VANESSA'S LAW:
Update & Implications for Members

PURPOSE

To advise members on recent revisions to federal regulations under Vanessa's Law that require hospitals to report on Severe Adverse Drug Reactions (SADRs) or Medical Device Incidents (MDIs) and to help members prepare for the transition to a regime of mandatory reporting.

BACKGROUND

In 2014, Canada passed C-17, the *Protecting Canadians from Unsafe Drugs Act* (known colloquially as *Vanessa's Law*), which empowers Health Canada to develop regulations governing mandatory reporting of SADRs and MDIs to the federal government.

Vanessa's Law was named in honour of former-MP Terrence Young's daughter, who died in 2000 after suffering complications while taking a drug prescribed for gastrointestinal symptoms. The purpose of the mandatory reporting regime enabled by *Vanessa's Law* is to allow Health Canada to more rapidly and efficiently generate signals on post-market medications or medical devices that may have unexpected and severe side-effects. Regulations enabled by *Vanessa's Law* are also considered to be a key pillar of Health Canada's Action Plan on Medical Devices published in December 2018, which is related to other avenues of HealthCare*CAN* advocacy.

Since Vanessa's Law was passed in 2014, Health Canada has been consulting with stakeholders to assist in developing regulations that will define the mechanics of the new mandatory reporting regime, including:

- Who will be required to report;
- What kinds of reactions or incidents will be defined as reportable;
- What information will be subject to mandatory reporting;
- What kinds of therapeutic products will be subject to mandatory reporting; and,
- What timelines will be imposed for reporting of SADRs and MDIs.

In 2015, HealthCare*CAN* convened a group of national advocacy organizations called the Vanessa's Law Ottawa Working Group to discuss the merits of Health Canada's approach and to share information on our organizations' responses to it. The working group included: HealthCare*CAN*, the Ontario Hospital Association, the Canadian Pharmacists Association, the Canadian Society of Hospital Pharmacists, the Canadian Medical Association, and the Canadian Nurses Association.

Based on these deliberations and consultations with members, HealthCare*CAN* provided written feedback to Health Canada on two occasions, first in August of 2017 before any proposal was made, and then in August of 2018 in response to the government's first set of draft regulations (known as Canada Gazette part i or CG1 regulations).

Our August 2018 submission made five recommendations addressing:

- the breadth of events the regulations considered 'reportable';
- the design of the government's mandatory reporting tools;
- the government's cost estimates for the financial burden of compliance;
- the information requirements of the mandatory reporting regime, and;
- the period between the regulations' publication and their coming into force.

Health Canada published its final regulations (called CG2 regulations) governing SADRs and MDIs in June. This policy brief sets out the general features of the new regulations and outlines implications for HealthCare*CAN* members.

VANESSA'S LAW REGULATIONS

WHO REPORTS?

The new regulations governing mandatory reporting apply specifically to hospitals, and not to medical or nursing staff or any healthcare worker working outside of an institution. A hospital, according to regulations, means: (1) a facility designated as a hospital by a province or territory to provide care; or (2) a facility that is operated by the Government of Canada and provides health services to persons who are inpatients.

This means that the regulations apply at the level of the hospital site, rather than at the level of, for instance, a regional health authority. The result is that a health authority would be responsible for compliance only in those facilities designated as hospitals, and not in all facilities operated by the health authority.

At an earlier stage, Health Canada considered applying regulations at the level of the practitioner (i.e. an individual clinician's mandate to report) or only in acute care hospitals, but determined that applying at the level of the facility and including all hospitals would best meet the government's objectives for comprehensiveness and enforcement.

WHAT EVENTS ARE REPORTABLE?

The regulations define a Severe 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"

Similarly, the new regulations define a Medical Device Incident as:

"…an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that 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."

For further interpretation of these definitions, we recommend consulting Health Canada's guidance document in Sections 2.2 and 2.3. Section 5 of the same document offers additional guidance on which kinds of events are serious enough to warrant a report.

WHAT INFORMATION MUST BE CAPTURED IN A REPORT?

Under the new regulations, certain information is required for a report to be considered complete. This information does not differ notably for SADRs versus MDIs. You can view the reporting form fields for SADRs and MDIs here and here respectively.

Much of this information is relatively easy to retrieve (e.g. drug identification number associated with the SADR, or the name or identifier of a medical device) though some data fields will require specific clinical knowledge to provide a report. For instance, an SADR report will require a clinical description of the SADR, the date on which the SADR was documented, the date on which the SADR first occurred, a description of the patient's pertinent medical conditions, a description of other therapeutic products used by the patient, and the effect of the SADR on the patient's health. It is anticipated that information at this level would require the efforts of an informed clinician; for instance a physician, nurse practitioner, or pharmacist.

Hospitals will be exempt from mandatory reporting if they do not have in their control certain basic information, such as the drug or device's name or a description of the SADR or MDI that would be the subject of the report, since the absence of such information would undermine the purpose of reporting.

WHAT PRODUCTS ARE SUBJECT TO MANDATORY REPORTING?

While the regulations apply to nearly all drug products or medical devices regulated for use in Canada there are some notable exceptions:

- vaccines used in provincial immunization programs;
- drugs used in clinical trials;
- drugs authorized by the Minister of Health on an emergency basis, all of which are exempt from mandatory reporting.

It should also be noted that reactions arising from the use of Natural Health Products (NHPs) – whether used in isolation or in combination with one or more other NHPs – are not subject to mandatory reporting. However, a suspected SADR resulting from the combination of an NHP and a regulated drug product would be reportable.

WHAT ARE THE RELEVANT TIMELINES FOR REPORTING?

The regulations require that a report be received by Health Canada within 30 days of first documentation of an SADR or MDI.

The regulations are set to come into effect on December 16th, 2019, meaning that any SADR or MDI documented after that date and meeting the criteria set out above will be subject to mandatory reporting to Health Canada.

IMPLICATIONS

HOSPITAL RESOURCES AND STAFF TIME

As part of our consultations with Health Canada, HealthCare*CAN* argued that the definition of SADR employed was too broad; that only *unexpected* SADRs should be subject to mandatory reporting. As we put it at the time:

> "SADRs frequently arise out of a calculated risk on the part of a physician and her patient. Often, a patient can emerge better off for having taken a medication, even if an SADR is the result. For instance: side-effects of chemotherapy administered in hospital clearly meet the definition of SADR established in the *Food and Drug Regulations*."

Our view was that the requirement to report *all* SADRs would impose considerable effort and expense for questionable benefit, and that these resources would be better served managing patients' drug therapy rather than reporting well-known adverse events to drugs like pain medications, anticoagulants, chemotherapy, and insulin.

Incidentally, the government's regulatory impact statement does acknowledge that two thirds of stakeholder groups consulted took the same view as HealthCare*CAN*. Nevertheless, the government has chosen to take a different and more expensive path.

The regulations place an additional burden on hospitals by requiring them to report on SADRs that take place elsewhere. This may escalate the level of investment required to achieve compliance. Studies show, for instance, that 3% to 10% of all hospital admissions among elderly people are attributable to adverse drug events, which by definition would become SADRs and thus reportable. Taking into account the large and growing proportion of hospital inpatients who are elderly, we estimate that the cost burden of compliance may be significant.

These costs may be magnified given the level of clinical expertise required for a coherent report to be made. Certain required reporting fields (e.g. age, sex, and drug information) may be filled by staff in more administrative roles; however, clinical acumen is required to identify and characterize an SADR or MDI. The input of a nurse or pharmacist will probably be required as a part of every report, with implications for a hospital's hiring and budget.

With all of this in mind, HealthCare*CAN* members are advised to take note of the impact of compliance on the hospital budget, and to budget accordingly.

TRAINING

Staff training and buy-in will be a necessary component to achieving compliance with the regulations pursuant to *Vanessa's Law* – a factor made more challenging given that the regulations are scheduled to come into force by mid-December of 2019. In our consultation with Health Canada, HealthCare*CAN* argued for a lead-time of two years between the publication of regulations and their coming into force. Health Canada has opted for a lead-time of six months.

Health Canada's regulatory impact statement advises that "[the department] will provide guidance, outreach, and education to all hospitals and health care professionals working within hospitals responsible for reporting". We understand that Health Canada has been reaching out to hospitals individually to facilitate the compliance process and that Health Canada has also sponsored a series of educational modules co-developed by the Institute for Safe Medication Practices, the Canadian Patient Safety Institute, and the Health Standards Organization. These modules are set to be released in late-July, and will be accessible here.

With this in mind, HealthCare*CAN* members are advised to ensure that staff are aware of their new compliance responsibilities as of December 16th, 2019.

FOR FURTHER INFORMATION

HealthCare*CAN* remains attentive to developments as they relate to *Vanessa's Law* and will keep members apprised of any changes in the landscape. If your organization has any questions, concerns, or feedback in connection with these developments we encourage you to contact us so we can ensure your voice is heard.

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