

Framework for a Canadian Pharmaceutical Strategy

Statement of the Coalition for a Canadian Pharmaceutical Strategy

Preamble

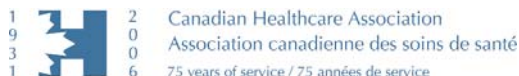
The Coalition for a Canadian Pharmaceutical Strategy brings together five organizations — the Best Medicines Coalition, Canadian Medical Association, Canadian Nurses Association, Canadian Pharmacists Association and Canadian Healthcare Association — who represent patients, health professionals, health system managers and trustees. Based on our knowledge and experience of the benefits and use of pharmaceuticals, we believe we can make important contributions to the development of a Canadian pharmaceutical strategy.

Introduction

Pharmaceuticals are important to the health of Canadians. For many patients prescription drugs and vaccines have prevented serious disease, reduced hospital stays, replaced surgical treatment and improved their capacity to function productively in the community, while at the same time often offsetting other potential health care costs. As patients become increasingly knowledgeable and politically aware, they will continue to expect and demand access to prescription drugs.

For some time, prescription drug expenditures have been growing faster than any other component of health care. It is realistic to expect that as the role of prescription drugs in health care increases, and as we close the “care gap” for untreated and undertreated patients, government expenditures on prescription drugs will rise accordingly.

Recognizing and accepting these realities, our Coalition has undertaken to outline the parameters it considers essential to any pharmaceutical policy or strategy developed in Canada.



Goal and Principles

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. To achieve this goal we propose the following principles to frame the strategy's development, implementation and evaluation:

- Canadians, no matter where they live, have equitable access to prescription drug coverage.
- Decisions are patient-centred, taking account of the unique needs and therapeutic outcomes of individual patients and respecting the relationship between patients and their health-care providers.
- All policy decisions, including drug approval and program coverage, are based on an impartial review of the best available scientific evidence, and on the adoption of best practices nationally and internationally.
- All initiatives are carefully assessed in accordance with a comprehensive evaluation strategy.
- Pharmaceuticals are evaluated not in isolation but as an integral part of the health system. They are assessed in the context of the overall burden of illness, and of their impact on direct and indirect illness costs and health system sustainability.
- Health care providers and health organizations have access to the knowledge and information necessary to facilitate optimal and appropriate pharmacotherapy.
- Appropriate use is made of the knowledge and skills of physicians, nurses, pharmacists and other health care providers.
- The decision-making process is open, transparent and accountable, and incorporates the active, meaningful participation of patients, health professionals, and other relevant stakeholders including public and private insurers.

Toward a Canadian Pharmaceutical Strategy

The above principles, and the following recommendations, apply broadly to any pharmaceutical strategy, including the nine-point National Pharmaceuticals Strategy (NPS) proposed by governments following the 2004 First Minister's Accord. The elements of a comprehensive Canadian pharmaceutical strategy are interdependent and should be developed concurrently to ensure that the strategy is coherent and holistic. In addition, they should form part of a broader framework that encourages research and development of new medicines in Canada.

Drug Coverage

- All Canadians should have access to prescription drugs for which evidence indicates effectiveness in the treatment, management and prevention of disease and/or significant benefits for quality of life.
- Public and private payers should conduct research to identify the current gaps in drug coverage and develop policy options for providing this coverage, focussing first on uninsured and underinsured patients.
- Coverage should be based on optimal and appropriate standards of treatment for all Canadians. It should be comparable across the country, minimizing disparities between provinces and territories.
- Coverage plans should include coverage for catastrophic drug costs. As a first step, governments should adopt a common operational definition of "catastrophic".

Common Formulary

- Governments should work toward national harmonization of formularies, based on optimal and appropriate standards of treatment.
- Decisions regarding inclusion of drugs in formularies should be based primarily on scientific evidence of their impact on health outcomes, and informed by evidence regarding their cost-effectiveness.
- A process should be in place for allowing patients to access non-formulary agents in cases of medical necessity.

Access to Drugs

- The federal government should continue to reduce the time required for regulatory review to the fastest level consistent with ensuring optimal health outcomes and the safety of the drug supply.
- The drug review process should provide updates on status and the opportunity for stakeholder input. The rationale for decisions should be made apparent to all stakeholders, and an appropriate appeal mechanism should be provided.
- Health Canada should continue to apply a priority review process to drugs that demonstrate a substantial improvement over products already on the market.
- Canada should develop a comprehensive drug policy for rare disorders that includes clear rules for setting prices that are fair to patients, governments and the pharmaceutical industry.

Post-Approval Surveillance for Safety and Effectiveness

- A strong, adequately-funded post-approval surveillance system is essential to ensuring drug safety and effectiveness. This system should include:
 - simple, comprehensive and user-friendly reporting processes, to which health-care providers are encouraged to promptly report adverse drug reactions. User-friendly reporting processes should also be available to patients and the public;
 - rigorous analysis of reports to identify significant threats to drug safety;
 - communications systems that produce useful information, distributed to health care providers and the public in a timely, easily understood manner; and
 - links to international post-approval surveillance systems.
- All newly approved products, either brand name or generic, should be evaluated with particular scrutiny in real-world practice.
- Post-approval surveillance should evaluate both the safety and the effectiveness of new drugs.
- Adverse drug reaction reports from patients and the public should be actively solicited.

Pricing and Purchasing

- Purchasing and price control strategies should aim to better manage drug costs without compromising access to optimal and appropriate treatments.
- Strategies related to drug purchasing and distribution should ensure that the supply of prescription drugs is sufficient to meet Canadians' needs.
- Pricing strategies should include an examination of the trade-offs between relative costs and benefits for patients, consumers, drug developers, drug manufacturers, pharmacies and governments.
- Substitution strategies, when used, should respect the clinical independence of prescribers, the patient-prescriber relationship and the uniqueness of patients.

Optimal Drug Therapy

- The federal government should fund 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;
 - include use of information technology and practice tools;
 - be organized and implemented by professional and patient organizations;
 - include strategies to improve patients' knowledge of and adherence to drug regimens; and
 - be accompanied by the development and maintenance of reliable, up-to-date, impartial drug information for consumers.
- Direct-to-consumer advertising of prescription drugs should not be permitted in Canada. The regulatory loopholes that currently permit a limited amount of drug promotion should be closed.

e-Prescribing

- Governments should support the development of electronic communication networks, and work with health professional and patient groups to establish standards for electronic prescribing, taking into consideration patient privacy and confidentiality requirements.

Non-Patented Drugs

- Governments should work together to develop policies for regulating the prices of generic and off-patent drugs.

Analysis of Cost Drivers

- A pharmaceutical strategy must support ongoing research into the factors contributing to the rapid growth in drug expenditures, and identify strategies to manage these expenditures in a fiscally sustainable manner.

Conclusion

Canada needs a strong nationwide pharmaceutical strategy to ensure that Canadians have access to safe, effective pharmaceuticals as an important and integral part of their health care. Building this strategy will require early, ongoing and meaningful consultation with all stakeholders, including health care providers and consumers. Our Coalition stands ready to work with governments and all other stakeholders to achieve this goal.



The following Best Medicines Coalition member organizations have endorsed this document: Arthritis Consumer Experts, Asthma Society of Canada, Canadian Arthritis Patient Alliance, Canadian Breast Cancer Network, Canadian Cancer Action Network, Canadian Hemophilia Society, Canadian Hepatitis C Networks, Canadian Society of Intestinal Research, Canadian Treatment Action Council, Epilepsy Canada, Osteoporosis Canada, Tourette Syndrome Foundation of Canada.