Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

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Outreach and Publishing Section
Bureau of Strategic Initiatives and Planning
Marketed Health Products Directorate
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Re: Regulatory proposal on mandatory reporting requirements for Serious Adverse Drug Reactions and Medical Device Incidents by hospitals

The Canadian Society of Hospital Pharmacists (CSHP) is grateful for the opportunity to provide feedback on the proposed mandatory reporting requirements for Serious Adverse Drug Reactions and Medical Device Incidents by hospitals.

In response to the invitation, CSHP invited members to provide feedback. The responses have been collated in the attachment to this letter. It is clear that the number of responses is not overwhelming, but it is acknowledged that the responses stem from people working in a variety of healthcare organisations, such as health regions, large, small, rural hospitals, or other healthcare centres. The following summarizes the comments received.

Comments

A wide variety of comments were received. The following list highlights the more common comments or questions received:

- Increased workload for already busy healthcare professionals will occur, resulting in increased expenses and reallocation from other value-add activities.
- An efficient reporting system is needed, particularly one that prevents duplication of effort.
- There are concerns that some serious adverse drug reactions may not be reported because the patient is treated for a serious adverse drug reaction outside of a hospital (e.g., free-standing emergency or urgent care facility).
- A phased in, or pilot project to report serious adverse drug reactions would be welcome.
- There are concerns about the perceived value for effort in reporting and the management of a large volume of data to be analyzed.
- There are questions about compliance and enforcement.

CSHP acknowledges Health Canada for granting an extension to review the full cost-benefit analysis report related to the proposed regulations. A high-level review of the analysis was conducted: the observations are noted below.

Cost-Benefit Analysis

Unfortunately the full cost-benefit analysis does not provide the level of details to challenge specifically, and appropriately, the assumptions. The following representations will therefore raise a number of queries:

1. Determining the baseline:
    a. The study by Zed et al. (reference 8 in CG1) was designed to evaluate neither the specific frequency of adverse drug reactions (i.e., drug toxicity) nor the occurrences for patients in hospital. It rather evaluated adverse drug events (i.e., patient safety incidents, near misses and hazards [= medication errors] and ADRs) in patients presenting to the emergency department. Of the 122 visits suspected of being related to medication use, 48 (39.3%) were attributed to ADRs, 19 (39.6%) of which were deemed preventable and 5 (10.4%), severe.
    b. Reference 11 in CG1 lumps 3 distinct studies:
        i. Gagliardi et al. "Medical Device Recalls in Canada from 2005-2015," Int J Technol Assess Health Care, 2017
        ii. Baker, R. Norton, P, et al. "Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada," CMAJ, 2004.
        iii. Gagliardi et al. "Factors Influencing the Reporting of Adverse Medical Device Events," BMJ, 2017.

        It is therefore impossible to tell which data, assumptions, and statements they ascertain. Furthermore, the Canadian Adverse Events Study is quoted out of context in a couple of respects:
        i. The article makes no mention of MDI-related events, although some could be inferred from the description of the clinical details of the adverse events occurring in 255 patients provided in Appendix 3.
        ii. Similar to the study by Zed et al, it aimed to estimate the incidence of adverse events, not specifically ADRs. An adverse event was identified in 255 of the 2745 charts reviewed and 116 charts were positive for an ADR during the preliminary screening by nurses or health records professionals. However, the article makes no further mention of ADRs following the review by physicians, although some could be inferred from the description of the clinical details of the adverse events occurring in 255 patients provided in Appendix 3.

2. Costs of the regulatory proposal:
    a. The consultation entitled "Toward Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Health Care Institutions" elicited only 25 submissions. The summary of the responses to the consultation does not provide a breakdown by hospital bed size. Even when supplemented with the results from the technical discussions with institutions and patient safety experts, the number of hospitals in each hospital bed-size category (small, medium, large, and large teaching) would be very small. During the technical discussion with representatives from

healthcare institutions in the Ottawa area, the distribution of responses by bed size was not established systematically. Therefore extrapolating the costs from these responses to the 597 hospital corporations operating in Canada is dubious and, even more so, when broken down by bed size.

b. Assuming that employees in small and medium hospitals earn less than those in large and large teaching hospitals is likely invalid since, in most provinces, hospitals are organized into larger corporations under common collective agreements.

3. Benefits of the proposed regulations:
    a. It is unclear how the proposed regulations could lead to significant cost avoidance. The cost-benefit analysis assumes that knowledge of all serious ADRs will prompt health care professionals to adjust prescribing behaviour. However, clinicians would consider more frequent serious ADRs (e.g., bone marrow suppression induced by antineoplastic agents) an unavoidable risk of providing standard of care and most rare serious ADRs, if known to them, a risk outweighed by the benefit. The only way costs could be avoided would be if an ADR would be considered so severe and frequent enough to warrant withdrawal from the market.

Please do not hesitate to contact me if you have any questions in regard to the information provided.

Sincerely,

Myrella Roy, BScPhm, PharmD, FCCP
Executive Director

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Patrick Fitch, CSHP President
Douglas Doucette, CSHP President Elect and External Liaison
Cathy Lyder, CSHP Director, Members and Programs

Comments provided by members

Respondent number and description of organization where respondent works	Comments
1 [independent practitioner]	I am in agreement with amending Food and Drug Regulations to include mandatory reporting of adverse drug events by all hospitals in Canada. Of prime importance will be the information specified to be reported on the data collection or reporting form. Certain elements must be mandatory, in order to obtain as much useful and cohesive information as possible. In addition, I suggest that additional elements be included under Required Information: • pharmacogenetic test results, if available • drug or metabolite blood levels, if available Genetic factors affect a patient's metabolism of drugs and subsequent potential for suffering adverse effects; likewise drug blood levels. Such information would be essential to building a comprehensive and meaningful database of information. It may be beneficial to have the reporting form undergo public review.
2 [large, teaching hospital]	1) Reporting requirements should be consistent throughout the continuum of care, not just hospitals. For example, biologics will be the future of drugs and most will be given in a for-profit infusion centre - these centres should have to report whenever they send a patient to hospital or have other adverse events not requiring hospitalization. 2) While Vanessa's Law does not include NHPs they are regulated by Health Canada with less rigorous means than drugs. This is an opportunity for Health Canada to gain data in possible harms (real harms) for which typical "prescribers" (naturopaths, homeopaths, holistic nutritionists, herbalists) have a financial bias/conflict (for-profit sale of NHPs) against voluntary reporting. 3) Rather than reporting disease states that may have contributed (which involves some causation from hospitals/health care workers – note it was highlighted in the Canada gazette paper that organizations would not be required to complete a causality assessment) all diseases and drugs should be reported... analysis of big data by

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	Health Canada may reveal a drug-disease interaction as the root cause even though providers may not have felt the disease contributed or was relevant to report. 4) Exemptions: not clear how relevant the exemption criteria are: hospitals would have access to the information listed in this section. 5) Reporting system: will there be further work to align the current Health Canada report with existing programs used in hospitals, to minimize duplication of reporting? 6) What are the impacts/consequences of missing the 30day reporting timeline? Enforcement section and proposed follow-up by Health Canada seems to deal more with quality of the reports. Also, how will Health Canada audit to be sure hospitals are reporting all identified cases?
3 [health region]	I had a look at CSHP's response from years ago and found them to be complete and reflective of the reality of hospital practice/resources limitations etc but also realistic in regards to data mining and utilization. Now I'm looking at the 2018 proposed changes and wonder what the value of this reporting will provide – "all" ADR vs "unexpected" ADR is the one section that struck me the most… I can't help but think that these requirements will result in a decrease in reporting rather than in an increase of important new data. I also have no idea how institutions that can't even meet the day to day workload are going to manage the data collection requirements and the follow-up that inevitably ensues from an ADR report. And then what. From my time on the EAC on the Vigilance of Health Products I recall that Health Canada had limited resources to respond to the ADR reports of that time – do you know if their resources have increased? Do they have analysts aligned to sift through these new data and respond in a constructive manner? I've always been a supporter of ADR reporting but a targeted one – specifically unexpected new reactions with older products and all ADR in products with limited market experience. I'll admit to being relieved that I will not be included in the operationalization of these proposed regulation changes.
4 [large, teaching hospital]	I noticed that the proposed amendments do not include the following statement for the definition of what constitutes a serious ADR: • Side effects that result in significant medical intervention to prevent one of these listed outcomes are also considered to be serious

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	Was this intended? A typical example would be management of suspected allergic reactions by administration drugs of antihistamines, epinephrine, to treat or prevent progression of hypotension, wheezing and respiratory depression. Would this still be considered a serious ADR for the proposed mandatory system? With regards to the reporting of bone marrow suppression induces by antineoplastics, I suggest that a caveat include that this delays further treatment cycles longer than that already established in standard chemotherapy protocols. I would expect clinician fatigue in filling out the forms. General interest questions and comments: Why is there an interest now to move from a voluntary program to a mandatory program at this time for reporting "serious adverse drug reactions? Why are hospitals being singled out for this change? It would be helpful for those commenting on the proposal to have more background information. Finally, there is also no discussion on how Health Canada expects to regulate a mandatory program. ___ I found of particular interest the January 2016 CSHP response and June 16, 2018 Health Canada "Regulatory Impact Analysis Statement". Not sure how the federal government can provide funding to support the mandatory program for hospitals (i.e., at [large teaching hospital, name removed] this would represent $150,000.00 annually for 1.5 FTE assuming pharmacist and not a physician) since this is a provincial responsibility to fund hospitals.
5 [medium size hospital]	As a pharmacist I support in principle amendments to the Food and Drug Regulations requiring mandatory reporting of SADR. However, as the pharmacy manager of a small-medium sized hospital (85 beds), I struggle with the anticipated increased salary costs to our department/hospital given the seemingly ever decreasing funding model. The past two years have been very fiscally trying for Ontario hospital pharmacies. Increased oversight from the Ontario College of Pharmacists has brought about many positive changes. However, these changes, such as increasing staffing to ensure all orders are reviewed, contracting out an after- hours pharmacist for 24/7 call, have

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	all been associated with an increase in labour costs for our department over a very short time frame with no increase in funding allocated by our provincial government who mandated this change. In 2016 the Ontario College of Pharmacist mandated we follow NAPRA standards for the provision of sterile preparations by Jan 2019. While I support this idea, the time frame to implement it was very short and therefore Ontario hospitals are again grappling with significant costs associated with meeting these standards. For our hospital this amounts to close to 100,000 dollars for infrastructure changes plus and additional $ 10,000 annually in staff training, recertification and quality procedures. In an ideal world there would not need to be discussions such as these for quality improvement initiatives and while the implementation of this change certainly tugs at your heartstrings at some point we need to take a look at the cost of doing business. I have reviewed the information provided in the Canadian Gazette and while I see the cost savings believed to be associated with this initiative as outlined I do not see where these savings are utilized to offset increased labor costs associated with the implementation or sustainability of this change. We are once again being asked to do more with less and herein lies the problem. I would like to see this legislation amended to reporting being limited to serious, **unexpected** ADRs initially until we determine what the actual costs to the system are. Secondly, I would like to see the government invest money into each hospital for this initiative **before** it gets underway to offset the cost of increased workload. If as the Canadian Gazette discusses there are cost savings these will be realized by the government in reduced health care costs and time away from work.
6 [small hospital]	Thanks for the opportunity to provide feedback – I support the move to report ALL serious adverse drug reactions – this should help us identify problems with medications and make the health care system safer for all. A few pieces of feedback though: • Definition of serious – Recommend a move to align definitions across organizations – CIHI vs. WHO vs. Health Canada… Lack of alignment will lead to confusion and potential over or under reporting – each with negative implications.

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	• Duplication of effort – Recommend a move to streamline documentation to minimize workload required to report events – can there be work down to develop electronic interfaces between Health Canada and leading providers of event reporting systems.
7 [> 300 beds, mental health centre]	While [name removed] agrees with many of the proposed amendments, we share the concerns that other organizations have brought forward in regard to the fiscal impact of implementing the changes; particularly, as it related to the types of reportable serious ADRs. It is anticipated that these legislative changes could result in the need for up to 1.0 FTE at a salary of $138,905.00, initial training, systems changes and policy changes of $33,000, plus ongoing yearly refresher training. These costs do not factor in the impact to patient care through front line costs of submitting all documents serious ASDRS, resulting in a potential decrease in the number of patient care hours. Additionally, [name removed] is concerned that the proposed regulations do not clearly identify which organization would report an SADR in the event that a patient at a tertiary care facility experiences an SADR and requires hospitalization at an acute facility. As the SADR would likely be documented at both organizations, there may be duplicate reporting of an ADR as the patient transitions between the two organizations, creating duplication of data and efforts to collect and submit information. Alternative solutions to the dilemma should be explored further. Thank you for the opportunity to provide this feedback. We look forward to hearing the outcomes of the proposed changes.
8 [large, teaching hospital]	I would like to also raise the following items for your consideration, as they represent differences from what was originally proposed, stakeholder feedback, and what is being proposed in the *new* draft Regulations: - Changing the reporting requirement to "all" hospitals is commendable, but this still excludes many areas of healthcare delivery that may actually see higher frequencies of serious ADR/MDI, out of the reporting requirement. For example, LTC homes, community pharmacies, family doctor's offices, clinics/walk-in centres, etc. It must also be recognized that increasing the breadth of mandatory reporting locations from

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	"acute care hospitals" to "all hospitals" will have a resource (staffing and time) impact on providers and especially on smaller hospitals; - Revising the type/definition of reportable ADRs from "serious, [sic, should be "unexpected"] <u>expected,</u> ADR" to "<u>all</u> serious ADRs" will have another significant impact on resources (staff, time, system, and take time away from patient care for investigations/documentation, etc). Under the revised definition/type, it will now be mandatory to report well-known serious ADR to medications (e.g. bone marrow suppression to antineoplastics, hair loss due to antineoplastics, etc.). Reporting these "known and documented" serious ADR will create unnecessarily large databases that will compromise the timely analysis needed for those "serious unexpected ADR" that need to be communicated to providers and patients quickly to avoid potential replication of the serious unexpected ADR in other patients; - The reporting system needs to build on existing reporting systems or infrastructure (eg. existing ADR form), and must be electronic; - The workload required to support timely submissions and reporting as mandated by these Regulations must be carefully balance to ensure compliance; - The review, analysis, and reporting back process for these ADR reports received by HC are not well delineated. There needs to be a robust and sustainable mechanism to make sure the hospitals and patients receive the information rapidly to prevent or observe patients for newly reported serious ADRs. I want to thank you for the opportunity to provide feedback on these draft Regulations. I would also encourage that your office re-examine those areas changed from prior consultations that will have a serious impact on compliance with reporting either due to staff, time or system impact; and especially the change in type/definition of the serious ADR.
9 [health region]	I support the proposed regulations, with the exception of the requirement to report all serious ADRs: I much prefer a requirement to report only the serious, <u>unexpected</u> ADRs.

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	Having actual numbers on occurrence rates of the expected serious ADRs would be ideal. However, at this time that information would come at the risk of not learning about the unexpected serious ADRs, largely because of the overwhelming workload required to capture both types of serious ADRs (expected and unexpected). The unexpected serious ADRs are probably more important, and the focus should be on reporting that data. Once the infrastructure (people, technology, processes) are updated and have the capacity to manage the increased workload, then we can progress to reporting all serious ADRs.
10 [large teaching hospital]	Thank you for the opportunity to respond to the proposed regulations to amend the Food and Drug Regulations to require hospitals to report serious adverse drug reactions. [Large teaching hospital, name removed] is an academic hospital affiliated with the University of [name removed], with [over 600] acute inpatient beds, [over 160] rehab beds and [over 500] long-term care beds. At [name removed], we are supportive of the legislation and are committed to investigating and reporting serious adverse drug reactions. However, we have concerns regarding the proposed types of reportable serious events. Under the current proposed regulations, hospitals would require to report all documented serious adverse drug reactions (ADRs), as well as medical device incidents. This would include not only serious unexpected ADRs (e.g., toxic epidermal necrolysis, hepatitis, pneumonitis) but predictable serious ADRs (e.g., bone marrow suppression induced by antineoplastic agents, bleeding due to warfarin use, bowel obstruction following opioids). We agree that reporting of serious unexpected adverse drug reactions would be beneficial in assessing the safety of medications. However, we have concerns about reporting predictable serious adverse drug reactions for the following reasons: 1. We question whether reporting predictable serious adverse drug reactions would result in any label changes or warnings, as these are already included in the product monographs and are well-recognized by healthcare providers. 2. In addition, the extra workload that would be generated by needing to report all serious adverse drug reactions is substantial, as indicated in the proposed regulations:

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	It is anticipated that a small hospital (fewer than 100 beds) would need to hire or reallocate 0.25 full-time equivalents (FTEs), representing a salary of $40,000 per year, while ***a large teaching hospital (more than 300 beds) would require 1.5 FTEs, representing a salary cost of $150,000 per year.*** 3. At [name removed], with over 1300 inpatient beds, reporting all serious ADRs would result in a significant operational impact on the institution, and affect direct patient care, as staff would need to be redeployed to report ADRs to Health Canada instead of taking care of patients. We ask that reconsideration be given regarding the reporting of all serious adverse drug reactions, and only limiting reporting to unexpected ADRs.
11 [large, teaching hospital]	I am providing my feedback on the proposed mandatory reporting of SAEs for hospitals within 30 days. Having worked in the pharmaceutical industry in medical information, I spend many hours reporting AEs of all kinds. According to regulations, we were obligated to report AEs any time we knew of a patient being on one of our medications and mention of any adverse event even it we did not know causality to the product in question. Drug safety physicians would determine causality based on the information provided. I agree with mandatory reporting of SAEs in hospital. In theory this is a good idea but I do have some concerns: • HCPs may not know causality between the drug and the AEs and may spend a lot of time reporting SAEs when not sure of causality • HCPs may report possible AEs not knowing causality for fear of not reporting and have subsequent fines applied. • The virtue of patients being admitted to hospital and on medications, technically constitutes an SAE! • Reporting takes a lot of extra time that HCPs would have to add to their busy days. • Who will decide on causality of a particular SAEs reported? (in drug companies there are Drug Safety physicians) • How do you plan to "police" if hospitals are not reporting? • Do we need to report all SAEs even if already reported in the Product Monograph? • Will these SAEs be reported to the pharma companies, generic and name brand?-SAEs for drug companies have stricter procedures for reporting (eg within 5 days) • What are other jurisdictions doings eg FDA, European Union?

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	• Would HC provide any assistance to hospitals with respect to this increase in workload?
12 [health region]	**Applicable Health Care Institutions:** The 2017 Consultation paper provided by Health Canada proposed only applying to 'hospitals that provide acute care services'. The 2018 proposal now recommends 'all hospitals'. This depends on the definition of hospital, but may exclude many facilities that provide medication such as Provincial Cancer Agencies, Private and Public Infusion clinics, private radiology clinics, and other medical offices that provide treatment to name a few. **Types of ADR's:** In the 2017 consultation paper, only serious, unexpected ADR's would be reported vs. the current proposed all serious ADRs. This leads back to applicable health care institutions, because all ADR's can present at any facility whereas a serious, unexpected ADR would be likely to present at an acute care hospital. The CMA recommended that these serious ADR's be limited to patients admitted to hospital for a minimum of 24 hours. The applicable therapeutic products do not include natural health products and do not include cannabis. **System concerns:** Health Canada will need an accessible, electronic, and relevant reporting tool that can be stand alone or link to other reporting software. Health Canada will also need to ensure that this information supplied by institutions is analyzed efficiently and quickly with communication expectations. What type of access to the information by the reporting institutions will be allowed? **Responsible Providers:**

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	Who will be responsible for reporting? Can public report? Can reporting be delegated from one health care partner to another (ie physician to pharmacist)? What follow up will be required by the reporting person and what expectations will Health Canada have for communication? **Anticipated Salary Costs:** I have concerns that these estimates will be low and will be very dependent on what services are offered at the institution. A hospital which offers stem cell transplant versus a facility that doesn't will have drastically different ADR numbers. Will this be billable by physicians?
13 [large, teaching hospital]	Thank you for providing us an opportunity to provide input related to the impending mandatory reporting of SADRs and MDI's. I have been a hospital pharmacist for 37 years. My hospital residency project in 1982 was a post-marketing surveillance study of zomepirac sodium which was removed from the market 6 months later. During my career I have typically been the hospital representative responsible for coordinating the Adverse Drug Reaction Program. I have the following thoughts: • Timeline - 30 days seems right • Products - leaving vaccines and natural products out seems right • Pilot - I would like to see a pilot start with maybe 10 % of the more engaged hospitals shortly after the publication in the Gazette allowing 4-6 months for the education and systems to be rolled out and tested before 100 % are required to do it. If the government does not have the systems in place to do it upon Gazette publication then delay until they are ready. This will allow the hospitals to develop the systems to make this work. For instance, how are we going to ensure that 3 people don't report some SADRs and no one report others between the various disciplines and 30 day period? It will take a system to be developed.

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	By having 10 % of hospitals in the pilot they will help act as champions for the other 90 % that start 4-6 months later. • Reporting System - Currently we have two choices to report ADRs. One page paper (faxed or e-mailed) or on line. Currently, I'm to get all the reports, summarize them for the Pharmacy & Therapeutics Committee and report semi-annually. I prefer the paper reports faxed in and the original given to me. This is because the electronic system has too many issues. If someone reports on-line and doesn't remember to print before they submit there is absolutely NO WAY of getting a copy of that report! (We had a student who submitted without printing and I tried 3 times to get the report by calling the government and could not get it.) Thus, not only can I not summarize or follow up, we don't know if someone has already reported. Also, if the government calls for more information, the report doesn't have a patient identification number, so there is absolutely no way we can answer their questions. Secondly, when the report is printed, any of the free text fields only print the first few lines requiring the user to write out the rest of the information on the hard copy. If they don't I can't summarize the report. In future, if a physician goes on line, a pharmacist goes on line and a week later another pharmacist goes on line, how we will know that we are wasting our time reporting the same thing?? How will we know what has not been reported? Will a hospital coordinator (the FTE's you speak of) be given access to pull reports from the system of reports generated from that hospital?? We need help with the system. We can't work blindly. It can't be one way if we are to facilitate the hospital meeting it's obligations. The benefit of paper is that you can do it at the bedside with the patient. Most hospitals don't have computers at the bedside so it is more efficient. Having said that it means the government needs to key in the information and legibility is a challenge. Thus, electronic is the goal via lap tops or bedside computers but it needs to be a system that allows the hospital to get reports, get all the information, somehow put in patient ID number for later follow-up and to determine multiples, NOT include multiple choice where you are forced to pick things that are not appropriate or are open to various interpretations and thus make it useless. It needs to be user friendly. It can't limit how or what you report. It has to be easy to add information in follow-up.

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	• I like the FTE's responsible person(s) at each hospital with managers/chiefs/supervisors supporting the efforts via the front-line approach. • I am unclear using the definition what would be included and if it is mandatory it must be clear. It says significant disability or incapacity or prolongs hospitalization. This could be a multitude of things many of which are clear but some of which might not be. e.g. high INR of 5.6 delays patient discharge, phenytoin level 92 delays discharge, 92 year old patient admitted on lorazepam 2 mg po qhs impaired memory, Hyperkalemia patient on IV KCl 40 mmol/L too long and discharge delayed, etc. We will need more parameters and examples with it being mandatory. • I have done a lot of teaching students and while most of the reports are done by pharmacists, I find pharmacy students come out never having completed an ADR. University/training programs should include this in their curriculum and they should be required to do at least 3 submissions during their training. Same for medical and nursing students. • Remind people that you still want [reports of] the other ADRs as well it's just the SADRs are mandatory. Thus, if in doubt report! • While I clearly support this and have for the duration of my career, we must realize that the time will come from other probably more worthwhile uses of the pharmacist's time e.g. BPMH, Medication Reconciliation, Deprescribing measures, Medication Reviews - consideration of risk/benefit - duration, etc. • I have lived through the "pigeon hole" method whereby we filled in ADR forms and Ottawa put the forms in pigeon hole boxes and when the box got fuller than others, they looked at them. For years I've filled in forms and got back a form in the mail saying thank you for each one (stop doing this) but not sure what good it did. I continued to lecture at the University about drugs only being trialled in young healthy people with no drugs and then we give them to 90 year olds on 20 drugs and 10 diseases and don't look systematically for issues. Now we want to spend a lot of time and money and despite all my support we shouldn't go ahead until we are ready to really deal effectively with the result. If we don't see a real benefit as a result of the efforts, the quality of the reports will go down. To this goal of getting RESULTS, consider having "focuses" identified in bulletins periodically. I see that a bit in the Health Canada bulletins. Play that up more. In the U.S. years ago, a hospital had a "hot-line" for ADRs and all the physician or nurse needed to do was to call the hot-line if they had any suspected reaction and a pharmacist with that responsibility would follow-up and report if needed. They identified focuses and when they saw a concerning number of

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	bleeds in heparin patients they raised the focus and asked for all bleeds on heparin to be reported. They were able to show that they had more bleeds with one brand of heparin than another. It will inject energy to give people the sense that we have specific problems we are working together to resolve rather than just filling in a form because we have to and it goes into a big black hole. • Information required - I have an issue with requiring Brand name as patients coming into Emerg will not know what Brand they were on. For ODB patients we can look it up but for others it's unknown. It must be clear, is the brand meant to be the brand the patient got or just the common brand name of the generic drug the patient was on. e.g. If we say Lasix it doesn't mean they were on Lasix, that would be unlikely. On the other hand, if they got Apo-furosemide, do you want Lasix or Apo-furosemide as the brand? • Information required - concomitant therapeutic products can be challenging. Working with the elderly this can be 15-20 drugs. Don't expect all the details for all drugs. If there are a couple that could also be involved we would spend time trying to get more info but otherwise just a list of generic drug names and that they have been on chronically should do it. If we have 6 fields for each of 15-20 drugs to complete, it will NOT be practical. When you say therapeutic products, are you including natural products there? Again I would leave them off unless suspected.
14 [health authority]	1) Are you aware of federal plans to capture and collate the responses? I am thinking a CIHI NSIR approach… 2) What are the timelines to initiate reporting by hospitals? 3) Are agencies exempt at this point as they are not hospitals, e.g. the Cancer Agency?
15 [CSHP]	Mandatory reporting by hospitals of prescribed information on all serious adverse drug reactions (SADRs) and medical device incidents (MDIs), within a prescribed time and in a prescribed manner, will place considerable strain on the staff and systems of these hospitals: the pharmacists, physicians, nurses, and other health professionals who work in these institutions, as well as on information management technicians and related workers. • The requirement will add to the already heavy workloads of Canadian health care professionals, which is often compounded by labour shortages. • To avoid increased healthcare expenditures related to the reporting of SADRs, hospitals will be required to divert personnel from direct patient care to the reporting of all serious adverse drug reactions: care that is designed to improve health outcome and prevent safety-related incidents and adverse drug reactions.

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	• To avoid diversion of personnel will require additional budget (re-)allocations from other goods and services to allow staff to be hired to capture and report data on all serious adverse drug reactions. ○ 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. It is difficult to provide feedback regarding the information management system required to capture and report the data about SADRs other than to say that the present system would not meet the needs to capture and report the required information in an efficient, timely manner. Knowledge of all SADRs that resulted in death outside of a hospital should also be mandatory. If this information is not already provided to Health Canada, can the definition of "healthcare institutions" be expanded to include the coroner's office? With regards to the required information, it could be difficult to accurately capture the date drug therapy started. There will be incidents when the SADR occurred a long time after therapy started, the patient (or family) has forgotten the date, or a lot of time and effort is required to obtain the information (e.g., out of province or country). The outreach and education programs to be provided by Health Canada to all relevant healthcare professionals and hospitals are welcome.