CMA Submission to the House of Commons Standing Committee on Health

Post-Market Surveillance of Pharmaceutical Products

Dr. John Haggie, Chair
Board Working Group on Pharmaceutical Issues

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ASSOCIATION MÉDICALE CANADIENNE
CANADIAN MEDICAL ASSOCIATION

A healthy population...a vibrant medical profession
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The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.

On behalf of its more than 67,000 members and the Canadian public, CMA performs a wide variety of functions, such as advocating health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 47 national medical organizations.

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1) INTRODUCTION

The Canadian Medical Association represents more than 67,000 physicians in Canada; its mission is to serve and unite the physicians of Canada and to be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.

In pursuit of this mission the CMA has developed a growing body of policy on pharmaceutical issues. We have previously presented to this Committee on the subject; in November 2003, at the time of its initial study on prescription drug issues, and in May 2007 during hearings on the Common Drug Review. In addition we are consulting regularly with Health Canada on its Progressive Licensing Program, and have commented on a number of related federal initiatives, including adverse drug reaction reporting, which is one of the elements of your study.

CMA believes that the goal of a Canadian pharmaceutical strategy should be to ensure that every Canadian has timely access to safe and effective prescription drugs, and that no Canadian is deprived of needed prescription drugs because of inability to pay. It is not by chance that the words "safe and effective" occupy a prominent place in this statement of principle.

A post-market surveillance system is essential to ensure drug safety and effectiveness. No matter how rigorous the drug approval process, it cannot identify all of a medication's effects. Pre-approval clinical trials tend to focus on small numbers of patients, and exclude vulnerable groups such as children and the elderly. They also tend to be short, whereas many drugs are taken by patients for years and have safety and effectiveness issues that are only identified after widespread, long-term use in the general population. For these and other reasons, it is essential that Canada develop a strong system to monitor the performance of prescription drugs after they come on the market. The CMA is prepared to work with other stakeholders toward building such a system.

What would a strong post-market surveillance system look like? In order to effectively monitor the safety and effectiveness of the country's drug supply, the CMA believes it should include:

- comprehensive processes for gathering drug safety and effectiveness data;
- a capacity for rigorous analysis of the data that has been gathered, to identify significant threats to drug safety; and
- a communications system that produces useful information, distributed to health care providers and the public in a timely, easily understood manner.

This system should be so designed as to encourage the active participation of physicians and other health professionals, engaging them early in an ongoing and meaningful way.

Does Health Canada currently have a post-market surveillance system that can accomplish these things? We believe the present system requires considerable development if it is to accomplish them satisfactorily. This situation is not unique to Canada: other countries, such as Britain and the United States, are also wrestling with the problem of achieving satisfactory post-market surveillance. We are pleased that Health Canada is developing a framework for reforming Canada's drug regulatory system, through its Progressive Licensing Program; CMA is consulting regularly with Health Canada on this initiative.

In this submission, the Canadian Medical Association will present its recommendations for moving toward an improved post-market surveillance system, one which will support optimal patient health and safety, and meet the information needs of health professionals and the public. First, we will respond to the items listed in the Committee's terms of reference; secondly, we will make recommendations regarding other elements that we believe will support a strong post-market surveillance system for Canada.

2) DISCUSSION OF THE COMMITTEE'S KEY ISSUES:

With respect to the items listed in the Committee's terms of reference, the CMA makes the following recommendations:

a) Regulatory Authority

Some stakeholders have expressed concern that Health Canada possesses few legislative tools to support a strong post-market surveillance process. Health Canada should be given these tools, including the authority to:

- require post-market studies of newly approved drugs if clinical trials identify possible safety risks;
- require manufacturers to disclose information if Health Canada thinks it germane to making a decision in the interest of patient safety; and
- take action if post-market research uncovers new safety concerns. This could mean ordering changes to product labels, or it could mean pulling a product off the market.

Granting Health Canada this regulatory authority is only the first step. Health Canada should not hesitate to use this authority if the situation warrants.

b) Capacity for monitoring, surveillance and research

Information gathering does not in itself constitute a strong post-market surveillance process. In our opinion, the most important element of the process is the monitoring and analysis that occurs within Health Canada, once an adverse drug reaction (ADR) report has been received.

Monitoring capacity 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 needed for this demanding task. Unless Health Canada has this capacity, increasing the number of ADR reports will only add to the backlog in analysts' in-boxes.

Post-market monitoring should do more than identify safety risks. It should also provide information about a drug's efficacy and effectiveness. Does it achieve the health outcome for which it is being marketed? Does it perform better than other drugs or therapies for the same condition? These are important questions if Canada hopes to use its limited health care resources most effectively and efficiently.

The CMA recommends that Health Canada allocate sufficient resources to enable it to perform these surveillance, monitoring and research functions effectively.

In 2007 a coalition of Canadian research centres prepared a *Business Plan for a Drug Effectiveness and Safety Network,* which proposed an integrated and comprehensive network of centres of excellence, to support the evaluation of drug safety and effectiveness in Canada. The government should consider working with Canada's research centres to move such a concept forward.

c) Consumer safety

CMA supports a risk-based approach to product assessment, with regulatory requirements that are greater for products with greater risk and lower for those with less risk. Risk assessment should take into account risk to the community as well as to individuals. While the risk assessment process should be science-based, it should also recognize that public perception might influence the management and communication of risk.

d) Compliance and inspection

Health Canada has declared its intention to seek meaningful penalties for existing infractions. The CMA supports this intention.

e) Public access to information

CMA believes that health professionals and the public should have access to accurate, practical information on drug safety and effectiveness. The government should make it a priority to communicate safety information regularly, succinctly, and in user friendly language.

In addition, it should work with health professionals and their associations to establish a solid system of communicating warnings and drug safety risks. If a drug is identified as having safety concerns but is not taken off the market, what are the implications for the patients who take it, for the physicians who prescribe it, and for the pharmacists who counsel patients on its use? Should all patients be taken off the drug? If not, which patients should be?

It is these answers that health professionals and the public are seeking. We recommend that Health Canada work with clinical experts to develop these answers, and disseminate them widely.

f) Adverse reaction reporting

At the outset, it is important to emphasize that spontaneous reporting of suspected ADRs is only one way to gather data on drug safety and effectiveness. The government should consider other, more systematic means of data gathering to augment these spontaneous reports. These could include formal post-market studies targeted to specific drugs, or recruitment of "sentinel" groups of health care providers who would contract to report ADRs in detail, and who, because of these contractual obligations, would be committed to assiduous reporting.

With regard to spontaneous ADR reporting, we believe that it could be strengthened by the following measures:

- A user-friendly reporting system, including appropriate forms, procedures that can be incorporated easily into a physician's busy schedule, and adequate reimbursement;
- Improved follow-up capacity. It should be made easier for Health Canada officials to contact reporters and request details on follow-up or outcomes.
- Linkages to international post-approval surveillance systems. This increases the body of data at researchers' disposal, as well as the capacity for meaningful analysis.
- Active solicitation of ADR reports from all health sectors. Pharmacists, for example, are well trained and positioned to identify adverse drug events and to capitalize on their relationships with patients to document their experiences.
- Limits on what should be reported. There is no reason to require reports of side effects that are already known to be associated with given drugs. The reactions Health Canada most needs to know about are those which are unexpected, or which occur in newly approved drugs. Health Canada should consult with health professionals and others on operational guidelines for clarifying what should be reported.
- Incorporation of the ADR reporting process directly into the Electronic Medical Record (EMR) as this is developed. This will enable health professionals to report more efficiently, fitting the reporting process conveniently into their daily workflow. It will also facilitate Health Canada's communication of safety alerts and other information, and it could enable rapid integration of advisories into the EMR so that safety warnings could appear on a computer screen at the time the physician is preparing a prescription.

You will note that this list does not include mandatory reporting of adverse drug reactions. We do not believe that mandatory reporting will contribute to a strengthened ADR reporting system. According to Health Canada's own 2005 discussion paper, it has not been shown to increase the number of ADR reports in jurisdictions where it has been implemented.

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.

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.

3) OTHER ISSUES RELATED TO POST-MARKET SURVEILLANCE

Canada's drug policy environment is very complex, and many factors outside the formal post-market surveillance system affect drug safety and effectiveness. In this section we will briefly discuss our position on some of these factors:

a) An Appropriate Drug Approval Process

Some critics have charged that an increase in drug safety problems is related to a decline in drug approval times. They maintain that the focus on shortening approval times, which has occupied regulators during the last decade, allows drugs to come on the market before they have been adequately evaluated. Health Canada should take care that this does not occur. A strengthened post-market surveillance system should not be used as justification for lowering approval standards.

It is important to make sure that if prescription drugs offer a significant improvement over products already on the market, they are made available to people who could benefit from them, as quickly as possible. However, pre-approval review of these drugs should also be consistent with ensuring optimal health outcomes and the safety of the drug supply.

It is important that health professionals and the public have access to *all* information – both positive and negative – about new products. If a drug performed disappointingly in clinical trials, or turns out to have only marginal benefits compared to others currently on the market, then Canadians should know this in order to make informed choices about their health care. Health Canada should make results of all clinical trials available to health professionals and the public.

b) Consumer Drug Information and Advertising

Direct to consumer advertising (DTCA) of prescription drugs has been accused of contributing to drug safety problems by aggressively promoting drugs to large numbers of people, including those for whom it might not be indicated, or for whom cheaper drugs with which we have longer experience are already available, therefore increasing the potential for adverse events.

The CMA believes that brand-specific advertising of prescription drugs to consumers inflates the market for potentially risky drugs and does not provide consumers with enough information to make appropriate choices. We recommend that brand-specific DTCA not be permitted in Canada, and that loopholes which currently permit a limited amount of brand-name promotion be closed.

CMA believes that the public has a right to accurate, unbiased information on prescription drugs and other therapies, to enable them to make decisions regarding their own health care. However, there are more effective ways to provide this information than brand-name advertising. Accordingly, we recommend that the federal government develop and fund a comprehensive program to provide accurate, unbiased prescription drug information for use by both patients and health professionals.

c) Best Practices in Prescribing

Drugs' safety and effectiveness improve when they are prescribed and taken appropriately. Given the rapid pace of drug development in the last 20 years, it is important that physicians and other health professionals remain current through receiving timely, reliable and objective prescribing information that they can absorb quickly and incorporate into their everyday practices.

The CMA is prepared to work with others in meeting this need, through a comprehensive program to promote optimal prescribing and drug therapy monitoring by health professionals. Such a program should:

- be founded not on sanctions but on education, including objective academic detailing, to ensure that the information health professionals receive is accurate and impartial;
- include use of information technology and practice tools;
- be organized and implemented with the participation of professional and patient organizations; and
- include strategies to improve patients' knowledge of and adherence to drug regimens.

CMA will be developing a vision for an optimal prescribing program, and beginning to implement portions of it over the coming year.

d) Supportive Information Technology

We have already mentioned the potential of electronic technology to increase ADR reporting, but we believe it deserves additional discussion.

Real-time information is essential for effective day-to-day health care. An investment in supportive technology would increase physicians' capacity to report adverse drug reactions. It would also facilitate Health Canada's reporting of drug safety information back to health professionals and consumers. Ultimately we hope that drug safety updates can be incorporated directly into electronic health record systems, which could feed information on a drug's risks (e.g. other medications that a patient is taking, with which the drug may interact harmfully) to the physician at the point of care, when it is most needed and most helpful.

CMA strongly recommends an investment in systems that can link physicians to one another and to the rest of the health care system. In developing such systems, patient privacy and confidentiality requirements must be taken into consideration, and governments should work with health professional and patient groups to establish standards for electronic health records.

4. CONCLUSION

The CMA commends both the Standing Committee and Health Canada on their intent to develop a strong and effective post-market surveillance system for Canada. This country's physicians are prepared to work with governments, health professionals and the public in strengthening this system, to ensure that the prescription drugs Canadians receive are safe and effective.