Responses from the Canadian Society of Hospital Pharmacists to Questions related to Mandatory Reporting of Adverse Drug Reactions and Medical Device Incidents by Provincial and Territorial Healthcare Institutions

Questions related to Types of Reportable Events:

1. What could be the operational impacts of reporting all serious adverse drug reactions and medical device incidents?

   - The Canadian Society of Hospital Pharmacists very much appreciates that Health Canada envisions to operationalize the proposed new legislation by making full use of existing information management systems to collect “prescribed information” about serious adverse drug reactions from prescribed health care institutions. However, existing systems are limited and this information is not currently coded in health records.

   - The reporting of all serious adverse drug reactions and medical device incidents will impose a significant operational burden on prescribed health care institutions, namely on front-line health care professionals and on health information management technicians and related workers.

   - Mandatory reporting, by the prescribed health care institutions, of all prescribed information on serious adverse drug reactions and medical device incidents, within a prescribed time and in a prescribed manner, will place considerable strain on the pharmacists, physicians, nurses and other health professionals who work in these institutions. The requirement to report all serious adverse drug reactions will add to the already heavy workloads of Canadian health care professionals, which is often compounded by labour shortages.

   - The workload related to mandatory reporting of all serious adverse drug reactions by the prescribed health care institutions will have a negative impact on budget and quality of care to patients, and thus on fulfilling the health care mandate and public purse of provinces and territories. Without additional resources, human and financial, institutions will be required to divert personnel from direct patient care to the reporting of prescribed information on all serious adverse drug reactions in order to comply with the regulations. The Canada Health Transfer payments from the federal government to provinces and territories should be adjusted to address allocation of the supplemental funding necessary for the prescribed institutions to meet the requirements of the regulations. Otherwise, the regulations would set these institutions for failure to comply with the Act.

   - Furthermore assessing the causality of serious adverse drug reactions by using of existing information management systems will be very challenging since there may be a number of active conditions being treated with a number of medications in any affected patient. Therefore it can be difficult to determine if a serious clinical reaction is attributable to one particular drug amongst all others or to the deterioration in the patient’s primary condition. The conclusion is often based on clinical judgment alone, yet studies have shown that the assessment based on judgment often vary greatly between clinicians.

2. Do you have any other recommendations with regard to the scope of reportable events? Please explain.

   - The reporting of all serious adverse drug reactions will create an avalanche of data that will make sieving through and finding the critical information within that data more difficult and
more time-consuming. Pharmacists and physicians are aware of known serious adverse reactions and expect their potential occurrence as an extension of the drug’s therapeutic effect. These risks are managed and monitored accordingly. It is known, for example, that patients who receive warfarin – a commonly used blood thinner – may experience an increased risk of serious hemorrhage (bleeding) or that patients undergoing chemotherapy may experience bone marrow suppression (low blood cell counts). Reporting on such well known and expected serious adverse reactions to medications would contribute little to the overall body of knowledge and better management of patients. The Canadian Society of Hospital Pharmacists calls for a more focused reporting that specifically targets new (unexpected) serious adverse reactions for long-market select therapeutic products and all serious adverse reactions for new select products. Focusing on these two types of adverse reactions will provide Health Canada, health care professionals and consumers with quality information they can use, and allow to identify and respond to emerging risks more quickly. Regardless of the scope of reportable reactions, provisions should be made to ensure Health Canada is adequately resourced to handle the influx of reports.

- An expanded education and awareness program targeting health care professionals and students should be designed to reduce or eliminate many of the motivational barriers to the reporting of adverse drug reactions, such as the fear of negative feedback or legal action, questioning the purpose and usefulness of reporting, or the desire to publish findings independently. The awareness communication should include the purpose of the data collection from a quality improvement and patient care outcomes perspective and the process by which the findings will be shared with relevant stakeholders (including healthcare providers, the public, pharmaceutical manufacturers) and how it will be used to improve patient safety. Without a thorough lack of understanding of the value of reporting there is a risk of avoidance and non-compliance with reporting requirements.

Questions related to Applicable Healthcare Institutions:

1. What are your thoughts on Health Canada’s proposed approach to only apply this requirement to all institutions that provide acute care services? Please explain.

   What considerations would you anticipate in establishing a federal definition of “acute care”?

   - Reactions occurring in the acute care setting represent only the tip of the iceberg. For example, a medication-related death in the community might involve solely the coroner and never be reported to Health Canada.

   - The definition of “acute care” varies between provinces. Furthermore the following definition of “hospital-based acute inpatient care” from the Canadian Institute for Health Information does not help in determining the prescribed institution: “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.”

   - How about free-standing emergency centres that are structurally separate and distinct from an acute hospital and provide emergency care? Would the requirement apply to these centres?

   - The regulations should clearly stipulate if a reaction that occurs in the community and leads to hospitalization is reportable by the acute care institution.
• Adverse drug reactions initiated in non-acute healthcare facilities may lead to acute care admissions. There would be value to understanding the contributing factors. One could argue that long-term care facilities might be a better setting for application of the requirement:
  o vulnerable, polymedicated population;
  o more time to observe evolution of the reaction and to report it.

2. Within these institutions, are there different considerations for medical device incident reporting and adverse drug reaction reporting? Considerations could include who would be responsible for reporting, when they would report, how reporting is done, etc.

• This question implies that the burden of reporting falls to individual healthcare workers, not reporting by the institutions in accordance with article 21.8 of the Food and Drugs Act as amended by Vanessa’s Law.

• Incident reporting on medical device might involve many more groups than reporting of drug reactions, e.g., materials management, biomedical engineering, and clinical practitioners. Furthermore, while drug use is overseen by a hospital pharmacy and therapeutics committee, typically no institutional committee oversees the use of medical devices.

Questions related to Data Fields for Reporting:

1. With regard to the attached data fields for reporting, do you foresee any challenges in completing any of the fields giving consideration to your existing or developing reporting capacity (e.g. paper reporting, electronic health record)?

• The current reporting of individual serious adverse drug reactions to the Canada Vigilance Program continues to be cumbersome. For example the online reporting could be accelerated by grouping the mandatory fields on the first screen, with a note at the bottom encouraging the reporter to continue onto the following sections to complete the optional items. In addition the online reporting should make use of contemporary technology, such as an app designed for mobile devices. Healthcare professionals need a more accessible and user-friendly platform to report individual serious adverse drug reactions.

• The process needs to be simple and straightforward enough to not discourage reporting. The time commitment to report a single reaction with the level of details expected from the attached data fields is daunting and can be as long as 30-60 minutes. The prescribed information should be narrowed down to critical data fields, which, one could argue, are simply the patient’s age and sex, the drug or device name, and the reaction or incident. Once a sentinel reaction or incident has been identified, the Minister can issue an order for further details.

• Although Vanessa’s Law makes provision for the Minister taking “into account existing information management systems, with a view to not recommending the making of regulations that would impose unnecessary administrative burdens”, it should be recognized at the outset that all of the data to glean information in order to complete the attached fields about a specific reaction are not currently coded in the health record.

• For reactions that occurred prior to admission to the institution, the collection of information on many data fields would be much more involved, e.g., manufacturer, lot number, product start date, and other health products taken at the time of the reaction.
2. Does the disclosure to Health Canada of any of these fields present privacy concerns for your jurisdiction? Please elaborate.

- Even though there is no field for patient name, other data fields can allow identification of patients.
- Some devices (e.g., pacemakers) are patient-specific (i.e., unique device identifier).
- The public reporting of the reactions and incidents should be in an aggregated format and not specify the reporting institutions.

Questions related to Reporting Systems and Programs:

1. Does your province or territory have information management systems, such as critical incident reporting or electronic medical records, that currently capture adverse drug reactions and medical device incidents? If not, could these systems be adapted to capture adverse drug reactions and medical device incidents?

- Current coding presents challenges in using an electronic medical record to report adverse drug reactions.
  - A pilot project is currently under development in Vancouver to explore the feasibility of an integrated electronic reporting system that would allow reporters to chart in the electronic health record and automatically feed to Health Canada and PharmaNet.

- Some provinces have access to an information management system that accommodates reporting of adverse drug reactions and medical device incidents which are then reported to Health Canada. Other jurisdictions rely on extracting this information from either critical incident reporting systems or health records.

- Critical incident reporting systems are not intended specifically for the reporting of serious adverse drug reactions (i.e., drug toxicity), but rather to report and learn about clinically serious adverse events (i.e., patient safety events, near misses and hazards = medication errors). Although some adverse drug reactions when documented prior to the administration of the responsible drug can become adverse events, a first-time adverse drug reaction would be deemed an unpreventable adverse event. Critical incident reporting systems typically stand alone and do not interface with health records. The data in critical incident reporting systems are entered manually.

- In a national survey of hospitals with 50 or more acute care beds, 54% (87/162) of respondents indicated that their hospitals use an electronic health record. It is unknown whether all of the data to complete the attached fields about a specific reaction are currently coded in these electronic medical records.

- The existing information management systems cannot be easily adapted to capture adverse drug reactions and medical device incidents. Making large-scale functional changes to these systems can be cumbersome and compromise the integrity of historical data.

- Electronic health records are not set up for easy data mining. Health Canada is advised to speak with health information management supervisors to learn about the current state of affairs.

2. If more than one system could be applicable for reporting adverse drug reactions and medical device incidents, please elaborate. In addition, please indicate if there is a preferred system.
• The absolutely critical data fields first need to be defined, then the preferred system should be adjusted accordingly.

• Health Canada should facilitate an open architecture approach that enables automatic download of data fields from the healthcare organization incident reporting systems to the Ministry database.

3. What are your current protocols for providing reports of serious adverse drug reactions and medical device incidents to manufacturers?

• Processes vary among health authorities.

Questions related to Reporting Timelines:

1. Please elaborate on the factors that could affect the development of appropriate timelines for mandatory reporting of serious adverse drug reaction and medical device incidents to Health Canada (for example, the steps that would be involved after an event is identified by a reporter within an institution until a report is eventually received by Health Canada.)

   • This question suggests manual reporting rather than electronic reporting. If the reporting is electronic, the report should be received instantaneously by Health Canada as soon as the information about the reaction or the incident is inputted into the institution’s information management system.

   • The information management system should allow to update data fields about a specific reaction or incident as additional information (e.g., end date of adverse drug reaction) becomes available. A long time can elapse between the suspicion of an adverse drug reaction, its confirmation, and its resolution after the discontinuation of the drug. The end date of an incident from a medical device may be more immediate after the removal of the device.

   • The timelines will be dependent on the number and type of data elements to be reported.

   • In some jurisdictions, it is expected that health practitioners report any critical incident (not limited to an adverse drug reaction) within 24 hours of discovery.

Questions related to Value to Healthcare Systems and Institutions:

1. What information would you like to see generated from Health Canada to support an institution’s ability to provide safe and effective care to their patients?

   • Health Canada should periodically report on sentinel reactions and incidents to institutions, such as through the existing summary safety reviews.

   • Institutions and healthcare practitioners should be able to search the database.

2. What groups within your healthcare environments would find value in having access to this information?

   • Public and patients

   • Anyone who is making decisions in the selection and use of drugs and medical devices (e.g., buyers from the purchasing department, healthcare professionals)