CMA's Submission to the Senate Committee on Social Affairs, Science and Technology as part of its study on:

Prescription Pharmaceuticals in Canada: The Post-Approval Monitoring of Prescription Pharmaceuticals

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Submitted by:

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ASSOCIATION MÉDICALE CANADIENNE | CANADIAN MEDICAL ASSOCIATION

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Founded in 1867, the Canadian Medical Association (CMA) is the national voice of Canadian physicians. , 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 76,000 members and the Canadian public, CMA performs a wide variety of functions. Key functions include advocating for 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 51 national medical organizations.

ASSOCIATION MÉDICALE CANADIENNE

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1) Introduction

The Canadian Medical Association is pleased to take part in the second phase of the study of prescription pharmaceuticals by the Senate Standing Committee on Social Affairs, Science and Technology. During the first phase, we presented the CMA's policy position regarding clinical trials and the process for approving new drugs for use. In this phase we will discuss our position and recommendations on post-approval surveillance of prescription drugs.

The Canadian Medical Association represents 76,000 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.

Prescription drugs are a very important part of high quality and cost-effective health care. They can prevent serious disease, reduce the need for hospital stays, replace surgical treatment and improve a patient's capacity to function productively in the community. Therefore, the CMA has developed a substantial body of policy on pharmaceutical issues, including on the post-approval surveillance of prescription drugs.

The essence of our position is contained in our first recommendation:

Recommendation 1:

The CMA recommends that federal and provincial/territorial governments collaborate to develop and implement a national pharmaceutical strategy to ensure that every Canadian has timely access to an adequate supply of safe and effective prescription drugs.

This recommendation has two elements: "safe and effective" and "adequate supply," both of which we will discuss in this submission.

2) Ensuring Safety and Effectiveness

As we have previously told this Committee, the CMA supports a robust regulatory framework and system for researching and approving new pharmaceutical products. But however strong Canada's pre-approval system is, it will not identify all potential problems with a new drug. 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 of short duration, whereas in the real world, patients may take these drugs for years. As a consequence, problems with a drug are often identified only after widespread, long-term use in the general population. For this reason, it is essential that Canada have in place a robust regulatory framework that includes a timely system to monitor the performance of prescription drugs after they come on the market.

The Government of Canada has taken several recent steps to enhance its drug surveillance system. In 2009, it established the Drug Safety and Effectiveness Research Network. In 2008, it introduced Bill C-51, *An Act to Amend the Food and Drugs Act*, to improve drug safety and effectiveness monitoring by Health Canada. Unfortunately, the bill died with the 2008 election call and has not been re-introduced. That is why we are pleased that the Senate has chosen to re-open this issue.

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

a) Comprehensive processes for gathering drug safety and effectiveness data

In gathering data about adverse drug reactions (ADRs) in Canada, Health Canada has traditionally relied on spontaneous reports from manufacturers and health professionals. The government could enhance its capacity to gather information by:

- making it easier for physicians and other health professionals to report ADRs voluntarily. This can be accomplished by making the reporting system user-friendly and easy to incorporate into a practitioner's busy schedule. Health Canada has improved the process by introducing online reporting, which may have contributed to the significant increase in the number of ADR reports over the past 10 years. The reporting process could be made even more efficient by incorporating it directly into the Electronic Medical Record (EMR) as this is developed.
- augmenting spontaneous reports with information gathered through other, more systematic means. These could include formal post-market studies of 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.

b) A capacity for rigorous and timely data analysis to identify significant threats to drug safety.

Information gathering does not in itself constitute post-market surveillance. In our opinion, the most important element of the process is the monitoring and analysis that occurs 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 the reports, find the ones that indicate unusual events, investigate their cause, and isolate those that indicate a serious health risk. It also requires that the analysis be timely: we note that in 2011 the Auditor General was particularly critical of Health Canada's post-market surveillance timeliness, noting that it could take several years for reports to be reviewed internally.

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?

c) Communication of useful information to health care providers and the public.

When new information is uncovered about a prescription drug, it is important that physicians and other health professionals are made aware of it as quickly and

efficiently as possible. Therefore, post-approval surveillance requires a system for communicating timely, reliable and objective information to physicians and other health professionals, which they can absorb quickly and incorporate into their everyday practice. Ideally, this communication would report not the safety problem alone but also its implications for their patients and practice: for example, whether some patients are particularly at risk, or whether therapeutic alternatives are available.

Recommendation 2:

The CMA recommends that Health Canada continue to improve the capacity of its post-approval surveillance system to:

- Make it easier for health professionals to submit voluntary ADR reports;
- Analyze the data that has been gathered in a rigorous and timely manner; and
- Communicate essential information to health care providers and the public in a timely and user-friendly manner.

d) Increased regulatory authority for Health Canada

Drug safety is a serious issue; recent research has revealed that nearly a quarter of new drugs approved in Canada will eventually receive a serious safety warning[1]. Given the potential risks to patient safety we believe Health Canada should have the legal authority to take strong action when a safety problem is identified.

The CMA recommends that Health Canada should be given 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 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.

3) Ensuring an Adequate Drug Supply

In the past few years Canada's doctors have become deeply concerned about the persistent shortages of drugs that they and their patients are encountering. In a survey of physicians conducted by the CMA in September 2012, two-thirds of respondents said that the shortage of drugs was a significant issue in terms of its impact on patient care and outcomes. Of these physicians, 70 per cent indicated that their patient received a less effective medication, and 20 per cent had patients who had suffered clinical deterioration because an alternate drug was substituted. This in turn leads to a greater demand on the health care system, whether in physician visits or emergency room treatments. Twenty-three per cent

[1] Lexchin J. New drugs and safety: what happened to new active substances approved in Canada between 1995 and 2010? *Arch Intern Med.* 2012;():1-2. doi:10.1001/archinternmed.2012.4444.

reported that their patient suffered financially due to the cost of the substituted medication, since many of the drugs in short supply are older, low-cost generics.

The lack of information about shortages compounds the stress of dealing with them. When physicians prescribe a medication, unaware that it is in short supply, they later have to provide the patient with a new prescription, which often requires an additional patient visit. Physicians have expressed their frustration at the time it takes to find an appropriate substitute drug – time which could better be spent in patient care.

As a consequence, the CMA strongly supports the development of a comprehensive system for monitoring domestic shortages of medically necessary drugs. To be of greatest benefit to doctors, such a system should include:

- Information about the product in short supply;
- Expected duration of the shortage;
- Therapeutic alternatives;
- Regions affected;
- Notification of the end of the shortage.

Although pharmaceutical industry associations and drug manufacturers are now supporting a drug shortage reporting website (http://www.drugshortages.ca/drugshortages.asp), there is room for improvement. The reporting website does not yet capture all of the drug product shortages. It must become more user friendly for health practitioners and the public, with search and sort functions to easily find product listings. In addition, a mechanism to obtain information on possible therapeutic substitutions would be of value to practitioners.

Recommendation 3:

The CMA recommends that Health Canada work with provincial and territorial governments, industry groups and health professionals to enhance the current system for reporting drug shortages and ensure its sustainability.

Finally, while a reporting system to provide information to health professionals and Canadians on drug shortages is valuable, it is essential that Canada address the root causes of drug shortages. A review of the supply processes, both domestic and international, is strongly recommended.

While the CMA acknowledges that provinces are responsible for purchasing drugs, we believe that solutions will be stronger if all provinces, and the federal government, work together on them. And since drug shortages are an international concern, it is the responsibility of the Government of Canada to work with other countries in seeking solutions.

Recommendation 4:

The CMA supports an investigation into the underlying causes of prescription drug shortages in Canada.

4) Other Important Elements of a National Pharmaceutical Strategy

As Recommendation 1 states, the CMA believes that Canada's federal and provincial/territorial governments should implement a national pharmaceutical strategy, one of whose objectives would be to ensure an adequate supply of prescription drugs. The strategy should address other important objectives, as well, notably:

- ensuring comprehensive prescription drug coverage for all Canadians. According to a recent CMA survey, one in 10 Canadians has gone without a prescription drug because they couldn't afford it. Governments should work with private insurers and other stakeholders to develop a system to provide equitable, comprehensive prescription drug coverage to all Canadians.
- encouraging optimal prescribing by health professionals. To accomplish this, the CMA has recommended a strategy that includes education, user-friendly guidelines and practice tools, and the provision of impartial information to health professionals and the public.

5) Conclusion

Once again, we commend the Senate Social Affairs Committee for bringing this issue to your table. Canada's physicians are prepared to work with governments, health professionals and the public in strengthening Canada's post-approval surveillance system, to ensure that the prescription drugs Canadians receive are safe and effective and in adequate supply.