for example, monitoring long-term complications with a device. The tests and studies provision could also address benefits and harms that are outside the stated use of a device or the parameters of the device licence, for example, when there are concerns regarding the risks of off-label device use. The proposed regulations would establish the following with respect to an order made under section 21.32 of the Act:

- The order must relate to a Class II, III or IV medical device;
- The person to whom the order relates must be the holder of the authorization (i.e. the medical device licence) for that device;
- The Minister must have reasonable grounds to believe that there are significant uncertainties relating to the benefits and harms associated with the medical device;
- The medical device licence holder must be currently unable to provide the Minister with information to manage those uncertainties;
- Any applicable requirements of the MDR as well as any terms and conditions made on the licence do not allow for sufficient information to be obtained to manage those uncertainties; and
- Before issuing an order, the Minister must consider whether the information-gathering activities proposed for the order are feasible and whether there are other less burdensome means of obtaining the information.

Activities specified in the order could include compiling information about the use of the device in other jurisdictions, conducting additional testing regarding the use of the device or monitoring the safety and effectiveness of the device on patients through a registry.

### Notifying Health Canada of foreign risk actions

The MDR would be amended to require medical device licence holders and importers for Class II, III and IV medical devices to advise Health Canada when they or certain foreign regulators take any of the following actions with respect to a serious risk [4] related to a device on the market in Canada:

- The communication of risks related to the medical device;
- Labelling changes on the device;
- Recalls;
- Reassessments; and
- Suspensions or revocations of the device licence.

Medical device licence holders and importers for Class II, III and IV medical devices would be expected to set up systems to monitor the information above in relevant foreign jurisdictions and, as per the proposed regulations, would be required to notify Health Canada within 72 hours of receiving the information above. As a result, preliminary and final reports with respect to incidents in foreign jurisdictions under section 59 will be repealed for these classes of device. No product licences are issued with respect to Class I devices; however, the sale and import of Class I devices are subject to the medical device establishment licence requirements of the Regulations. Manufacturers and importers of Class I devices will continue to be subject to the reporting provisions for domestic and foreign reports that currently exist under section 59 of the MDR.

For Class II, Class III and Class IV, the intention is to limit the list of relevant foreign jurisdictions to foreign jurisdictions with regulatory bodies with which Health Canada has a Memorandum of Understanding or Mutual Recognition Agreement for medical devices and those countries that are part of the International Medical Device Regulators Forum. The list would be incorporated by reference into the regulation to ensure flexibility should agreements or membership change over time. At the present time, the list would contain fewer than 20 jurisdictions overall. Restricting the number of jurisdictions and specifying a timeline to report for medical device licence holders will provide Health Canada with targeted information from key regulatory partners and be less burdensome for reporting by medical device authorization holders. Section 59 of the MDR, which currently refers to the reporting of incidents involving medical devices that occur outside Canada, would be amended to align with the new foreign risk reporting requirements for Class II, III and IV medical devices.

Custom devices, devices available through special access and devices under investigational testing are currently subject to mandatory problem reporting requirements under section 59. The amendments would maintain the current requirements for custom, special access and Class I devices under investigational testing; however, the regulations would be amended so that Class II, III and IV devices, which are authorized for investigational testing, would be required to follow the new foreign reporting provisions.

## Regulations to improve post-market surveillance

### Annual summary reports

The regulations would be amended to create a requirement similar to section C.01.018 of the FDR that would require medical device licence holders (i.e. manufacturers of Class II, III and IV devices) to

(1) review the information they received under the regulations or became aware of in the last 12 months about the medical device related to

- adverse effects;
- reported problems;
- incidents; and
- risks;

(2) prepare an annual summary report (ASR).

In preparing the report, licence holders would need to assess the benefit and risks of their devices and determine whether

- there has been a decrease in any of the benefits of the device;
- the risks are more likely to occur;
- the consequences for patients or users may be more serious, if a risk occurs; or
- any new risk has been identified.

If, after preparing the report, a licence holder finds that there has been a change in the risk-benefit profile of the medical device, they will be required to notify Health Canada in writing within 72 hours.

The requirement would also specify that

- the Minister may request the ASRs and the information used to create them;
- the Minister may set a date when the ASRs must be submitted to Health Canada once requested; and
- manufacturers are required to retain copies of the ASRs for seven years.

Additional information regarding the preparation of an ASR would be provided in guidance.

**Issue-related analysis of safety and effectiveness**

Sections 25 and 39 of the MDR would be amended to give the Minister the ability to require manufacturers of Class I devices and medical device licence holders for Class II, III and IV devices to prepare an analysis of an issue related to the safety and effectiveness of a device when requested to do so. The analysis would be requested when the Minister needs it in order to complete a post-market review of safety and effectiveness in response to a signal regarding the device. In keeping with the current requirements of sections 25 and 39, the Minister could request that the manufacturer provide analysis regarding a particular event or events related to the safety and effectiveness requirements set out in sections 10–20 of the regulations. The intention is to provide details regarding the form of the analysis in guidance, which could include

- analysis of the device incidents;
- exposure data;
- the manufacturer’s conclusions regarding the safety and effectiveness of the device; and
- if necessary, a risk mitigation strategy.

Other additional information relating to the applicable safety and effectiveness standards could also be requested. Paragraph 40(1)(d) of the MDR would also be amended so that, should manufacturers fail to comply with a request for analysis pursuant to section 39, the Minister would have the ability to suspend the

licence for devices from Class II through Class IV. The Minister would also have the discretion to order a stop sale of Class I devices (pursuant to subsection 25(2)) should a manufacturer not comply with a request for analysis pursuant to section 25.

### Provisions to remove unnecessary burden

#### Revising the reference to quality systems

Section 32 of the MDR would be amended to provide an ambulatory incorporation by reference to the ISO document that addresses quality management systems for medical devices.

## Regulatory development

### Consultation

Health Canada has engaged stakeholders extensively since 2010 to understand their various positions on the concepts underlying Vanessa's Law. For example, Health Canada hosted a series of three technical discussions with stakeholders in late 2010 and early 2011 on regulatory modernization and regulating drugs and medical devices based on a life cycle approach. These discussions covered topics such as terms and conditions, tests and studies, suspension, and revocation. Many of these components resulted in provisions found under Vanessa's Law. For more information on these technical discussions, visit Health Canada's website (http://www.hc-sc.gc.ca/ahc-asc/activit/strateg/mod/reg/tech-eng.php).

A notice of intent (NOI) was posted on the Health Canada website on April 10, 2018, announcing Health Canada's intention to propose regulatory changes to strengthen the post-market surveillance and risk management of medical devices in Canada, including regulations relating to Vanessa's Law. The NOI was also sent by email to all medical device licence holders (roughly 3 700 manufacturers of Class II, III and IV devices, both Canadian and foreign). Three stakeholders posed questions of clarification following the email, but none raised concerns with the proposals.

From May to July 2018, the regulatory proposals were presented at several events including two conferences held on May 16, 2018: the Canadian Association of Professional Regulatory Affairs conference and the bi-annual MedTech conference. Health Canada also discussed the proposal during a bilateral meeting with MEDEC, [5] in May 2018. An additional webinar presentation was made to 60 representatives from MEDEC companies on July 11, 2018, as part of a larger session on all device-related initiatives under the regulatory review of drugs and devices (https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices.html). Throughout these events, points of clarification were asked regarding the proposals, for example regarding the scope of applicable devices, timelines and how often Health Canada anticipates using the order powers. No negative feedback was received during these meetings regarding the nature or impact of these proposals.

In addition to the events held between May and July 2018, a webinar was held on November 22, 2018, with over 200 industry representatives. The purpose of the online information session was to provide additional details on the proposals to medical device manufacturers and importers. There were no comments received; however, participants did ask questions about the timing of the proposal and when draft regulations could be expected. Participants who were not able to participate in the webinar were sent the

presentation materials and a link to the audio version of the webinar. Following the webinar, one set of follow-up questions was received regarding the anticipated use of the tests and studies provision. An update was given to MEDEC on November 8, 2018, during a bilateral meeting between MEDEC and Health Canada.

A costing survey was sent out on January 7, 2019, to all medical device licence holders and establishment licence holders for importation, those who hold establishment licences to manufacture Class I devices, and industry associations to support the cost-benefit analysis. A webinar was held on January 15, 2019, to review the costing survey with industry, and to answer questions on the survey itself. Approximately 200 stakeholders dialled in to the presentation and were offered the opportunity to ask questions about the costing survey and the proposal. Some participants asked about the applicability of the proposed provisions to different device classes but no negative comments were made about the proposal.

### Modern treaty obligations and Indigenous engagement and consultations

Indigenous peoples are not expected to be disproportionately impacted by these proposals.

### Instrument choice

Health Canada considered regulatory and non-regulatory options including:

# *1. Status quo*

## Vanessa's Law Order powers under sections 21.31 and 21.32 of the FDA

Vanessa's Law order powers under sections 21.31 (to require assessment) and 21.32 (to require tests and studies) of the FDA are not currently being used for medical devices. Regulations are required to clarify the circumstances and scope of the power that the Minister would exercise in orders made pursuant to sections 21.31 and 21.32.

## Notifying Health Canada of foreign risk actions

The existing requirements specifying the content of the incident reports (subsection 60(2) and section 61 of the MDR) do not provide Health Canada with sufficiently detailed information regarding the corrective actions taken in the foreign jurisdictions and the potential impact of those corrective actions on medical devices in Canada. Furthermore, the existing regulations specify only that the manufacturer should send in the reports "as soon as possible" (paragraph 60(1)(b) of the MDR) instead of a specific time frame.

## Annual summary reports

Health Canada does not currently receive any information comparable to an annual summary report for medical devices. If the status quo is maintained, Health Canada would not have access to annual analyses of incidents for Class II, III and IV medical devices.

## *Issue-related analysis of safety and effectiveness*

While Health Canada currently requests some analytical information from manufacturers on a voluntary basis, there is no obligation for manufacturers to provide this information.

### Revising the reference to quality systems

At the present time, the reference to the ISO standard is included directly in the regulations and therefore, when the international standard is updated, it requires a change in the regulations to reference the new standard. There is no non-regulatory option to address a change to the international standard.

## *2. Consideration of non-regulatory options*

### Vanessa's Law order powers under sections 21.31 and 21.32 of the FDA

The orders that the Minister may issue under sections 21.31 and 21.32 can be time-consuming and financially burdensome for authorization holders. A nonregulatory option could lead to uneven application of the order powers for devices. Further, it would be inconsistent with the approach for drugs, in which regulations were introduced in 2018.

### Notifying Health Canada of foreign risk actions

After consideration, Health Canada determined that issuing guidance would not be sufficient to receive additional information about corrective actions resulting from incidents, due to the prescriptive nature of the existing incident report sections in the MDR. In addition, a non-regulatory approach would not be consistent with the approach taken for drugs and would therefore result in inconsistencies across product lines.

### Annual summary reports

Health Canada considered using guidance for the annual summary report provision; however, in that instance, Health Canada would not be able to require manufacturers to notify when there was a change to the risk/benefit profile of a device. Given that this is an important safety component of this reporting requirement, Health Canada decided that a regulatory option would be preferable.

### Issue-related analysis of safety and effectiveness

Consideration was given to making issue-related analysis a guidance-based tool, but this was not the preferred approach for the following reasons: (1) Health Canada could not require manufacturers to provide analysis of the safety and effectiveness of their devices with respect to particular signals; and (2) Health Canada already has a tool that requires manufacturers to provide information when there is a question about safety or effectiveness, but it does not specify "analysis" and is therefore insufficient.

### Revising the reference to quality systems

As described above, there is no non-regulatory option to address a change to the international standard which is referenced in the MDR.

# *3. Regulatory*

## Vanessa's Law order powers under sections 21.31 and 21.32 of the FDA

Regulations are the preferred option in order to specify how and when the Minister would be authorized to exercise these powers. They would set, in the MDR, the thresholds and procedures to be used with these powers. The proposed regulations are meant to ensure the effectiveness of the new provision of the Act and provide transparency while outlining procedural fairness steps for medical device licence holders.

## Notifying Health Canada of foreign risk actions

Regulations are necessary for this provision, as the existing mandatory incident reporting requirements for foreign incidents do not provide sufficient information for licensed and higher-risk products.

## Annual summary reports

Regulations are necessary as, in the absence of regulations, Health Canada would not be able to compel manufacturers to prepare annual summary reports and provide them to Health Canada when requested.

## Issue-related analysis of safety and effectiveness

Given that sections 25 and 39 specify that information may be requested from manufacturers, amending the MDR would allow Health Canada to request an analysis of that information, and specify the time frame in which the manufacturer must submit the analysis.

## Revising the reference to quality systems

As described above, currently, regulations are always required to address a change to the international standard that is referenced in the MDR. The ambulatory reference proposal would eliminate the need for further regulatory amendments each time the international standard is changed.

## Regulatory analysis

### Benefits and costs

An analysis of the reported cost and benefit determined that the proposed regulations would have a low-cost impact on the medical device industry. This section provides a description of the methodology used in the analysis, a quantitative depiction of costs and a qualitative listing of potential direct benefits due to the proposed regulatory package.

Table 1 outlines the incremental costs to industry should it be required to report on an incident involving a medical device under either of the two proposed regulatory amendments. Costs reflect the average for each activity based on survey responses.

**Table 1: Cost-benefit statement (in 2019 dollars)**

| | Stakeholder | Base Year Year 1 | Final Year Year 10 | Total (Present Value) | Annual Average [6] |
|---|---|---|---|---|---|
| **Quantitative impacts** | | | | | |
| Annual summary report | Industry | $457,800 | $457,800 | $3,440,473 | $457,800 |
| Analysis of safety and effectiveness | Industry | $486,150 | $486,150 | $3,653,530 | $486,150 |
| **Total costs** | | **$943,950** | **$943,950** | **$7,094,003** | **$943,950** |

## Methodology

A survey was drafted and distributed to over 4 000 potentially impacted stakeholders in order to determine the costs and benefits of the proposed regulatory amendments; the survey was sent to industry associations, some establishment licence holders (importers and Class I device manufacturers) and medical device licence holders.

Responses were divided into two categories, those originating from Canada and those originating from outside of Canada. This categorization was used to determine the effect of the proposed regulations on Canadian respondents and to use foreign responses as a comparator to determine response validity. Health Canada estimates were used to determine the multiplier that best represented the number of potentially affected regulatees for each proposed regulatory amendment in order to determine the total estimated cost to industry. The mean cost for each proposed regulatory amendment was used as the basis for the cost calculation. The mean was further adjusted to account for outliers in the responses. These outliers were most likely due to respondents providing numerical values that represented the costs per activity for the entire company's product lines.

The formula for calculating the costs is as follows:

$M^{adjust} \times N = cost\ of\ activity$

Where

- $M^{adjust}$ represents the adjusted mean cost for a given activity; and
- $N$ represents the number of times the activity is expected to occur each year.

Annual costs are presented over a 10-year period starting in 2020 and are discounted at 7%, as per Treasury Board requirements. [7] Only costs that were determined to be incremental (i.e. outside of existing legislation and/or regulations) were included as being the cost of the regulatory proposal.

## Costs

In the analysis and assessment of anticipated costs to industry, Health Canada only provided incremental cost estimates where new activities through the proposed regulations were identified. Activities that were already a requirement under existing regulations or legislation were not included in the final cost estimates. The net impact on government resources is not expected to be significant.

**Vanessa's Law order powers under sections 21.31 and 21.32 of the FDA**

The costs that would be imposed on manufacturers should the Minister choose to exercise the power to require an assessment, a test or a study stem from the Act and not the proposed amendments (as was the case for similar regulations that were brought into force for prescription drugs [8]). It is estimated that these powers may be exercised twice a year for assessments, and twice a year for tests and studies. The survey was used to ask stakeholders how much the incremental cost of the Minister's use of these powers would be. The average cost submitted from the survey responses to conduct an assessment was $42,484 and the average cost for additional tests and studies ranged from $76,137 to $769,384, depending upon the complexity of the request. However, as the costs are borne by the Act, they have not been included to calculate the net cost of the proposed regulations.

**Annual summary reports**

Current ISO standard 13485 (Quality Management Systems for Medical Devices) instructs medical device manufacturers to compile information that Health Canada would want included in an annual summary report, such as an investigation into all reported complaints. However, the ISO standard falls short of specifying that the analyzed information must be assessed on an aggregate basis and compiled into an annual summary report. The proposed regulation specifies that manufacturers will compile this information into an annual summary report with content specified by Health Canada. Therefore, there will be costs associated with the proposed regulation for Class II, Class III and Class IV device manufacturers.

With the proposed regulations in place, Health Canada would expect to receive approximately 30 of these types of reports annually; this figure was determined by taking the average number of letters requested annually since 2013–14. The cost estimate takes into account industry that is headquartered in Canada and those members of industry with Canadian staff, but that may be headquartered elsewhere. While similar regulations are under way in other regulatory jurisdictions, the costs were still assumed to be a new activity. Based on survey responses and applying the mean adjustment to account for the outliers, the cost to industry per product report would be $15,260. This figure includes the collection and collation of reports, an analysis of the information and the submission of the report to Health Canada. The total cost across all medical device manufacturers would be $457,800 per year in current dollars or $3.4 million in present value (PV), discounted at 7% over a period of 10 years.

**Amendments to sections 25 and 39: Analysis of safety and effectiveness**

The analysis, activities and processes that would be associated with the completion of these reports may be wide-ranging and infrequent, as they would be specific to an already identified risk communicated to the manufacturer by Health Canada. It is anticipated that in a given year, Health Canada would only ask a very small number of manufacturers to provide these reports, as the proposed amendment is only intended to be used in the event that a signal has been identified by Health Canada and there is insufficient information to determine whether risk mitigation is necessary.

With the proposed regulations in place, Health Canada would expect to request and receive approximately 30 of these types of reports annually; this figure was determined by taking the average number of letters requested annually since 2013–2014. Although some of these reports may be reported to Health Canada on a voluntary basis, in order to produce a conservative estimate, the costs are considered to be new activities. Based on survey responses, the mean adjusted (i.e. removal of outliers) cost per product report would be $16,205. Activities associated with the completion of these reports would include the collection of

specified issue information and/or materials, the completion of an analytical report, and the submission of the report to Health Canada. The total cost to industry for this proposed amendment would be $486,150 per year in current dollars or $3.7 million PV over a period of 10 years.

### *Benefits*

There are a number of benefits associated with the proposed amendments that, in concert, would improve Health Canada's ability to take risk mitigation measures when a risk is identified. The direct benefit of the proposed regulations is information gathering for the purposes of mitigating risk to health; this direct benefit cannot be quantified.

#### Ability to collect necessary risk data

Medical devices cover a wide range of classes, each with varying risk and benefit thresholds. While a number of vigilance reporting regulations are already in place, the proposed regulations would provide Health Canada with an additional means of collecting risk information. For example, when a potential risk comes to the attention of Health Canada, the regulations would provide new measures to allow for the study of a specific issue related to the device.

#### Provide greater certainty to industry and critical information to Health Canada

Under the current regulations, manufacturers may be asked to provide additional post-market information to Health Canada when a risk has been identified; however, they are not required to provide analysis. As a result, in the absence of the requirement for analysis, manufacturers may not provide Health Canada with critical analysis and Health Canada may face delays in receiving the specific information needed to perform a risk assessment. The amendment would eliminate any uncertainty by clarifying the type of information that Health Canada would ask for in a post-market analysis and how it ought to be presented. Further, the regulations would specify when additional information could be requested and the form in which it must be presented, allowing industry to better prepare for requests for post-market reports.

#### Ambulatory reference to ISO 13485 standard

Survey responses indicated that industry was supportive of the proposed amendment to include an ambulatory reference to the latest ISO 13485 standard. This would continue Health Canada's alignment of the regulations with those of similar regulatory jurisdictions and allow industry to use a single audit standard in all of their markets. This will improve certainty for manufacturers and avoid potential delay in medical devices being brought to the Canadian market. It will also eliminate the need for a regulatory amendment each time the international standard changes.

#### Notifying Health Canada of foreign risk actions

Under section 59 of the MDR, medical device manufacturers are presently required to report to Health Canada incidents involving a medical device occurring inside or outside Canada. The proposal would limit the amount of information required in these reports and specify which jurisdictions manufacturers would be required to report on for products in Class II, III and IV. Because the MDR currently have a reporting requirement for actions in foreign jurisdictions and the proposed regulation would focus reporting to key international regulatory jurisdictions and specific activities for reporting, no new costs are anticipated. The program area currently receives approximately 900–1 000 reports per year; by specifying the reporting jurisdictions, the proposed amendments are anticipated to reduce this figure to an average of 441 reports

per year. The provisions would lead to an estimated reduction in reports of approximately 560 reports from all industry or 27 fewer reports from Canadian firms alone. Based upon survey information submitted by industry, the average cost for submitting a report about foreign risk actions is $19,302 per report.

**More timely communication of risks**

A component of Health Canada's mandate to help ensure the health and safety of the Canadian population through the regulation of the sale of therapeutic products is the timely communication of risks to Canadians. The proposed regulations would facilitate the communication of medical device risks by supporting the gathering of information of intrinsic value. Health Canada could then share the submitted information with Canadians through updates to product labelling, public statements, or information accessible by Canadians on the Government of Canada website. Similarly, by placing an emphasis on the analysis and study of the identified potential risk instead of simply reporting on the incident, industry would be in a stronger position to communicate their strategies to resolve the identified issue to Health Canada.

## *Total cost-benefit statement*

Over a 10-year period, the proposed regulations would represent an annual cost burden on the medical device industry of $943,950 or $7.09 million PV over 10 years. This cost would be offset by a number of qualitative benefits that would increase post-market surveillance of medical devices and remove unnecessary burden to industry.

### *Small business lens*

Primarily based in Ontario, Quebec and British Columbia, [9] Canada's medical device sector is comprised of approximately 1 500 companies, employing 35 000 people; [10] the sector is dominated by small and medium-sized enterprises (SMEs). [11] Over half of its companies (57%) have fewer than 25 employees and 37% have 25 to 49 employees. Only 4% of companies hire 50 to 150 employees and fewer than 1% have more than 150 employees. [12] Nearly 90% of the medical device facilities in Canada are Canadian-owned, [13] however, foreign-owned global companies enjoy a larger share of the Canadian market. [14]

Canada's medical device sector is export-oriented, often bypassing the domestic market due to the stringent regulatory structures and relatively small market size. [15] From 2011 to 2016, Canadian medical device exports increased from $1.8 billion to $3.1 billion. [16] In 2016, Canada's medical device exports to the United States were $2.1 billion, or 67% of Canada's total medical device exports. [17] Netherlands (4%), Germany (4%), and China (3%) ranked the next three largest export destinations for Canada's medical devices. [18]

Although the majority of the Canadian medical device industry would be small business, the impacts stated in the proposed regulations would not disproportionately affect small business; approximately 40% of SMEs would be affected by the regulations annually. The regulations would not create any specific carve outs or exemptions for small business in Canada. Many small business respondents expressed general concerns about how increased regulation may negatively impact their business.

The proposed regulations would only require additional action by small businesses in the event of there being a change in risk linked to a device. Industry survey responses indicated that the majority of devices sold in Canada are manufactured in foreign jurisdictions and only a relatively small product line of devices are produced by Canadian firms.

***One-for-one rule***

The entirety of the cost calculations represents an administrative burden due to the additional reporting requirements. Administrative burden calculations are aggregated from survey responses, and mean values are used in order to develop cost-per-activity figures. The average wage is $58 per hour, which is an average of all submitted staffing levels (i.e. all staffing levels presented as a single hourly wage) per industry respondent. It was necessary to use a single average hourly wage due to the high variability between the amount and level of staffing required. It would take industry respondents approximately 263 hours to complete the annual summary report and 279 hours to complete the analysis of safety and effectiveness; this represents the average time in hours to complete each type of report inclusive of all staffing levels. All reported wage costs are associated with the completion of the two required reports in the event that a change in a medical device risk occurs. The proposed regulatory amendments for annual summary reports and issue-related analysis of safety and effectiveness would impose an administrative burden on industry. This administrative burden would represent an “IN” of approximately $587,303 per year (2012 dollars), or $19,577 per firm.

Limiting reporting to a list of specified events in the foreign risk notification amendments is anticipated to reduce the overall administrative burden on industry. These potential administrative cost savings to industry are not quantifiable at this time as the Department does not have sufficient data to estimate reductions in reporting as a result of reduced requirements. If data and information becomes available after prepublication, these cost savings will be updated.

***Regulatory cooperation and alignment***

While this regulatory proposal is not part of any existing formal regulatory cooperation initiative, it would provide for alignment with other jurisdictions in some cases, although it would create specific Canadian requirements in others. Analysis of the European and American medical device regulations was undertaken by Health Canada as part of the policy analysis for the proposed regulations. The analysis considered whether the regulations in Europe and in the United States would be appropriate for a Canadian context, and which regulations would yield the most robust post-market surveillance information for medical devices. Given the differences between the regulatory schemes for medical devices in Europe, the United States and Canada, not all regulations were deemed appropriate for the Canadian context.

## *Vanessa’s Law provisions that require supporting regulations*

### Ability to request an assessment

No similar provisions were found in the European Union, Australia or in the United States requiring manufacturers to conduct an assessment of their device at the request of the regulator in light of new information. Nevertheless, this provision is part of Vanessa’s Law and is intended to be applied to therapeutic products in Canada, both drugs and devices. The ability to request an assessment will improve Health Canada’s ability to regulate devices from a life cycle approach.

### Ability to request tests and studies

The U.S. Food and Drug Administration (U.S. FDA) may issue requirements for manufacturers to conduct post-market tests and studies under section 522 of the *Federal Food, Drug and Cosmetic Act*. The Secretary may issue the order at the time of approval of a device or at any time thereafter. The order can

only be applied to medium-to-high-risk devices. The regulations prescribe the amount of time allotted to the manufacturer to begin the study. The U.S. FDA may also take further action with regard to label changes or the marketing of the device once the term of study is complete.

The proposed tests and studies provision would function in a similar manner to the studies requested by the U.S. FDA under section 522. The Minister would be able to issue the order at any point when new information points to new uncertainties about the safety and effectiveness of a medium-to-higher-risk medical device. The Minister would then be able to take further action depending on the results of the study.

### Foreign risk notification

The provision on foreign risk notification can be compared to mandatory reporting requirements in the United States and Europe, which require manufacturers to report adverse medical device incidents and/or corrective actions that have occurred in other countries. The European Union regulations require manufacturers to have systems in place to report field safety corrective actions (FSCA). The American medical device regulations also require manufacturers to have systems to report both device incidents and FSCAs. Neither the United States nor the European Union have differing requirements for lower-risk devices [19] as Health Canada is proposing. While the United States and the European Union collect this information from all other countries, as will continue to be the case for Class I devices in Canada, for Class II, III and IV devices, these proposed regulations would limit the relevant jurisdictions as mentioned in the "Description" section above. This would ensure that Health Canada receives timely, targeted and high quality information without being unnecessarily burdensome on medical device authorization holders.

## *Regulations to improve post-market surveillance*

### Annual summary reports

In May of 2017, the European Commission passed new regulations (http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0745&from=EN) that set out more stringent post-market requirements. Manufacturers must be in compliance with the new requirements by May 2020 (2022 for in-vitro diagnostic devices). As per the new regulations, manufacturers of some medium-risk and all higher-risk devices must prepare an annual summary report, known as a periodic safety update report, for each device, category or group of devices. Other medium-risk device manufacturers will be required to prepare a report biennially. Manufacturers of low-risk devices are exempt from this requirement. Manufacturers are required to report any statistically significant increase in the frequency or severity of (1) non-serious incidents or (2) expected undesirable side effects that could have a significant impact on the benefit-risk analysis.

The proposed annual summary report provision sets out similar requirements in that it applies only to medium-to-higher risk devices, and that manufacturers are required to report increases in the frequency of device incidents or new incidents that are occurring. However, certain medium-risk device manufacturers will be required to prepare a report every two years under the European Commission's regulations and annually under Canadian regulations. Health Canada's decision to require annual reporting for medium-risk devices helps ensure sufficient information to support surveillance activities since these types of devices can, in certain cases, pose a significant risk of harm.

The United States Food and Drug Administration (U.S. FDA) has been shifting its surveillance model of medical devices toward a total product life cycle approach by leveraging expertise, data, knowledge and tools at all stages of a device's life. In addition, as part of this approach, the U.S. FDA is exploring regulatory options to streamline and modernize timely implementation of post-market mitigation.

The U.S. FDA also has an annual reporting regulatory mechanism for devices. This requirement is used as a condition of a pre-market approval for Class III devices, the highest risk class. The FDA has the authority to request supporting and additional information, including copies of the reports.

### Issue-related analysis of safety and effectiveness

These proposed amendments to the MDR are not modelled directly after European or American medical device regulations, but after existing Canadian drug regulations. The drug regulations function well in order to address issues raised through post-market safety assessments, so it was determined that this approach would also work well for medical devices, by amending the existing provisions.

#### *Provisions to remove unnecessary burden*

## Incorporation by reference of international quality management standards

This amendment will allow Canada to maintain regulatory requirements that are harmonized with those of its global trading partners, and allow current import and export schemes to remain in place. For example, the European Union uses the ISO standards, and the United States, while not formally referencing the ISO standard in their Quality System Regulations (QSR), have proposed replacing certain aspects of the existing QSR with specifications outlined in the most up-to-date ISO 13485 standard by spring 2019.

### *Strategic environmental assessment*

In accordance with the *Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, a preliminary scan concluded that a strategic environmental assessment is not required.

## *Gender-based analysis plus (GBA+)*

Evidence suggests that women are impacted differently than men by medical devices. There are numerous devices intended for use by women, such as breast implants, vaginal meshes and methods of birth control, which have caused many reported health problems from proper use, in Canada and abroad. Furthermore, there are differences in how devices intended for both sexes affect women. For example, one study found that women experience more hypersensitivity than men to metals used in joint implants, [20] while another study found that women who received a particular type of cardiac implant were three times more likely than men to experience stroke. [21]

Some differences in how men and women react can be due to sex-related differences in anatomy (e.g. women's smaller heart size) or gender-related differences (due to many women's caregiving role, they may not take the same recovery time as men after implant surgery). Other groups, such as seniors and those with disabilities, also use devices more frequently than other populations. Therefore, changes in risk management for devices also affect them to a greater degree than they do the general population.

Health Canada's pre-market work related to drugs and medical devices takes sex, gender and age into account through the drug and medical device review processes, and these processes will remain intact. Health Canada issued a guidance document in 2013 outlining key considerations for including women in pre-market studies for therapeutic products: Guidance Document: Considerations for Inclusion of Women in Clinical Trials and Analysis of Sex Differences (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/womct_femec-eng.php). Once therapeutic products are on the market, identified risks to particular groups such as women or children are taken into consideration, usually through additional risk management measures. For example, Health Canada has issued notices to the public and health professionals regarding additional risks present for children using pacemakers [22] and women using metal-on-metal hip implants. [23]

Health Canada recently announced plans for the formation of a new expert advisory committee on women's health issues related to drugs and devices, in collaboration with the Canadian Institutes for Health Research. [24]

The regulatory proposals described here would provide Health Canada with greater authority to compel information from manufacturers when there is evidence of a problem, including identified risks or uncertainties related to specific groups such as women, people with disabilities, or children.

### *Vanessa's Law provisions that require supporting regulations*

## Ability to request assessment

The proposed regulations would facilitate the exercise by Health Canada of its authority under section 21.31 of the FDA to compel medical device licence holders to reassess the risk/benefit profile of their products in light of new information, including information indicating that a certain group is disproportionately affected by a device (e.g. that women are experiencing a higher rate of stroke from a cardiac device). Based on the results of the medical device licence holder's assessment, Health Canada could take action such as a change to the device's labelling or revisions to the device's indications that would better protect that group with regard to the device.

## Ability to request tests and studies

Similarly, the proposed regulations would facilitate the exercise by Health Canada of its authority under section 21.32 of the FDA to ask the medical device licence holder to monitor the impact of any device more closely, including products aimed at women, such as breast implants or vaginal mesh. Furthermore, the tests and studies provision could be used to request studies or information on uncertainties outside the parameters of the licence. This could include studies on off-label use, which could be targeted at pediatric populations, but also uncertainties related to any sub-population (e.g. women of childbearing age or postmenopausal women).

## Notifying Health Canada of foreign risk actions

The proposed regulations to require medical device authorization holders to inform Health Canada about foreign risk actions could also be a valuable tool to support the health of specific sub-populations. Through this proposed provision, Health Canada would receive information indicating corrective actions (recalls,

communications of risk, labelling revisions, etc.) taken in other jurisdictions due to serious risk, including corrective actions due to an identified serious risk to sub-populations, such as those with disabilities, women, children, etc. By receiving this information in an expedited time frame (72 hours), Health Canada would then be able to better assess the risks to Canadians and take appropriate action (such as through a risk advisory, labelling revision, or recall).

***Regulations to improve post-market surveillance***

## Annual summary reports

The proposed regulations on annual summary reports would require manufacturers to perform aggregate analyses of the incidents and problems identified with their device. These types of aggregate analyses could be used by manufacturers to both track and identify changes in the risks or benefits of their device, including risks posed to specific sub-populations.

## Issue-related analysis of safety and effectiveness

The ability to request an issue-related analysis of the safety and effectiveness of a device would provide Health Canada with the ability to target issues relating to a device, including those affecting women or other sub-populations who might be differently affected by a medical device. For example, if scientific literature were to identify that women were experiencing adverse incidents at a higher rate than men in relation to a particular device, then Health Canada would be able to request an issue-related analysis from the manufacturer specific to that population.

## Implementation, compliance and enforcement, and service standards

These amendments would not alter existing compliance and enforcement mechanisms under the provisions of the Act and the MDR. For example, if a manufacturer were to refuse to comply with an assessment order, the Minister could seek an injunction or recommend prosecution, which could result in the imposition of fines and penalties.

Health Canada intends to work with manufacturers to achieve compliance with all proposed regulations by addressing issues and providing the necessary information to comply by way of guidance documents and corresponding templates.

Implementation activities, such as the training of staff, the development of standard operating procedures, as well as the updating of internal databases and Health Canada’s website, would be needed to support these amendments. Resources for these few incremental implementation activities would be drawn from existing departmental funds.

## Contact

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## PROPOSED REGULATORY TEXT

Notice is given that the Governor in Council, pursuant to section 30 [a] of the *Food and Drugs Act* [b], proposes to make the annexed *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Post-market Surveillance of Medical Devices)*.

Interested persons may make representations concerning the proposed Regulations within 70 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Bruno Rodrigue, Director, Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Department of Health, Address Locator: 3000A, 11 Holland Avenue, Suite 14, Ottawa, Ontario K1A 0K9 (email: hc.lrm.consultations-mlr.sc@canada.ca (mailto:hc.lrm.consultations-mlr.sc@canada.ca)).

Ottawa, June 6, 2019

Julie Adair
Assistant Clerk of the Privy Council

# Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Post-market Surveillance of Medical Devices)

## Food and Drug Regulations

**1 The portion of subsection C.01.014.6(3) of the *Food and Drug Regulations* [25] before paragraph (a) is replaced by the following:**

**(3)** The Minister may cancel the assignment of a drug identification number for a drug if, after he or she has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(a)(i) or (iii) to conduct an assessment of the drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health,

**2 (1) Subsection C.01.052(1) of the Regulations is replaced by the following:**

**C.01.052 (1)** The Minister's power to make an order under section 21.31 of the Act in respect of a drug is subject to the following conditions:

**(a)** the person to whom the order is made shall be the holder of one or more of the following therapeutic product authorizations in respect of the drug:

**(i)** a drug identification number that has been assigned under subsection C.01.014.2(1),

**(ii)** an establishment licence that has been issued under subsection C.01A.008(1), and

**(iii)** a notice of compliance that has been issued under section C.08.004 or C.08.004.01; and

**(b)** the Minister shall have reasonable grounds to believe that

**(i)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(i) or (iii), the benefits or risks of injury to health associated with the drug are significantly different than they were when the authorization was issued,

**(ii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) who is an importer, the manner in which one or more of the following activities is conducted may present a risk of injury to health associated with the drug:

**(A)** *importation*, within the meaning of subsection C.01A.001(1), of the drug,

**(B)** *fabrication* or *packaging/labelling*, within the meaning of subsection C.01A.001(1), of the drug outside Canada, or

**(C)** testing of the drug outside Canada, or

**(iii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) other than an importer, the manner in which an activity that is authorized under the authorization is conducted may present a risk of injury to health associated with the drug.

**(2) The portion of subsection C.01.052(2) of the Regulations before paragraph (a) is replaced by the following:**

**(2)** The Minister shall, after examining the results of an assessment that was ordered under section 21.31 of the Act in respect of a drug,

**3 Section C.01.053 of the Regulations is replaced by the following:**

**C.01.053** The Minister's power to make an order under section 21.32 of the Act in respect of a drug is subject to the following conditions:

**(a)** the person to whom the order is made shall be the holder of one or more of the following therapeutic product authorizations in respect of the drug:

**(i)** a drug identification number that has been assigned under subsection C.01.014.2(1),

**(ii)** an establishment licence that has been issued under subsection C.01A.008(1), and

**(iii)** a notice of compliance that has been issued under section C.08.004 or C.08.004.01;

**(b)** the Minister shall have reasonable grounds to believe that

**(i)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(i) or (iii), there are significant uncertainties relating to the benefits or harms associated with the drug,

**(ii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) who is an importer, the manner in which one or more of the following activities is conducted has introduced significant uncertainties relating to the benefits or harms associated with the drug:

**(A)** *importation*, within the meaning of subsection C.01A.001(1), of the drug,

**(B)** *fabrication* or *packaging/labelling*, within the meaning of subsection C.01A.001(1), of the drug outside Canada, or

**(C)** testing of the drug outside Canada,

**(iii)** in the case of a holder of a therapeutic product authorization referred to in subparagraph (a)(ii) other than an importer, the manner in which an activity that is authorized under the authorization is conducted has introduced significant uncertainties relating to the benefits or harms associated with the drug,

**(iv)** the holder of the therapeutic product authorization is unable to provide the Minister with information that is sufficient to manage those uncertainties, and

**(v)** the applicable requirements of these Regulations, together with any terms and conditions that have been imposed on the authorization, do not allow for sufficient information to be obtained to manage those uncertainties; and

**(c)** the Minister shall take into account the following matters:

**(i)** whether the activities that the holder of the therapeutic product authorization will be ordered to undertake are feasible, and

**(ii)** whether there are less burdensome ways of obtaining additional information about the drug's effects on health or safety.

**4 The portion of subsection C.08.006(3) of the Regulations before paragraph (a) is replaced by the following:**

**(3)** The Minister may, by notice to a manufacturer, suspend for a definite or indefinite period a notice of compliance issued to that manufacturer in respect of a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions, if, after the Minister has, under section 21.31 of the Act, ordered the holder of a therapeutic product authorization referred to in subparagraph C.01.052(1)(a)(iii) to conduct an assessment of the new drug in order to provide evidence establishing that the benefits associated with the drug outweigh the risks of injury to health,

## Medical Devices Regulations

**5 The definition *système de gestion de la qualité* in section 1 of the French version of the *Medical Devices Regulations* [26] is replaced by the following:**

***système de gestion de la qualité*** Vaut mention de l'expression « système de management de la qualité » figurant à la norme nationale du Canada CAN/CSA-ISO 13485 intitulée *Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires*, avec ses modifications successives. (*French version only*)

**6 Section 1 of the Regulations is amended by adding the following in alphabetical order:**

***regulatory agency*** means a government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements. (*organisme de réglementation*)

**7 (1) The heading before section 25 of the Regulation is replaced by the following:**

## Requests by Minister — Class I Medical Devices

**(2) Subsection 25(1) of the Regulations is replaced by the following:**

**25 (1)** If the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that a Class I medical device may not meet the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, by the day specified in the request, an analysis or other information to enable the Minister to determine whether the device meets those requirements.

**(3) Paragraph 25(2)(a) of the Regulations is replaced by the following:**

**(a)** the manufacturer does not comply with the request by the day specified in the request; or

**(4) Paragraph 25(2)(b) of the English version of the Regulations is replaced by the following:**

**(a)** the Minister determines, on the basis of the information submitted, that the medical device does not meet the applicable requirements of sections 10 to 20.

**(5) The portion of subsection 25(3) before paragraph (b) of the Regulations is replaced by the following:**

**(3)** The Minister shall lift the direction to stop the sale if

**(a)** the Minister determines, on the basis of the information submitted, that the medical device meets the applicable requirements of sections 10 to 20;

**(6) Paragraph 25(3)(b) of the English version of the Regulations is replaced by the following:**

**(b)** corrective action has been taken to ensure that the medical device meets the applicable requirements of sections 10 to 20; or

**8 (1) Paragraph 32(2)(f) of the Regulations is replaced by the following:**

**(f)** a copy of the quality management system certificate certifying that the quality management system under which the device is manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*, as amended from time to time.

**(2) Paragraph 32(3)(j) of the Regulations is replaced by the following:**

**(j)** a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*, as amended from time to time.

**(3) Paragraph 32(4)(p) of the Regulations is replaced by the following:**

**(p)** a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*, as amended from time to time.

**9 Section 39 of the Regulations and the heading before it are replaced by the following:**

## Requests by Minister — Class II, III and IV Medical Devices

**39** If the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that a licensed medical device may not meet the applicable requirements of sections 10 to 20, the Minister may request the manufacturer to submit, by the day specified in the request, samples — or an analysis or other information — to enable the Minister to determine whether the device meets those requirements.

**10 Paragraph 40(1)(d) of the Regulations is replaced by the following:**

**(d)** the licensee does not comply with a request made under section 39 by the day specified in the request;

**(d.1)** the samples — or the analysis or other information — submitted by the licensee in response to a request made under section 39 are insufficient to enable the Minister to determine whether the medical device meets the applicable requirements of sections 10 to 20;

**11 The Regulations are amended by adding the following after section 41:**

**41.1** The Minister may suspend a medical device licence if, after the Minister has, under section 21.31 of the Act, ordered the licensee to conduct an assessment of the medical device in order to provide evidence establishing that the benefits associated with the medical device outweigh the risks to the health or safety of patients, users or other persons,

**(a)** the licensee does not comply with the order; or

**(b)** the licensee complies with the order but the Minister determines that the results of the assessment are not sufficient to establish that the benefits associated with the medical device outweigh the risks to the health or safety of patients, users or other persons.

**12 Paragraph 45(h) of the Regulations is replaced by the following:**

**(h)** if the establishment imports Class I devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of the making of reports under subsections 59(1) and (1.1);

**(h.1)** if the establishment imports Class II, III or IV devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of the making of reports under subsection 59(1) and the provision of information under section 61.2;

**13 (1) The heading before section 59 of the Regulations is replaced by the following:**

## Incident Reporting — Manufacturers and Importers

**(2) Subsection 59(1) of the Regulations is replaced by the following:**

**59 (1)** The manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring in Canada that involves the medical device if

**(a)** the medical device is sold in Canada; and

**(b)** the incident

**(i)** is related to a failure of the medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use, and

**(ii)** has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.

**(1.1)** Subject to subsection (2), the manufacturer and the importer of a Class I medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring outside Canada that involves the medical device if the conditions in paragraphs (1)(a) and (b) are met.

**14 Subsection 61.1(1) of the Regulations is replaced by the following:**

**61.1 (1)** Despite subsection 59(1) or (1.1), the manufacturer of a medical device may permit the importer of the device to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that the manufacturer and importer must include is identical.

**15 The Regulations are amended by adding the following after section 61.1:**

## Information — Serious Risk of Injury to Human Health

**61.2 (1)** This section applies to a holder of one of the following therapeutic product authorizations:

**(a)** a medical device licence; and

**(b)** an establishment licence to import Class II, III or IV devices.

**(2)** The holder of a therapeutic product authorization in respect of a medical device shall submit to the Minister information in respect of any serious risk of injury to human health that the holder receives or becomes aware of and that is relevant to the safety of the medical device, regarding

**(a)** risks that have been communicated by any regulatory agency that is set out in the *List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations*, published by the Government of Canada on its website, as amended from time to time, or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a regulatory agency, and the manner of the communication;

**(b)** changes that have been made to the labelling of any medical device and that have been communicated to or requested by any regulatory agency that is set out in the list referred to in paragraph (a); and

**(c)** recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device, that have taken place within the jurisdiction of any regulatory agency that is set out in the list referred to in paragraph (a).

**(3)** The information shall be submitted to the Minister within 72 hours after the holder receives or becomes aware of it, whichever occurs first.

**61.3 (1)** Despite subsection 61.2(2), if the holder of a therapeutic product authorization in respect of a medical device is the manufacturer, they may permit the importer of the medical device to submit the information required under that subsection on the manufacturer's behalf if the information that the manufacturer and importer must submit is identical.

**(2)** The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to submit the information on the manufacturer's behalf.

## Annual Summary Report and Supporting Information

**61.4 (1)** The holder of a medical device licence shall prepare an annual summary report of all of the information that relates to the following in respect of the medical device that the licensee received or became aware of during the 12 months following the issuance of the medical device licence or the anniversary of its issuance, as the case may be:

**(a)** adverse effects;

**(b)** problems referred to in paragraph 57(1)(a);

**(c)** incidents referred to in subsection 59(1); and

**(d)** serious risks of injury to human health that are relevant to the safety of the medical device and are referred to in subsection 61.2(2).

**(2)** The report shall be prepared within 90 days after the end of the applicable 12-month period.

**(3)** The report shall contain a concise, critical analysis of the information referred to in subsection (1).

**(4)** In preparing the report, the licensee shall determine, on the basis of the analysis, whether what is known about the benefits and risks associated with the medical device has changed as described in any of the following paragraphs:

**(a)** any of the benefits that may be obtained by patients through the use of the medical device may be less;

**(b)** in respect of any of the risks,

**(i)** the risk is more likely to occur, or

**(ii)** if the risk occurs, the consequences for the health or safety of patients, users or other persons may be more serious; or

**(c)** any new risk has been identified.

**(5)** The licensee shall include the conclusions they reach under subsection (4) in the report.

**(6)** If, in preparing the report, the licensee concludes that what is known about the benefits and risks associated with the medical device has changed as described in any of paragraphs (4)(a) to (c), they shall notify the Minister, in writing, within 72 hours after having reached the conclusion, unless this has already been done.

**61.5 (1)** The Minister may, for the purposes of determining whether the medical device meets the applicable requirements of sections 10 to 20, request that the holder of a medical device licence submit, by the day specified in the request, any of the following:

**(a)** annual summary reports;

**(b)** information on the basis of which annual summary reports were prepared.

**(2)** The licensee shall submit to the Minister the reports or information, or both, that the Minister requested not later than the day specified in the request.

**61.6 (1)** The holder of a medical device licence shall maintain records of the annual summary reports and the information on the basis of which the annual summary reports were prepared.

**(2)** The licensee shall retain the records for seven years after the day on which they were created.

**16 The Regulations are amended by adding the following before the heading "Recall" before section 63:**

## Assessments Ordered Under Section 21.31 of the Act

**62.1 (1)** The Minister's power to make an order under section 21.31 of the Act in respect of a medical device is subject to the following conditions:

**(a)** the person to whom the order is made shall be the holder of a medical device licence in respect of the medical device; and

**(b)** the Minister shall have reasonable grounds to believe that the benefits — or the risks to the health or safety of patients, users or other persons — that are associated with the medical device are significantly different than they were when the medical device licence was issued.

**(2)** The Minister shall, after examining the results of an assessment that was ordered under section 21.31 of the Act in respect of a medical device,

**(a)** provide the holder of the medical device licence with the results of the examination; and

**(b)** ensure that a summary of the results of the examination, together with a description of any steps that the Minister has taken or may take as a consequence of the examination, is published on the Government of Canada website.

## Activities Ordered Under Section 21.32 of the Act

**62.2** The Minister's power to make an order under section 21.32 of the Act in respect of a medical device is subject to the following conditions:

**(a)** the person to whom the order is made shall be the holder of a medical device licence in respect of the medical device;

**(b)** the Minister shall have reasonable grounds to believe that

**(i)** there are significant uncertainties relating to the benefits or adverse effects associated with the medical device,

**(ii)** the licensee is unable to provide the Minister with information that is sufficient to manage those uncertainties, and

**(iii)** the applicable requirements of these Regulations, together with any terms and conditions that have been imposed on the medical device licence, do not allow for sufficient information to be obtained to manage those uncertainties; and

**(c)** the Minister shall take into account the following matters:

**(i)** whether the activities that the licensee will be ordered to undertake are feasible, and

**(ii)** whether there are less burdensome ways of obtaining additional information about the medical device's effects on the health or safety of patients, users or other persons.

**17 Section 77 of the Regulations is replaced by the following:**

**77** The health care professional referred to in subsection 71(1) shall, within 72 hours after becoming aware of an incident that occurs in or outside Canada that involves the medical device for which an authorization has been issued under section 72 and that meets the following criteria, report the incident to the Minister and to the manufacturer or importer of the device, and specify the nature of the incident and the circumstances surrounding it:

**(a)** the incident is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use; and

**(b)** the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.

**18 Subparagraph 81(k)(v) of the Regulations is replaced by the following:**

**(v)** in the event of an incident involving the device that occurs in or outside Canada and that meets the following criteria, report the incident and the circumstances surrounding it to the Minister and to the manufacturer or importer of the device within 72 hours after the qualified investigator becomes aware of the incident:

**(A)** the incident is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use; and

**(B)** the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.

**19 Paragraph 88(c) of the Regulations is replaced by the following:**

**(c)** sections 59 to 61.1 with respect to reports on incidents;

**20 The Regulations are amended by adding the following after section 88:**

**88.1** Subsections 61.2(2) to (3) and section 61.3 apply in respect of medical devices to which this Part applies except that the references to "holder of a therapeutic product authorization" shall be read as references to "holder of an authorization issued under subsection 83(1)".

## Coming into Force

**21 These Regulations come into force on the day that, in the sixth month after the month in which they are published in the *Canada Gazette*, Part II, has the same calendar number as the day on which they are published or, if that sixth month has no day with that number, the last day of that**

**sixth month.**

# Footnotes

1 Health Canada relies on rules in the MDR to categorize medical devices into one of four risk classifications: Class I, II, III or IV. Class I represents devices that are the lowest risk to health, for example a wound dressing, and Class IV represents devices that are the highest risk to health, for example a coronary stent.

2 The transitional provisions mean that provisions regarding in vitro devices will not be fully implemented until 2022 in the European Union.

3 Health Canada relies on rules in the MDR to categorize medical devices into one of four risk classifications: Class I, II, III or IV. Class I represents devices that are the lowest risk to health, for example, a wound dressing, and Class IV represents devices that are the highest risk to health, for example, a coronary stent.

4 The elements used to determine ”serious risk” can include, but are not limited, to (a) the seriousness of the adverse health consequence; (b) the vulnerability of the patient population; and (c) the extent of the population’s exposure to the therapeutic product. For more information on serious risk, see Annex A of the Health Canada document Amendments to the *Food and Drugs Act: Guide to New Authorities* (https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/amendments-food-drugs-act-guide-new-authorities-power-require-disclose-information-power-order-label-change-power-order-recall.html#a13).

5 MEDEC is a national association representing 100 of the largest medical device manufacturers in Canada. While it is considered the primary medical device stakeholder in Canada, it only represents a fraction of medical device manufacturers in Canada.

6 The annual average is the total cost over 10 years in current dollars, divided by 10.

7 Treasury Board Secretariat, *Policy on Cost-Benefit Analysis* (https://www.canada.ca/en/treasury-board-secretariat/services/federal-regulatory-management/guidelines-tools/policy-cost-benefit-analysis.html).

8 *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):SOR/2018-84* (/rp-pr/p2/2018/2018-05-02/html/sor-dors84-eng.html)

9 Innovation, Science and Economic Development Canada (ISED). Medical Devices — Industry Profile (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html). Retrieved on February 1, 2019, from the ISED website.

10 MEDEC (https://www.medec.org/page/Industry?). Retrieved on February 1, 2019, from the MEDEC website.

11 Innovation, Science and Economic Development Canada (ISED). Medical Devices – Industry Profile (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html). Retrieved on February 1, 2019, from the ISED website.

12 Snowdon, A., Zur, R., and Shell, J. (2011). Transforming Canada into a global centre for medical device innovation and adoption. Ivey Centre for Health Innovation and Leadership, University of Western Ontario.

13 Ibid.

14 Innovation, Science and Economic Development Canada (ISED). Medical Devices – Industry Profile (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html). Retrieved on February 1, 2019, from the ISED website.

15 Snowdon, A., Zur, R., and Shell, J. (2011). Transforming Canada into a global centre for medical device innovation and adoption. Ivey Centre for Health Innovation and Leadership, University of Western Ontario.

16 Innovation, Science and Economic Development Canada (ISED). Medical Devices — Industry Profile (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html). Retrieved on February 1, 2019, from the ISED website.

17 Ibid. (Medical Devices — Industry Profile (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html))

18 Ibid. (Medical Devices — Industry Profile (http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01736.html))

19 It is important to note that while Canada has four classes of medical devices, both the United States and the European Union each have only three. Therefore, each device class in the United States and European Union contains a wider variety of devices than does each Canadian class of device.

20 Caceido, MS et al., *Females with Unexplained Joint Pain Following Total Joint Arthroplasty Exhibit a Higher Rate and Severity of Hypersensitivity to Implant Metals Compared with Males: Implications of Sex-Based Bioreactivity Differences*, The Journal of Bone and Joint Surgery, Issue: Volume 99(8), April 19, 2017, p 621–628.

21 Hallman, Ben. *Are women more likely to be harmed by medical device failures?* (https://www.icij.org/blog/2018/12/are-women-more-likely-to-be-harmed-by-medical-device-failures/), International Consortium of Investigative Journalists. December 17, 2018.

22 http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15067a-eng.php (http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15067a-eng.php)

23 http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15835a-eng.php (http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15835a-eng.php)

24 *Health Canada's Action Plan on Medical Devices* (https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/medical-devices-action-plan.html). December 20, 2018

25 C.R.C., c. 870

26 SOR/98-282

a S.C. 2016, c. 9, s. 8

b R.S., c. F-27

# Government of Canada activities and initiatives

**#YourBudget2018 – Advancement**

(https://www.budget.gc.ca/2018/docs/themes/advancement-advancement-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Advancement&utm_campaign=CAbdgt18)
Advancing our shared values

**#YourBudget2018 – Reconciliation**

(https://www.budget.gc.ca/2018/docs/themes/reconciliation-reconciliation-en.html?utm_source=CanCa&utm_medium=%20Activities_e&utm_content=Reconciliation&utm_campaign=CAbdgt18)
Advancing reconciliation with Indigenous Peoples

**#YourBudget2018 – Progress**

(https://www.budget.gc.ca/2018/docs/themes/progress-progres-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Progress&utm_campaign=CAbdgt18)
Supporting Canada's researchers to build a more innovative economy