

**Bill C-17 An Act to amend the Food and Drugs
Act - Protecting Canadians from Unsafe Drugs**

Canadian Medical Association:

Submission to the House of Commons Standing
Committee on Health

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A healthy population and a vibrant medical profession
Une population en santé et une profession médicale
dynamique

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 80,000 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.



The Canadian Medical Association (CMA) is pleased to present this brief to the House of Commons Standing Committee on Health for consideration as part of its study of Bill C-17, *Protecting Canadians from Unsafe Drugs Act*, which proposes amendments to the *Food and Drugs Act*.

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Prescription medication has a very important role as part of a high-quality, patient-centred and cost-effective health care system. Prescription medication 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. As such, the CMA has developed a substantial body of policy on pharmaceutical issues, including on the post-approval surveillance of prescription medication. Over the last several years, the CMA has prepared several briefs and reports on pharmaceutical medication and prescribing-related issues.¹ It is a priority to physicians that all Canadians have access to medically-necessary drugs that are safe, effective, affordable, appropriately prescribed and administered, as part of a comprehensive, patient-centered health care and treatment plan.

The CMA supports a robust legislative framework and unbiased, evidence-based system for the oversight of pharmaceutical products. As outlined below, the CMA has identified opportunities to strengthen elements of Bill C-17 toward this end.

1) Clarify ministerial authority and responsibility

The current legislative limit to the health minister's authorities is troubling. The CMA, along with many other stakeholders, has long called for an expansion of ministerial authorities related to the pharmaceutical legislative framework, including both pre- and post-approval, in support of patient safety.

The CMA supports the underlying intent to expand the authority of the health minister to require the submission of information, modify the label or replace the package, to order a recall or relocation of a product. However, the CMA has two concerns regarding the limitations to this expanded authority (section 3, proposed new FDA sections 21.1, 21.2 and 21.3):

- Firstly, that the threshold for the new authorities in section 3 (new proposed section 21.1, 21.2, and 21.3 of the FDA) may be too high. The term "serious risk of injury to health" will be the standard for these new ministerial powers and may limit the authority of the minister to take action when the concern may be serious, but not necessarily permanently debilitating or life threatening.
- Secondly, that the minister is not required to take any of the actions proposed in Bill C-17 even if the threshold is met (these sections specify that the minister "may" take the specified action, rather than the minister "shall"). While seemingly minor, the difference between "may" and "shall" is the difference between having the authority to take action and being responsible to take this action. This difference is critical to a robust legislative framework for patient safety.

Recommendation 1

In order to clarify the health minister's authority to take appropriate measures to protect patient safety, the CMA recommends that the standard "a serious risk of injury to human

health” in section 3 proposed new FDA section 21.1 and “serious or imminent risk of injury to health” in section 3 proposed new FDA section 21.3 be amended to ensure an appropriate threshold that does not constrain ministerial authority.

Recommendation 2: To ensure that the health minister has the clear responsibility to take appropriate measures to protect patient safety, the CMA recommends that the word “may” is replaced with “shall” in section 3, proposed new FDA sections 21.1, 21.2 and 21.3.

2) Oversight of natural health products

The extensive use of natural health products, such as vitamins and herbal medicines, is partially due to a belief that such products are “natural” and thus low risk. Increasingly, it has become clear that these products can have adverse effects, including drug interactions. However, relatively little is known about the adverse effects associated with natural health products due to its limited legislative and regulatory requirements, including reporting.

To ensure that patient safety risks associated with natural health products are addressed, these products should be included in the new patient safety legislation, as proposed in the previous iteration of this legislation in 2008, Bill C-51 *An act respecting foods, therapeutic products and cosmetics*. The CMA encourages the Health Committee to include natural health products within the scope of Bill C-17, as a first step toward ensuring that natural health products are subject to the same regulatory requirements and oversight as are prescription and over-the-counter pharmaceuticals in order to promote patient safety.

Recommendation 3: The ministerial authorities and measures proposed in Bill C-17 should be extended to include natural health products and, as such, CMA recommends that the definition of “therapeutic product” in section 2(3), be amended to include natural health products.

3) Comprehensive post-market surveillance and response system

The CMA has advocated for significant improvements to Health Canada’s post-market surveillance and response system in light of significant shortcomings.

A) Increasing accountability and public transparency

Robust accountability and transparency are important elements in the legislative framework governing the post-market surveillance and response system. The 2011 report of the Office of the Auditor General of Canada (OAG) highlighted significant concerns regarding this system, not least of which being Health Canada’s failure to meet its own benchmarks in reviewing and responding to pharmaceutical safety issues. While there was no assessment of the benchmarks themselves, as is typical with an audit, the OAG report highlighted a number of issues with Health Canada’s approach to measuring its performance against its benchmarks.

Following the publication of the OAG audit report, Health Canada’s *2013-14 Main Estimates and Report of Plans and Priorities*² shows cuts in both budget and staff allocation for health products

(which includes drug oversight). The 2011 OAG report states that “Canada’s small population reduces the likelihood of serious, rare adverse drug reactions being identified in this country; therefore, the capacity to search and analyze foreign reports electronically would contribute to more comprehensive safety monitoring.”³ Of note, the audit found that Health Canada “does not take timely action in its regulatory activities” (...). “In particular, the Department is slow to assess potential safety issues. It can take more than two years to complete an assessment of potential safety issues and to provide Canadians with new safety information.”⁴

Despite Health Canada’s March 2013 update on its efforts to address the OAG recommendations⁵ the status of the improvements to the reporting tools, timeliness of information or quality of information provided to practitioners and patients remains unclear.

The preceding paragraphs capture a number of issues pertaining to the post-approval surveillance and response system; it is imperative that Health Canada not only address these issues, but that Health Canada has adequate resources to do so. This is paramount prior to any consideration of expanding the input of reporting data.

Recommendation 4: The CMA recommends that Bill C-17 be amended to require Health Canada undertake public consultations in establishing its performance benchmarks related to adverse drug reaction reporting, analysis and response communication.

Recommendation 5: The CMA recommends that Bill C-17 be amended to establish a new public reporting requirement of its performance in meeting its performance benchmarks.

B) Improving the reporting and communication system

The CMA cautions against the advancement of new legislative authority with respect to mandatory reporting of serious adverse drug reactions prior to the improvement of the system and model currently in place.

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 report has been received. Monitoring capacity requires rigorous data analysis and, to be useful in preventing further adverse events, it must be timely. As well, it should also provide information about a drug’s efficacy and effectiveness.

When new information is uncovered about a prescription drug, it is important that 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 in a manner that allows them to incorporate it 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. Such feedback will encourage further reporting.

In order to improve patient safety, the CMA recommends that Health Canada’s establish a model that includes:

- Making it easier for physicians and other health professionals to report adverse drug reactions by making the reporting system user-friendly and easy to incorporate into a practitioner's busy schedule. Currently the existing system imposes an unnecessary administrative burden that comes at the expense of time dedicated to patient care.
- Making the reporting process even more efficient by incorporating it directly into the Electronic Health Record systems. Health Canada has improved the process by introducing online reporting, which may have contributed to the significant increase in the number of reports over the past 10 years, but being able to connect patient information with drugs they are taking, reporting of adverse drug reactions and safety information would improve care on the front line.
- 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 adverse drug reactions in detail, and who would be committed to assiduous reporting.
- Linking to international post-approval surveillance systems, thus increasing the body of data at researchers' disposal, as well as the capacity for meaningful analysis.

Health Canada should take a leadership role in ensuring that the public has access to appropriate information on drugs and drug safety, engaging civil society at the appropriate phases of the process. In providing this information, Health Canada should consider the management and communication of risk, and take into account the diversity of Canada's population. Access to accurate, unbiased information allows people to make decisions regarding their own health.

In addition to ensuring a comprehensive model is in place, it is essential that there be more clarity in Bill C-17 regarding what constitutes a "prescribed health care institution". There are very different changes to the system that would need to be in place should it refer to tertiary care hospitals, community hospitals, clinics or doctors in family practice. Bill C-17 must not place an unnecessary administrative burden, which would ultimately fall on health professionals. Further, it is unclear whether a cost assessment of the proposed new requirements for health care institutions with respect to provincial/territorial resources has been undertaken. Only those health care institutions that are best positioned to improve the quantity and quality of reporting should be required to report.

Another term that requires clarification in the legislation is "serious adverse drug reaction". It should be clear whether it means adverse drug reactions that require visits to emergency departments or hospitalization, or whether there are other criteria to define it.

Recommendation 6: The CMA recommends that Bill C-17 be amended to require that Health Canada implement comprehensive post-surveillance monitoring and reporting model that includes:

- Accessible, comprehensive and user-friendly reporting tools that are clinically relevant and linked to electronic health records;
- Rigorous and timely analysis of reports for the early identification and response to emerging drug safety threats; and
- Communication of timely, user-friendly and clinically-relevant information to health care practitioners and the public.

Recommendation 7: The CMA recommends amendment of Bill C-17 section 5, proposed new FDA section 21.8, to require that an assessment by the minister for reporting regulations be undertaken following a prescribed period after this new model is established; that this assessment precede the coming into force of expanded mandatory reporting.

Recommendation 8: The CMA recommends that essential terminology be defined in Bill C-17, including (a) “serious adverse drug reaction” and (b) “health care institution”.

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.

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² Health Canada (2013) *2013-14 Report on Plans and Priorities*. Government of Canada.

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³ Office of the Auditor General of Canada (2011) *Chapter 4 Regulating Pharmaceutical Drugs - Health Canada*. 2011 Fall Report of the Auditor General of Canada. Government of Canada. Retrieved from: http://www.oag-bvg.gc.ca/internet/docs/parl_oag_201111_04_e.pdf (pg 21)

⁴ Office of the Auditor General of Canada (2011) *Chapter 4 Regulating Pharmaceutical Drugs - Health Canada*. 2011 Fall Report of the Auditor General of Canada. Government of Canada. Retrieved from: http://www.oag-bvg.gc.ca/internet/docs/parl_oag_201111_04_e.pdf (pg 2)

⁵ Health Canada (2013) *Update and response to OAG recommendations for the regulation of pharmaceutical drugs in Fall 2011*. Government of Canada. Retrieved from:

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