ISSUE IDENTIFICATION PAPER

Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Healthcare Institutions

Marketed Health Products Directorate
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1. ISSUE

Prior to implementing a new regulation for healthcare institutions to report serious adverse drug reactions (ADRs) and medical device incidents (MDIs), Health Canada must define:

- which institutions will be required to report;
- what information must be reported; and
- how it must be provided.

To better understand the key issues associated with this regulation, consultations were initiated with:

- the provincial and territorial health ministries;
- national professional organizations; and
- groups that represent the organization and delivery of health care in Canada.

2. PURPOSE

This issue identification paper outlines the comments received to date by Health Canada in its consultations on implementing a reporting requirement for healthcare institutions. This paper is intended to summarize the feedback received with respect to how a new reporting requirement could affect the provincial and territorial healthcare environments. This document serves solely as a background for policy development and does not present options for implementation.

3. BACKGROUND

The reporting of serious ADRs and MDIs are important for managing the risks associated with the use of these therapeutic products[1]. In Canada, reporting is currently mandatory for manufacturers and voluntary for healthcare professionals, patients and consumers. The reports are sent either through the manufacturer or directly to Health Canada. These reports represent one source of information about a possible safety problem with a product. Other sources include safety information received from manufacturers, knowledge shared by other regulatory agencies, and scientific literature.

The *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), makes several amendments to the *Food and Drugs Act* (F&DA). Included is a new requirement for certain healthcare institutions to provide Health Canada with information on serious ADRs and MDIs. This requirement is intended to improve the reporting of ADRs and MDIs, to enable a better understanding of the benefits and harms of marketed health products. Specifically, Vanessa's Law adds two provisions to the F&DA:

[1] For the purpose of this paper, "therapeutic product" means a drug or device or any combination of drugs and devices as defined in Vanessa's Law. It does not include a natural health product within the meaning of the *Natural Health Products Regulations*. Drugs include both prescription and non-prescription pharmaceuticals; biologically-derived products such as vaccines, serums, and blood and blood derived products; cells, tissues and organs; biotechnology products; disinfectants; and radiopharmaceuticals.

> Section 21.8: "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."
>
> 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."

While Vanessa's Law received royal assent in November 2014, changes to both the *Food and Drug Regulations* and the *Medical Devices Regulations* are necessary for this new requirement to come into force. In its choice of regulatory approach, Health Canada will aim to also minimize the operational impact on institutions.

4. CONSULTATION DESIGN

In spring 2015, Health Canada began discussions with provincial and territorial ministries of health and key external stakeholders to gather information that would help inform the design of new regulations. A complete list of the consulted parties is provided in Appendix A.

Health Canada initiated these discussions by meeting with the provincial and territorial ministries of health. The ministry representatives provided their perspectives on this initiative and identified key individuals from within their own jurisdictions to participate in more detailed discussions on key policy issues. Health Canada similarly engaged several national organizations representing various healthcare professions. To facilitate these discussions, the consulted parties were asked to consider several general questions on the following key themes:

- types of applicable institutions:
- types of reportable reactions;
- data fields;
- reporting timelines;
- reporting processes; and
- reporting systems.

Responses were provided to Health Canada in written form and/or verbally, and with varying amount of detail. It is also noted that each respondent did not necessarily comment on every theme.

While this issue identification paper is focussed on the information received to date, Health Canada's consultations on this initiative will continue. The publication of this document also provides the opportunity for other interested Canadians to comment specifically on its contents or on this initiative in general. Instructions on how to participate are provided in section 7.

5. OVERVIEW OF RESPONSES

In general, the responses received indicated that the provincial and territorial reporting environments are highly variable with respect to programs, systems and the ability to accommodate a federal requirement for reporting. The following sections, which are presented in thematic groupings, provide a more detailed overview.

5.1 Challenges to Reporting Adverse Drug Reactions and Medical Device Incidents

Although the new reporting requirement under Vanessa's Law is specific to healthcare institutions, the challenges faced by healthcare professionals when reporting adverse events, including existing workload, the ability to gather sufficient information for reporting, and motivational barriers, remain relevant to this discussion.

5.1.1 Workload

Respondents noted that healthcare professionals face a considerable workload with competing demands. With these constraints, the creation and submission of a report might require the diversion of healthcare resources from direct patient care.

Feedback also indicated that physicians and pharmacists would need to be involved in reporting to confirm events and to gather the additional evidence required to support the submission of a report to Health Canada.

5.1.2 Incomplete Information

Reporters frequently encounter obstacles to gathering the necessary information about a patient or a product that might have led to an adverse drug reaction or medical device incident. Access to a patient's full health record is often not readily available, making it difficult to distinguish the effect of a drug from the underlying condition of a patient. This situation is exacerbated when a patient with an ADR presents to an emergency department.

Respondents noted that the reporting of medical device incidents is made more complicated and challenging by the scope of products that can be involved. These can range from syringes and pumps to ventilators and magnetic resonance imaging machines. For smaller devices, it is difficult to capture events that have occurred elsewhere unless the device accompanies the patient. In addition, identifiers such as serial numbers for single-use and consumable devices are generally indicated on the product packaging, which tends to be discarded prior to use.

Several respondents expressed concerns with the ability to establish a causal relationship between a drug or device and an adverse event, and suggested that it should be sufficient to report based on just a suspicion of causality.

5.1.3 Knowledge and Motivational Barriers

Many respondents identified the need for healthcare professionals to be educated on how to recognize serious ADRs and MDIs and how to properly prepare a report. Various types of educational tools were recommended to accompany the implementation of a new requirement to provide guidance to frontline staff, such as a dedicated webpage, posters and/or pamphlets.

In addition to the challenges already listed, there are potential motivational barriers that could affect the reporting practices of healthcare professionals. It was recommended by several respondents that Health Canada be more transparent with respect to what it does with the information it receives in reports. In particular, how Health Canada assesses reports and makes decisions on specific actions. This knowledge could help impart the reporting community with a greater sense of value from their efforts and brings greater confidence to institutions that their reporting was not to simply comply with legal requirements. It was also proposed that Health Canada provide an acknowledgement:

- that a report was received;
- indication of whether this reaction or incident had already been reported; and
- periodic summaries of reporting trends, such as volume and incident type, for the respective provinces and territories.

5.2 Scope of Applicable Types of Healthcare Institutions

Vanessa's Law refers specifically to "a serious adverse drug reaction… or a medical device incident." The term, "serious adverse drug reaction" is defined in the *Food and Drug Regulations* as involving a physical response that, among other outcomes, leads to hospitalization or the prolongation of hospitalization. Although the *Medical Devices Regulations* do not explicitly define "medical device incident", the criteria listed under the Mandatory Problem Reporting section (s. 59) of these regulations may be used to infer that an MDI would involve a serious deterioration in a patient's state of health. The facilities most likely to treat patients with serious ADRs and MDIs would therefore be those that provide acute care services. Based on this understanding, Health Canada engaged its health partners with the position that reporting would be required by **all healthcare institutions that provide acute care services**.

During the consultations, many respondents advocated for the reporting of ADRs and MDIs across the entire continuum of care, in particular by long-term care facilities. The reporting by other facilities, such as community health centres and home care settings, was also encouraged. Some respondents observed that while only acute care institutions would be subject to mandatory reporting, other types of institutions are still able to report voluntarily, and this should continue to be encouraged by Health Canada.

Some respondents noted that there could be cases where patients receive acute care services in non-acute care settings, such as in rural or remote areas where there are no hospitals and smaller nurse-led centres are the only options for this type of care. Such centres would likely not have the resources,

systems or programs to enable the investigation of serious ADRs or MDIs. Concerns were also expressed about whether the regulation might apply to services that are not acute care in nature yet occur in acute care facilities. These services could include long-term care, palliative care, and outpatient surgical care. The practicality of including emergency care within the scope of the reporting requirement, given the limited access to patient information and the limited time to dedicate to reporting in this setting was questioned by some respondents.

With respect to how "acute care" might be legally defined, there were suggestions to consider the respective definitions of the Canadian Institute for Health Information[2] and/or the World Health Organization (WHO)[3]. One respondent highlighted the broad range in the WHO definition, which includes pre-hospital emergency care, urgent care, and short-term inpatient stabilization. Another respondent stated that a new legal definition should specify the applicable services within an acute care facility. Finally, one respondent cautioned that the definition of "acute care" varies between provinces and that Health Canada would need to strive for consistency with the existing definitions.

5.3 Scope of Reportable Events

The ultimate goal of a new reporting requirement is the improved safety of drugs and medical devices. Accordingly, Health Canada entered into consultations with a position that required the reporting of **all serious adverse drug reactions and medical device incidents**. This scope of reportable events would allow Health Canada to identify new ADRs and MDIs as well as any increase in the frequency of reactions already documented in the approved product information or product monograph. However, it was also recognized that capturing all serious ADRs and MDIs or having a broad scope of reportable events could present a significant operational burden to institutions and discourage reporting.

Several respondents suggested that limiting reporting to serious and unexpected ADRs or clinically significant events could reduce the burden of reporting on institutions and provide more meaningful information. The example of oncology drugs was cited, in which serious ADRs are well-known and expected and it is unlikely that any new knowledge would be gained from the substantial efforts to report these reactions. Some respondents also advocated for the reporting of all serious adverse reactions that are associated with certain new therapeutic products, such as those that have higher associated risks. The idea of targeted reporting, which could focus on specific patient populations or disease states, was also encouraged by some respondents. Regardless of the scope, most respondents highlighted the need for Health Canada to have adequate resources for managing the additional volume of reports.

[2] The Canadian Institute for Health Information states that "hospital-based acute inpatient care… 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."

[3] The *Bulletin of the World Health Organization* 2013;91:386-388 states that "the term *acute care* encompasses a range of clinical health-care functions, including emergency medicine, trauma care, pre-hospital emergency care, acute care surgery, critical care, urgent care and short-term inpatient stabilization."

With regard to medical devices, some respondents recommended that the definition of an MDI be revised to be based on the severity and impact of the event and involve only those incidents that result in permanent and irreversible harm to patients. The classification of medical devices as either medical products or medical equipment was also emphasized, with the expectation that reporting numbers would be significantly higher if the scope of all serious MDIs included those involving medical equipment. One respondent asked whether reporting would be required for events associated with contaminated equipment.

Finally, some respondents expressed concern regarding the application of penalties for not reporting in certain cases. For example, cases when a serious event is not reported because it is not recognized by a health professional as drug or device-related or if the onset of the reaction or incident is delayed were questioned.

5.4 Data Fields and Privacy Considerations

Participants were provided with a detailed list of all data elements that can be captured in Health Canada's database of reported ADRs and MDIs. Of those who responded, a large number commented that it would not be possible to provide all or even most of these data elements. Health Canada was encouraged to identify a mandatory subset of only critical data fields. Most concluded that, since information would need to be gathered from multiple sources, reporters would likely be unable to complete all of the data fields immediately after observing an adverse reaction or incident. Respondents noted that for reactions or incidents resulting in admission to an institution, rather than those that occur within an institution, the collection of even minimum information would be impossible in many cases.

Some respondents advised that if ADR and MDI reporting was to be integrated into their existing systems, many new data fields would need to be added. Additionally, it was suggested by several respondents that identifier fields (such as Drug Identification Numbers or Unique Device Identifiers) could be used to automatically populate drug or device details. Although many respondents indicated a preference for electronic reporting, some jurisdictions noted that reporting in many of their regions is still paper-based, and that there should be the ability to provide reports in both paper and electronic form.

With respect to disclosure of this information to Health Canada, there were no concerns noted regarding the federal management of patient information. One respondent observed that the Canada Vigilance Adverse Reaction Monitoring Program has policies currently in place to ensure that patient-based information is protected as personal information under the *Privacy Act*. However, the need for jurisdictions to complete Privacy Impact Assessments prior to releasing information was identified.

Many respondents insisted on the de-identification of patient information reported to Health Canada. Some respondents also indicated that their jurisdictions extend privacy protection to reporters, in cases where clinicians who report prefer to remain anonymous.

5.5 Reporting Policies and Processes

Through engagement of its health partners, Health Canada wanted to explore if existing policies and processes at the provincial and territorial level could be leveraged or expanded to accommodate the mandatory reporting of serious ADRs and MDIs by healthcare institutions.

The consultations found that several provinces currently have legislation for the mandatory reporting of critical incidents[4] involving drugs and medical devices. In addition, most of the remaining jurisdictions confirmed that critical incidents are reported voluntarily. While critical incident reporting can include the reporting of medical device incidents, it does not necessarily capture ADRs. Most respondents outlined their respective processes for reporting critical incidents. These generally involve reporting by the institution to the respective Ministry of Health or a party acting on its behalf, either directly or through a regional health authority.

Most provincial and territorial respondents confirmed that their respective jurisdictions have policies in place to encourage the reporting of ADRs and MDIs to Health Canada. Only one formal process for reporting ADRs to manufacturers was identified. Some jurisdictions have policies or protocols to report serious MDIs to the manufacturer, while others indicated that manufacturers have occasionally been consulted on whether similar reports might exist.

Several respondents noted that since the reporting requirement under Vanessa's Law focuses on healthcare institutions rather than healthcare professionals, the roles in the reporting process would need to be clarified. Questions were raised specifically about who would be responsible for providing the reports to Health Canada on behalf of an institution.

For those provincial and territorial jurisdictions with reporting policies and processes currently in place, a number of respondents confirmed that these could potentially be evolved to meet the new requirements. There were, however, still some concerns about potential duplication and excess work for institutions that could result from a new federal requirement.

5.6 Information Management Systems for Reporting

With these consultations, Health Canada was interested in exploring the feasibility of expanding critical incident reporting systems to help enable the implementation of a new reporting requirement. Overall, the consultations found a large variance across the jurisdictions with regard to existing critical incident reporting systems and their respective capacities to integrate ADR and MDI reporting. At this time, there is no single standardized system.

[4] A *critical incident* is defined by the Institute for Safe Medication Practices Canada as "an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence."

Several respondents indicated that no reporting systems currently exist in their respective jurisdictions, and that reports on ADRs and MDIs are often prepared by a paper-based process. These respondents suggested that a new regulation should allow for reporting in both paper and electronic formats.

One province noted that it was pilot testing the addition of an ADR reporting module to its existing critical incident reporting system. Two other jurisdictions commented that their critical incident systems potentially could be modified to accommodate reporting requirements for ADRs. Other information received suggested that although medical device incidents were within the scope of events currently captured by an existing provincial system, the different nature of ADR reporting would prevent the ability to evolve the system to meet Health Canada's requirements. One province noted that healthcare institutions were reporting medication events required by provincial legislation through a third party developed and administered reporting system and that potentially consideration could be given to evolving this system to capture information required by Vanessa's Law.

Three provinces responded that their existing provincial systems included medical device incident reporting, although the systems do not capture the same data fields that are used by Health Canada. Several respondents noted that medical device incidents are reported through the Canadian Medical Devices Sentinel Network (CMDSNet).

Many respondents identified the need for more accessible reporting systems and user-friendly interfaces. Some respondents advocated for integrated reporting systems, in which existing patient information could be extracted to complete an ADR or MDI report. It was similarly noted that, where there are multiple reporting requirements, system integration would avoid the redundancy of reporting into multiple systems. One respondent added that to facilitate the reporting of ADRs or MDIs, systems should be flexible enough to add new information as it becomes available. Health Canada also sought to confirm the extent to which electronic health records (EHRs) could be used to gather information on serious ADRs and MDIs. Many respondents noted at present, access to electronic health records is limited. One respondent quoted a survey that found less than 50% of hospital pharmacists with access to EHRs. In addition, no jurisdictions have integrated critical incident reporting system and patient EHRs.

5.7 Timelines for Reporting

The timely reporting of suspected safety issues would support Health Canada's early identification and communication of safety issues associated with drugs and medical devices. However, most respondents observed that timeliness and completeness could be competing objectives. The amount of information required in regulation (that is, the number and type of data elements) could affect the time required to complete a report. As noted in section 5.1, there can be significant challenges for a reporter to gather information on a patient and/or the therapeutic product in question, including workloads, access to information, and internal processes. Respondents observed that shift work and staff rotations of healthcare professionals, reduced staffing at night and on weekends, and patient transfers would affect the timeliness of data collection. Several respondents also suggested that ADR reports should not be completed until after it has been confirmed that an ADR has occurred. Some institutions also noted that

the vetting of details prior to submitting an ADR or MDI report may involve numerous individuals or departments, such as the involvement of internal risk management or legal reviews. These steps could be needed to mitigate concerns of professional liability or to confirm that there are no breaches of patient confidentiality.

It was also observed that MDI reporting often involves many more groups within an institution than are typically required for ADR reporting. The support of manufacturers and/or vendors when identifying an MDI and preparing a report, was another consideration.

Given these limitations, several respondents recommended that a new regulatory requirement should focus on more immediate reporting of preliminary information, with an ability to submit additional details in a follow-up report to better describe the reaction or incident.

Some respondents observed that paper-based reports require a greater amount of time to complete than electronic reports since automated data entry is not possible with paper-based reporting. It was also suggested that integration with existing incident reporting systems would be advantageous, as a separate report would not need to be created and sent to Health Canada.

6. NEXT STEPS

With the publication of this issue identification paper, Health Canada will proceed in its analysis of the key policy considerations (such as types of applicable institutions, types of reportable reactions, required data fields, and reporting timelines) for implementing a new reporting requirement for healthcare institutions. . The information gathered through consultations, including the comments received on this issue identification paper, will inform this analysis.

7. HOW TO GET INVOLVED

Health Canada is seeking general feedback of interested parties on the issues identified in this paper or on this initiative in general.

This consultation is open for a 60-day comment period starting **April 26, 2016** until **June 24, 2016**.

Interested in our other consultations? Sign up and stay informed about topics that matter to you.

Please submit your comments via e-mail, fax or by mail.

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APPENDIX A

The following groups participated in consultation discussions and provided comments on this initiative:

- 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 (Province de Québec)
- 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)