

## NATIONAL PHARMACEUTICALS STRATEGY

### Introduction

Pharmaceuticals are a vital component of the Canadian health care system. When used appropriately, they save lives, treat diseases, and enhance the quality of life for millions of Canadians. Despite these benefits, pharmaceuticals give rise to a number of challenges related to safety and effectiveness, access, optimal drug therapy, and health care system sustainability. Prescription drugs also constitute the fastest growing and second largest category of health care expenditure in Canada.

### Government Action

To date, the federal, provincial and territorial (FPT) governments have individually made significant efforts to address the challenges and manage pharmaceuticals in a way that maximizes patient health outcomes while contributing to system sustainability.

In 2004, as part of the “10 Year Plan to Strengthen Health Care”, Prime Minister Martin and the leaders of the provinces and territories agreed that no Canadian should suffer undue financial hardship in accessing needed drug therapies, and that affordable access to drugs is fundamental to equitable health outcomes for all citizens. In October of that year FPT ministers of health established the Ministerial Task Force (MTF) to guide the development and implementation of the National Pharmaceuticals Strategy (NPS). Since then, health ministry officials have been actively engaged in developing the nine elements of the NPS. **(See attached Backgrounder)**

### Challenges and Opportunities

The challenges and opportunities that Canada faces in the area of pharmaceuticals relate to three fundamental themes: access; safety, effectiveness and appropriate use; and system sustainability. Pharmaceuticals not provided within a hospital are not covered under the Canada Health Act and access to these is determined predominately by where one resides or works. Increasingly, Ontario hospitals are requiring patients to purchase drugs privately that are then administered in the hospital, which avoids its obligation under the Act. **(See attached Backgrounder for further details)**

Improper drug selection, inappropriate dosage, adverse drug reactions, drug interactions, therapeutic duplication, and patient non-compliance threaten the health of Canadians and add to system costs. By collaborating with academic experts, health care institutions, health care professionals and the public, governments can coordinate existing activities, support synchronized evidence standards and encourage evidence-based treatment, utilization and prescribing decisions.

Since 2000, the total public and private expenditure on prescription drugs has grown by approximately 12% annually. This rapid escalation in drug costs threatens the sustainability of public drug programs. By collaborating on drug price and purchasing issues, Canada’s public drug plans can encourage greater competition, increase transparency and reduce market fragmentation to ensure Canadians get the best possible prices for pharmaceuticals.

### Proposed Action Plan

While efforts to date have focused on the five priority elements of the NPS (see attached Backgrounder), work has continued outside the NPS process in a number of other areas, including electronic prescribing (e-Rx), and appropriate drug prescribing and use. The MTF has identified several specific actions for governments to move towards the implementation of a NPS. We recognize changes that have been made and encourage the government to move quickly to full implementation of the principles established in 2004.

## Questions

### For a Federal Member:

1. What is your government/party prepared to do to accelerate the implementation of the National Pharmaceutical Strategy, since it was initiated in 2004?

### For a Provincial Member:

1. How can your government/party bring pressure to bear on the Federal Government to accelerate the implementation of the National Pharmaceutical Strategy, since it was initiated in 2004?
2. How can your government/party bring about more changes in Ontario's health care to implement more of the principles of the National Pharmaceutical Strategy?

## BACKGROUNDER

### Principal Actions of the National Pharmaceuticals Strategy

- Develop, assess and cost options for catastrophic pharmaceutical coverage;
- Establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness;
- Accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
- Strengthen evaluation of real-world drug safety and effectiveness;
- Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
- Enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem;
- Broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record;
- Accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and,
- Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

[It is understood that Quebec will maintain its own pharmacare program.]

### The Challenge of Access

Jurisdictions are facing challenges in determining which drugs should be reimbursed through their public drug plans and under what conditions. Until recently, there has been limited coordination among jurisdictions on determining which drugs are actually covered. The federal, provincial and territorial (FPT) Common Drug Review (CDR), however, has the potential to increase consistency of the drug plan listing decisions.

Recent Canadian experience with expensive drugs for rare diseases has also demonstrated the particular challenge of determining when, or under what conditions, it is appropriate to publicly reimburse the cost of therapies that do not meet generally accepted standards of evidence for coverage.

### Focus for the Future

While recognizing that substantive, long-term improvement in pharmaceuticals management is contingent on advancing all elements of the National Pharmaceuticals Strategy (NPS), in order to facilitate timely and concrete results for Canadians, the Ministerial Task Force (MTF) identified five areas for short-to-medium term focus:

#### i. Catastrophic Drug Coverage

Catastrophic Drug Coverage (CDC) aims to address the issue of undue financial hardship faced by Canadians in gaining access to required drug therapies, regardless of where they live and work. In this first phase of the NPS, work on CDC was directed toward defining "catastrophic" and identifying the general level of drug coverage necessary to protect Canadian families from undue financial hardship.

## **ii. Expensive Drugs for Rare Diseases**

Drugs for rare diseases benefit only a small number of patients and can be prohibitively expensive. In exploring this issue, the MTF undertook research and consulted on how EDRDs are defined, evaluated, funded, priced and regulated internationally.

## **iii. Common National Formulary**

A national approach to formulary management would promote optimal use of drugs, reduce inequities across FPT plans, achieve administrative efficiencies, and support consistent and evidence-based decision-making.

The benefits of a collaborative, national approach have already been demonstrated by the Common Drug Review (CDR). NPS work to date in this area has involved exploring the feasibility and benefits of expanding the CDR to all drugs, focusing specifically on new indications for old drugs, and oncology drugs. A comparative analysis of formularies has also been conducted to inform the development of a common list of drugs reimbursable by jurisdictions.

## **iv. Drug Pricing and Purchasing Strategies**

Today there is limited price or purchasing coordination among FPT drug plans, and this lack of collaboration means public plans potentially under-utilize their significant purchasing power and allow the industry to command higher prices. Work in the area of pricing and purchasing seeks to address this issue and contribute to the sustainability of public drug programs by achieving international parity on the prices of non-patented drugs; developing pricing and purchasing strategies to obtain the best prices for prescription drugs and vaccines in Canada; and accelerating access to affordable medicines for Canadians.

Activities have focused on attaining more competitive prices for non-patented drugs (multiple and single source) in Canada by developing and analyzing strategic options for a comprehensive national pricing and purchasing framework. The Patented Medicine Prices Review Board (PMPRB) is also now monitoring and reporting on international non-patented prescription drug prices; the first of these monitoring reports was published on July 4, 2006. Based on the data used in that report, PMPRB estimates that, if Canadian prices did not exceed corresponding international median prices, 2005 Canadian non-patented prescription drug spending could have been reduced by as much as \$1.47 billion.

## **v. Real World Drug Safety and Effectiveness**

Drugs approved by Health Canada are required to undergo rigorous pre-market clinical testing. Evidence based only on controlled clinical trials in carefully selected patient groups, however, can not completely predict a drug's safety and effectiveness in the real world. Work to date to strengthen the evaluation of drug safety and effectiveness has resulted in the development of four independent strategies: creation of a national oversight body to support collaboration and priority setting; establishment of a research network to strengthen existing capabilities; building "front-line" participation and new opportunities; and the establishment of clear standards and transparency of evidence.

Thanks to Political Action Committee members Gary Zinck and Janet Poudrier for the research for this paper

**April, 2008**