

Building a Comprehensive Post-Market Surveillance System

Canadian Medical Association Response to Health Canada's Discussion Paper
"Designing a Mandatory System for Reporting Serious Adverse Reactions"

Submitted to Health Canada
July 28, 2005



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Overview

The CMA believes that all stakeholders should work together to improve adverse drug reaction (ADR) reporting, in the interests of improving patients' safety and health. However, we believe that activity in pursuit of this end must be based on two fundamental premises:

a) *Reporting is only one part of a comprehensive post-market surveillance system.*

In order to effectively monitor the safety of Canada's drug supply, this system should include:

- a simple, comprehensive and user-friendly reporting process;
- rigorous analysis of reports to identify significant threats to drug safety;
- a communications system that produces useful information, distributed to health care providers and the public in a timely, easily understood manner.

There is no point in enacting a mandatory reporting requirement until all of these elements are in place. We wonder why mandatory reporting has been singled out for discussion when a holistic approach to reforming Canada's drug safety system is called for.

b) *Health care providers should be encouraged to participate willingly and voluntarily in the reporting process.* To be successful, Canada's post-market surveillance system will depend on the active participation of physicians and other health professionals. Experience with health system quality and safety improvement efforts over the past several years has demonstrated that meaningful acceptance is most effectively obtained when those involved are willing participants.

If you build a comprehensive, efficient and effective post-market surveillance system, physicians will participate actively in it. Forcing them to participate before the system has been built will result in alienation, frustration and failure.

Comments on Discussion Paper

a) Is Mandatory Reporting Necessary?

This is a fundamental question and the discussion paper does not satisfactorily address it. There are two reasons why we question the necessity for imposing an ADR reporting requirement on health professionals.

First, as awareness of the drug-safety system's importance has increased, the number of ADR reports has increased along with it - more than 10% in 2004, as the discussion paper notes - without a mandatory reporting requirement. Given this trend, it is highly probable that time, education, adequate resources and increasing familiarity with the surveillance system will raise reporting rates to the desired level (however defined) without mandatory reporting.

Second, as the discussion paper points out, there is no evidence that mandatory reporting has been effective in other jurisdictions where it has been implemented. The paper offers no clear explanation for this lack of success. More importantly, it does not indicate how Health Canada plans to ensure that mandatory reporting will succeed in this country when it has proven ineffective elsewhere. A primary principle of any system change is that we should not repeat the mistakes of others. Before launching a program whose success has not been proven, other viable, and possibly more effective, alternatives should be examined.

b) Addressing known barriers to reporting

The CMA acknowledges that ADRs are under-reported, in Canada and worldwide. The discussion paper identifies a number of barriers to reporting, and its list mirrors the observations and experiences of our own members. We believe most of these barriers can, and should, be overcome.

We also agree that it is necessary to raise health professionals' awareness of the importance of, and process for, ADR reporting. But we question the curious assertion that "Mandatory reporting could raise awareness of the value of reporting simply by virtue of the public debate." Surely there are more positive ways to raise awareness than publicly speculating about the punitive consequences of non-compliance. We suggest that instead, Health Canada work with physicians and other health professionals to address the existing barriers to reporting. Specifically, we recommend that Health Canada implement:

- a well-funded and targeted awareness-raising campaign focused on provider education and positive messaging,
- a user-friendly reporting system, including appropriate forms, efficient processes and adequate fees.

These measures are within Health Canada's purview in the existing policy and legislative environment. We believe they would increase reporting without the need for coercive measures. At a minimum, positive system improvements should be tried first before considering a mandatory-reporting requirement.

With regard to specific questions posed in the discussion paper:

Question 1: Health professionals should be explicitly protected from any liability as a result of reporting an adverse drug reaction. This should be the case regardless of whether reporting is voluntary or mandatory.

Question 2: Professionals should be compensated for all meaningful work including the completion of forms and any follow-up required as a result of the information they have provided. We would be happy to expand further on this issue on request.

Question 3: Issues of confidentiality should be covered in legislation. The CMA has developed an extensive and authoritative body of knowledge on privacy issues in health care, which we would be pleased to share with Health Canada.

c) Improved report quality

We agree that increasing the quality and richness of ADR reports is as important as increasing their number. Perhaps it is even more important, since high-quality reports allow for high-quality analysis. Mandatory reporting will not improve the *quality* of ADR reports; it will simply increase their *quantity*. It may even compromise the system's efficiency and effectiveness by increasing the volume of clinically insignificant reports. Experience elsewhere has taught us that true quality cannot be legislated or imposed; any attempt to do so would be pointless.

If ADR reports included the information listed in Table 4, this would improve their usefulness and the effectiveness of the overall surveillance process. However, it is unrealistic to expect all reports to contain this level of information. The treating physician may not be able to provide all of it, especially if he or she is not the patient's regular primary care provider. Some of this information, particularly about outcomes, may not be available at the time of the reporting, and gathering it would require follow-up by Health Canada.

Health Canada should consider measures other than mandatory reporting to improve the quality of ADR reports. The CMA suggests that consideration be given to:

- *Improving follow-up capacity.* We agree that it should be made easier for Health Canada officials to contact reporters and request details on follow-up or outcomes. This should be considered as part of a comprehensive initiative to improve Health Canada's capacity to analyze ADR reports.

- *Establishing a sentinel system.* Another option for increasing high-quality reports would be to establish a “sentinel” group of practicing physicians who would contract to report all ADRs in detail. These physicians, because of their contractual obligation, would be committed to assiduous reporting. Sentinel systems could be established concurrently with efforts to increase voluntary ADR reporting by the broader health professional community.

In addition to the current information provided, consideration should be given to including on reporting forms the option to allow Health Canada officials to act on information the physician provides; for example, in the reporting of sexually transmitted diseases physicians provide certain information and have the option to request that public health officials undertake follow-up and contact tracing.

d) Minimize administrative burden

We agree that Health Canada should give consideration to making the ADR reporting system user-friendly, non-complex and easy to integrate into the patient-care work stream. These reforms can and should be implemented regardless of whether a mandatory requirement is in place. They do not need mandatory reporting to make them work; in fact, they are more likely to encourage ADR reporting than any form of coercive legislation.

Rather than making a mandatory reporting requirement “fit” with the traditional patient-care framework, we invite Health Canada to work with us to increase health professionals’ capacity to report ADRs voluntarily.

We are already working with Health Canada to improve physicians’ access to drug safety material. Health Canada’s ADR reporting form can now be downloaded from the cma.ca web site, which also posts the latest drug alerts from Health Canada and from the Food and Drug Administration in the U.S. We have developed an on-line course in partnership with Health Canada, to teach physicians when and how to make ADR reports.

We hope to build on this collaboration, with the goal of making it possible for physicians to report ADRs online via cma.ca. This will permit them to fit reporting more conveniently into their daily workflow. (Note: the “MedEffects” Web portal now being developed at Health Canada does not fit well into the workflow and therefore will not make reporting easier for health professionals.)

In the future, we hope that ADR reporting can be built directly into the Electronic Medical Record (EMR). We think this will be a critical element in the bi-directional communicating that ADR reporting requires. It will also enable rapid integration of advisories into the EMR so that they can be available to physicians at the time they are writing a prescription. Before electronic ADR reporting can work, a standard for electronic data should be in place (at present it is not) and Health Canada should develop the capacity to accept data electronically.

Health Canada's discussion paper makes reference to cost-benefit analysis. We recommend that you take great care not to over-emphasize cost-benefit when it comes to enhancing patient safety. Meaningful improvements in the post-market surveillance system will be costly whatever solution Health Canada eventually embraces, and it is impossible to measure financially the value of safety. What is an acceptable cost for one life saved?

e) Minimize Over-Reporting

The discussion paper acknowledges that not *all* adverse reactions need be reported. We strongly agree that one of the dangers of mandatory reporting is its potential to overwhelm the system with an unmanageable flood of reports. There is no reason to require reports of minor side effects that are already known to be associated with given drugs.

We agree that the reactions Health Canada most needs to know about are those which are severe and/or unexpected. If Health Canada insists on implementing a mandatory reporting system, it should be limited to these reactions (possibly with the corollary that well known serious ADRs would not need to be reported). However, the operating definitions may need clarification, and we recommend that Health Canada consult with health professionals and others on operational guidelines for defining "serious adverse reaction."

Health Canada's desire to encourage reports on drugs approved within the last 5 years is understandable (though some drugs may be on the market for longer than this before their true risks are known). In practice, however, many physicians do not know which drugs these are, and seeking out this information may impose a heavy administrative burden. As we move toward an EMR-based reporting system, a tag on the Drug Identification Number to tell when the drug was approved will allow physicians to identify which medications require special vigilance.

Appropriate reporting could be encouraged, and over-reporting discouraged, by clear guidelines as to what should be reported as well as appropriate compensation for reporting.

f) Match Assessment Capacities

In our opinion, this is one of the most important sections in the document. What happens once the reports have been received is crucial if we want to identify a serious drug risk as quickly as possible. Under the current system, one of the most significant barriers to physicians' reporting is lack of confidence that anything meaningful will be done with their reports.

Enhancements to the analysis function must be made concurrently with efforts to increase ADR reporting. ADR reports are only cyber-bytes or stacks of paper unless we can learn from them.

This requires rigorous data analysis that can sort “signal from noise” – in other words, sift through thousands of reports, find the ones that indicate unusual events, investigate their cause, and isolate those that indicate a serious public health risk. This requires substantial resources, including an adequate number of staff with the expertise and sensitivity required for this demanding task. Unless Health Canada has this capacity, increasing the number of reports will only add to the backlog in analysts’ in-boxes.

The CMA recommends that Health Canada allocate sufficient resources to enable it to effectively analyze and respond to ADR reports and other post-market surveillance information.

g) Respect privacy

Privacy of both patient and physician information is a significant concern. Physicians’ ethical obligation to maintain patient confidentiality is central to the patient-physician relationship and must be protected.

We acknowledge that issues of privacy and confidentiality must be resolved when designing an ADR reporting system, particularly as we work toward electronic communication of drug surveillance data and its incorporation into an EMR. For example, regulations should explicitly state that ADR reports are to be used only for the purpose for which they were submitted, i.e. for post-market drug surveillance. In addition, Health Canada should ensure that any privacy provisions it develops meet the legislative test outlined in Section 3.6 of CMA’s Health Information Privacy Code (Attachment I).

Health Canada can be assured that physicians take their privacy obligations seriously. The CMA has been a strong and pro-active player in debate on this issue, and our Privacy Code lays the groundwork on which we believe any privacy policies involving ADR reporting should be based.

h) Compliance through sanctions

Physicians are motivated to report ADRs by their concern for public health and their patients’ well-being. In addition, they are guided by the CMA Code of Ethics and governed by regulatory authorities in every province.

A clear ethical and professional obligation already exists to report anything that poses a serious threat to patient safety. If physicians do not comply with this obligation, sanctions are available to the provincial regulatory authorities. In fact, the most serious threat for physicians is loss of standing with the professional regulatory authority, not the courts or any external judicial system. It would be superfluous to add a second level of regulation or scrutiny when remedies already exist.

The discussion paper presents few alternatives to the existing self-regulatory system. As the paper itself acknowledges, it is unrealistic to impose sanctions based on failure to report an ADR, since it is not always easy to determine whether an adverse effect is attributable to a health product. But the only suggested alternatives - requiring physicians to demonstrate knowledge, or to have the required reporting forms in their office - seem intrusive, crude and unreasonable; they are also meaningless since they have no direct relation to a physician's *failure to report*. If Health Canada is considering a large outlay of taxpayers' dollars for post-market surveillance, we suggest they target those funds to education and awareness raising, and to enhancing the system's ability to generate and communicate meaningful signal data, rather than to enforcing a mandatory reporting system based on weak compliance measures, with no evidence of its effectiveness in other jurisdictions.

Physicians who are in serious breach of their ethical and legal responsibility to report are subject to sanctions by provincial regulatory authorities. Most provincial colleges have policies or guidelines regarding timely reporting and appropriate enforcement mechanisms. Medicine's tradition of self-regulation has served it well, and we recommend that Health Canada respect and support existing regulatory authorities as they maintain the standards for appropriate professional behaviour.

As we have said before - the preferred quality improvement tools to enhance performance and encourage compliance are education and positive reinforcement, not legislation and the threat of sanctions.

Conclusion

In its discussion paper Health Canada has invited stakeholders to provide their input on how best to develop a mandatory system for reporting ADRs. The Canadian Medical Association believes that the best way to do this is not to develop one at all. Instead, we believe stakeholders should concentrate on building a sustainable, robust and effective post-market surveillance system which:

- encourages and facilitates voluntary reporting, by designing a simple and efficient process that can be incorporated into a physician's daily workflow;
- effectively uses reporting data to identify major public health risks;
- communicates drug safety information to providers and the public in a timely, meaningful and practical way.

The CMA is committed to working, in partnership with Health Canada and other stakeholders, toward the ultimate goal of a responsive, efficient and effective post-market drug surveillance system. This is part of our long-standing commitment to optimizing Canadians' safety and health, and achieving our vision of a healthy population and a vibrant medical profession.