Stakeholder Consultation on Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents

D - Areas Informing the Development of the Regulations

D.1. - Applicable Health Care Institutions

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?

Respondent Number	Comment
1	From a professional perspective, I'm supportive of initiatives to improve ADR reporting, but I question why this requirement would be limited to acute care hospitals. In my experience, they don't have the abundance of resources that the proposal suggests. Perhaps more importantly, all health care professionals have a duty to report ADRs already, and I don't think the bar should be set so high as to require mandatory of only those that result in hospitalization. This would exclude mandatory reporting in the larger community setting – and it's plausible some of these reactions are managed outside of the hospital setting, or managed in the emergency department, which is not considered in-patient hospitalization. As such, does the definition of acute care setting include the Emergency departments, where patients with a serious ADR may be managed and not admitted?
2	CIHI definition used in the document seems to exclude Emergency Departments. Including EDs would capture those patients who experience ADRs or MDIs outside of hospital, and are treated and released by ED
4	In addition to acute care hospitals, I would have included the "post-acute hospitals" such as Baycrest, Bridgeport, Providence, etc. where they have a full pharmacy staff monitoring patients typically on many drugs, many co-morbidities and have more continuity than most acute care hospitals. Yes, you will get the Emerg events in acute care but things that develop during

Respondent Number	Comment
	hospitalization are just as likely and more easily identified and documented where the patient stays for longer. I was at [name removed] (geriatric hospital post-acute care but not LTC) and now I'm in acute care hospital. I had a lactic acidosis from metformin in our ICU (not required to be reported as part of this as it is not unexpected) but when I asked the ICU pharmacist to report the ADR she said the patient was being transferred to the floor and by the time I caught the new pharmacist the patient was discharged and no longer their issue - they have another 30 patients. In post-acute care you have vitals and monitoring over weeks. It's a great place to know the patient and identify unexpected events that perhaps are different and wouldn't bring patients to the Emerg but are still severe.
5	I agree that hospitals that provide acute care services would be the most appropriate for documenting adverse drug reactions as they will be the ones identifying, treating and hopefully rectifying these issues. This will capture all patients that are being admitted from nursing homes, special care homes etc. where these ADRs may occur.
6	I do support this proposal for hospitals that provide acute care services to have mandatory reporting requirements SADR and MDIs. Voluntary reporting will never capture the full-extent of SADR and MDIs therefore making it mandatory makes sense. Restricting the mandatory reporting to only hospitals that provide acute care services makes the most sense to me, and I appreciated the pro/con approach that was presented in the consultation paper for considering other options.
7	ok with recommendation to focus on acute care hospitals
8	I support this proposal after review of the 3 other alternatives and agree that this makes the most sense. I question whether there will be additional funding provided to the facilities in question to reflect this additional workload requirement.
9	The following definition is taken from CIHI's website: Emergency and ambulatory care Medical care delivered on an outpatient basis. It is one of the largest-volume patient activities in Canada, making it a key component of the continuum of health services in Canada.

Respondent Number	Comment
	The following definition, as taken from the consultation paper, refers to CIHI's definition of "acute care": 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. By these definitions only serious adverse drug reactions that are treated in an inpatient setting, and not emergency or ambulatory care departments, would be subject to mandatory reporting. Consequently, the reporting of an ADR-related death in the community, emergency, or other non-acute care setting would not be mandatory. Is that the intention?
10	I am supportive of the proposal to apply mandatory reporting requirements to all hospitals that provide acute care services. I agree that acute care hospitals are well positioned to report serious ADRs and MDIs.

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.

Respondent Number	Comments
6	I do not have any expertise on this to be able to comment.
8	support the use of the CIHI definition of "acute care" as this clearly delineates which hospitals will be expected to fulfill the new requirements
10	My preference to confine the regulations to CIHI's definition of acute care.

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

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.

Respondent Number	Comments
1	I question the definition of "in its control". That is highly interpretable, and suggest that term be clearly defined. Finally, there seems to be some nomenclature issues at Health Canada and this may be an opportunity to improve that. For example, some pages on the www.canada.ca website refer to Drug Adverse Reactions (DARs), others Adverse Drug Reaction (ADRs). They should be encouraged to choose one. I'm guessing ADR is the more familiar of the two.
2	I don't understand this definition: "only serious unexpected ADRs in its control". I think this will reduce the effectiveness of reporting. E.g. if a patient is prescribed a medication as an outpatient, experiences a serious ADR that requires an ED visit or admission- that ADR was not in the control of the institution- so would not need to be reported. I would also like to see reporting of a wider range of ADRs within a defined time period of market approval. E.g. 2-5 years
4	I would have included all three groups [seen in hospital or prolong hospitalization, unexpected/rare, or drug on market less than 5 years] we have now as mandatory. Given that they will be few and far between, how is Health Canada going to know if organizations are complying? Will this be added to the hospital accreditation on ADRs?
6	I agree with the proposal to limit the reporting of serious ADRs to serious unexpected ADRs that are in the control of the institution. A requirement to report all serious ADRs would create an enormous burden on the institution and likely not assist greatly in identifying new signals.
7	based on definition of 'serious ADR', this should limit the impact on HCPs [health care professionals] to report

Respondent Number	Comments
8	-it makes sense to limit to serious ADRs. Not sure why they have included the phrase “in control of the institution” in the language. -does "in the control of the institution" mean that the ADR could have been avoided? If a drug is necessary to give to a patient, despite severe ADRs, would it be seen as "in control"? The institution did give the drug and could have refused to, but if refusing meant negative patient outcomes of even greater severity it seems like the institution is handcuffed and didn't really have a "choice" in the matter. -if a severe and unexpected but still unavoidable (due to the necessity of the treatment) ADR occurred in a patient this data would still be useful for weighing potential risks and benefits in the future. -perhaps all serious and unexpected ADRs should be reported regardless of the degree of "control" the institution had over them.
9	I agree with the proposal. However, additional clarity is required to understand the definition of “in its control” and the subsequent implications of that definition. Does it mean the prescription was started while the patient was admitted as an inpatient of the acute care hospital?
10	I’m very supportive of restricting the reporting to serious, unexpected ADRs. However “in its control” needs to be qualified.

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.

Respondent Number	Comments
1	Also, should the proposal drop the word “unexpected” and stick with the term *serious ADR*? From the current proposal: It is proposed that health care institutions be required to provide Health Canada with only **serious <u>unexpected</u> ADRs** in its control…. However, using Health Canada’s own definition, a serious ADR is <u>already</u> unexpected: “a ***serious adverse drug reaction*** *is defined as a noxious and* ***unintended*** *response to a drug, which occurs at any dose and requires in-patient hospitalization or prolongation of*

Respondent Number	Comments
	existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death" https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-information.html
6	In order for a healthcare professional to identify an "unexpected" serious ADR it seems to be implied that they would refer to the Canadian product monograph. The following should be taken into account: a) Access to the most recent version of the Canadian product monograph must be provided to the healthcare professional and this should be provided at no cost to the user, and be available 24 hours a day, 7 days a week. Manufacturers holding licenses (DIN) should be required to provide the most recent version of their Canadian product monograph. The monograph should be linked to the DIN number. b) Organization of the Canadian Product Monograph. At the moment, "expected" serious ADRs may appear in various sections of the Canadian Product Monograph (e.g., Contraindications, Serious Warnings and Precautions Box, Adverse Reactions, Drug Interactions etc.). The templates used for Canadian Product Monographs have changed quite dramatically over the years. The content of a Canadian Product Monograph for a drug that was approved decades ago, is often very different from drugs that have been recently approved. If manufacturers were required to update their Canadian Product Monographs to adopt the latest Product Monograph Template from Health Canada this would greatly assist the health care professional. Consistent organization of the product monograph format would make it easier to navigate. c) Harmonizing terminology used in the Canadian Product Monograph with the terminology/definitions used for defining serious unexpected ADRs would also be helpful. As mentioned above, serious ADRs may appear in multiple sections of the product monograph. Introducing a new section into the Canadian Product Monograph that summarizes "serious adverse drug reactions" would be helpful.
8	-unexpected should mean an ADR not previously causally linked to the drug, not merely a low probability event.

Respondent Number	Comments
	For instance, an ADR linked to a drug by a single post-market case study should be reported because that report could provide further evidence necessary to establish a causal link. In contrast, an ADR shown to be rarely caused by a drug (e.g., an antibiotic and toxic epidermal necrolysis) may not be reported because while you do not expect it to occur on a basis of probability (in the same way to do not "expect" to get heads 5 coin flips in a row) it is not "unexpected" as it is a known ADR for that drug (in the same way that getting heads 5 coin flips in a row is a known possible outcome).
9	Under what conditions is an ADR considered "unexpected"? Is it only those that were not reported in the product monograph, regardless of the nature, severity, or frequency of a reported ADR? If that is the case then the product monograph needs to be up to date and easily accessible. (Not all product monographs are available in Health Canada's drug product database.) Would the expectation to report change if the severity or frequency of the ADR *appears* (either through voluntary reporting or personal experience) to be significantly higher than what is stated in the product monograph?
10	I support the existing definition of serious "unexpected" ADR as one that is not identified in nature, severity, or frequency in the risk information set out in the label of the drug. However this assumes that the product monograph is up to date.

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?

Respondent Number	Comments
4	MDIs - I'm not sure what to report.
6	I don't have any comments on this.

D.3. - Applicable Therapeutic Products

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?

Respondent Number	Comments
2	I don't like that natural products are exempted, but that seems to be in the Act so there's no way to change that at this point. My preference would be that any product with a DIN, NPN or DIN-HM are included.
3	Regarding the reporting of serious adverse events, my only comment is on excluded products. I would like to think that if we are seeing serious reactions with vaccines or SAP products, these too would be of concern and Health Canada should be aware.
5	I absolutely disagree with NHP's not being on the reportable drugs list. NHPs can lead to serious and life threatening adverse effects on their own and in combination with other drugs. With more reporting on them then hopefully and should also be on this list!!!
6	Natural Health Products and Drugs on Urgent Public Health Need List should also be included. Natural Health Products may cause serious unexpected ADRs due to their known ingredients and sometimes due to contaminants (intended or unintended). Drugs on Urgent Public Health Need List do not appear to have any ADR reporting program established with them. For example, naloxone nasal spray - both a medical device and a drug used to manage life-threatening opioid overdose. Failure of the device (or drug) to achieve the intended effect would seem to me to be something that should be mandatory to report.
7	ok with groups of products listed; vaccines are not listed but assume these products will continue with their existing reporting system
8	Natural health products are under-researched, easily accessed, and may be pharmacologically active. Monitoring these should be as important as other pharmaceuticals. Vaccines also run the risk of adverse reactions and should not necessarily be excluded.
9	The list of applicable therapeutic products is reasonable given the scope of Vanessa's Law. Mandatory reporting of serious adverse reactions to natural health products would also be helpful,

Respondent Number	Comments
	knowing for that to occur a separate piece of legislation would be required.
10	I 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. However future legislation should extend the requirement for mandatory reporting of serious reactions to natural health products.

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?

Respondent Number	Comments
6	I do not agree with a subset proposal, particularly with "incorporation by reference" list. Lists tend to not be consulted and if they are used, the user often does not use the most recent version. The idea of a black triangle is interesting but would require knowledge that the drug carries this symbol.
8	Do not support. Do not see the rationale for further limiting the subset, unless there is only enough funding to provide for some of this monitoring, then there may be necessity to prioritize.
9	I do not support the alternative. Lists and the use of symbols on packages introduce added operational complexities (e.g., loss of information when repackaging the product, needing to refer to a list) and defeats the requirement for a serious adverse reaction to be "unexpected". (If a drug is not on the list someone could infer that reporting is not required despite how serious the reaction is.)
10	I do not support the alternative limiting the reporting requirements to a subset of the products in Health Canada's proposal. It would be difficult to apply the black triangle symbol in the institutional setting because of the extent of repackaging of drug products into a ready-to-administer form.

D.4. - Applicable Data Fields

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.

Respondent Number	Comments
2	Additional data fields for ADRs: Lot number of product may be useful.
4	As the report is an unexpected ADR, often the patient will be on multiple drugs none of which are reported to cause it and thus, it's important that there is room for more than one "possible" cause. Terminology is important as it's going to be hard to say that you just suspect one drug if the patient is on 12 and none have been reported to cause it.
5	The minimum requirements for reporting seem appropriate as they will capture most of the relevant information needed
6	I do support the approach of requiring a minimum set of data fields and a set of additional fields to be completed if this information is known. The minimum data fields for serious ADRs are sufficient and appropriate. For the MDIs, the age and gender of the patient should be a requirement as this may help identify if certain populations may be more susceptible.
7	hard to tell but the elements listed in the proposal seem reasonable to allow a regulatory authority to gather info on type/severity/frequency of reaction, likelihood of true association of suspect product with adverse effect, etc.
8	Support. The proposal loses its teeth if "mandatory reporting" doesn't actually require certain mandatory elements in the report. The additional fields mentioned give greater context to the incident.
9	I support the proposal– the list is reasonable.
10	I support Health Canada's proposal to require both a minimum set of data fields and a set of additional data fields. However, in most cases the relevant tests/lab data, the relevant medical history, and concomitant health products will be known.

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.

Respondent Number	Comment
[Intentionally left blank]	Director of professional services at our institution. [McGill]

D.5. - Timelines for Reporting

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?

Respondent Number	Comments
2	Agree with 30 day timeline
4	Yes, 30 days seems reasonable. Most should come in within 5 days or they won't come.
5	30 days is too long a period for reporting events. Information and details may be forgotten which can lead to lesser quality reports. I feel that a 10-15 day timeline would be more appropriate.
6	30 days seems reasonable.
7	30 days is reasonable through perhaps will still be a challenge for many in busy acute care hospitals. Education will be needed to familiarize HCPs with online reporting processes to HC which are quick & easy to use. In my opinion, the report should be able to be submitted online within 10 minutes or less if the HCP has the requested information in his/her possession.
9	Having the same timeframe to report for both serious ADRs and MDI reporting is reasonable. To say that an ADR or MDI needs to be reported sooner or later than the other implies that the reactions of one are more (or less) significant than the other: such a generalisation should not be made without evidence to support it. A 30-day period is reasonable.
10	A 30-day timeframe for reporting ADRs is reasonable.

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?

Respondent Number	Comments
6	Option 1 seems more reasonable.
8	Although it sounds like a reasonable alternative, most likely most efficient to do the complete report at the same time and send it in within the 30 day period. Having it sent in 2 possible submissions means more follow-up for both the institution and Health Canada as the second submission may fall off of the radar and not be submitted without reminders.
9	Having the option of a 2-step reporting process offers a level of appeal, but requires organizations to have an internal mechanism to return to complete their submissions, which might be problematic for some. It also prompts the question of what would Health Canada do differently with the partial information versus a completed report submitted within 30 days? Reports of a similar nature for the same drug (or class of drug) will not arrive at the same time, so there will always be "incomplete" data. Perhaps the level of seriousness of the reaction would be a consideration.
10	I am not supportive of alternative 2 because it implies reporting on 2 separate occasions for the same ADR and would increase the workload.

What are the considerations around a more expedited timeframe for serious ADR/MDIs that have resulted in the death of a patient?

Respondent Number	Comments
6	Reporting at the earliest opportunity would make sense.
8	30 days seems reasonable unless there was a real risk that this issue was a common and repeatable issue to the extent that other deaths were very possible within that 30 day timeframe.
9	As long as causality can be established quickly, earlier reporting would be favoured. Keep in mind that the timeframe between drug administration and death due to the drug is not always short.
10	If the death can immediately be attributed to a drug or medical device earlier reporting is reasonable.

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

Outreach and Education

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).

Respondent Number	Comments
6	online
8	As many people have different learning preferences, education tools specific to ADR/MDI reporting should be available in the widest range possible.
9	Online, conferences
10	Mostly online; conferences

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.

Respondent Number	Comments
2	My thoughts- since the responsibility lies with the institution, not the individual health care professionals (HCP) any outreach or education needs to be aimed at both HCP and people like risk managers, patient safety, etc. These people will be responsible for implementing processes at the institution, while the HCP will be the ones completing the reports.
6	All healthcare professionals. Patient safety is everyone's responsibility.
8	The education should meet the needs of all professionals working in an institution as there are numerous professionals expected to be identifying the applicable agent(s) as having caused a serious ADR and then doing the follow up reporting. It would be the institutions decision regarding their internal reporting structure and who would be receiving education/training for this task.
9	All healthcare professionals, risk managers, and patient safety leaders in the institution.
10	All professionals, risk managers, patient safety coordinators working in the institution because Vanessa's Law puts the onus of reporting ADRs and MDIs on the institution.

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.

Respondent Number	Comments
4	I'm concerned about the current documentation process. The current on-line system results in a 6 page form with many of the fields cut off when printed and thus, it's hard for me to summarize for the semi-annual P&T report. Also, it's easy to miss printing it and you can't get it afterwards. A student reported one on-line and after 3 calls to Health Canada we gave up trying to get a copy of it. The hard copy is nice as it is all on one page but then Health Canada needs to re-enter. It would be nice if the on-line allowed a 1-2 page printed report that prompted you to print it before submitting and that all fields fully printed. With on-line many P&T's are finding they aren't getting reports and are wondering if they are being done but they aren't getting the copy or they are not being done.
6	Canadian Product Monograph Template, Health Canada DPD with links to Canadian Product Monographs for all licensed, marketed drugs using the DIN.
10	If the expectation is to file the ADR and MDI reports through the MedEffect Canada program then this platform and the Canada Vigilance Adverse Reaction Online Database should be more user-friendly. In addition the online reporting should make use of contemporary technology, such as an app designed for mobile devices.

How important would education at the professional teaching institutions be? (Very important, somewhat important, not very important, not at all important)

Respondent Number	Comments
2	Assume "professional teaching institutions" means the universities? If so then the ideal situation would be for reporting of ARDs be included in the curriculum, both to teach how it is done, but also why it is important to do it.
6	Very important
9	Very important
10	Very important. 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

Respondent Number	Comments
	(healthcare providers, the public, pharmaceutical manufacturers) and how it will be used to improve patient safety. Without a through lack of understanding of the value of reporting there is a risk of avoidance and non-compliance with reporting requirements.

Meaningful Feedback

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.

Respondent Number	Comments
6	The broader the communication the better. This will serve to highlight the importance of voluntary reporting.
8	Support. This makes sense as it allows external actors to assess trends independently of Health Canada.
9	I support the proposal. Providing aggregate information to the broader healthcare community helps to demonstrate the value of reporting ADRs and MDIs, and ultimately improve care provided.
10	Providing aggregate information should help to reduce or eliminate many of the motivational barriers to the reporting of ADRs, such as questioning the purpose and usefulness of reporting or publishing findings independently. Without a thorough understanding of the value of reporting there is a risk of avoidance and non-compliance with reporting requirements.

What would be the most effective way to communicate aggregate safety information to the health care community?

Respondent Number	Comments
6	Probably a combination of approaches. Communications from Health Canada via their website. Communications sent from Health Canada to organizations involved in provincial drug formularies, professional orders, etc.
8	Online memos in simple, summarized language, with links to more in depth information, similar to the MedEffect e-Notices that we currently receive.

Respondent Number	Comments
9	MedEffect Canada and the Summary Safety Review work well. It would be good if the Canada Vigilance Adverse Reaction Online Database could provide aggregate safety information.
10	MedEffect Canada and the Summary Safety Review

What other types of feedback would be meaningful to provide to the health care community?

Respondent Number	Comments
6	Not sure exactly.
10	Key performance indicators to measure how well mandatory reporting is working

General Feedback

Respondent Number	Comments
4	In principle I don't have an issue with it; we should have been doing it all along. My issue is that I don't think it goes as far as we should but it's a start.
7	Success adoption of these activities could be important to identifying new & verifying significant trends in serious ADRs. Undoubtedly, it will be a challenge for practitioners however we are in the best position to identify the reaction, gather the relevant information & submit it to a central agency. My final wish is that HC use this information wisely & share appropriately to alert Canadians to potential or actual harms of licensed pharmaceuticals.