



CANADIAN
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DU CANADA

Canada's Place in a Competitive World

PRE-BUDGET CONSULTATIONS 2006

*Submission to the
House of Commons Standing Committee on Finance Prepared by
the Canadian Pharmacists Association*

September 2006

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By the Canadian Pharmacists Association

SUMMARY

The Canadian Pharmacists Association (CPhA) is the national voice of Canadian pharmacists, committed to advancing the profession of pharmacy and contributing to the health of Canadians. In its news release, the Standing Committee on Finance identified legislators' need to ensure the health of Canadians and give consideration to the rapid pace of technological change. In response to this requirement, the focus of our submission is patient safety and the need for more effective post-marketing surveillance of pharmaceuticals.

We recommend significant investment in infrastructure to bring our systems into the 21st century by ensuring that available technology is used and appropriate training is provided to health practitioners, which will allow for better evaluation and measurement of real world drug safety and effectiveness.

RECOMMENDATIONS

1. The federal government, through Health Canada, should invest in an electronic ADR reporting system that integrates reporting forms into software used by health care professionals at the point of care.
2. The federal government, through Health Canada, should establish and aggressively promote a training program for health professionals on the structure and mandate of the ADR program and how to use an electronic reporting system.
3. The federal government should make certain that adequate funds are made available to ensure the effectiveness of a revised progressive drug licensing framework.

CPhA would like to see \$150 million, over 10 years committed to improving drug safety and effectiveness for all Canadians.

OVERVIEW

Pharmaceuticals play an increasingly important role in our health care system. Prescription drugs can prevent and treat disease, reduce hospital stays, replace surgery and improve overall quality of life for Canadians. In 2005, drug spending (prescribed and non-prescribed drugs) made up the second largest proportion of the health care budget, almost \$25 billion (18%) of total health expenditures.

That same year, Canadians filled approximately 396 million retail prescriptions, an average of 12 per person.

Yet, as more and more Canadians benefit from drug therapy, the number of drug safety concerns and adverse drug reactions (ADR) rises. Many of the risks associated with drugs are identified in pre-market testing and can be managed as “expected” or “tolerable” side effects that are outweighed by the product’s benefits. However, once a drug is made available on the Canadian market, new “unexpected” or “undesirable” side effects (adverse drug reactions [ADRs]) are sometimes discovered after extended use in “real world” conditions. Thousands of ADRs are reported to Health Canada each year, an estimated one tenth of actual occurrences.

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NEED FOR FURTHER INVESTMENT IN HEALTH CANADA

The federal government has invested in Health Canada’s Adverse Drug Reaction Monitoring Program, responsible for collecting and assessing adverse reaction reports for pharmaceuticals and natural health products, and the Canadian Adverse Drug Reaction Information System (CADRIS), which houses this data.

Health Canada is also developing a new progressive drug licensing framework designed to monitor drug safety and effectiveness

throughout the product’s lifecycle. While these are excellent initiatives, more can be done to improve drug and patient safety.

CPhA is strongly supportive of measures to improve patient safety, including the need to increase reporting of ADRs. Much discussion has taken place on whether Canada needs a mandatory adverse drug reporting system. CPhA feels that mandatory reporting, while being both costly and time consuming, would likely increase the number of reports filed but would not necessarily improve the quality or usefulness of those reports. One of CPhA’s main concerns about a mandatory system is the issue of enforcement. In recent years, we have seen Health Canada reduce its staffing for programs that require reporting, such as for prescription

narcotic and controlled drugs. We question whether Health Canada would be able to devote and maintain a sufficient level of resources needed to sustain a mandatory ADR reporting process.

We suggest consideration of the following alternatives:

1. Investment in an Electronic ADR Reporting System

As of January 2004, CADRIS stored over 160,000 reports of suspected adverse drug reactions that have occurred in Canada since 1965. However, this is only a fraction of the estimated true number of drug reactions. It is not enough to collect and store this information. To increase both ADR reporting and the usefulness of the data, Health Canada needs to invest in an electronic reporting system that integrates reporting forms into software used by health care professionals at the point of care.

The reporting system must be designed to fit into the usual day-to-day flow of care rather than require the pharmacist or other health care professional to disrupt daily routine. It should be easy to use so that administrative support personnel, under the guidance of a health professional, can complete the forms. For example, for pharmacists, the ideal system for reporting ADRs would link to the pharmacists' prescription processing

software. This link would facilitate inclusion of data elements, such as existing medications, recorded allergies, basic demographics such as age and gender, and avoid the need to re-enter data. Any integration costs must be borne by Health Canada. CPhA would like to see \$50 million allocated to develop such an electronic ADR reporting system.

Appropriate training and clear, concise help functions for electronic submission mechanisms are essential to ensure reports are

completed with an acceptable level of quality. Access to a toll-free call centre may help to facilitate quality since health care

professionals may need guidance when completing a form, especially at first or if changes are made to data requirements.

2. Investment in an ADR Training Program

A Health Canada study found that only 63% of physicians, 44% of nurses, 19% of naturopaths and 13% of dentists know how to report ADRs (compared to 92% of pharmacists). We recommend that Health Canada establish and aggressively promote a training program for health professionals that would familiarize them with the structure and mandate of the ADR reporting program, along with the processes of an electronic system. The

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training program should include the use of the submitted data and show health care professionals how their reports will contribute to improved health outcomes. This training should be made available at no cost to the health care professionals covered by the legislation and, in fact, consideration should be given to paying them for taking the training. We estimate that the costs to implement such a program would be \$10 million per year for five years.

Under progressive licensing, patients could receive newly marketed medicines from pharmacies. Monitoring and reporting on these new drugs for safety, efficacy and effectiveness would be completed by qualified health care professionals. The reporting of post-marketing adverse drug reactions could be a part of the electronic ADR system mentioned previously.

3. Progressive Licensing

It is commonly agreed that the current licensing framework is outdated and has many regulatory gaps. CPhA is pleased that Health Canada is developing an updated drug licensing process that will better address the needs of the regulator, the industry and the public. According to Health Canada, a new licensing framework would “support access to promising new drug therapies while continuously monitoring and assessing for potential safety, quality, efficacy and effectiveness” .

While CPhA recognizes the necessity of a new progressive licensing framework, we are concerned that the funding and resources required to implement and maintain such a program are inadequate. A new progressive licensing framework would be ineffective without adequate resources. This system could encompass or be integrated with the ADR reporting system referred to previously.