Toward Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Health Care Institutions

A Consultation Paper to inform the design of the regulations

Summary:

Purpose:

The *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law*) makes several amendments to the *Food and Drugs Act (F&DA*), including a new requirement for certain health care institutions to provide Health Canada with information on serious adverse drug reactions (serious ADRs) and medical device incidents (MDIs). The central objective of this authority is to improve the quality and increase the quantity of ADR and MDI reports, thereby ensuring that there is sufficient data to detect safety problems.

This consultation paper follows Health Canada's engagement activities and responds to comments received from the provinces and territories and stakeholders since 2015. Health Canada is now seeking advice and input from stakeholders on the regulatory proposals in the following five areas:

- Applicable health care institutions,
- Types of reportable serious adverse drug reactions and medical device incidents,
- Applicable therapeutic products,
- Applicable data fields, and
- Timelines for reporting.

Health Canada's approach to improving the reporting of serious ADR/MDIs will be multi-pronged in nature and include non-regulatory approaches such as outreach and education as well as meaningful feedback to reporting institutions. Thus, we are also seeking feedback from stakeholders on the proposed non-regulatory approaches in the following areas:

- outreach and education, and
- providing meaningful feedback to reporting institutions.

Proposals Informing the Development of the Regulations

Proposal for Applicable Health Care Institutions:

- Mandatory reporting requirements should apply to all hospitals that provide acute care services, as these hospitals are most likely to treat patients with serious ADRs and MDIs and are therefore well-positioned to make and report these observations.
- By targeting hospitals that provide acute care services, there is also the potential to capture serious ADRs and MDIs that occurred from other institutions through patient transfers.
- Hospitals that provide acute care are more likely to have the infrastructure to effectively support quality serious ADR and MDI reporting.
- Outreach and education could be used effectively as tools in hospitals that provide acute care services for influencing health care professional reporting behaviour with respect to both the identification of reportable events and recording the necessary information to ensure quality reporting.

Proposal for Scope of Reportable Serious ADRs/ MDIs:

- For ADRs, it is proposed that health care institutions be required to provide Health Canada with only serious unexpected ADRs in its control, as this would focus on reports that have the highest potential to add to the understanding of real world performance of drugs.

- For MDIs, it is proposed that health care institutions are required to provide Health Canada with all MDIs in its control; this would include MDIs with the potential to cause harm if it were to recur.

Proposal for Applicable Therapeutic Products	
What's Included	**What's Excluded**
• Pharmaceuticals (prescription and non-prescription) • Biologic Drugs (that are not vaccines) • Radiopharmaceuticals • Disinfectants • Medical Devices	• Natural Health Products • Cells, Tissues, Organs (CTO) • Blood and Blood Components • Semen • Preventative Vaccines • Clinical Trial/ Special Access Program (SAP) drugs • Drugs on Urgent Public Health Need List[i]

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Proposal for Data Fields • It is proposed that the regulations define both a minimum set of information data fields and a set of additional data fields to be 'required to be completed, if the information is known' to be provided to Health Canada within the prescribed time frame. • The rationale for this approach is that it has the potential to encourage more complete reports.	
Minimum Required Data Fields for Serious ADRs	**Additional Data Fields for Serious ADRs (Required if known)**
• The name of the health care institution and the contact information of a representative of that institution; • The name or the Drug Identification Number of the drug that is suspected of causing the reaction; • Age and gender of patient; and • A description of the suspected serious unexpected adverse drug reaction.	• Therapy and reaction dates (dates the drug was started and stopped; and dates the adverse reaction occurred and was resolved); • Relevant tests/lab data; • Relevant medical history (concomitant disease states); and • Concomitant health products; and • Patient outcome.
Minimum Required Data Fields for MDIs	**Additional Data Fields for MDIs (Required if known)**
• The name of the health care institution and the contact information of a representative of that institution; • The device name; • The manufacturer or importer name; and • A description of the medical device incident.	• Device identifier (lot/serial number, model/ catalogue number); • Patient outcome; and • Contributing factors to MDI.

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Proposal on Timelines

- It is proposed that timelines for institutions to report be set at 30 days for both serious ADR and MDI reporting, with the regulatory reporting time clock starting on the day on which the serious ADR/MDI is first documented.
- The rationale for this proposed timeline is that it sets an appropriate balance between timeliness of reporting and report completeness. A 30 day target may allow sufficient time for institutions to provide reports to Health Canada and may better avoid unnecessary burden on health care institutions when reporting ADRs/MDIs. It is anticipated that the 30 day timeframe would be proportionate to the respective efforts of health care institutions in completing, validating and vetting reports of acceptable quality.

Summary of Regulatory Proposal

It is proposed that:

- Hospitals that provide acute care services be required to provide to Health Canada information about serious, unexpected adverse drug reactions and medical device incidents that are in its control.
- Timelines for institutions to report be 30 days for both serious ADR and MDI reporting
- The regulatory reporting time clock starts on the day on which the serious ADR/MDI is first documented.
- The regulations define both a minimum set of information data fields and a set of additional data fields to be 'required to be completed, if the information is known' to be provided to Health Canada.

The scope of therapeutic products to which these reporting requirements apply would include:

- Pharmaceuticals (prescription and non-prescription)
- Biologic drugs (that are not vaccines)
- Radiopharmaceuticals
- Disinfectants
- Medical devices

The online form to submit comments to the discussion paper is available at https://na1se.voxco.com/SE/?st=xwjTYxFyhQcaN76NqpMbVMmOHK41k%2fxAKHWRvEVmiHI%3d&p=[$PIN]&lang=en

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A - Purpose

Health Canada is continuously looking for ways to strengthen the knowledge base on product safety in the interest of improving patient outcomes and public health. The *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law*) makes several amendments to the *Food and Drugs Act (F&DA*), including a new requirement in section 21.8 of the *F&DA* for certain healthcare institutions to provide Health Canada with information on serious adverse drug reactions (serious ADRs) and medical device incidents (MDIs). The central objective of this authority is to improve the quality and increase the quantity of serious ADR and MDI reports, thereby ensuring that there is sufficient data to detect safety problems. Under-reporting has been a long-standing issue for Health Canada and therapeutic product regulators worldwide. Although Vanessa's Law received Royal Assent in November 2014, this requirement will come into effect when accompanying changes are made to both the *Food and Drug Regulations* and the *Medical Devices Regulations.*

This consultation paper follows Health Canada's engagement activities and responds to comments received from the provinces and territories and stakeholders since 2015 (Appendix A). Some of the engagement activities included: teleconferences with provinces and territories, a webinar with Health Care Can members, and the issuance of an issue identification paper entitled Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Health Care Institutions that closed in July 2016. Based on the feedback received through these engagement activities, Health Canada has sought to strike a balance between achieving the policy objectives of the regulatory proposal and the burden of the proposed scope of the regulatory requirements on the health care system. Health Canada has integrated the feedback received in our analysis of the key policy issues and we are seeking further comments from stakeholders prior to publishing a regulatory proposal in *Canada Gazette* Part 1. Health Canada is seeking advice and input from stakeholders on the regulatory proposals in the following five areas:

- Applicable health care institutions,
- Types of reportable serious adverse drug reactions and medical device incidents,
- Applicable therapeutic products,
- Applicable data fields, and
- Timelines for reporting.

Health Canada's approach to improving the reporting of serious adverse drug reactions and medical device incidents in an institutional setting will be multi-pronged in nature. We are also seeking feedback from stakeholders on the proposed non-regulatory approaches in the following areas:

- outreach and education, and
- providing meaningful feedback to reporting institutions.

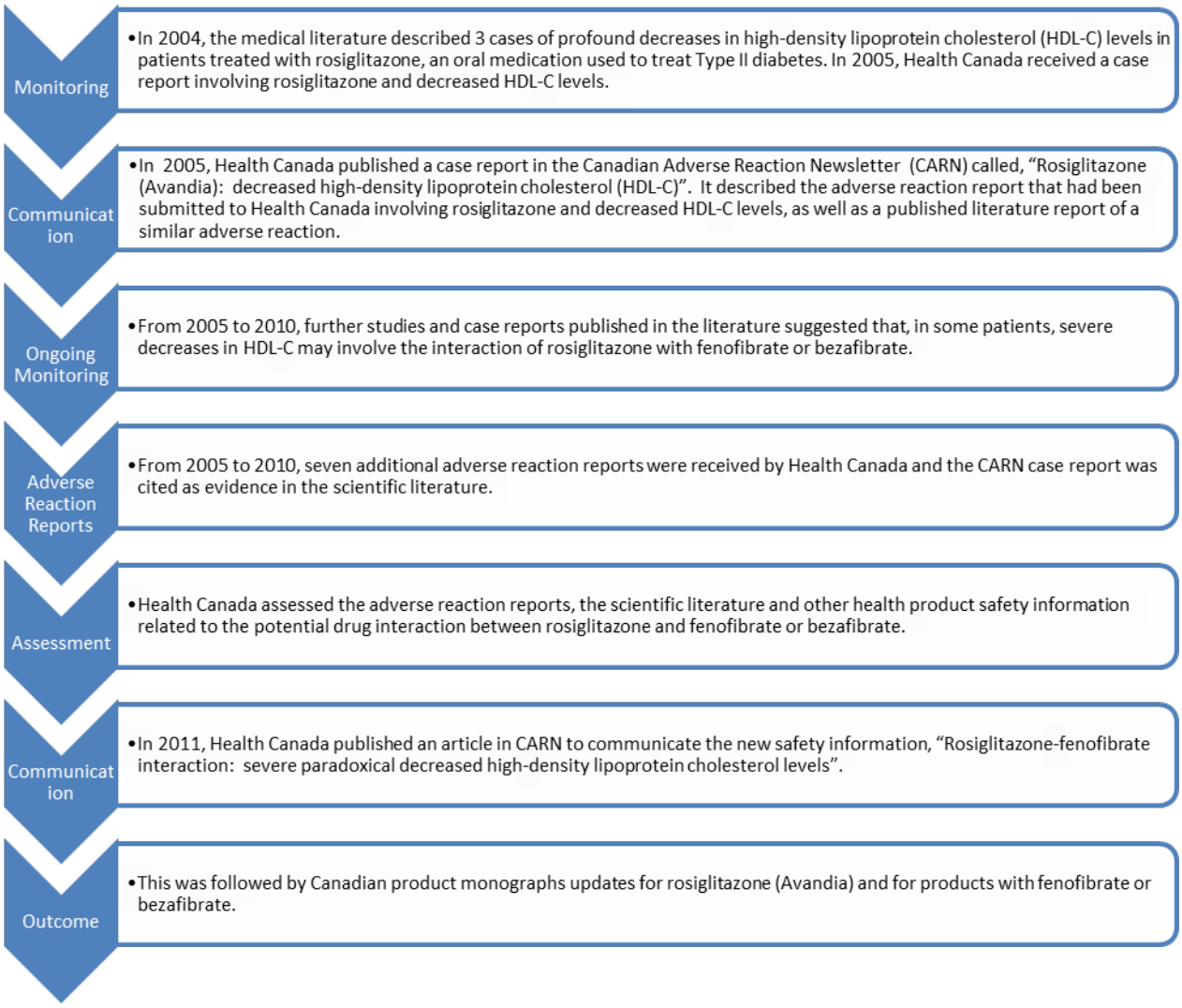
Both regulatory and non-regulatory approaches will be aimed at improving the quality and increasing the quantity of serious ADR/MDI reports, to enable a better understanding of the benefits and harms of therapeutic products[ii]. Improving the knowledge base on product safety will empower Canadians along with their health care providers to make better, more informed decisions regarding their medical treatment and support overall patient safety.

B - Introduction

Therapeutic products, such as drugs and medical devices, can save lives, reduce suffering and improve the lives of Canadians. However, these products can cause serious adverse events and Canadians can be hospitalized as a result of these events. This is a public health concern resulting in significant costs to the health care system as well as individual impacts to Canadians. Health Canada's monitoring of therapeutic product safety plays a vital role in public health and patient safety, providing health care providers and patients with the most up-to-date knowledge on product safety so as to prevent and mitigate ADRs and MDIs.

Like all global therapeutic product regulators, Health Canada recognizes that there are limitations in our understanding of the benefits and harms of a product even after a product has been approved for marketing. It is generally understood that there is a progression of knowledge about drugs and medical devices over their life-cycle that is required to adequately support patient safety. Increasing this knowledge reduces the uncertainty associated with the real-world benefits and harms of a product which may not be evident during the clinical trial/ investigational testing phases, and can ultimately lead to improved health outcomes for Canadians. The product monograph (drugs)/instructions for use (devices) is the basis of information for health care professionals on how to use the therapeutic product safely and effectively. As more knowledge and experience are gained, the safety information in the product labelling is modified and improved. Health Canada builds this post-market safety knowledge, which is integral to effective clinical use, from several data sources, including ADR and MDI reports; by reporting ADRs and MDI, patients and healthcare professionals are participating in the system that makes health products safer. Drug safety issues evolve over time; the example below illustrates how one adverse drug reaction report can ultimately lead to a change in the product monograph's safety information.

Figure 1: Example of how a safety issue involving rosiglitazone (Avandia®) evolved over time



Shared Responsibility for Therapeutic Product Safety

The maintenance and improvement of health and safety is understood to be a shared responsibility. In addition to Health Canada and the regulated industry, health professionals, patients, and consumers play an important role in reporting therapeutic product safety related issues. Health care professionals within and outside an institutional setting, consumers and patients will continue to be encouraged to inform Health Canada of any problems they encounter with regulated therapeutic products throughout their lifecycle. Health professionals, patients and consumers all play a role in deciding whether or not to use therapeutic products and it is important that they have access not only to safe and effective products but also to up-to-date information that will increase the chances of accurate diagnosis, successful treatment or prevention as the situation may require.

Manufacturers have the primary responsibility for the safety of any products they sell, manufacture, import or distribute to the Canadian public. They must report promptly, to Health Canada, significant new information relating

to the benefit-risk of their products. In recognition of the important role played by the manufacturers, Health Canada is exploring a feasible and efficient mechanism to provide them with information in the ADR/MDI reports received by health care institutions to consider in their ongoing assessment of their product's safety.

Taking Action on Serious Health Risks

Health Canada has considered and taken action on the recommendations in the 2015 Prescription Pharmaceuticals in Canada Final Report by the Standing Senate Committee on Social Affairs, Science and Technology (2015 Senate Report) to make changes to drug legislation and regulations to improve post-approval monitoring activities so that appropriate action can be taken to protect Canadian patients and consumers. Under the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), the *Food & Drugs Act* was amended to enhance patient safety through improved serious ADR and MDI reporting and post-market tools that strengthen the regulation of a therapeutic product by providing Health Canada with the necessary authorities to take quick and appropriate action when a serious health risk is identified. Upon Royal Assent, many of the key authorities of Vanessa's Law came into force immediately, including the ability to order a recall or direct a labelling change. Other post-market powers necessary to fully implement a life-cycle approach (i.e., an approach to regulating where drugs and devices are evaluated before and after they reach the market) will require changes to current regulations. This approach is being adopted by regulatory agencies worldwide and is based on the recognition that new important information about the safety and effectiveness of a drug or device can only be learned after a product is marketed and as more people use the product. A proposal, Regulations Amending the Food and Drug Regulations (Vanessa's Law), pre-published in the *Canada Gazette*, Part I on April 22, 2017 outlines the initial phase of the implementation and would add to the *Food and Drug Regulations* the ability for the Minister to order the therapeutic authorization holder to conduct an assessment of a drug based on new information, to compile information, conduct tests or studies or monitor experience and provide the Minister with the information or results.

Vanessa's Law also introduced the ability to make regulations respecting the reporting of serious adverse drug reactions and medical device incidents by Canadian health care institutions as follows:

> Section 21.8 of the *Food and Drugs Act*: "A prescribed health care institution shall provide the Minister, within the prescribed time and in the prescribed manner, with prescribed information that is in its control about a serious adverse drug reaction that involves a therapeutic product or a medical device incident that involves a therapeutic product."

This requirement is intended to improve the reporting of these types of events and enable more timely identification and communication of emerging safety issues associated with the use of drugs and medical devices. The regulatory changes will define the applicable health care institutions, the data to be provided, and when it must be provided to Health Canada. In drafting the regulatory proposals in this discussion paper that would apply to section 21.8, Health Canada has considered section 30 (1.3) of the *F &DA* and the need to avoid recommending the making of regulations that would impose unnecessary administrative burden on health care institutions*:*

> Section 30(1.3): "Before recommending to the Governor in Council that a regulation be made ... the Minister shall take into account existing information management systems, with a view to not recommending the making of regulations that would impose unnecessary administrative burdens."

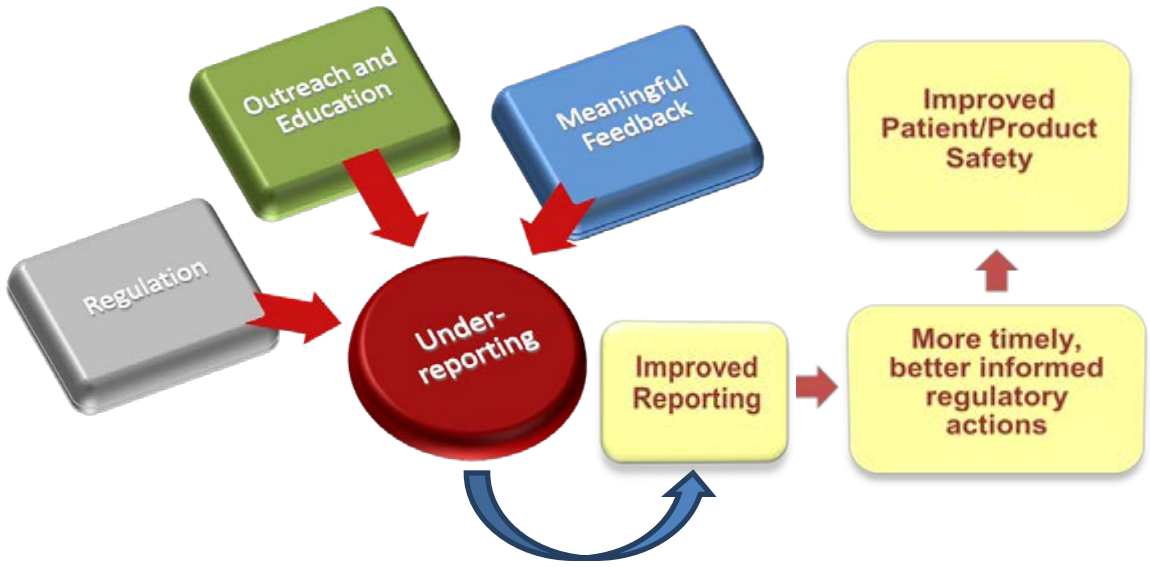
Did you know?

- **Health Canada recently made regulatory amendments respecting the reporting of serious ADRs by health care institutions as part of new regulations allowing the importation of drugs identified for an urgent public health need, when those drugs appear on a list maintained by the Minister of Health.**
- **This separate regulatory amendment, Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need), currently in force, would allow importation of medications for immediate and urgent public health needs that have authorized for sale in the United States, European Union or Switzerland, but that are not yet available in Canada.**
- **Health care institutions authorized by the laws of a province to provide acute care services would be required to report serious ADRs in the use of the drugs on the list.**
- **Some stakeholders may be concerned that these measures imply Health Canada's intention to move forward with earlier implementation of mandatory adverse drug reaction reporting. However the intent is to limit it at this time to drugs on the List.**
- **Relevant stakeholder feedback received on the regulatory amendment to import drugs for an urgent public health need will be used along with input to this paper to inform the design of the regulations for the broader implementation of the mandatory reporting requirement for health care institutions.**

C - Multi-pronged approach to improve reporting

Health Canada's approach to improving the reporting of serious ADR/MDIs will be multi-pronged in nature and include non-regulatory approaches such as outreach and education as well as meaningful feedback to reporting institutions.

Figure 2: Multi-pronged approach to improve reporting



Outreach and Education

It is envisaged that educational efforts will be introduced in advance of new regulatory requirements with a focus on raising awareness on what constitutes a serious ADR and MDI, the types of events to be reported and the role that each piece of information plays in contributing to high-quality reports from which Health Canada can complete analysis to understand if the reaction/incident was caused by the drug/device or other factors. Health Canada and selected patient safety organisations will work together to understand the needs of existing and prospective reporters and explore the most appropriate and efficient strategies to make educational materials widely accessible. Educational efforts focussed on encouraging quality reporting can contribute to a more informed understanding of both the benefits and risks of drugs and devices. Quality reporting improves the knowledge base on product safety; as the information from this improved knowledge base is shared by Health Canada with the health care community and the public, it will empower Canadians along with their health care providers to make better, more informed decisions regarding their medical treatment and support overall patient safety.

We are seeking input (in Section E) on what would constitute useful outreach and education activities for health care professionals and health care institutions.

Meaningful Feedback

During our recent consultations on mandatory reporting, stakeholders commented on the lack of feedback from Health Canada following the reporting of reactions/incidents. Understanding the importance of being transparent and proactively informative about what is done with the reports received, Health Canada is committed to working with the healthcare community to explore mechanisms that will provide reporters with better feedback on various aspects of our collection and analysis of reports including the number and types of events that are occurring and the populations most affected.

When considering the type and quality of feedback stakeholders would like to receive from Health Canada, it is important to be cognizant of the fact that these reports represent only one source of information about a possible safety problem with products. In addition to Canadian ADR/MDI reports, a variety of other data sources contribute to therapeutic product safety monitoring and these include: foreign data such as manufacturer assessment of worldwide safety data and information sharing with foreign regulatory agencies, medical literature and information generated from the Drug Safety and Effectiveness Network (DSEN).

As an ongoing commitment to openness and transparency, Health Canada has taken concrete steps to improve access to timely, useful and relevant therapeutic product safety information and the data sources that contribute to the Department's assessment of real-world safety and effectiveness. The list below includes some examples of Health Canada's activities:

- The Canada Vigilance Adverse Reaction Online Database allows consumers, health professionals, Market Authorization Holders, and the general public to view and search for suspected adverse reactions that have been reported to Health Canada.
- More recently, Health Canada began publishing summaries of its reviews of potential new safety issues; these summaries capture a review of the information received from all the data sources listed above. These summaries complement other safety related information to help prescribers and Canadians make informed decisions about their medication choices. Each summary outlines what was assessed, what was found and what action was taken by Health Canada, if any.
- The Health Product InfoWatch helps Canadians stay informed about emerging safety issues related to drugs and medical devices marketed in Canada. It is published monthly in an easy to read format that includes a monthly recap of health product advisories and summary safety reviews, as well as a growing selection of new health product safety information that is made available before comprehensive benefit/risk evaluations and regulatory decisions can be undertaken.

Given the considerations regarding the role of Canadian reports in therapeutic product safety monitoring and the existing initiatives aimed at making more data and information available to Canadians, **we are seeking input (in Section E) on what would constitute meaningful feedback for health care professionals and health care institutions.**

D - Areas Informing the Development of the Regulations

The five areas that will inform the development of the Regulations are proposals to prescribe, for the purposes of section 21.8 of the *F & DA*: (1) Applicable health care institutions, (2) Types of reportable serious adverse drug reactions and medical device incidents, (3) Applicable therapeutic products, (4) Applicable data fields, and (5) Timelines for reporting. Based on feedback received in consultations, Health Canada has drafted proposals in these five areas and is now seeking stakeholder input on the recommendations proposed. The following key principles were applied in developing each of the proposals. A mandatory reporting approach for health care institutions would:

- Enable the capture of meaningful, quality data;
- Minimize burden on health care institutions and the health care system;
- Where possible, leverage existing processes, systems or technology; and
- Be effectively implemented by Health Canada and be sustainable.

An overarching principle applied to all the proposals is that the burden of the proposed scope of the new requirement would be justified by the value of the information received.

D.1. - Applicable Health Care Institutions

Background

As part of its implementation of a new serious ADR/MDI reporting requirement under Vanessa's Law, Health Canada must define the scope of health care institutions that would be subject to this requirement.

Considerations

Relative to other health care institutions, hospitals may be better positioned to provide more robust data because of their size, multi-disciplinary makeup, wide range of services offered, information systems, or internal support infrastructure e.g., Risk Management and Patient Safety Committees and pharmacy consultation service for potential drug-related health problems. These facilities may already have internal processes and systems in place for monitoring, reporting and preventing adverse events/critical incidents and could therefore respond effectively to a regulatory reporting requirement for serious ADR/MDIs with less direct impact on delivering patient care. Multi-disciplinary collaboration among health professionals within these facilities would reduce the time burden on individual health professionals.

Moreover, to mitigate the impact on the broader health care system, new reporting requirements would best be limited to those settings where patient harm caused by serious ADRs and MDIs is most likely to be treated and key information such as patient outcome can be captured.

Division 1 of the *Food and Drug Regulations* defines a “serious adverse drug reaction” as

> “a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.”

Additionally, based on the Mandatory Problem Reporting requirements in section 59 of the *Medical Devices Regulations*, a "medical device incident" could be described as

> "related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and 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 it to recur."

Based on the use of the words "could do so were it to recur" within the description of medical device incident, "near miss" MDIs are included in our understanding of what the scope of MDI includes.

Proposal

It is proposed that the new regulatory requirements apply to all hospitals that provide acute care services. The rationale is that hospitals that provide acute care services are more likely to treat patients with serious ADRs and MDIs and are therefore well-positioned to make and report these observations. By targeting hospitals that provide acute care services, there is also the potential to capture serious ADR and MDIs that occurred at other institutions through patient transfers. Hospitals that provide acute care are more likely to have the infrastructure to effectively support quality serious ADR and MDI reporting. Outreach and education could be used effectively as tools in hospitals that provide acute care services for influencing health care professional reporting behaviour with respect to both the identification of reportable events and recording the necessary information to ensure quality reporting.

For the purposes of this discussion paper, the Canadian Institute for Health Information (CIHI) definition of 'acute care' will be used. According to CIHI, 'acute care[iii]' is defined to be hospital-based acute inpatient care that provides necessary treatment for a disease or severe episode of illness for a short period of time; the goal is to discharge patients as soon as they are healthy and stable. A hospital that provides acute care services would be the party responsible for forwarding all reports generated at the hospital to Health Canada, regardless of the specific service area in the hospital where the report originated. This does not preclude a hospital's use of regional health authorities or other agents to send reports to Health Canada, on the hospital's behalf. It is reiterated that under the proposed regulatory approach, the responsibility to report to Health Canada rests with the institution and not the individual health care professional.

Various questions were raised in consultations about institutions that provide acute care services but are not hospitals. Some respondents noted that in rural or remote areas, patients may be receiving acute care in smaller nurse-led centres, as opposed to hospitals, as they are the only options for this type of care. As these centres would likely not have the infrastructure to the extent a hospital would have to investigate serious ADRs or MDIs, there would be no requirement to provide serious ADR/ MDI reports under the proposed approach, however, they would be encouraged to continue to report on a voluntary basis.

Alternatives Considered

The alternatives considered include applying the new requirements to:

1. targeted hospitals (a subset of acute care hospitals such as teaching and large community hospitals),
2. long-term care facilities in addition to hospitals that provide acute care, and

3. all health care institutions.

Alternative 1: New requirements apply only to targeted hospitals

Pros:

Targeted hospitals, a subset of acute care hospitals such as teaching and large community hospitals, were considered because CIHI information suggests that among the population of acute care hospitals, certain types of hospitals (such as teaching and large community hospitals) have higher rates of hospitalization because of ADRs due to their size, teaching mandate and complexity of care provided. Serious ADRs/MDIs would likely be treated here and these hospitals may have the infrastructure in place to effectively support reporting. Given the small number of targeted hospitals in Canada, this may facilitate the effective use of outreach and educational tools.

Cons:

However, this alternative may not be broad enough in scope as it would limit the capture of serious ADRs/ MDIs to geographical areas with these types of hospitals.

Alternative 2: Expand the scope of applicable institutions to include long-term care institutions

Pros:

We acknowledge that long-term care institutions could be an appropriate setting for the application of the reporting requirement for the following reasons: Polypharmacy is more likely to occur at long-term care institutions and there may be more time at these types of institutions for health care professionals to observe the ADR and report it. This alternative would capture "near misses" involving MDIs that are detected at long-term care institutions; if there is no transfer of the patient to an acute care hospital, these "near miss" MDIs would not be captured.

Cons:

The key consideration for not extending the scope of institutions to include long-term care institutions is that many of the serious ADR/MDIs that occur in long-term institutions would likely be transferred from these care settings to acute care hospitals for treatment; this is where reports of these events, including important information such as patient outcome is likely to be captured. As the policy intent is to limit the reporting requirement to settings where serious ADR/ MDIs are most likely to be treated as opposed to where they are observed, this argument supports limiting the scope of reporting to acute-care hospitals. Long-term care institutions may likely not have the infrastructure to the extent a hospital would to effectively support reporting. Given the high number of long-term care institutions, it would be difficult to provide effective outreach and education to the large number of institutions included in this alternative.

Alternative 3: Expand the scope of applicable institutions to include all healthcare institutions

Pros:

This alternative is the broadest in scope as, in theory, serious ADR/MDIs from all healthcare institutions would be required to be reported. As this alternative contemplates that anyone in the health care system contribute to ADR/MDI reporting, there is value in the breadth of reports that would be captured here.

Cons:

The main reason for not expanding the scope of institutions to include all health care facilities is that it is not expected that the treatment of most serious ADR/MDIs would occur in healthcare facilities outside of an acute-care hospital and any serious ADR/MDIs observed in these healthcare facilities would likely be transferred to an acute-care hospital for treatment and this is where reports of these events would be captured. Healthcare facilities outside of acute-care hospitals may not have the infrastructure to the extent that hospitals would to investigate and report serious ADRs/MDIs. As this alternative was the broadest in scope, it would be even more challenging to rely on outreach and education as effective tools for influencing reporting behaviour.

Summary of Proposal for Applicable Health Care Institutions:

- **It is proposed that the mandatory reporting requirements apply to all hospitals that provide acute care services.**
- **The key consideration for this proposal is that hospitals that provide acute care services are most likely to treat patients with serious ADRs and MDIs and are therefore well-positioned to make and report these observations.**
- **By targeting hospitals that provide acute care services, there is also the potential to capture serious ADR and MDIs that occurred from other institutions through patient transfers.**
- **Hospitals that provide acute care are more likely to have the infrastructure to effectively support quality serious ADR and MDI reporting.**
- **Outreach and education could be used effectively as tools in hospitals that provide acute care services for influencing health care professional reporting behaviour with respect to both the identification of reportable events and recording the necessary information to ensure quality reporting.**

Consultation Questions

1. **Please explain why you support/ do not support Health Canada's proposal to apply mandatory reporting requirements to all hospitals that provide acute care services?**
2. **A separate regulatory amendment, the Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need) describes prescribed health care institutions to be health care institutions authorized by the laws of a province to provide acute care services. Does this description enable health care institutions to clearly identify themselves as one of the prescribed health care institutions? If it could be improved, please explain how.**

D.2. - Types of Reportable Serious Adverse Drug Reactions and Medical Device Incidents

Background

The scope of reportable serious adverse drug reactions and medical device incidents must be defined in regulations. The mandatory reporting requirement under Vanessa's Law was intended to increase the number of serious ADR and MDI reports submitted by health care institutions to Health Canada so as to broaden the evidence base that Health Canada uses to identify a new safety signal[iv] or confirm an existing safety signal generated from other data sources. Although an increase in reports would not necessarily lead to an increase in the number of new signals, it could lead to earlier validation or confirmation of a safety issue impacting the safe use of a therapeutic product by the Canadian population.

Considerations

When considering the options on the types of reportable serious ADRs and MDIs, it is necessary to balance the need to maximize the scope of reportable events aimed at improving health product safety with the need to minimize any unnecessary burden on health care institutions in providing reports. It is also important to acknowledge the prioritization of the reporting of some types of serious ADR/MDI events that may have higher contribution to product safety monitoring.
In consultations to date stakeholders raised the issue that it can be difficult to establish causality in order to determine if a serious ADR/ MDI is reportable. As with all reporters, the information to be submitted only needs to represent the suspicions of the reporter and there is no need to establish causality in order to send a serious ADR/MDI report to Health Canada.

Proposal:

It is proposed that the prescribed health care institutions be required to only provide Health Canada with information about a subset of serious ADRs that is in their control. Based on previous feedback received on the type of reportable serious ADRs/MDIs, the subset proposed for serious ADRs would be all serious unexpected ADRs in its control. The rationale for this approach is that it focuses on information that would have the highest potential to add to the understanding of real world performance of drugs. As no subsets were proposed for MDIs in the feedback received, it is proposed that health care institutions are required to provide Health Canada with information about all MDIs[v] in its control; this would include MDIs with the potential to cause harm if it were to recur.

Documented information about a serious ADR/MDIs in the control of an institution could include:

(i.) a separate reporting form (online or hard copy) completed by a healthcare professional, or
(ii.) a serious ADR/MDI that is identified by a health care professional in a patient's clinical record.

In both (i.) and (ii.) health care institutions will be expected to set up a process or system to ensure that documented information about serious ADRs/ MDIs are identified to be submitted to Health Canada.

A serious unexpected ADR is defined in Division 1 of the *Food and Drug Regulations* to be "a serious ADR that is not identified in nature, severity or frequency in the risk information set out on the label of the drug". For clarity,

Health Canada interprets label in the definition to refer to a Canadian product monograph. It is acknowledged that the subset proposed may generate additional burden on health care institutions such as the technical burden on health care institutions to confirm "unexpectedness". However, this consideration has to be balanced with the fact that this approach focuses on reports that have the highest potential to add to the understanding of real world performance of drugs.

The proposed regulatory approach would allow for the judgement of healthcare professionals to identify what are believed to fall within the scope of serious unexpected ADRs. Outreach and education will be used to clarify to health care professionals what types of ADRs would fall within the scope of serious unexpected ADR.

Example of an ADR that would fall within the subset of serious unexpected ADR:

As of January 31, 2015, Health Canada received 12 reports of suicidality suspected of being associated with the use of finasteride for both benign hyperplasia and male-pattern baldness and conducted a safety assessment. The potential link between finasteride and suicidality had also been reported in the medical literature, including the persistence of symptoms after treatment discontinuation. However, because the evidence was limited at the time the assessment was completed and was insufficient to confirm a link, a change to the product monograph could not be made at that time. Health Canada communicated its concern about these adverse reaction reports in its publication, Health Product InfoWatch, to raise awareness among health care professionals and to stimulate reporting. **As this is a serious ADR that has not been previously identified in relation to finasteride, it is an example of a serious unexpected ADR report that Health Canada would require reporting on.**

Alternative Considered: All suspected serious ADR and MDIs are to be reported by health care institutions.

An alternative considered was to require health care institutions to report to Health Canada all suspected serious ADR and MDIs in their control.

Pros:

This alternative maximizes the scope of reportable events to include all suspected serious ADRs and MDIs and aims to help improve health product safety.

Cons:

This option would likely capture not only new suspected serious ADRs and MDIs but also commonly "known" ADRs that may not enhance health monitoring at a population level and serve the purpose of improving the knowledge base for drug safety. For ADRs, the alternative does not focus on reports that have the highest potential to add to the understanding of the real world performance of drugs. Earlier feedback received identified that the disadvantage with this alternative is the large volume of reports that would be generated by it; this would result in a significant administrative burden on institutions.

Summary of Proposal for Scope of Reportable Serious ADRs/ MDIs:

- **For ADRs, it is proposed that health care institutions be required to provide Health Canada with only serious unexpected ADRs in their control.**
- **The rationale for this approach for ADRs is that it focuses on reports that have the highest potential to add to the understanding of real world performance of drugs.**
- **For MDIs, it is proposed that health care institutions be required to provide Health Canada with all MDIs in their control**; **this would include MDIs with the potential to cause harm if it were to recur.**

Consultation Questions

1. **Please explain why you agree/ disagree with the Health Canada's proposal to limit the reporting of serious ADRs to serious unexpected ADRs that are in the control of the institution.**
2. **In order to make the determination of "unexpectedness" of a serious ADR easier for institutions to make, please describe any considerations that Health Canada may want to take into account.**
3. **Please explain why you agree/ disagree with Health Canada's proposal that health care institutions be required to provide Health Canada with all MDIs in their control?**

D.3. - Applicable Therapeutic Products

Background

This new reporting requirement applies specifically to adverse events that involve therapeutic products. Vanessa's Law defines "therapeutic product" as "a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the *Natural Health Products Regulations*." Therefore, the requirement for reporting by health care institutions does not apply to natural health products.

Considerations

Health Canada interprets "drug" under the *Food and Drugs Act* to include pharmaceuticals (prescription and non-prescription), biologics (including vaccines), radiopharmaceuticals, cells, tissues and organs (CTO), blood and blood components, semen, and disinfectants. While new reporting requirements for adverse drug reactions would apply ideally to all types of drugs in order to maximize the amount of safety data provided, it would be excessive to apply these requirements in those cases where a product type is already subject to adverse reaction reporting requirements by either health facilities or health care professionals. As the mandatory reporting of adverse reactions to CTO, blood and blood components and semen by certain types of health facilities is already contained in other federal regulations, it has been recommended to exclude these product types from the new reporting requirements under Vanessa's Law. Drugs that are defined in the *Food and Drug Regulations* as clinical trial and Special Access Program (SAP) have separate ADR reporting schemes in place; thus, it has been recommended to exclude these types of drugs from the new reporting requirements. With respect to vaccines, as several provincial and territorial jurisdictions have mandatory reporting regimes in place for health professionals to report adverse events following immunization (AEFI) and established AEFI networks to monitor vaccine safety, it is recommended that vaccines be exempted from the scope of the reporting requirements proposed here.

Proposal

It is proposed that the scope of these mandatory reporting requirements be limited to information about pharmaceuticals (prescription and non-prescription), biologic drugs (excluding vaccines), radiopharmaceuticals, disinfectants and medical devices. For the purposes of this document, references to "drugs" are in this limited sense.

Alternative Considered: Targeted Subset of Drugs/ Devices

An alternative considered was to further limit the scope of the mandatory reporting requirements to a subset of products within the list of products captured by the proposal above. The subset of products would be a targeted list of drugs and/or devices. A targeted subset was considered because of feedback received in consultations that reporting requirements should apply only to the highest priority products for safety monitoring. The targeted subset of products would need to be readily identifiable to reporters and responsive to changing safety monitoring priorities.

Two ways of delivering this alternative have been considered: (i) use of a 'black triangle' symbol or (ii) use of an incorporated by reference list.

(i) 'Black triangle' symbol

We have reviewed the recommendation in the 2015 Senate Report to consider other initiatives that have been implemented in key regulatory jurisdictions (eg. United States and European Union). An example of a relevant initiative in the European Union is that drugs requiring enhanced safety oversight must carry a 'black triangle' warning. The purpose of the 'black triangle' symbol is to enable health care professionals and patients to easily identify the products subject to enhanced safety monitoring. The 'black triangle' symbol is intended to highlight the need for extra vigilance on products containing the symbol and to stimulate reporting. Health Canada has considered limiting the applicable therapeutic products to a list of products that would carry a similar type of 'black triangle' symbol, however, preliminary policy analysis has indicated that this initiative may not be feasible in an institutional setting. This being said, Health Canada is engaging in ongoing exploration of the use of the 'black triangle' concept in other reporting settings such as those involving community pharmacies, and patients.

(ii.) 'Incorporated by Reference' List

The second method considered for delivering alternative 1 would be through the use of an "incorporated by reference" (IBR) list. Institutions would be expected to consult this list in order to determine whether the product was within the scope of the reporting requirements. Incorporation by reference means that the list would become part of the Food and Drug Regulations. The benefit of having an IBR list is that rather than needing to amend a regulation to revise the list, the list can be changed as needed, without an amendment to the Regulations. If an 'IBR' list were to be used, the added step of having to check an IBR list before confirming that an event is reportable to Health Canada may increase the workload and administrative burden on health care institutions. In addition, as new products are added to the list, timely communication of the updated products to health care professionals and institutions is a consideration.

Pros :

The benefit of the having a targeted list of drugs/devices is that it allows us to focus on highest priority products for safety monitoring. While all marketed drugs and devices are carefully monitored, some products may be subject to enhanced safety monitoring because, for example, they are new to the market or approved contingent upon the provision of additional information by the manufacturer.

Cons :

While there is some merit in focusing on highest priority products for safety monitoring, this alternative greatly limits the scope of drugs and devices to which the reporting requirement applies. As such, the narrow nature of this alternative may not be sufficient to provide an adequate safety net for all drugs/devices on the market.

Summary of Proposal for Applicable Therapeutic Products	
What's Included	**What's Excluded**
• **Pharmaceuticals (prescription and non-prescription)** • **Biologic Drugs (that are not vaccines)** • **Radiopharmaceuticals** • **Disinfectants** • **Medical Devices**	• **Natural Health Products** • **Cells, Tissues, Organs (CTO)** • **Blood and Blood Components** • **Semen** • **Preventative Vaccines** • **Clinical Trial/ Special Access Program (SAP) drugs** • **Drugs on Urgent Public Health Need List**[vi]

Consultation Questions

1. **Please explain why you support/ do not support Health Canada's proposal to limit the scope of mandatory reporting to information about pharmaceuticals (prescription and non-prescription), biologic drugs (excluding vaccines), radiopharmaceuticals, disinfectants and medical devices?**
2. **Please explain why you support/ do not support the alternative suggested which would involve limiting the reporting requirements to a subset of the products in Health Canada's proposal?**

D.4. - Applicable Data Fields

Background

As part of its implementation of the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), Health Canada needs to define the prescribed information data fields required when Canadian health care institutions report serious ADRs and MDIs. Within the context of its current reporting programs, Health Canada has established a comprehensive list of data elements that can be captured for both ADRs/ MDIs in Appendices B and C. In consultations, many respondents commented that, because much of this information may not necessarily be available or readily accessible, it would not be possible for them to provide all or even most of these data elements. Health Canada was encouraged to identify a mandatory subset of only critical data fields that would support the identification and validation of a safety issue.

Considerations

Prescribed information requirements defined in regulations would effectively screen out the reports that are not sufficiently complete. The adoption of a higher number of prescribed information requirements could improve the quality of reports received which would better support product safety monitoring activities. However, a higher number of prescribed information requirements could potentially lead to fewer reports submitted by institutions to Health Canada than that which would otherwise be provided with a lower threshold.

Proposal

It is proposed that the Regulations define both a minimum set of data fields and a set of additional data fields to be 'required to be completed, if the information is known' to be provided to Health Canada within the prescribed time frame. The rationale for the proposed approach is that it has the potential to encourage more complete reports. It is anticipated that requiring the completion of additional data fields, if known, is that this could improve the quality of reports received which would better support product safety monitoring activities.

The minimum data fields for serious ADR reporting are as follows:

- the name of the health care institution and the contact information of a representative of that institution;
- the name or the Drug Identification Number of the drug that is suspected of causing the reaction;
- age and gender of patient; and
- a description of the serious unexpected adverse drug reaction.

The minimum data fields for MDI reporting are as follows:

- the name of the health care institution and the contact information of a representative of that institution;
- the device name;
- the manufacturer or importer name; and
- a description of the medical device incident.

Proposed additional data fields for serious ADRs that would be required to be submitted, if the information is known to the institution, includes:

- therapy and reaction dates (dates the drug was started and stopped; and dates the adverse reaction occurred and was resolved);
- relevant tests[vii]/lab data;
- relevant medical history (concomitant disease states);
- concomitant health products; and
- patient outcome.

Proposed additional data fields for MDIs that would be required to be submitted, if the information is known to the institution, includes:

- device identifier (lot/serial number, model/ catalogue number);
- patient outcome; and

- contributing factors to MDI.

In order to address the risk that requiring these additional fields may result in fewer reports submitted by institutions to Health Canada than that which would otherwise be provided with a lower threshold, the additional fields are proposed to be "required for submission to Health Canada if the information is known". The purpose of attaching this instruction to the additional fields is so that if the additional data fields are filled out with nil responses because the information is not known at the time, the nil responses will not lead to fewer serious ADR/MDI reports submitted to Health Canada.

Non-regulatory tools such as the use of guidance documents and outreach/education would be used to encourage the completion of all data fields (as applicable) outlined by Appendices B & C by health care professionals and institutions to ensure the highest quality reports possible. Health Canada acknowledges the feedback already received about the mechanism for submitting serious ADR/MDI reports and is seeking to better understand the processes/ systems that are already in place in institutions and determine whether and how these can be leveraged to facilitate reporting to Health Canada. Health Canada intends to consult separately on how existing information management systems in institutions can be leveraged to facilitate reporting to Health Canada.

Alternative Considered: Only Prescribed Minimum Data Fields for Serious ADR/MDI Reporting

Based on the feedback already received, an alternative considered was to only have the prescribed minimum data fields for serious ADR / MDI reporting in the Regulations.

Pros:

It is likely that the minimum prescribed information requirements would be readily accessible. This alternative may be less administratively burdensome for institutions.

Cons:

A minimum set of prescribed information requirements may not be enough to encourage reports that are sufficiently complete to be of any value for improving product safety through signal detection and validation. A key consideration in preferring the proposed approach to the alternative is that requiring the institution to provide information in the "additional data fields, if the information is known to the institution" in addition to the minimum data fields is that the additional data fields would likely improve the quality of reports received which would better support product vigilance activities.

Table 1

Summary of Proposal for Data Fields • **It is proposed that the Regulations define both a minimum set of data fields and a set of additional data fields to be 'required to be completed, if the information is known' to be provided to Health Canada within the prescribed time frame.** • **The rationale for the proposed approach is that it has the potential to encourage more complete reports.**	
Minimum Required Data Fields for Serious ADRs	**Additional Data Fields for Serious ADRs (Required if known)**
• **the name of the health care institution and the contact information of a representative of that institution;** • **the name or the Drug Identification Number of the drug that is suspected of causing the reaction;** • **age and gender of patient; and** • **a description of the suspected serious unexpected adverse drug reaction.**	• **therapy and reaction dates (dates the drug was started and stopped; and dates the adverse reaction occurred and was resolved);** • **relevant tests[viii]/lab data;** • **relevant medical history (concomitant disease states);** • **concomitant health products; and patient outcome.**
Minimum Required Data Fields for MDIs	**Additional Data Fields for MDIs (Required if known)**
• **the name of the health care institution and the contact information of a representative of that institution;** • **the device name;** • **the manufacturer or importer name; and** • **a description of the medical device incident.**	• **device identifier (lot/serial number, model/ catalogue number);** • **patient outcome; and** • **contributing factors to MDI.**

Consultation Questions:

1. **Please explain why you support/ do not support Health Canada's proposal to require both a minimum set of data fields and a set of additional data fields 'to be completed, if the information is known' to be provided by health care institutions to Health Canada within the prescribed time frame.**
2. **Please provide a contact at the institutional or jurisdictional level to discuss opportunities to leverage current processes and/or systems that are already in place to facilitate reporting to Health Canada.**

D.5. - Timelines for Reporting

Background

As part of its implementation of the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), Health Canada needs to define the prescribed time in which prescribed Canadian health care institutions are required to report serious ADRs and MDIs.

Considerations

In setting an appropriate timeline for the reporting of serious ADRs and MDIs by health care institutions, Health Canada is taking into account the following factors: the timeliness of reporting, the ability of the health care institution to complete reports of good quality, and the burden of the timelines on health care institutions. The time frame chosen needs to meet the objective of timely reporting of suspected safety issues to support Health Canada's early identification of trends and communication of safety issues associated with drugs and medical devices; in other words, the time frame cannot be too long as suspected serious safety issues associated with health products and devices are being reported. The time frame chosen needs to take into consideration the ability of the health care institution to complete reports of good quality - consideration needs to be given to ensuring there is a reasonable amount of time that is provided for the institution to gather the requisite information/elements needed for high quality reports. In setting a time frame for reporting, care must be taken to ensure that no unnecessary administrative burden is imposed on health care institutions.

Appropriate timelines for the reporting of serious ADRs and MDIs by health care institutions should be largely determined by the amount of effort required to review and send a report to Health Canada. Some institutions may require the vetting of details prior to submitting a serious ADR or MDI report, which could involve numerous individuals or departments, such as the involvement of internal risk management or legal reviews. These steps are done to mitigate concerns of professional liability or to confirm that there are no breaches of patient confidentiality. In setting timelines, it is also necessary to consider provincial/territorial legislation on critical medication incident reporting.

It is envisioned that the required timelines would commence when the prescribed information requirements are first documented. An overarching consideration is that a shorter timeline would apply in cases where the suspected serious unexpected ADR or MDI has resulted in the death of a patient.

Proposal

It is proposed that timelines for institutions be set at 30 days for both serious ADR and MDI reporting. The regulatory reporting time clock is considered to start on the day on which the serious ADR/MDI is first documented. The rationale for this proposed timeline is that it sets an appropriate balance between timeliness and report completeness. A 30 day target may allow sufficient time for institutions to provide reports to Health Canada and may better avoid unnecessary burden on health care institutions when reporting serious ADRs/MDIs. It is anticipated that the 30 day timeframe would be proportionate to the respective efforts of health care institutions in completing, validating and vetting reports of acceptable quality.
Alternatives Considered:

Based on the feedback already received regarding appropriate timelines for reporting by institutions, the following three alternatives were considered.

Alternative 1: Align reporting timelines for institutions with reporting timelines for manufacturers[ix].

Pros:

This alternative may meet the objective of timely reporting of suspected safety issues.

Cons:

This alternative may not allow for sufficient time for institutions to provide complete reports to Health Canada. It does not take into consideration the barriers to reporting that are unique to institutions and the additional steps that institutions need to take in order to review and send a report to Health Canada. These additional steps may include the vetting of details by internal risk management prior to submitting a serious ADR or MDI report.

Alternative 2: Set the preliminary reporting timeline to 15 days for the provision of an initial report with a follow-up report to be pro-actively provided by the institutions within 30 days.

Pros:

The benefit of this alternative is that the use of preliminary reporting may better meet the objective of timely reporting of suspected safety issues to Health Canada. At the same time the use of follow-up reports would allow for a reasonable time for health care institutions to provide more complete reports.

Cons:

However, based on Health Canada's current experiences with preliminary and follow-up reporting by market authorization holders, it was felt that the generation of additional reports (a preliminary and follow-up report per serious ADR/ MDI) with this alternative would create administrative burden for both Health Canada and institutions.

Alternative 3: Batching[x] of reports (e.g. quarterly/ semi-annually) sent to Health Canada.

Pros:

A longer time frame may allow institutions to provide complete reports. Batch reporting may be less administratively burdensome for some institutions.

Cons:

After consideration of the feedback received on this alternative, it was felt that batch reporting (e.g. quarterly/ semi-annually) would be unlikely to meet the objective of timely reporting of suspected safety issues to support Health Canada's early identification and communication of safety issues associated with drugs and medical devices.

Summary of Proposal on Timelines

- **It is proposed that timelines for institutions be set at 30 days for both serious ADR and MDI reporting.**
- **The regulatory reporting time clock is considered to start on the day on which the ADR/MDI is first documented.**
- **The rationale for this proposed timeline is that it sets an appropriate balance between timeliness of reporting and report completeness.**
- **A 30 day target may allow sufficient time for institutions to provide reports to Health Canada and may better avoid unnecessary burden on health care institutions when reporting serious ADRs/MDIs. It is anticipated that the 30 day timeframe would be proportionate to the respective efforts of health care institutions in completing, validating and vetting reports of acceptable quality.**

Consultation Questions

1. **The proposal suggests that timelines for institutions be set at 30 days for both serious ADR and MDI reporting? Should the timelines be the same or different for serious ADR and MDI reporting. Should the timelines be 30 days, shorter or longer?**
2. **Given workflow considerations at institutions, is alternative 2 (setting the preliminary reporting timeline to 15 days for the provision of an initial report with a follow-up report to be pro-actively provided by the institutions within 30 days) a reasonable option? Why or why not?**
3. **What are the considerations around a more expedited timeframe for serious ADR/MDIs that have resulted in the death of a patient?**

E - Non Regulatory Approaches to Improve Reporting of Serious ADRs/MDIs.

Outreach and Education

Health Canada's proposed approach to improve reporting will include outreach and education efforts to improve awareness and participation of health professionals who work in health care institutions that are proposed to be subject to the reporting requirement. Health Canada continues to encourage all health professionals to participate in voluntary reporting. It is hoped that these outreach and educational tools will also be useful for the broader reporting community outside of the prescribed health care institutions.

One quality report can be enough evidence to identify a safety problem of clinical significance. However, despite their commitment to product safety and more importantly patient safety, many health professionals are not aware of how to report, what to report, where to report and the significance that a small number of well detailed reports can make to the improved safety and effectiveness of a product. These factors can contribute to underreporting of events that are important to understanding the safety of a drug or medical device once it is used in patient populations with varying medical histories.

Efforts will be made by Health Canada to understand where the awareness and knowledge gaps exist and the most practical strategies for learning. For example, given busy schedules and the diverse work force employed on a shift system, consideration will be given to the development of online learning tools that can be accessed individually or materials that can be delivered internally during previously scheduled learning events. These tools and materials can be developed in a manner that allows learners to move beyond general awareness of reporting to increasing awareness of the most important events from an improved drug and medical device safety perspective through the use of practical examples gained through many years of analysis by Health Canada.

Consultation Questions:

1. **How would you like to receive education tools specific to ADR/MDI reporting? (E.g. In person at an on-site location, online, conferences, other).**
2. **Should outreach and education on ADR/MDI reporting be focussed on certain groups of healthcare professionals (e.g. physicians, pharmacists and nurses) or developed to meet the needs of all professionals working in an institution environment (e.g. healthcare professionals, risk managers, and Patient Safety Coordinators)? Please explain.**
3. **Please list and describe any existing tools/materials that can be revised to include information on the reporting of serious ADR/MDIs to Health Canada.**
4. **How important would education at the professional teaching institutions be? (Very important, somewhat important, not very important, not at all important)**

Meaningful Feedback

Meaningful, targeted feedback is instrumental in building motivation and buy-in with reporting programs. All reporters are looking for some form of feedback that will demonstrate that the effort they have invested in sharing information is making a difference. Outside of an individual acknowledgment letter such as those that are currently provided to voluntary ADR reporters, feedback to every individual reporter is a difficult undertaking. **It is therefore proposed that regular feedback be provided to the broad healthcare community on a more aggregate level to**

describe the numbers and types of events and the population characteristics. Following more detailed assessment by Health Canada, some of these reports will result in regulatory actions such as updates to the product label or enhanced monitoring by the manufacturer and Health Canada. These results will continue to benefit from existing tools such as the posting of Summary Safety Reviews.

Consultation Questions:

1. **Please explain why you support/ do not support Health Canada's proposal to provide aggregate information to the broader health care community about ADR/MDI reports received.**
2. **What would be the most effective way to communicate aggregate safety information to the health care community?**
3. **What other types of feedback would be meaningful to provide to the health care community?**

F - Conclusion

This discussion paper presents proposals for consultation which have been informed by the last 2 years of engagement on this initiative. The alternative options that have been considered and felt to be less satisfactory relative to the proposal are presented for information purposes and to enable respondents to understand the options that have been seriously considered.

Health Canada is seeking responses from all stakeholders on the proposals identified in this consultation paper. Submissions will help inform the design of the regulations as well as Health Canada's proposed approaches on outreach and education and providing meaningful feedback to health care institutions and health care professionals. The consultation is open for a 45 day comment period starting June 28, 2017 until August 11, 2017. All stakeholders are invited to submit their views by email, mail, or by completing our online questionnaire.

Appendix A - Feedback to date (2015 to present)

Comments from the following groups have been considered in drafting this paper:

- British Columbia Ministry of Health
- Alberta Health Services
- Saskatchewan Ministry of Health
- Manitoba Health
- Ontario Ministry of Health
- Ministère de la Santé et des Services sociaux (Québec)
- Eastern Health
- Winnipeg Regional Health Authority
- Trillium Health Partners
- St. Joseph's Health Care London
- New Brunswick Department of Health
- Health PEI
- Nova Scotia Health Authority (NSHA)
- IWK Health Centre (Nova Scotia)
- Newfoundland and Labrador Department of Health and Community Services
- Health and Social Services, Government of Yukon
- Legislation and Communications, Government of the Northwest Territories
- Territorial Health Services, Government of the Northwest Territories
- Nunavut Department of Health
- HealthCareCAN
- The Vancouver Island Health Authority (representing the Western Quality and Patient Safety Group)
- Canadian Patient Safety Institute (CPSI)
- Canadian Medical Association (CMA)
- Canadian Nurses Association (CNA)
- Canadian Pharmacists Association (CPhA)
- Canadian Society of Hospital Pharmacists (CSHP)
- Health Canada First Nations and Inuit Health Branch (FNIHB)
- Corrections Services Canada (CSC)
- Department of National Defence (DND)
- Baxalta Canada Corporation
- BDX
- BIOTECanada
- GS1 Canada
- Hoffmann-La Roche Limited
- Innovative Medicines Canada
- Sanofi
- National Association of Pharmacy Regulatory Authorities (NAPRA)

Appendix B - Adverse reaction reporting data elements

*This is a list of comprehensive data elements that could be captured for ADRs. They may not all be applicable for the purposes of reporting by institutions. Mandatory reporting is not required for all these data elements.

Category	Data Elements
Patient Information	Age
	Sex
	Height
	Weight
	Medical history and other related information (allergies, pregnancy, smoking/alcohol use, liver disease, etc.)
Reporter Information	Name
	Telephone
	Address
	City
	Province/Territory
	Email
	Preferred language
	Organization (if applicable)
	Select one that best describes you (Physician, Pharmacist, Other)
Side Effect (ie. Adverse Drug Reaction)	Recovered after the side effect (Yes, No, Unknown, Recovering)
	Side effect start date
	Side effect end date
	Describe the side effect (timelines, treatment, etc.)
	Seriousness of the side effect (death, life-threatening, admitted to hospital, lengthened hospital stay, disability, birth defect, needed medical attention)
Health Product	Product Name
	Dosage (strength and quantity)
	How the product was taken (e.g. by mouth)
	What was the product prescribed/taken for?
	Strength
	Manufacturer
	Lot #
	DIN #
	Country of purchase (Canada, United States, other)
	How it was purchased/obtained (pharmacy, grocery store, internet, other)
	Product start date
	Product end date
	Frequency
	Did use of the product stop after the side effect appeared?
	If the product was stopped, did the side effect stop?
	Was the product restarted after the side effect stopped?
	If the product was restarted, did the side effect return?

Category	Data Elements
	Likelihood that the product caused the side effect (certain, probably/likely, possibly, not available/unable to assess, unlikely, unrelated)
	Other health products taken at the time of the side effect, excluding treatment (length of use, timelines, etc.)
	Related test/laboratory results

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Appendix C - Medical device incident reporting data elements

*This is a list of comprehensive data elements that could be captured for MDIs. They may not all be applicable for the purposes of mandatory reporting by institutions. Mandatory reporting is not required for all these data elements.

Category	Data Elements
Report Information	Report Type (new, update)
	Report Purpose (hospital mandatory.)
	Reporter File Number
Reporter Information	Reporter Type (health care facility)
	Organization (business name, health care facility)
	Name
	Title
	Address
	City
	Province/State
	Country
	Postal Code
	Telephone
	Email
	Fax
Incident Information	Date of Incident
	Description of Incident
	Identify the type of environment where the incident occurred (hospital, home, nursing home/long term care, outpatient, unknown)
	Incident Contributing Factors (patient/environment)
	Device Contributing Factors
Affected Persons	Relationship of affected person to incident (patient, health care provider, other)
	How was the affected person impacted by the incident? (death, serious injury, potential for death or serious injury, injury, unknown)
	Age (years)
	Gender (male, female, unknown)
	Weight (lbs or kg)
Device Information	Health Canada Case Number
	Device Name (including model name, if applicable)
	Manufacturer's Catalog or Reference Number
	Canadian Device Risk Classification (I, II, III, IV)
	Software Version
	Serial Number
	Global Medical Device Nomenclature (GMDN) Number
	Unique Device Identifier
	Lot/Batch Number
	Is the device a radiation emitting device?
	Was it a single-use device that was reprocessed and reused on a patient?

Category	Data Elements
	Is the device authorized or licensed by Health Canada? (licensed, investigational testing authorization, Special Access authorization, not authorized, not applicable, unknown)
	Licence or Authorization Number
	Is the device available for evaluation?
Manufacturer/Importer Information	Organization Type (manufacturer, importer)
	Business Name
	Company ID (Health Canada assigned number)
	Name
	Title
	Address
	City
	Province/State
	Country
	Postal Code
	Telephone
	Email
	Was the incident reported to this organization?
Investigation and Corrective Actions (as done by the institution)	Investigative Actions and Timeline
	Root Cause
	Corrective Actions

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References

[i] The Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need), currently in force, provides that drugs which are included on the "List of Drugs for an Urgent Public Health Need" have a separate ADR reporting scheme in place as per Division 10 of the *Food and Drug Regulations.*

[ii] For the purposes of this discussion paper, the term therapeutic product refers to drugs and devices.

[iii] Description of 'Acute Care' on CIHI website found at: https://www.cihi.ca/en/types-of-care/hospital-care/acute-care.

[iv] A signal is considered to be the preliminary indication of a product related issue. While the identification of a signal is not by itself the proof of the association of an adverse event to a health product, it triggers the need to further investigate a potential association.

[v] Currently there is no definition of 'medical device incident' in the *Medical Devices Regulations.* There is a description of 'medical device incident' in section 59 of the Medical Devices Regulations which describes a 'medical device incident' to be 'related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and 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 it to recur.'

[vi] The Regulations Amending the Food and Drug Regulations (Importation of Drugs for an Urgent Public Health Need), currently in force, provides that drugs which are included on the "List of Drugs for an Urgent Public Health Need" have a separate ADR reporting scheme in place as per Division 10 of the *Food and Drug Regulations.*

[vii] There is no expectation for further investigation. Relevant tests/ lab data refers to any existing tests/lab data that may have been performed and documented at the time of the ADR documentation.

[viii] There is no expectation for further investigation. Relevant tests/ lab data refers to any existing tests/lab data that may have been performed and documented at the time of the ADR documentation.

[ix] Manufacturers are currently required to report ADRs to Health Canada within 15 days of receiving or becoming aware of this information. Manufacturers are required to report MDIs within 10 days of becoming aware of this information, where the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or within 30 days where the incident could lead to death or a serious deterioration in the state of health of a patient, user or other person, if it were to reoccur.

[x] Batching in this context would mean that rather than sending Health Canada individual serious ADR/MDI reports, the institution would forward Health Canada a set of all serious ADR/MDI reports collected within a time period (quarterly or semi-annually).