



NATIONAL PHARMACEUTICALS STRATEGY PROGRESS REPORT

FEDERAL/PROVINCIAL/TERRITORIAL MINISTERIAL TASK FORCE
JUNE 2006



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Table of Contents

Executive Summary	6
Introduction	15
Background and Rationale	15
Purpose of this Report	16
Part I - Prescription Drugs and the Canadian Health Care System: Opportunities and Challenges	17
1.1 Federal and provincial/territorial roles with respect to pharmaceuticals	17
1.2 Role and value of pharmaceuticals in health care	18
1.3 Challenges and Opportunities	19
Access	19
Safety, Effectiveness and Appropriate Use	20
System Sustainability	21
Part II - National Pharmaceuticals Strategy	24
2.1 Purpose & Objectives	24
2.2 An Integrated, Collaborative and Comprehensive Approach	26
Collaboration and cooperation among governments	26
2.3 Stakeholder engagement	27
Part III - A Snapshot of Progress & Recommendations: Five Priority Areas	28
3.1 Catastrophic Drug Coverage	29
3.2 Expensive Drugs for Rare Diseases	34
3.3 Common National Formulary	37
3.4 Drug Pricing and Purchasing Strategies	39
3.5 Real World Drug Safety and Effectiveness	42
Part IV - Progress on Other NPS Elements	45
4.1 Electronic-prescribing (e-Rx)	45
4.2 Appropriate Drug Prescribing and Utilization	46
Part V - Moving Forward	47
List of Acronyms	48

National Pharmaceuticals Strategy

The founders of Medicare a half-century ago established the principle of equity of access to hospitals and doctors' services for all Canadians. First Ministers agree that no Canadians should suffer undue financial hardship in accessing needed drug therapies. Affordable access to drugs is fundamental to equitable health outcomes for all our citizens.

First Ministers directed Health Ministers to establish a Ministerial Task Force to develop and implement the National Pharmaceuticals Strategy and report on progress by June 30, 2006. The strategy will include the following actions:



- 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.]

Extract from *A 10-Year Plan to Strengthen Health Care*, September 16, 2004

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Executive Summary

Background and Rationale

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. New forms of drug therapy are enabling more patients to be treated at home and close to their families. By shortening and preventing hospital stays, pharmaceuticals can also ease the burden on health care facilities and services.

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. Like governments around the world, Canada is faced with the challenge of optimizing the benefits of prescription drugs for Canadians while managing the risks and complexities associated with this rapidly evolving sector.

To date, the federal, and 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. However, as the responsibility for many aspects of pharmaceuticals in Canada is shared among jurisdictions, there are interdependencies and limitations with respect to what individual jurisdictions can achieve on their own.

Recognizing the growing importance of pharmaceuticals in health care, and the cross-jurisdictional nature of the issues, in September 2004 First Ministers directed Health Ministers to establish a Ministerial Task Force (MTF) to develop and implement the National Pharmaceuticals Strategy (NPS). All Health Ministers (with the exception of Quebec)¹ were included in the MTF under the co-chairmanship of the federal and British Columbia Ministers of Health.

The purpose of the NPS is to address the challenges and opportunities across the drug life cycle using an integrated, collaborative, multi-pronged approach to pharmaceuticals within the health care system.

This report provides a series of recommendations and a snapshot of progress on the development and implementation of the Strategy to date.



¹ As understood in both *A 10-Year Plan to Strengthen Health Care and Asymmetrical Federalism that Respects Quebec's Jurisdiction*, Quebec is maintaining its own pharmacare program and, consequently, is not part of the development of this Strategy. However, Quebec is open to sharing information and best practices.

Key Issues and Opportunities

The challenges and opportunities that Canada faces in the area of pharmaceuticals management relate to three fundamental themes:

1. Access
2. Safety, Effectiveness and Appropriate Use
3. System Sustainability

Access

Canadians currently face a patchwork of public and private drug plans, as pharmaceuticals that are not provided within a hospital do not fall under the purview of the Canada Health Act. As a result, access to pharmaceuticals, outside of a hospital, is determined predominantly by where one resides or works and not necessarily by need. In this environment, some Canadians lack protection from ‘catastrophic’ drug costs.

Jurisdictions are also 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. However, the FPT Common Drug Review (CDR) 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. This challenge is especially acute in the case of diseases for which there are no alternative therapies. Developing collaborative, structured, and coordinated approaches to the issues of access to pharmaceuticals in Canada will require that governments work together with key stakeholders, including patients, medical practitioners, private insurers and employers.

Safety, Effectiveness and Appropriate Use

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. It is critical that treatment and reimbursement decisions are informed by accurate, unbiased and up-to-date information about a drug’s effectiveness and its impacts in different contexts and populations. The majority of evidence regarding pharmaceutical therapies is gathered through clinical trials in highly controlled environments in the pre-market phase. This limits the ability to predict a drug’s performance in the ‘real world.’ Evidence from pre-market testing also provides little basis for gauging the benefits and risks of new medications relative to existing drugs or non-drug therapies.

These challenges can be met by working together to enhance and focus research capacity so that decision-makers have the information they need to make optimal treatment and reimbursement decisions. 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.

System Sustainability

After hospital care, Canada spends more on drugs than any other major category of the health care system. Since 2000, the total public and private expenditure on prescription drugs has grown by approximately 12 per cent annually. This rapid escalation in drug costs threatens the sustainability of public drug programs.

To ensure that Canadians continue to benefit from robust public drug coverage, public dollars must be used efficiently. 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.

The NPS Approach

In the context of equitable access to safe, effective and appropriately prescribed and used drugs and system sustainability, First Ministers laid out nine elements for the NPS in the 2004 *10-Year Plan to Strengthen Health Care*. While recognizing that substantive, long-term improvement in pharmaceuticals management is contingent on advancing all elements of the NPS, in order to facilitate timely and concrete results for Canadians, the MTF identified five areas for short-to-medium term focus:

- i) Catastrophic drug coverage;
- ii) Expensive drugs for rare diseases;
- iii) Common national formulary;
- iv) Pricing and purchasing strategies; and
- v) Real world drug safety and effectiveness

The MTF is working to develop and implement practical solutions in each of these areas in a manner that recognizes the interplay of forces, considers the perspectives of diverse stakeholders and addresses the issues in a comprehensive and integrated manner.

A snapshot of progress featuring summaries of key achievements in each of the five NPS priority areas is provided below along with recommendations and planned actions for moving forward.

Nine Elements of the NPS

1. Develop, assess and cost options for catastrophic pharmaceutical coverage;
2. Establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness;
3. Accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
4. Strengthen evaluation of real-world drug safety and effectiveness;
5. Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
6. 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;
7. Broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record;
8. Accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and,
9. Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

Snapshot of Progress and Recommendations

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. A 2002 study estimated that two per cent of Canadians have neither public nor private drug coverage², even for catastrophic levels of drug expenses. As well, earlier research suggested that up to 20 per cent of Canadians were under-insured for catastrophic levels of drug expenses.³

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. The following principles were established and agreed to as a guide for the development and assessment of CDC options:

1. Universality: all Canadians are eligible
2. Equity: comparable coverage across the country
3. Transparency: coverage levels are easy to understand and access
4. Evidence-based: eligible drug selection based on best evidence
5. Integrated: catastrophic protection is integrated with other public and private drug plans
6. Sustainable: affordable, sustainable, and balanced with other health care priorities

In developing CDC options, the MTF considered how best to protect Canadian families from unaffordable drug expenses, i.e., high drug costs relative to income. This could be done through either a variable percentage of income threshold (i.e., a threshold that is lower at lower income levels and rises as income increases), or a fixed percentage of income threshold (i.e., a threshold that is a fixed percentage for all families regardless of income level). Further work will focus on the variable option as it could more effectively protect lower income families.

RECOMMENDATIONS

The Ministerial Task Force recommends that:

- Further policy, design, and costing analysis be focused on the variable percentage of income threshold option that maintains a private payer role;
- A parallel fixed percentage (5 per cent) option also be analyzed and costed; and,
- The impact and feasibility of maintaining a private payer coverage role be analyzed as part of this further work.



² Drug Expense Coverage in the Canadian Population: Protection from Severe Drug Expenses, Fraser Group & Tristat Resources, August 2002, for the Canadian Life and Health Insurance Association, and as quoted in the Kirby/Lebreton Report, The Health of Canadians – The Federal Role: Final Report, 2002 (Senate Standing Committee on Social Affairs, Science and Technology).

³ Canadians' Access to Insurance for Prescription Medicines, Volume 2: The Un-Insured and Under-Insured, Applied Management in association with Fraser Group/Tristat Resources, Health Transition Fund, Health Canada, March 2000.

Expensive Drugs for Rare Diseases

Drugs for rare diseases benefit only a small number of patients and can be prohibitively expensive. Further, with advances in technology, both the number of treatments available and the number of treatable patients are increasing.



Canada is not alone in facing the issue of expensive drugs for rare diseases (EDRDs). Many other countries are also faced with the challenge of how to address these drugs within public health care systems. In exploring this issue, the MTF undertook research and consulted on how EDRDs are defined, evaluated, funded, priced and regulated internationally. International practice and recent Canadian experience underscore the value for Canadian jurisdictions of a structured and coordinated approach to rare diseases.

RECOMMENDATION

The Ministerial Task Force recommends that officials:

- Accelerate work on a framework for EDRDs, focusing primarily on the areas of evidence, ethics, and the need to appropriately align regulatory and reimbursement systems.

Common National Formulary

Despite efforts by FPT governments to provide appropriate access to medications outside hospital settings, there is inconsistency and inequity in prescription drug coverage for Canadians across the country. 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).⁴ 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.

RECOMMENDATIONS

The Ministerial Task Force recommends that officials:

- Pursue a staged expansion of the Common Drug Review and common review processes to increase commonality of public plan formularies;
- Continue work to design a common national formulary.

⁴ The Common Drug Review (CDR) is a single process for reviewing new drugs and providing listing recommendations to participating publicly-funded federal, provincial and territorial drug plans.

Drug Pricing and Purchasing Strategies

The Canadian pharmaceuticals market is complex, with multiple payers, competing incentives, priorities and interests. 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 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:

- (1) achieving international parity on the prices of non-patented drugs;
- (2) developing pricing and purchasing strategies to obtain the best prices for prescription drugs and vaccines in Canada; and
- (3) 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. Academics and the generic pharmaceuticals industry have been engaged in the development of options to achieve more competitive pricing and address rebate and marketing-conduct issues within the non-patented drug supply chain. 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, the PMPRB estimates that, if Canadian prices did not exceed corresponding international median prices, 2005 Canadian non-patented prescription drug spending⁵ could have been reduced by as much as \$1.47 billion.⁶

⁵ Refers to ex-factory sales, and excludes any mark-ups or fees applied at the retail level.

⁶ Based on Canadian non-patented generic and non-patented name brand spending totals from the 2005 PMPRB Annual Report.



RECOMMENDATIONS

The Ministerial Task Force recommends that:

- A non-regulated, business-management approach to drug pricing issues, with priority on non-patented drugs, be pursued;
- Consideration of regulatory approaches also continue.

Real World Drug Safety and Effectiveness

Drugs approved by Health Canada are required to undergo rigorous pre-market clinical testing. However, evidence based only on controlled clinical trials in carefully selected patient groups can not completely predict a drug's safety and effectiveness in the real world. This information gap is a barrier to effective, evidence-based decision making for all involved in the regulation, prescribing, utilization and reimbursement of medications. Work in the area of real world drug safety and effectiveness aims to develop a stronger system for gathering, interpreting and applying drug safety and effectiveness information in Canada.

Work to date to strengthen the evaluation of drug safety and effectiveness has resulted in the development of four interdependent 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. These strategies came in large measure from a two-day, multi-stakeholder conference, held to gather input and identify areas of consensus. This conference revealed a variety of opportunities and the existence of broad support for building the mechanisms and capacity necessary to optimize real world safety and effectiveness.⁷

⁷The report from the Working Conference on Strengthening the Evaluation of Real World Drug Safety and Effectiveness can be found at: www.hc-sc.gc.ca/hcs-sss/pharma/nps-snpp/securit/index_e.html

RECOMMENDATION

The Ministerial Task Force recommends that:

- ▶ Stakeholder consultations be undertaken on the four interdependent strategies (i.e., an oversight body, a research network, engagement of primary care and hospital teams, and the establishment of clear standards and transparency of evidence).



Progress on other NPS Elements

While efforts to date have focused on the five priority elements of the NPS, work has continued outside the NPS process in a number of other areas, including electronic prescribing (e-Rx), and appropriate drug prescribing and use.

Moving Forward

The submission of this report to First Ministers marks the beginning of a new phase for the NPS. The next phase will include continued work in the five priority areas, as follows:

- On **catastrophic drug coverage**, governments will proceed with a policy and costing analysis, revising the methodology as necessary, to refine the CDC option(s) and gain a better understanding of the different costing and policy implications.
- On **expensive drugs for rare diseases**, governments will draw on a wide range of expertise, both from within government as well as the research community, patients and providers to ensure that a comprehensive EDRD framework is developed.
- On the **common national formulary**, governments will direct their efforts towards expanding the CDR at the Canadian Agency for Drugs and Technologies in Health (CADTH) to include new indications for old drugs; preparing a business plan on the development of a common review process for oncology drugs; continuing the analysis of the comparability of formularies, focusing on alignment of formulary policy approaches; and initiating an analysis of the expansion of the CDR process to class reviews.
- On **pricing and purchasing strategies**, governments will focus on: developing a business case and implementation plan for a non-regulated, business-management approach to non-patented drug prices while continuing to consider possible regulatory approaches; reviewing the findings of the first PMPRB report on non-patented drug prices and evaluating implications for pricing strategies; and monitoring developments in the pharmaceutical industry and the impacts of new legislation. The issue of expanded indications for patented medicines and approaches to related price reviews will also be explored.
- On **real world drug safety and effectiveness**, governments will complete work on a business plan for a pharmaceutical research network and a governance structure, while respecting federal regulatory responsibilities in this area. Governments will also engage key stakeholders in the fall of 2006 on the business plan and surveillance/research priorities. A discussion paper outlining the full scope of the safety and effectiveness issues, including issues related to surrogate endpoints and biomarkers, will also be used in engaging stakeholders.

The next phase of the NPS will see further opportunities for stakeholder engagement. Appropriate and targeted consultation with stakeholders will be a critical success factor in the further development and successful implementation of the NPS.

Introduction

Background and Rationale

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. New forms of drug therapy are enabling more patients to be treated at home and close to their families. By shortening and preventing hospital stays, pharmaceuticals can also ease the burden on health care facilities and services.

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. In particular, prescription drugs constitute the fastest growing and second largest category of health care expenditure in Canada. Like governments around the world, Canada is faced with the challenge of optimizing the benefits of prescription drugs for Canadians while managing the risks and complexities associated with this rapidly evolving sector.

To date federal, provincial and territorial (FPT) governments have (usually individually and sometimes collectively) made significant efforts to address the above challenges, and manage pharmaceuticals in a way that maximizes patient health outcomes while contributing to system sustainability. However, as the responsibility for many aspects of pharmaceuticals in Canada is shared among jurisdictions, there are interdependencies and limitations with respect to what individual jurisdictions can achieve on their own.

Recognizing the growing importance of pharmaceuticals in health care, and the cross-jurisdictional nature of the issues, in September 2004 First Ministers directed Health Ministers to establish a Ministerial Task Force (MTF) to develop and implement the National Pharmaceuticals Strategy (NPS). All Health Ministers (with the exception of Quebec)⁸ were included in the MTF under the co-chairmanship of the federal and British Columbia Ministers of Health.

The purpose of the NPS is to address the challenges and opportunities across the drug life cycle using an integrated, collaborative, multi-pronged approach to pharmaceuticals within the health care system.

While it is recognized that genuine and long-term improvements in pharmaceuticals management is contingent on advancing all elements of the NPS, the MTF has identified the following five areas for short-to-medium term focus:

- i) Catastrophic drug coverage;
- ii) Expensive drugs for rare diseases;
- iii) Common national formulary;
- iv) Pricing and purchasing strategies; and
- v) Real world drug safety and effectiveness.

In selecting these areas, the MTF attempted to balance long-term and immediate needs, while supporting the achievement of practical, concrete and timely results for Canadians.



⁸ As understood in both *A 10-Year Plan to Strengthen Health Care* and *Asymmetrical Federalism that Respects Quebec's Jurisdiction*, Quebec is maintaining its own pharmacare program and, consequently, is not part of the development of this strategy. However, Quebec is open to sharing information and best practices.

Purpose of this Report

This report provides a snapshot of progress to date and MTF recommendations on the development and implementation of the multi-year National Pharmaceuticals Strategy. The Report builds on the NPS progress discussed by FPT Health Ministers in October 2005, at which time they reaffirmed their commitment to the Strategy and agreed to a number of actions (listed in Part III).

Part I of the Report provides an overview of the current Canadian pharmaceuticals environment and some of the associated challenges and opportunities.

Part II outlines the purpose and goals of the NPS, as well as the MTF's approach to the NPS.

Part III describes progress to date and recommended next steps for the five action areas identified for priority focus.

Part IV discusses ongoing work on the other elements of the NPS.

Part V briefly discusses the next phase of work on the NPS.

Part I - Prescription Drugs & the Canadian Health Care System: Opportunities and Challenges

1.1 Federal and provincial/territorial roles with respect to pharmaceuticals

In Canada, FPT governments share responsibility for managing prescription drugs.

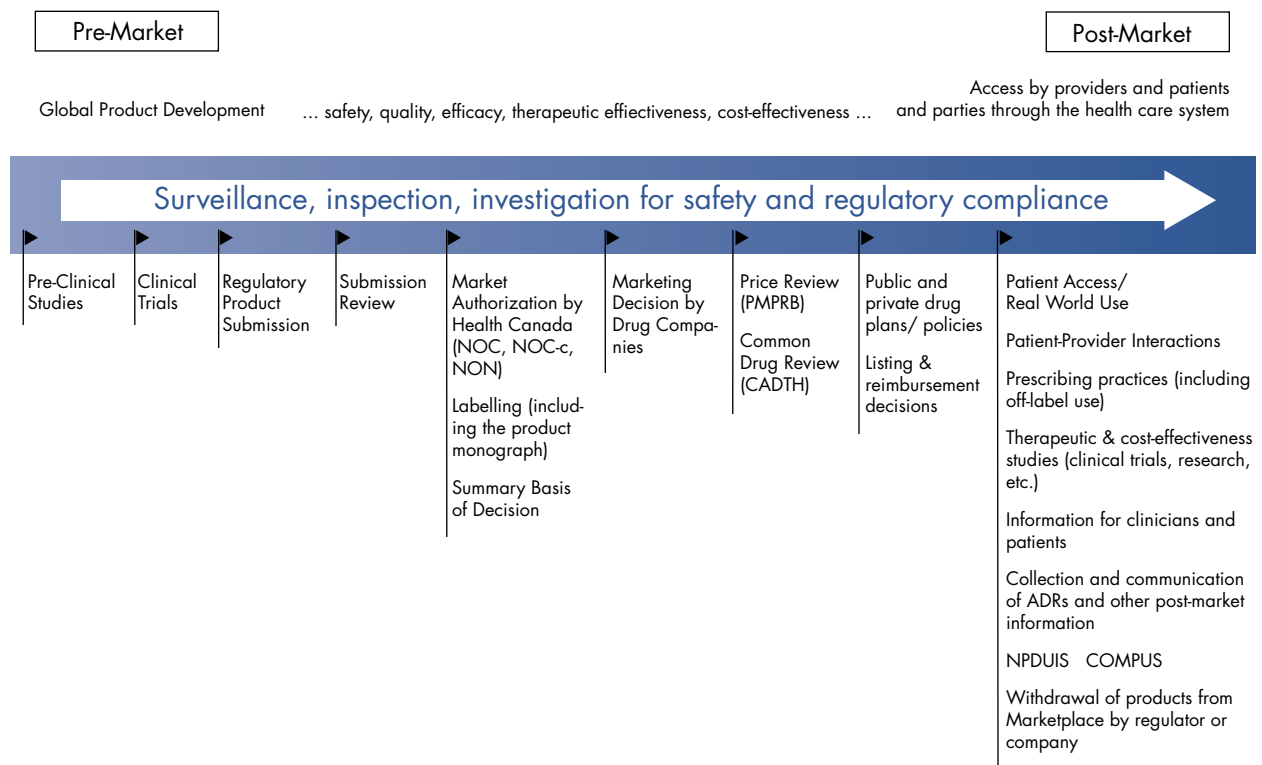
At the federal level, Health Canada regulates clinical trials and authorizes entry to the market based on assessments of drug safety, efficacy and quality, monitors the safety of products once they reach the market, and reviews the prices of patented drugs through the Patented Medicine Prices Review Board (PMPRB). The federal government provides or facilitates drug coverage for populations under its jurisdiction (e.g., First Nations, veterans, Canadian Forces, federal inmates). It is also a significant supporter of health research.

The provinces and territories (PTs) each provide

public drug benefits for either all residents or specific groups such as seniors, social assistance recipients, and individuals with certain diseases or conditions. PTs determine which drugs will be reimbursed under public plans. PTs also interact with manufacturers and set broad regulatory frameworks for health professionals.

While some of the roles with respect to pharmaceuticals are unique to each level of government, responsibilities on some issues are shared among FPT jurisdictions. The Common Drug Review (CDR) process is an example of FPT cooperation in the review of drugs for reimbursement. The need for alignment of FPT activities and processes is particularly acute in the pharmaceuticals sector because evidence requirements and decision-making processes related to entry to market, reimbursement and pricing are closely interconnected.

Figure 1: Drug product Life Cycle (See Glossary for acronyms)



1.2 Role and value of pharmaceuticals in health care

Drugs are a vital part of the Canadian health system. Appropriate use of safe and effective drugs can prevent, treat and cure diseases, improve quality of life and lengthen and save lives. Pharmaceuticals have radically decreased the mortality rates for AIDS, Leukaemia, Hodgkin's Disease and heart disease, among others. They have also had a transformative impact in the treatment of asthma, stomach ulcers and cancer.

Through advances in technology and the emergence of new forms of drug therapy such as home infusion technology, Canadians are increasingly being treated at home and close to their families. Moreover, in preventing or shortening the length of hospital stays, pharmaceuticals can ease the burden on health care facilities, thereby contributing to system sustainability.

In addition to the benefits, there are also challenges associated with the use of pharmaceuticals. Canadian jurisdictions, and governments around the world, struggle to manage system-wide issues of equitable access, sustainability, and drug safety and effectiveness, while ensuring that individual patients receive optimal drug therapies.



1.3 Challenges and Opportunities

The nine elements (see page 25) of the NPS can be usefully grouped under three themes:

Access

1. Develop, assess and cost options for catastrophic pharmaceutical coverage
2. Common National Drug Formulary
3. Accelerated access to breakthrough drugs through regulatory improvements

Safety, Effectiveness and Appropriate Use

4. Strengthen the evaluation of real world safety and effectiveness
5. Influencing prescribing behaviours
6. E-prescribing implementation (linked to Electronic Health Accord)

System Sustainability

7. Accelerating access to, and improving pricing of non-patented medicines
8. Pricing and purchasing strategies for drugs and vaccines
9. Analysis of cost drivers and cost-effectiveness

The challenges and opportunities associated with each theme are outlined in the following section.

Access

CHALLENGES

Canadians currently face a patchwork of public and private drug plans, as pharmaceuticals provided outside a hospital do not fall under the purview of the *Canada Health Act*. As a result, access to pharmaceuticals outside of a hospital is determined predominantly by where one resides or works and not necessarily by need. In this environment, some Canadians – particularly those in Atlantic Canada – lack protection from ‘catastrophic’ drug costs.

Jurisdictions are also 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 what drugs are actually covered. However, the FPT Common Drug Review (CDR) has the potential to increase the consistency of 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 therapies that do not meet common standards of evidence of coverage, but for which there are no alternative therapies.

OPPORTUNITIES

- FPT governments, private insurers and patients can work together to develop options for catastrophic drug coverage to address the undue financial hardship that Canadians face in obtaining access to required drug therapies;
- A similar collaborative approach can be used to develop an approach to expensive drugs for rare diseases;
- Building on the Common Drug Review (CDR)⁹, governments can work to further harmonize reimbursement decision-making among jurisdictions in support of more consistent access for Canadians to safe and effective drugs; and
- Patient involvement through the CDR can also make reimbursement decisions more open and transparent.

⁹ The Common Drug Review (CDR) is a single process for reviewing new drugs and providing listing recommendations to participating publicly-funded federal, provincial and territorial drug plans.

Safety, Effectiveness & Appropriate Use

CHALLENGES

Governments, physicians, pharmacists and patients are important decision-makers in the management and appropriate use of safe and effective drug treatments. Improper drug selection, inappropriate dosage, adverse drug reactions, drug interactions, therapeutic duplication, and patient non-compliance¹⁰ threaten the health outcomes of Canadians and add to system costs. It is therefore critical that decision-makers have access to accurate, unbiased and up-to-date information about a drug's effectiveness and impacts in different contexts and populations. With the continuing development of promising new products, timely information will be key to reaping the full benefits of pharmaceutical advances.

While there is increasing recognition of, and reliance on, scientific evidence in treatment and reimbursement decisions, currently the majority of this evidence is gathered through clinical trials in highly controlled environments in the pre-market phase. The requirements for market approvals of new drugs in Canada are rigorous. Nonetheless, pre-market testing cannot predict a drug's performance in the 'real world.' It also provides little basis for gauging the benefit of new medications relative to existing drugs or non-drug therapies.

¹⁰ Refers to when patients do not take medication in accordance with instructions by the prescriber and/or pharmacist (e.g., skipped doses).

OPPORTUNITIES

- Through greater collaboration with all stakeholders, governments can enhance current research capacity;
- Governments can work to synchronize standards of evidence in decision-making and encourage evidence-based treatment and utilization decisions; and
- Working with academic experts, health care institutions, health care professionals and the public, governments can coordinate existing activities to better manage drug prescribing and utilization.

System Sustainability

CHALLENGES

Prescription drugs are the leading cost driver in the health care system. Canada spends more on drugs than any other major component of health care after hospitals, and drug costs are growing at a much greater rate than other elements of health care (figure 2). According to the Canadian Institute for Health Information (CIHI), total public and private expenditures on prescription drugs have grown by approximately 12 per cent annually since 2000, and nationally, prescription drug costs are estimated to have reached \$20.6 billion in 2005.¹¹ This rapid escalation in drug expenditures (figure 3) potentially threatens the sustainability of the health care system and creates challenges

for government spending in non-health sectors as well. The growth in spending on drugs is not primarily a result of increased prices for existing products. Rather it is attributable to the rapid uptake of new, more expensive products and to the fact that Canadians now use more drugs per capita than in the past.¹²

¹¹ *Drug Expenditure in Canada, 1985 to 2005*, Canadian Institute for Health Information, May 2006.

¹² *Ibid*, p. 37: “numerous factors, many of which are interrelated, may influence drug expenditure. Since drug prices, as measured by several price indices, have been relatively stable over the past ten years, factors affecting increased drug spending in Canada essentially relate to the volume of drug use and the entry of new drugs (typically introduced to the market at higher prices).”

Figure 2: Annual Expenditure Growth of Leading Sources of Health Care Costs, 1990–2005

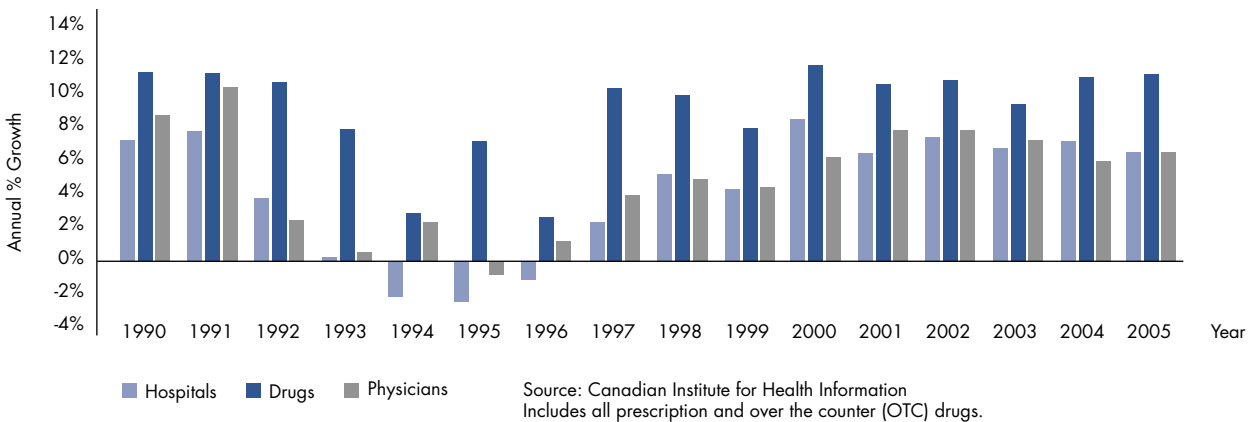
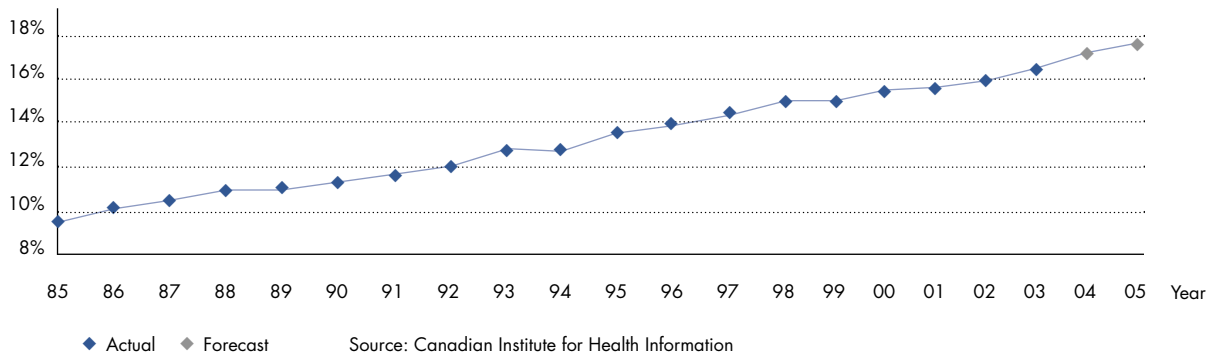


Figure 3: Total Drug Expenditure as a Percentage of Total Health Expenditure, Canada, 1985–2005



The role of the federal Patented Medicine Prices Review Board (PMPRB) is to ensure that patented drug prices are not excessive – that they are comparable to or below – those in other countries. Although it has no regulatory jurisdiction over non-patented drugs, the PMPRB is now monitoring and reporting on international non-patented prescription drug prices as well. The first of these monitoring reports was published on July 4, 2006. The Report reaffirms the findings of previous studies that Canada’s prices for non-patented drugs typically exceed those in foreign comparator

countries. (Visit www.pmprb-cepmb.gc.ca for the full report.) As shown in Figure 4, Canada’s prices for generics exceed those in all eleven comparator countries, including the United States. Figure 5 shows that Canada’s prices for non-patented brand name drugs exceed those in nine of the eleven comparator countries.

Figure 4: Average Foreign-to-Canadian Price Ratios, Generic Drugs by Bilateral Comparator, 2005

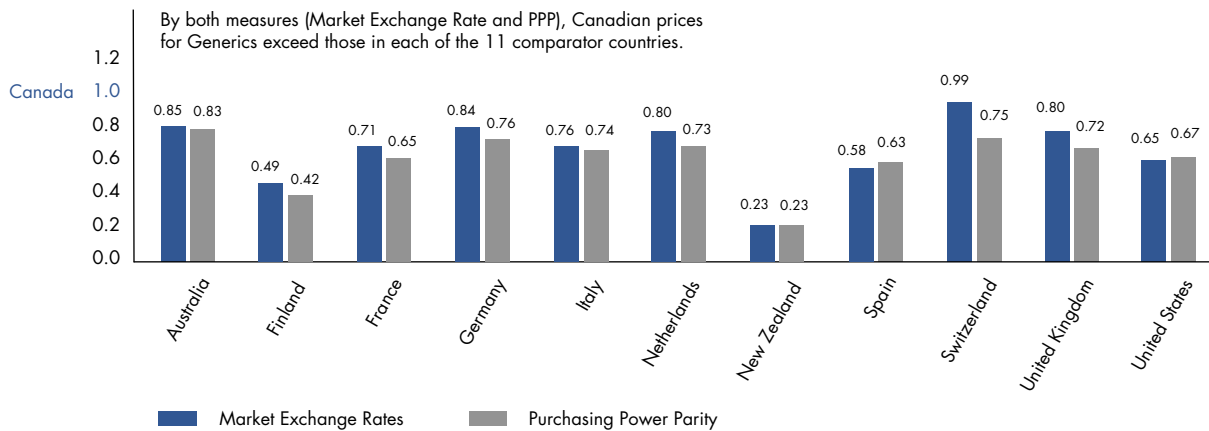
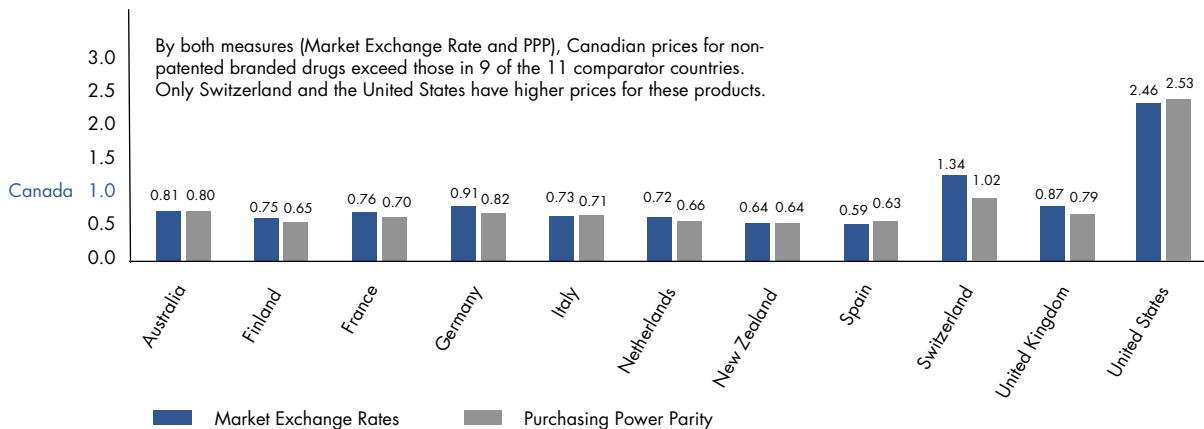


Figure 5: Average Foreign-to-Canadian Price Ratios, Non-Patented Branded Drugs by Bilateral Comparator, 2005



Private and employer-sponsored plans are equally challenged by these rising costs, which increase pressure to contain costs, often at the expense of individuals and/or public plans.

The need to balance health and fiscal priorities is common across jurisdictions, and governments are responding in a variety of ways. A 'made in Canada' approach stands to benefit from lessons learned internationally.¹³ These solutions can build on recent individual PT efforts to address pricing and purchasing issues (Quebec Bill 130,¹⁴ December 2005; Ontario Bill 102,¹⁵ June 2006). They can also be significantly enhanced through a more coordinated approach among FPT jurisdictions that capitalizes on the collective purchasing power and market position.

OPPORTUNITIES

- Address non-patented medicine pricing issues;
- By pooling the purchasing power of public drug plans, governments can encourage greater competition and market transparency and reduce market fragmentation. This change will increase government's ability to get the best possible prices for pharmaceuticals.

¹³ For example, innovations from Australia offer lessons in the area of prescriber and patient education, and New Zealand has made strides in the area of pharmaceuticals management.

¹⁴ An amendment to the Act Respecting Prescription Drug Insurance and other legislative provisions, Bill 130 enables the Government of Quebec to enter into agreements with drug manufacturers on financial risk sharing for specific medications, and on compensatory measure. It also requires that drug manufactures and wholesalers establish rules to govern their commercial practices.

¹⁵ Bill 102, which received third and final reading in the Ontario Legislature on June 19, 2006, features proposed amendments to Ontario's Transparent Drug System for Patients Act to, among other things, provide remuneration for "professional pharmacy services", permit increased dispensing fees, and reduce generic drug prices to 50 per cent of their brand equivalents while outlawing all supplier-to-pharmacy rebates (with the exception of a prompt payment discount and some allowance for professional spending).

Part II - National Pharmaceuticals Strategy

2.1 Purpose & Objectives

Through the NPS, jurisdictions are working to develop and implement policies, programs and initiatives in support of equitable and affordable access to safe, effective and appropriately used medicines for all Canadians. Through these efforts, the NPS is expected to yield real benefits for Canadians with respect to health outcomes, access to and coverage of prescription drugs, and affordable and sustainable public health care. Anticipated outcomes include:

- **Better evidence** to help governments, health care professionals and patients make the right decisions;
- **Safer, more effective drug treatments for Canadians** enabled through improved evidence;
- **More consistent and equitable drug coverage for Canadians** based on need, not ability to pay;
- **Greater value for patients and for a sustainable public health care system** through sound investments in pharmaceuticals management and coverage, as well as improved decision-making and collaboration under the NPS;
- **More open and transparent drug-related decision-making** at all stages in the drug life cycle;
- **An open and transparent framework for ethical resource allocation** that balances both population and individual health outcomes;
- **Ultimately, improved health outcomes for Canadians.**

All partners in the delivery of health care are shifting their focus away from 'paying for prescription drugs' and towards 'investing in health outcomes.' Governments, industry, health professionals and academia must continue to develop and expand upon their early efforts in this area so that, in the future, improved generation and application of scientific evidence will help to ensure that resources are directed toward the best possible treatments for Canadians. The approach taken under the NPS has been designed to achieve these objectives.



The NPS Approach

In the context of equitable access to safe, effective and appropriately prescribed and used drugs and system sustainability, First Ministers laid out nine elements for the MTF in the 2004 *Ten Year Plan to Strengthen Health Care*. While recognizing that substantive, long-term improvement in pharmaceuticals management is contingent on advancing all elements of the NPS, in order to facilitate timely and concrete results for Canadians, the MTF identified five areas for short-to-medium term focus:

- i) Catastrophic drug coverage;
- ii) Expensive drugs for rare diseases;
- iii) Common national formulary;
- iv) Pricing and purchasing strategies; and
- v) Real world drug safety and effectiveness

The MTF is working to develop and implement practical solutions in each of these areas in a manner that recognizes the interplay of forces, considers the perspectives of diverse stakeholders and addresses the issues in a comprehensive and integrated manner.

A snapshot of progress featuring summaries of key achievements in each of the five NPS priority areas is provided in Part III along with recommendations and planned actions for moving forward.

Nine Elements of the NPS

1. Develop, assess and cost options for catastrophic pharmaceutical coverage;
2. Establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness;
3. Accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
4. Strengthen evaluation of real-world drug safety and effectiveness;
5. Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
6. 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;
7. Broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record;
8. Accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and,
9. Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

2.2 An Integrated, Collaborative and Comprehensive Approach

The pharmaceuticals sector is characterized by a complex mix of participants: multiple government jurisdictions; public health care institutions and agencies; health professionals; private insurers; employers; the brand and generic pharmaceutical industries and patients and advocacy groups. Achievement of NPS objectives requires a collaborative approach that recognizes the interplay of forces, incorporates the perspectives of diverse stakeholders, and addresses the issues in a comprehensive and integrated manner.

Collaboration and cooperation among governments

FPT partners under the NPS are approaching pharmaceuticals management as an integral component of the health care system, and as such are working to promote the more seamless integration of pharmaceuticals into the system. These governments recognize the shared and interdependent nature of many of their pharmaceutical-related responsibilities and that they all have key roles to play in this sector. All jurisdictions are engaged in addressing pharmaceuticals management challenges, in pursuing greater integration of pharmaceuticals with other aspects of health care, and in facilitating the system-level evolution necessary to long-term health care sustainability.

2.3 Stakeholder Engagement

Stakeholders have expressed their views through a number of major studies and consultations in recent years.¹⁶ Although they may view and understand pharmaceutical issues from different perspectives, the large majority of stakeholders agree on the need to address the issues collaboratively. There is also a high level of agreement that affordable access to safe, effective and appropriately used drug treatment is an important contributor to health. The MTF recognizes the role stakeholders have to play in the development and implementation of the NPS – particularly as work on the Strategy progresses.

NPS officials have held a number of information sessions and consultations to date, including:

- In September, 2005, over 100 participants attended the *Working Conference on Strengthening the Evaluation of Real World Drug Safety and Effectiveness* in Ottawa;
- Governments have been working in consultation with the Canadian Generic Pharmaceuticals Association, Rx&D (“Canada’s Research-Based Pharmaceutical Companies”), and BIO-TECanada on the issue of international parity on the prices of non-patented products; and
- In May 2006, stakeholders participated in NPS information sessions held in St. John’s, Toronto, Calgary, and Ottawa.

In the first phase of the NPS, as governments worked to construct a common understanding of the underlying issues and desired objectives, opportunities for stakeholder engagement have been limited. Going forward, appropriate and targeted stakeholder consultation will be important to the Strategy’s successful development and implementation. As such, further opportunities for stakeholder engagement are expected in the next phase of work. Preliminary detail on the various forms and levels of anticipated engagement are provided, but not limited to those outlined, as part of the detailed description of progress on the five priority areas in Part III.

¹⁶ Examples include the *Commission on the Future of Health Care in Canada* (Romanow Commission) and the Standing Senate Committee on Science, Technology and Social Affairs’ study, *The Health of Canadians – The Federal Role* (Kirby/Lebreton Report).

Part III - A Snapshot of Progress & Recommendations: Five Priority Areas

A snapshot of progress featuring summaries of key achievements in each of the five priority areas is provided below along with recommendations and planned actions for moving forward. While progress to date is described separately for each of the priorities, the collaborative and integrated manner in which the Strategy is being implemented ensures a final outcome that is greater than the sum of its parts.

The progress outlined builds on past FPT work on pharmaceuticals and on NPS progress discussed by FPT Health Ministers at their October 2005 meeting. At this meeting, Health Ministers agreed on a number of actions in the five NPS priority areas (see Figure 6).



figure 6: Extract from Health Ministers' Communiqué (October 2005)

- Accelerate work related to catastrophic drug coverage options.
- Take the necessary steps to proceed with time-limited research programs – including clinical studies for patients meeting treatment guidelines for Fabry's disease and MPS1-Hurlers Schie. Ministers committed to this research on a risk-shared basis with manufacturers as quickly as possible.
- Jurisdictions are committed to better align their regulatory and reimbursement regimes to ensure the best possible outcomes for Canadians.
- Expand the Common Drug Review, which makes recommendations on which drugs are eligible for reimbursement, to all publicly funded drugs, and to work towards a common national formulary, which will lead to more consistent access to drugs across the country.
- Give the Patented Medicine Prices Review Board responsibility to monitor and report on non-patented drug prices. It was also agreed that, in order to allow the Board to regulate the price of non-patented drugs, provinces will consider formally delegating their responsibility in this area to the federal government.
- Work together to collect, integrate and disseminate information on the real-world risks and benefits of drugs.

3.1 Catastrophic Drug Coverage

Objective

To develop, cost and assess options for Catastrophic Drug Coverage (CDC) that could address the undue financial hardship faced by Canadians in gaining access to required drug therapies, regardless of where they live and/or work.

Background & Rationale

Canada's public health care system ensures that Canadians have universal access to medically necessary hospital and medical services, regardless of ability to pay. Though many employers provide drug coverage, and all provinces provide some level of drug coverage for at least portions of their populations, the level of protection available to Canadians varies depending on where they live and work, and some Canadians have no protection from catastrophic drug costs. A 2002 study estimated that two per cent of Canadians (concentrated in the Atlantic Provinces) had neither public nor private drug coverage¹⁷, even for catastrophic levels of drug expenses. As well, earlier research suggested that up to 20 per cent of Canadians were under-insured for catastrophic levels of drug expenses.¹⁸ Lack of access to CDC can produce potential adverse health and economic impacts.



Progress & Achievements

As part of this first phase of the NPS, work on CDC was directed toward establishing and agreeing to the following principles as a guide for the development and assessment of CDC options:

1. Universal – All Canadians have protection from undue financial hardship for needed drug therapies.
2. Equitable – The level of protection from catastrophic prescription drug costs is comparable for all Canadians.
3. Transparent – The protection provided is transparent – Canadians can identify their maximum personal exposure for eligible drugs.
4. Evidence-based – Conscientious, explicit and judicious use of current best evidence is applied in making decisions regarding eligible drugs.
5. Integrated – Protection from catastrophic drug costs is integrated with other public and private drug plans.
6. Sustainable – Catastrophic drug cost protection must be delivered in a plan, which is affordable, sustainable and balanced with other health care priorities.

¹⁷ Drug Expense Coverage in the Canadian Population: Protection from Severe Drug Expenses, Fraser Group & Tristat Resources, August 2002, for the Canadian Life and Health Insurance Association, and as quoted in the Kirby/Lebreton Report, The Health of Canadians – The Federal Role: Final Report, 2002 (Senate Standing Committee on Social Affairs, Science and Technology).

¹⁸ Canadians' Access to Insurance for Prescription Medicines, Volume 2: The Un-Insured and Under-Insured, Applied Management in association with Fraser Group/Tristat Resources, Health Transition Fund, Health Canada, March 2000.

CDC work focused on developing, costing and assessing catastrophic drug coverage options by:

1. Identifying the CDC threshold: The point at which a Canadian family faces undue financial hardship due to drug expenses;
2. Identifying high-level design elements: Eligible population and qualifying expenditures; and
3. Costing: the total level of current public, private and out-of-pocket catastrophic drug expenditure was identified. Public plan expenditures below any given threshold were not included.

Costing work initially addressed a series of broad threshold options with multiple variations (such as fixed or variable percentage of incomes and fixed or variable flat dollar thresholds). Subsequent discussions and comparisons against the principles resulted in a narrowed focus on two primary threshold options (see figure 7 following page) for determining when a Canadian family would become eligible for CDC:

Option 1 – Variable percentage

A threshold based on drug costs exceeding a percentage of family income, which increases as family income increases:

- A variable scale of 0/3/6/9 per cent of family income with those families with an income below \$20,000 being provided with a 0 per cent threshold and a maximum of 9 per cent at incomes of \$90,000 and above.¹⁹

Option 2 – Fixed percentage

A threshold based on drug costs exceeding a fixed percentage of family income:

- Fixed percentage set at 4.3 per cent of income – the average percentage above which current public drug plans consider expenses catastrophic.

Payers

All jurisdictions have drug programs, which cover at least a portion of their population. When drug coverage is available, it covers all or a portion of a family's catastrophic drug costs. Costs above the threshold incurred by families, in addition to those incurred by public drug plans on families' behalf, have been included in total public CDC cost estimates.

Private insurance also pays some of the catastrophic costs on behalf of Canadian families. However, employers typically cover the cost of this insurance. To demonstrate the impact of maintaining private insurance coverage, cost estimates have been provided both with and without a private insurance role in paying catastrophic drug costs.

¹⁹ Increases throughout this scale would be based on one per cent per \$10,000 income to provide a smoothing effect thus avoiding the impact of large increases in CDC thresholds as family incomes increase.

Considerations

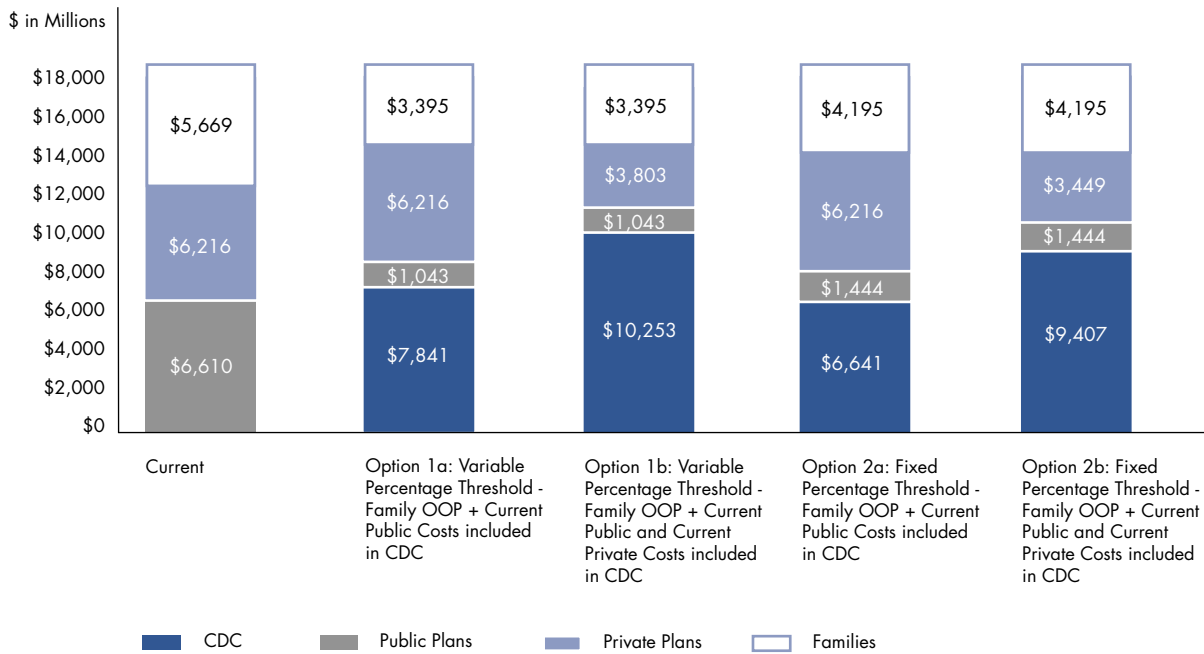
- The estimates do not assume that any Canadian family's current level of drug coverage would be reduced.
- The work to date has not included discussion of financing approaches, nor has it presupposed a particular design or implementation approach.
- At this time, various estimates have been produced of the current coverage gaps – the catastrophic drug costs incurred only by Canadian families (not covered by public and private plans on their behalf). For example, while the graph on the following page (figure 8) includes current out-of-pocket family expenditures above the two CDC thresholds of between \$1.4 billion and \$2.2 billion, other analyses have suggested lower estimates (e.g., less than \$1 billion)²⁰. Further work needs to be done to achieve consensus on the estimated size of these gaps.
- The cost estimates reflect total catastrophic drug costs above the 'catastrophic threshold' including current and new public money.
- The fixed threshold was initially costed at 4.3 per cent of family income as this was the average of the maximum income percentage thresholds of the four income based public drug plans (BC, SK, MB, ON). Going forward, the 4.3 per cent threshold will be rounded to 5 per cent as analysis to date suggests that this adjustment makes little quantitative difference and is easier to communicate.

²⁰ Various third-party studies/reports have addressed the estimated cost of addressing the CDC gaps (e.g., "The Challenge of Catastrophic Drug Coverage," Ken Fraser of the Tristat/Fraser Group presentation to Atlantic Institute of Market Studies (AIMS) workshop on catastrophic drug coverage in Atlantic Canada, 16 May 2006 and "The Health of Canadians - The Federal Role," Final Report, Volume Six: Recommendations for Reform, The Standing Senate Committee on Social Affairs, Science and Technology, Chair: M. J.L. Kirby, Deputy Chair: M. Lebreton, October 2002).

Figure 7: Two Options and Four Variations

Options	Variations	Estimated Costs
Variable Percentage of Family Income (0/3/6/9 per cent)	Private Payer Maintained	\$7.8 billion
	Without Private Payer	\$10.3 billion
Fixed Percentage of Family Income (4.3 per cent)	Private Payer Maintained	\$6.6 billion
	Without Private Payer	\$9.4 billion

Figure 8: Comparison of the Estimated Cost of CDC: Two Options and Four Variations



- Figure 8 above provides high-level impact analysis of the CDC options. Costing and allocations of costs to payer categories (public plan, private, family) are based on modeling and should be considered directional, not actuals.
- The **Current** column (far left) illustrates current expenditure by payer and is used as the baseline for the comparison of options. Note that family out-of-pocket costs are those costs that are currently not covered under either public or private plans.
- Each of the CDC options/variations illustrates how the current baseline spending would potentially be realigned among public plans, private plans and family payers.
- The CDC costs (in dark blue) identified under each of the CDC options/variations include both current and new public dollars that would potentially be needed to reimburse costs above a given CDC threshold:
 - Option 1a: the total CDC cost estimate includes current \$5.6 billion public expenditure above the CDC threshold and \$2.2 billion in new public dollars.
 - Option 1b: the total CDC cost estimate includes current \$5.6 billion public expenditure above the CDC threshold and \$4.7 billion in new public dollars.
 - Option 2a: the total CDC cost estimate includes current \$5.2 billion public expenditure above the CDC threshold and \$1.4 billion in new public dollars.
 - Option 2b: the total CDC cost estimate includes current \$5.2 billion public expenditure above the CDC threshold and \$4.2 billion in new public dollars.
- Figure 8 does not attempt to illustrate how drug consumption and total spending might evolve as a consequence of expanded catastrophic coverage, or otherwise change over time.

A comparison of options identified that:

- The variable percentage of income option could more effectively protect lower income families – it is, however, more expensive; and
- Total public CDC costs would be lower if private plans continued to provide drug coverage for those Canadians currently with private insurance, including those facing high drug expenses.

RECOMMENDATIONS

The Ministerial Task Force recommends that:

- Further policy, design, and costing analysis be focused on a variable percentage of income threshold option that maintains a private payer role;
- A parallel fixed percentage (5 per cent) option also be analyzed and costed; and
- The impact and feasibility of maintaining a private payer coverage role be analyzed as part of this further work.

Next Steps

In order to facilitate decision-making, work will proceed on the following policy and costing analysis of the two recommended options:

PLAN DESIGN

Further work is required on refining the formula for the qualifying threshold, so that the threshold would, to the extent possible, best protect all Canadians from “undue financial hardship,” while meeting all the strategic principles. This work will include further analysis of the impact of different ways of measuring ‘income’, including possible adjustments (e.g., for family size).

IMPLEMENTATION CONSIDERATIONS

Thus far, work on financing and other implementation considerations has not taken place, but work in this area could start in the next phase of NPS work. Of particular importance will be coordination with existing public drug plans and the role of private drug coverage.

SUSTAINABILITY CONSIDERATIONS

Several issues have been identified for further analysis (e.g., inflation leveraging, population aging, pent-up demand, changes in utilization patterns, prescribing patterns and formulary management), recognizing that some of these factors can be mitigated by plan design while others are broader societal issues. In addition, it is recognized that these factors are not of equal weight either in terms of when or the extent to which they would affect CDC.

COSTING

Further work will be necessary to refine the costing of public CDC options/variations, particularly with respect to the breakdown (out-of-pocket, public payer, and private payer) of costs. This work may entail revising the methodology used to conduct the current costing estimates, as well as exploration of the availability of more robust data to reduce the need for reliance on assumptions in the modeling.

ENGAGING STAKEHOLDERS

Stakeholders will be engaged in further policy analysis work. It will be necessary to consider the objectives of various stakeholders and ensure that the impact on stakeholders and their potential reactions are appropriately understood and considered in future work.

3.2 Expensive Drugs for Rare Diseases

Objective

To develop and implement consistent national processes and standards to ensure that Canadians with rare, severe and progressive or life-threatening diseases have access to appropriate and affordable treatments.

Background & Rationale

Expensive drugs for rare diseases (EDRDs) present a host of complex challenges to public health systems. Many international jurisdictions have also individually struggled with the challenges of EDRDs. These drugs can be prohibitively expensive and often benefit only a small number of patients. Historically, the number of treatable rare diseases have been relatively low, however with scientific and technological advances, the number of treatments and treatable patients are increasing.

Canadian jurisdictions are under increasing pressure to fund EDRDs and develop procedures to deal with the ethical dilemmas in determining access to these and other drugs. As rare diseases affect few patients, they challenge traditional data collection approaches in both a clinical trial and a 'real-world', post-market setting. However, the need for effective treatment is no less significant for Canadians suffering from rare diseases than for those suffering from common diseases. Therefore, there is a perception that existing decision-making processes may need to take special consideration of EDRDs. All jurisdictions are faced with the challenge of determining when, or under what conditions, it is appropriate to publicly reimburse therapies that do not meet common standards of evidence for coverage, particularly in cases where there are no alternative drug therapies.

The issue of EDRDs touches many, if not all, of the elements of the NPS, underscoring their interconnectedness. A comprehensive framework for EDRDs will help improve Canadian understanding

of rare diseases, align current programs and processes across jurisdictions, improve decision-making, and provide guidelines to address research, evidence, cost, access, funding and ethical issues.

Progress & Achievements

Activities toward developing a framework for EDRDs have focused on:

- ▶ Building an understanding about EDRDs and facilitating a common understanding of key issues;
- ▶ Developing a post-market research study for Fabry's Disease.



Towards building an understanding about EDRDs and facilitating a common understanding of key issues:

- A series of background papers on EDRDs was developed to examine the policies and definitions with respect to “rare” or “orphan” drugs from five international jurisdictions: Australia, Japan, Singapore, the United States and the European Union (Summer 2005);
- A working session was held with individuals from FPT governments, the Canadian Expert Drug Advisory Committee, the pharmaceutical industry, practicing clinicians and researchers to discuss challenges related to evaluating rare disease therapies and explore draft concepts for an EDRD framework (Fall 2005); and
- A small working group met with international delegates to gain insight on issues related to EDRDs, share best practices in the management of these drugs, and explore opportunities for international collaboration (Fall 2005).

Research to date has revealed that there is no single internationally accepted definition or set of criteria for rare diseases. Definitions that do exist are somewhat arbitrary in nature and are not well suited to informing coverage and market access decisions. Similarly, none of the jurisdictions reviewed has a robust and meaningful approach to addressing ethical resource allocation issues and evidence-based decisions for EDRDs. Findings have underlined the importance of processes and standards that move towards:

- International consistency in the assessment of the risk/benefit profile for breakthrough therapies;
- Appropriate access (commercially available and publicly-funded) to evidence-based therapies;
- Application of consistent national evaluation standards that are appropriate and specific to rare disease treatments and breakthrough therapies;

- Sustainability of public funding for rare disease treatments;
- The development of appropriate monitoring and evaluation mechanisms for new therapies for rare diseases; and,
- Incorporation of ethical considerations and public input into decision-making processes.

Developing a post-market research study for Fabry’s Disease:

- Consistent with direction provided by FPT Health Ministers in October 2005, FPT governments and manufacturers have completed the development of an agreement for a time-limited research study of drug therapies for Fabry’s Disease through which approximately 100 Canadian patients will have access to enzyme replacement therapy.
- The knowledge gained from the development and outcomes of this study will better inform governments in addressing the special challenges presented by drugs for rare diseases. Chief among these is the need to find new approaches to assessing the effectiveness of drugs used in very small patient populations.

RECOMMENDATION

The Ministerial Task Force recommends that officials:

- Accelerate work on a framework for EDRDs focusing primarily in the areas of evidence, ethics and the need to appropriately align regulatory and reimbursement systems.

Next Steps

FPT jurisdictions are accelerating their work in this area and fully engaging experts, the federal drug regulator, patients and Canadians. Given the complexity of this area a collaborative approach is needed to ensure that the EDRD therapies funded by the public health care system have demonstrated value for Canadians. The next phase of work will focus on:

INTERNATIONAL EXPERIENCE

- Further assessment of international approaches to EDRDs, with a view to collectively addressing their challenges.

ENGAGING STAKEHOLDERS

- A small group of experts will be convened to identify short, medium, and long-term strategies for improving the existing processes and mechanisms for determining access to drugs for rare diseases and other breakthrough treatments.
- Officials will also review public engagement models and identify an appropriate mechanism to achieve meaningful exchange on the societal choices involved in determining access to and payment for these drugs. Engagement is expected to begin in late 2006.

DEVELOPING A FRAMEWORK

- Drawing on expertise from government, the research community, patients, and providers to ensure that a comprehensive EDRD framework is developed that will include:
 - Developing approaches to evidence and ethics for EDRDs; and
 - Identifying means to align regulatory and reimbursement decision-making.

3.3 Common National Formulary

Objective

To provide Canadians with equitable and affordable access to safe, effective, and cost-effective drug treatment.

Background & Rationale

Equitable access to health services is a fundamental pillar of the Canadian health care system. However, there are inconsistencies and inequities in prescription drug coverage for Canadians across the country.

A national approach to formulary management would:

- Promote optimal use of drugs;
- Reduce inequities across FPT plans through improved consistency and harmonization of FPT formularies;
- Achieve administrative efficiencies; and
- Support consistent and evidence-based decision-making (therapeutic and cost-effectiveness).

The Common Drug Review (CDR) has exemplified the benefit of a collaborative, national approach in the area of pharmaceuticals. Established in 2003, the CDR informs and supports drug plan decision-making through expert advice and listing recommendations based on therapeutic and cost-effectiveness reviews. In October 2005, Health Ministers agreed to expand the CDR to all publicly funded drugs, and to work towards a common national formulary, which will lead to more consistent access to drugs across the country.

Progress & Achievements

To date, work has focused on exploring the feasibility and benefits of expanding the CDR to all drugs. Governments have agreed that this work proceed in order of priority, beginning with: (1) new indications for old drugs, and followed by (2) oncology drugs, (3) therapeutic class reviews,

(4) hospital drugs, and (5) all other drugs. In accordance with these priorities, work to date has focused on the following components:

TOWARDS EXPANDING THE CDR

- A feasibility study and a business case revealed that the activity of reviewing new indications for old drugs closely aligns with current CDR activities. The Canadian Agency for Drugs and Technologies in Health (CADTH), where the CDR is housed, appears well-positioned to accommodate expanded functions in this area.

TOWARDS DEVELOPING A COMMON REVIEW PROCESS FOR ONCOLOGY DRUGS

- Research revealed that access to and review processes for oncology treatments under public plans in Canada varies greatly across the country, as do the provincial and territorial policies and processes used to consider coverage for new cancer drugs.
- There is strong support across jurisdictions for a structured review process for new intravenous oncology drugs²¹, and for further consultations with stakeholders.

²¹ The CDR already reviews new oral and take-home cancer drugs.



ANALYSIS OF THE COMPARABILITY OF FORMULARIES TOWARDS A COMMON LIST OF BENEFITS

- Analysis conducted with the National Prescription Drug Utilization Information System (NPDUIS) revealed that the majority (approximately 90 per cent) of reimbursement occurs within a set of core drugs reimbursed by all plans. However, the comparability of the list of drugs common across jurisdictions is significantly lower (55-60 per cent).
- This comparison may be useful in exploring approaches to a Common National Formulary. As a first step, a Common Benefits List could be developed using modifications of a current list from one of the provinces or building on a list of common drug classes.
- Moving towards a Common Drug Benefits List is complex and requires further analysis that can feed into the development of a national approach to formulary management.

RECOMMENDATIONS

The Ministerial Task Force recommends that officials:

- Pursue a staged expansion of the Common Drug Review (CDR) and common review processes to increase the commonality of public plan formularies; and
- Continue work to design a common national formulary.

Next Steps

The next phase of work will focus on the following components, carried out in order of priority as listed:

- Expand the CDR at CADTH to new indications for old drugs in accordance with the methods outlined in the business case;
- Prepare a business plan on the development of a common review process for oncology drugs (March 2007);
- Continue analysis of the comparability of formularies, focusing on alignment of formulary policy approaches, with a view to moving towards a national approach to formulary management; and
- Conduct an analysis of the expansion of the CDR process to include class reviews with a view to providing advice to public drug plans on previously evaluated classes of drugs.

ENGAGING STAKEHOLDERS

- Various stakeholder groups, including industry representatives and patient advocates, will be engaged in the next steps. Stakeholder engagement will begin with consultations on a common review process for oncology drugs.

3.4 Drug Pricing and Purchasing Strategies

Objective

To contribute to the sustainability of public drug programs so that Canadians have timely and affordable access to prescription drugs by:

(1) achieving international parity on the prices of non-patented drugs; (2) developing pricing and purchasing strategies to obtain the best prices for prescription drugs and vaccines in Canada; and (3) accelerating access to affordable medicines for Canadians.

Background & Rationale

PRICING AND PURCHASING STRATEGIES

Given the complex and fragmented nature of the Canadian pharmaceuticals marketplace, there is a strong case for a collaborative national approach to achieve the Pricing and Purchasing mandate.

Multiple payers, competing incentives, priorities and interests characterize the Canadian pharmaceuticals market. This fragmentation benefits the pharmaceutical industry, which uses the current market structure to leverage one jurisdiction against another for access and to obtain product listings. This fragmented market also allows for the maximization of profit margins, at a level which would not otherwise be realized in a single/unified market. To date there has been 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 industry to command higher prices.

The Patented Medicine Prices Review Board (PMPRB) regulates the price of patented medicines, and ensures that Canadian patent drug prices are not excessive. Prices in the non-patented sector do not face such regulations.

A non-patented drug price study conducted by FPT jurisdictions and the PMPRB in 2002 found Canadian prices for non-patented drugs to be 21 to 51 per cent higher than international median prices.²²

The PMPRB is now monitoring and reporting quarterly on international non-patented prescription drug prices, with the first report published on July 4, 2006. Based on the data used in that report, the 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 32.5 per cent²³, or \$1.47 billion.²⁴



²² Other research is consistent with these findings: (United States Food and Drug Administration white paper issues in November 2003; Australian Productivity Commission – International Pharmaceuticals Price Differences Research Report July 2001)

²³ Potential savings are based on Purchasing Power Parity Rates (rates adjusted for differences in cost of living). The same calculation at Market Exchange Rates (annual average spot-market exchange rates) suggests savings of up to 29.5 per cent, or \$1.34 billion.

²⁴ Based on Canadian non-patented generic and non-patented branded spending totals from the 2005 PMPRB Annual Report

While international price parity is an important objective, analysis of the Canadian market suggests that additional savings are possible. Addressing the practice of rebates (where manufacturers use cash and/or other incentives to influence pharmacy purchasing decisions) would help in achieving “best” prescription drug prices for Canadians. Conservatively estimated to average 40 per cent of the retail price for generic drugs, these rebates are not passed on to either consumers or the public purse, building the case for increased transparency²⁵.

A nationally coordinated pricing and purchasing strategy could be achieved through two broad approaches: a national legislative/regulatory or a national collaborative business management approach.

- PT governments hold authority for regulating prices of non-patented drugs through s.91 (13) of the Constitution Act, 1867. This authority could be exercised individually, collectively, or through delegation. A legislative/regulatory approach would require each jurisdiction to enact and/or amend legislation governing the price of non-patented pharmaceuticals and then delegate its authority to a federal administrative body. This would be a difficult and lengthy process, particularly as only Ontario and Quebec currently have explicit drug price legislation.
- A business management approach would require FPT jurisdictions to act in concert on issues of pricing and purchasing. Governments and other potential payers could negotiate with industry on price as well as rules of conduct for supply chain transparency. Such rules would address concerns over current rebate and marketing practices.

EXPANDED INDICATIONS FOR PATENTED MEDICINES

Introductory price assessments for patented drugs by the PMPRB (i.e., the maximum non-excessive introductory price) are based on the approved indications, or uses, of the drug at the time of its initial review. Although a drug might later be approved for additional indications characterized by lower prices, the PMPRB lacks a mechanism in its Excessive Price Guidelines to re-evaluate the price of the product.

ACCELERATING ACCESS TO NON-PATENTED MEDICINES

As non-patented medicines are generally less expensive than patented medicines, First Ministers, in the September 2004 Health Accord recognized the need to “accelerate access to non-patented drugs”.

Governments recognize the crucial role the innovative pharmaceutical industry plays in the development of breakthrough drugs and that intellectual property protection is key to encouraging and supporting innovation.

Current amendments proposed for the Patent Medicine (Notice of Compliance) Regulations and Food and Drug Regulations (Data Protection) indicate that Industry Canada and Health Canada similarly recognize the need to balance effective patent enforcement with timely market entry of generic drugs.

²⁵ Some provinces are moving independently to address market dynamics and achieve better pharmaceuticals pricing. On June 19, 2006, Ontario passed Bill 102, the Transparent Drug System for Patients Act. Quebec has also made independent efforts to regulate their pharmaceutical industry (i.e., Bill 130)

Progress & Achievements

To date, activities have focused on attaining more competitive prices for non-patented (multiple and single source) drugs, with a focus on developing strategic options for a comprehensive national pricing and purchasing framework.

Highlights are as follows:

- As endorsed by Health Ministers in October 2005, the PMPRB began monitoring non-patented prescription drug prices. The first quarterly report focuses on trends, Canadian-to-foreign price comparisons and market structures for non-patented prescription drugs.
- Discussions with the generic pharmaceutical industry and academics have informed the development of options to achieve more competitive non-patented drug prices, including approaches to address rebate and marketing-conduct issues within the non-patented drug supply chain.

RECOMMENDATIONS

The Ministerial Task Force recommends that:

- A non-regulated, business-management approach to drug pricing issues, with priority on non-patented drugs, be pursued; and
- Consideration of regulatory approaches also continue.

Next Steps

The next phase of work to develop strategies for pricing and purchasing would focus on:

- Developing a business case and implementation plan for the non-regulated, business-management approach to non-patented drug prices;
- Further examination of the incremental benefits (particularly for private payers) of a legislative/regulatory approach, and examination of any implementation issues;
- Reviewing the findings of the first PMPRB report on non-patented prescription drug prices and evaluating implications for pricing strategies;
- Monitoring the impact of new prescription drug legislation in Ontario and Quebec;
- Monitoring and assessing developments and providing input as required into possible amendments to the Canadian patent system to align with the NPS objective of accelerating access to non-patented drugs; and
- Developing a policy document that defines the issues within the current regulatory framework for patented medicines with expanded indications, and outlines and evaluates possible policy/regulatory changes. This policy document would detail potential courses of action to improve the patented drug pricing system in Canada.

ENGAGING STAKEHOLDERS

Consultation would occur with both primary and secondary stakeholders. Primary stakeholder groups would cross government and industry; consultation with secondary group(s) would be largely information-out sessions intended to keep them abreast of developments.

3.5 Real World Drug Safety and Effectiveness

Objective

To develop a stronger system for gathering, interpreting and applying drug safety and effectiveness information in Canada.

Background & Rationale

Drugs approved by Health Canada must undergo rigorous pre-market clinical testing. However, evidence based only on short-term, controlled clinical trials in carefully selected patient groups does not provide the basis for accurately predicting a drug's safety and effectiveness in the 'real world' (where it is used in different population groups at varying doses and for long periods of time). The pattern of risks and benefits of a drug also changes over time as therapeutic use evolves.

As highlighted by the recent events concerning cox-2 inhibitors (Vioxx® and Bextra®), the performance of a drug can only be fully measured based on real world experience and compared to alternatives. Currently, such real world evidence and conclusions drawn from it are critically limited, or when available, are generally not coordinated or linked in any systematic way. As well, these activities do not tend to involve the patient perspective, and health care provider input is confined to relatively small groups of experts.

The resulting gap in information acts as a barrier to effective, evidence-based decision-making for all involved in the regulation, prescribing, utilization and coverage of medications. This gap is particularly acute for products receiving a Notice of Compliance with conditions²⁶, where the evidence of clinical benefit is considered promising but not definitive.

Addressing the issues of safety and effectiveness, while respecting federal regulatory responsibilities in this area, requires the participation of many players, and suggests the need for national oversight and planning with respect to the generation and use of safety and effectiveness evidence.

A consistent national approach would help make the most effective use of Canada's resources in this area, both financial and human. A system for prioritizing drugs and drug classes of greatest surveillance interest based on their impact on health outcomes and on Canada's publicly funded health care system would also be needed.



²⁶ A Notice of Compliance with conditions is an authorization from Health Canada to market a drug (i.e., a Notice of Compliance), with the condition that the sponsor undertake additional studies to verify the clinical benefit.

Progress & Achievements

Work to date on improving drug surveillance and on strengthening mechanisms for integrating real world evidence into decision-making has focused on:

- Establishing the broad-based support necessary to develop a shared responsibility model; and
- Developing a set of interdependent strategies that can lead to a stronger system for the evaluation of drug safety and therapeutic effectiveness, which supports the needs of patients, healthcare providers, and the responsibilities of governments.

In September 2005, the NPS hosted a working conference to obtain stakeholder input on strengthening the evaluation of drug safety and effectiveness, drawing together more than 100 participants representing industry, public and private drug insurance programs, regulators, researchers, health care providers and patients. The conference and subsequent dialogue informed the development of the following four *interdependent* strategies:

1. Support collaboration and priority-setting – using a national oversight body, composed of key stakeholders and all jurisdictions, with the mandate to plan, set priorities, coordinate and budget for answering real world safety and effectiveness questions, while respecting the federal regulatory responsibility for post-market safety.
2. Strengthen existing capabilities – through the establishment of a network of pharmaceutical research ‘centres of excellence,’ hospital-based teams and enhanced regional Adverse Drug Reaction Reporting (ADR) centres to develop strong education and provide outreach to local providers and patients.

3. Build ‘front-line’ participation and new opportunities – through the active engagement of primary care and hospital-based teams, the development of education programs to build drug knowledge, and various approaches (i.e., electronic health records) to support generation of data by patients and providers.
4. Establish clear standards and transparency of evidence – through a strengthening of linkages among regulatory and health system decision-making experts, frameworks and processes; supporting dialogue and guideline development on the levels and standards of evidence; making evidence and its interpretation by regulatory and health system decision-making experts publicly available.

A discussion paper has been developed to provide details of what is being considered under each strategy. This paper would provide the basis of consultation with stakeholders going forward.

Work to date has focused on Strategies (1) and (2):

- Officials are collaborating with a coalition of researchers and the Canadian Institutes of Health Research (CIHR) on a business plan for a pharmaceutical research network and a governance structure. Other key stakeholders should be engaged in the fall of 2006; and
- To ensure the proposed network can deliver meaningful results reasonably early in its mandate, a set of early surveillance priorities were identified during an invitational stakeholder workshop convened for this purpose:
 1. Long-term safety and effectiveness of glitazones for diabetes versus metformin, glyburide and insulin;
 2. Safety and effectiveness of newer antipsychotics in the treatment of schizophrenia and dementia;
 3. Safety and effectiveness of the different drugs for treatment of Alzheimer's disease
 4. Effectiveness of new cancer drugs; and
 5. Long-term safety and effectiveness of biologics used for treatment of rheumatoid arthritis and Crohn's disease.

RECOMMENDATION

The Ministerial Task Force recommends that:

- Stakeholder consultations be undertaken on the four interdependent strategies (i.e., a research network, an oversight body, engagement of primary care and hospital based teams, and the establishment of clear standards and transparency of evidence).

Next Steps

Key projects for the next phase of work would include:

- Complete work on a business plan for a pharmaceutical research network and a governance structure which respects the federal regulatory responsibilities in this area;
- Engage stakeholders on the four interdependent strategies, including the research network and governance structure, as well as the proposed early surveillance / research priorities; and
- Use a discussion paper outlining the full scope of safety and effectiveness issues, including issues related to surrogate endpoints and biomarkers, in the context of stakeholder engagement activities.

ENGAGING STAKEHOLDERS

- Engagement of stakeholders in the fall of 2006 on the four interdependent strategies and on options for a research network and oversight body.

Part IV - Progress on Other NPS Elements

While collaborative efforts to date have focused on the five priority elements of the NPS outlined above, work has continued in a number of other areas, including electronic prescribing (e-Rx) and appropriate drug prescribing and utilization. Brief descriptions of advances made on both of these fronts are provided below.

4.1 Electronic-prescribing (e-Rx)

Background

The implementation of e-Rx ultimately promises to contribute to improved health outcomes and patient safety by helping to reduce incidences of medication error. E-Rx will also enhance optimal drug therapy by supporting quick access to important prescribing information and tools.

ONGOING ACTIVITIES

Achievements have included:

- Health Canada and Canada Health Infoway, on behalf of participating jurisdictions, have collaborated on identification of a suitable pan-Canadian technical standard and protocol for ensuring the *veracity* of e-prescriptions; and
- During consultations in the fall of 2005, stakeholders achieved overall consensus on the proposed standard, and support was voiced to amend any regulations needed to enable e-Rx. Health Canada officials are examining the need for and the mechanism to enable regulatory amendments.

The implementation of e-Rx across Canada will require integration with other existing and emerging electronic systems and modes of practice, and promotion of e-Rx uptake. It will also require ensuring that relevant PT regulatory frameworks for the health professions are amended if, and as, necessary, to fully support and allow e-Rx. This work will build on the advances of the different provincial jurisdictions in the areas of e-Rx, drug information systems and electronic health records.



4.2 Appropriate Drug Prescribing and Utilization

Background

While there is strong evidence to suggest that many drug expenditures represent money well spent, considerable evidence also points to significant waste, driven by inappropriate prescribing and use.²⁷ When drugs are not prescribed or used appropriately, the quality of care is reduced, unnecessary costs are incurred and patients can be seriously injured. The gap between evidence and practice has been shown to result in provision of care that is either not needed, or is potentially harmful in 20 to 25 per cent of patients. Inappropriate prescribing and/or drug utilization have been identified as key factors in rising drug expenditures and overall health costs.²⁸

Gaps between evidence and actual practice exist for a variety of reasons. The inappropriate use of drugs, meaning the over, under, or misuse of medications, is also attributable to a mix of factors. Research suggests that the magnitude of the problem varies by drug category, by setting and the criteria used to assess appropriateness.²⁹

Ongoing Activities

There are a number of pan-Canadian initiatives already in various stages of development that will contribute to addressing these challenges. These include:

- The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), established in 2004 by Deputy Ministers of Health and funded by Health Canada to support FPT governments in working towards optimal use; and
- The National Prescription Drug Utilization Information System (NPDUIS), established in 2001 by FPT Ministers to provide key analyses of price, utilization and cost trends and to be a source of comprehensive, accurate information on how prescription drugs are being used, and on the sources of cost increases.

It is recognized that the implementation and uptake of best practices in drug prescribing and use will involve the longer-term challenge of affecting behavioural change, which is closely related to proposed future work under the Real World Safety and Effectiveness priority area.

Next Steps

Moving into the next phase, the Ministerial Task Force would continue to monitor progress and, where appropriate, form links with relevant initiatives related to the NPS.

²⁷ Written submission by the Canadian Pharmacists Association to the Romanow Commission, 2001.

²⁸ Grol R, Crimshaw J. (2003) *From best evidence to best practice: effective implementation of change in patients' care* in *Lancet* 362:1225-30, as referenced in the COMPUS Business Plan, 2004-2008.

²⁹ e.g., Michael J. Doyle, thesis submitted May 2004, Discipline of Community Health/Faculty of Medicine, Memorial University of Newfoundland, *An Evaluation of the Development, Implementation, and Outcome of Pilot Prescription Monitoring Program in Newfoundland and Labrador*.

Part V - Moving Forward

The submission of this report to First Ministers marks the beginning of a new phase of work for the NPS. Work will continue on the development and implementation of the five NPS priority areas, based on the recommendations in this Report. The MTF will also determine the timing for expanding work into other areas of the NPS.

Key to this next phase will be ongoing dialogue among governments and with stakeholders.



List of Acronyms

CADTH	Canadian Agency for Drugs and Technologies in Health (formerly Canadian Coordinating Office for Health Technology Assessment (CCOHTA))
CDC	Catastrophic Drug Coverage
CDR	Common Drug Review
CIHI	Canadian Institute for Health Information
COMPUS	Canadian Optimal Medication Prescribing and Utilization Service
EDRD	Expensive Drugs for Rare Diseases
e-Rx	Electronic Prescribing
FPT	Federal, Provincial and Territorial Governments
MTF	NPS Ministerial Task Force
NOC, NOC-c, NON	Notice of Compliance, Notice of Compliance with conditions, Notice of Non-Compliance
NPS	National Pharmaceuticals Strategy
NPDUIS	National Prescription Drug Utilization Information System
PMPRB	Patented Medicine Prices Review Board
POSP	Physician Office System Program
PT	Provincial and Territorial Governments

