CMA's Response to Health Canada's Consultation Questions

Regulatory Framework for the Mandatory Reporting of Adverse Drug Reactions and Medical Device Incidents by Provincial and Territorial Healthcare Institutions

January 20, 2016

ASSOCIATION MÉDICALE CANADIENNE
CANADIAN MEDICAL ASSOCIATION

Helping physicians care for patients
Aider les médecins à prendre soin des patients

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is helping physician care for patients.

On behalf of its more than 80,000 members and the Canadian public, CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 51 national medical organizations.

The Canadian Medical Association (CMA) is pleased to provide this submission in response to Health Canada's consultation document Questions related to Mandatory Reporting of Adverse Drug Reactions and Medical Device Incidents by Provincial and Territorial Healthcare Institutions.

Prescription medication has an important role as part of a high-quality, patient-centred and cost-effective health care system. Prescription medication can prevent serious disease, reduce the need for hospital stays, replace surgical treatment and improve a patient's capacity to function productively in the community. In consideration of this important role, the CMA has developed a substantial body of policy on pharmaceutical issues which includes policy on Canada's post-approval surveillance system for prescription medication.

It is a priority to physicians that all Canadians have access to medically-necessary drugs that are safe, effective, affordable, appropriately prescribed and administered, as part of a comprehensive, patient-centered health care and treatment plan.

The CMA welcomes Health Canada's consultation on the new legislative authority established by Vanessa's Law to implement mandatory reporting of adverse drug reactions (ADR) and medical device incidents by provincial and territorial healthcare institutions. The CMA appreciates all opportunities to work with governments, health care professionals and the public in strengthening Canada's post-approval surveillance system and ensuring that the prescription drugs Canadians receive are safe and effective.

The CMA's submission is organized in three main sections. In the first section, the CMA's concerns with the current ADR reporting system are identified as critical context for this regulatory development process. The second section provides an overview of the CMA's recommendations on necessary improvements to this system. Finally, the CMA's responses to the questions outlined in Health Canada's discussion document are presented in the third section.

Part 1: Context of CMA's Recommendations

The CMA shares the position that robust accountability and transparency are important elements of Canada's legislative framework governing the post-market surveillance and response system for prescription pharmaceuticals. From the CMA's perspective, the advancement of this new regulatory authority is a unique opportunity for Health Canada to invest in improving this system.

In this context, it is important that the findings of the 2011 report of the Office of the Auditor General of Canada (OAG) are considered as part of the development of this regulatory framework.

Of significant concern, the 2011 OAG audit found that Health Canada "does not take timely action in its regulatory activities" (…). "In particular, the Department is slow to assess potential safety issues. It can take more than two years to complete an assessment of potential safety issues and to provide Canadians with new safety information"[1].

Despite Health Canada's March 2013 update on its efforts to address the OAG recommendations[2] the status of the improvements to the reporting tools, timeliness of information or quality of information provided to practitioners and patients remains unclear.

The CMA strongly supports investment in Canada's post-approval surveillance and response system to ensure that the issues identified by the OAG are addressed as Health Canada advances with the development and implementation of the new regulatory framework to implement the mandatory ADR reporting requirements.

Part 2: CMA's Recommendations to Improve Canada's Surveillance System

When new information is uncovered about a prescription medication, it is imperative that health care professionals are made aware of it as quickly and efficiently as possible. Therefore, post-approval surveillance requires a system for communicating timely, reliable and objective information in a manner that allows them to incorporate it into their everyday practice. Ideally, this communication would report not only the safety problem but also its implications for their patients and practice.

In order to improve the existing surveillance system and contribute to improved patient safety, the CMA recommends that Health Canada establish a reporting model that includes:

- Facilitating reporting of ADRs by physicians and other health care professionals by making the reporting system user-friendly and easy to incorporate into a practitioner's busy schedule. Currently the existing system imposes an unnecessary administrative burden that comes at the expense of time dedicated to patient care.
- Making the reporting process even more efficient by incorporating it directly into the Electronic Health Record systems. Health Canada has improved the process by introducing online reporting, which may have contributed to the significant increase in the number of reports over the past 10 years, but being able to connect patient information with drugs they are taking, reporting of ADRs and safety information would improve care at the front line.
- Augmenting ADR reports with information gathered through other, more

[1] Office of the Auditor General of Canada (2011) Chapter 4 Regulating Pharmaceutical Drugs - Health Canada. 2011 Fall Report of the Auditor General of Canada. Government of Canada. Retrieved from: http://www.oag-bvg.gc.ca/internet/docs/parl_oag_201111_04_e.pdf (pg. 2)

[2] Health Canada (2013) Update and response to OAG recommendations for the regulation of pharmaceutical drugs in Fall 2011. Government of Canada. Retrieved from: http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/oag-bvg-eng.php

systematic means. These could include formal post-market studies of specific drugs, or recruitment of "sentinel" groups of health care professionals who would contract to report ADRs in detail, and who would be committed to assiduous reporting.

- Linking to international post-approval surveillance systems, thus increasing the body of data at researchers' disposal, as well as the capacity for meaningful analysis.

Part 3: Responses to Health Canada's Questions

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

- Vanessa's Law, which received Royal Assent in November 2014, introduces amendments to the Food and Drug Act (FDA), which include the obligation for reporting serious ADRs, as well as serious medical device incidents to Health Canada. The amendment reads:

> 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.[3]

- A serious ADR is already defined by Health Canada 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." Health Canada is proposing a definition for serious medical device incidents 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."
- Although it is difficult to estimate the operational impacts of reporting all serious ADRs, studies carried out in hospitals have attempted to quantify these events; most

[3] Bill C-17, An Act to amend the Food and Drugs Act – Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), (2014, c. 24). Retrieved from http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6767163&File=42#6

would require hospitalization due to the need for specialized resources for assessment, diagnosis and treatment. Some studies show that about 1.5% of patients admitted to acute care hospitals have experienced a serious ADR. With about 3 million hospitalizations a year in Canada, there could be at least 45,000 serious ADRs per year.

- According to the 2011 OAG report, Health Canada received about 33,000 domestic ADR reports in 2010 – and this number is not restricted to the serious ADRs. 82% of these were submitted by industry, and about 5% were submitted by consumers / patients. Health care professionals were responsible for about 13% of the total, or only about 4,000 reports. These were not limited to serious ADRs or to hospital settings.
- Therefore, mandating reporting of serious ADRs would represent a monumental increase in reporting in healthcare institutions, and would require a robust, national reporting system to be put in place to collect and process this information.
- Whether hospital systems have the capacity to support mandatory
- reporting of <u>all</u> serious ADRs will depend on whether reports are simple, integrated into clinical processes, and support clinical decisions at the point of care with the most current drug safety data. This concern is expressed in Vanessa's Law, when it amends the FDA with the following:

  > 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.[3]

- Presently, reporting requires that health care professionals assess, analyze and transcribe information into separate forms or databases. Often ADRs are not clear cut events, and can involve uncertainty in the attribution of causality. It is difficult to determine whether an ADR is due to a particular drug, the interaction of drugs or something related to the patient's health condition. The diagnosis is often not a discrete event, as testing for different hypotheses takes time. Often patients are on many drugs, and seen by many clinicians whose recommendations would have to be considered for the report. ADR reports can be very time consuming to complete, taking away time from patient care, so efficient and provider-friendly reporting systems and supports need to be put in place.
- Integrated electronic platforms need to be developed that are intuitive, provider-friendly, and connected to existing electronic medical record systems. If reporting is integrated into existing systems, anonymized patient identification data as well as diagnostics and other information could be transferred automatically to a report, saving significant time and reducing transcription errors.
- Regarding the scope of the serious ADRs to be reported, the CMA recommends that Health Canada ensure clarity. In some countries, reporting is only required for new drugs or those that have higher risks, and are identified by a special sign such as a black box (U.S.) or the black triangle (U.K.). These options could

be considered as part of a phased in approach to reporting, as the Canadian mandatory reporting system increases its capacity.

- To be enforceable, the mandatory reporting of serious ADRs needs to be feasible for Health Canada as well. Large volumes of data are not useful if Health Canada has not developed the capacity and the systems to assess, analyze, provide feedback to health care professionals, the industry and the public and, ultimately, take action to support patient safety. A phased in approach might be productive to achieve the purposes of a mandatory reporting system.

B) 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.
2. What considerations would you anticipate in establishing a federal definition of "acute care"?"
3. 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.

- The CMA recommends that the requirement to report serious ADRs be limited to patients admitted to acute care hospitals. In addition, CMA would recommend that the patient will have been in hospital for a minimum of 24 hours. This would capture most of the serious ADRs, due to the gravity of the patients' conditions, and situate reporting within institutions that have better diagnostic and reporting
- capacity, including access to specialists. Reporting could also possibly be better incorporated into the hospital discharge process. Exceptions to this would probably have to include situations where a death has occurred out of hospital and the death is attributed to an ADR or medical device incident.
- It is important that the mandatory reporting system of serious ADRs and medical device incidents be put in place without detriment to the voluntary reporting system already in place, where health care professionals in other settings as well as patients and families continue to be encouraged to report ADRs and medical device incidents, regardless of severity.
- The term "acute care" refers to the care given to patients with acute health conditions, i.e., "sudden, often unexpected, urgent or emergent episodes of injury and illness that can lead to death or disability without rapid

intervention"[4]. The World Health Organization describes a range of acute care functions[5] that is very broad and includes pre-hospital care, short term stabilization, and urgent care, besides care that usually is given in hospital such as critical care, trauma care, acute care surgery and emergency care. Many of these services that are available out of hospital would probably not have the systems and supports or allow enough time for health care professionals to adequately investigate serious ADRs for reporting. Again, due to the gravity of the situation, these patients would probably be taken to hospital after or for further stabilization and assessment.

- Hospitals are better equipped to report events, and often designate reporting champions or teams to work with their clinical staff for this purpose. For example, the reporting of infectious diseases and outbreaks to public health authorities is usually managed by infection control teams which each hospital is required to have.
- These recommendations are made based on the need for the ADR and medical incident reporting to be enforceable and feasible, while ensuring much better information is available for patient safety purposes than within the present voluntary system. This includes adequate and increased Health Canada capacity to assess reports, provide necessary feedback and make decisions regarding action on these.

C) 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)?
2. Does the disclosure to Health Canada of any of these fields present privacy concerns for your jurisdiction? Please elaborate.

- In addition to the data fields that have been listed in Health Canada's questionnaire, it is important to consider that often there are not definitive answers. The form must allow some flexibility, both in terms of being able to change responses as the investigation progresses and having open ended spaces for when the options provided not fit the case in question.
- CMA considers it essential to require demographic information, such as age and sex, in order to be able to assess the impact of serious ADRs on sub-groups of the population that might be more vulnerable to certain drugs, e.g., the elderly or

[4] Hirshon, J. M., Risko, N., Calvello, E. J., Stewart de Ramirez, S., Narayan, M., Theodosis, C., & O'Neill, J. (2013). Health systems and services: the role of acute care. Bull World Health Organ, 91(5), 386-388. doi: 10.2471/blt.12.112664. Retrieved from http://www.who.int/bulletin/volumes/91/5/12-112664/en/

[5] Hirshon, J. M., Risko, N., Calvello, E. J., Stewart de Ramirez, S., Narayan, M., Theodosis, C., & O'Neill, J. (2013). Health systems and services: the role of acute care. Bull World Health Organ, 91(5), 386-388. doi: 10.2471/blt.12.112664. Retrieved from http://www.who.int/bulletin/volumes/91/5/12-112664/en/.

children. As well, CMA recommends that there be a field that identifies whether a patient is pregnant or is nursing, since clinical trials don't usually include pregnant or breastfeeding women and the effects of drugs on that sub-population and their children are not well known.

- Should there be a reporting system that is integrated with electronic health or medical systems, many of these fields could be auto-populated with demographic data and the physician or other health care professionals would be able to also add laboratory results or other clinical information relevant to the case, without exiting one system to enter another.
- As with all medical records, privacy concerns would need to be addressed according to federal, provincial and/or territorial legislation. Information would be anonymized and aggregated if referring to more than one case affected by the same drug or device.

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

These questions are to be answered by provincial and territorial ministries of health.

E) 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.)

- Timelines for reporting serious ADRs would be influenced by factors such as (see discussion of these in previous responses):
    - complexity of the case and time needed to investigate alternate hypotheses and causality;
    - ease of use of the reporting system and how integrated it is with the existing electronic health and electronic medical records;

    - support systems in place to assist health care professionals in reporting, both within the institution and from Health Canada.
- There needs to be a balance between timeliness of reporting and accuracy of diagnosis, given the need to prevent further occurrences. Consideration should be given to interim reporting. Patient safety goals are better met when feedback is provided in a timely manner.

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

- Serious ADR and medical device incident information is important for prescribers, as well as pharmacists, nurses and other professionals involved in patient care. This would also be valuable to professionals who are ordering medical equipment or involved in its maintenance. It would be important for professionals that report to receive prompt replies acknowledging receipt of a report, as well as information on whether this has been reported before and what the process and timelines will be to analyze and follow up on the report.
- There are different levels of risk communications to health care professionals that should be in place when reporting serious ADRs and medical device incidents is a requirement. When a drug or device is identified as a concern by Health Canada as a result of the detection of risk signals and safety trends in reports, then emails (advisories) need to be sent promptly. "Dear healthcare provider" letters need to be sent to prescribers, particularly. Many health care professionals still use faxes given the issue of privacy and concerns with emails.
- Health Canada should also report on the information generated from the reporting process on a regular basis, possibly annually. As well, the information should be made publicly available on Health Canada's website, in such a form that health care professionals and the public are able to search through a database for certain drugs or devices with which they have a concern, and also for research purposes.