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PHARMACEUTICALS IN CANADA

A background paper to accompany
Health Care Renewal in Canada: Accelerating Change
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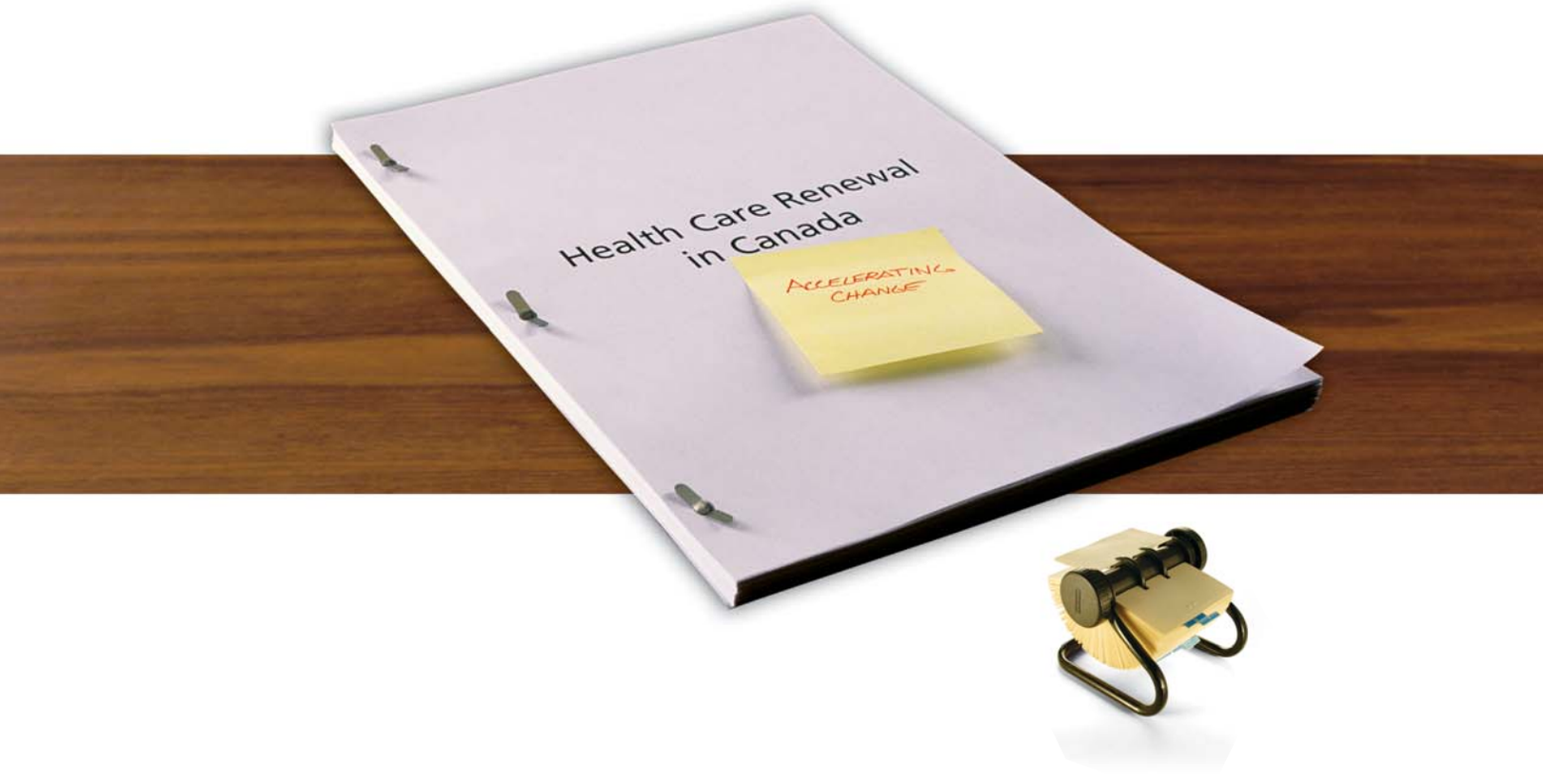

Health Council of Canada
Suite 900 90 Eglinton Avenue East Toronto, Ontario M4P 2Y3 416.481.7397
www.healthcouncilcanada.ca

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1. Why is the issue of pharmaceuticals important?

(a) The value of pharmaceuticals

Drugs play an ever-increasing role in the health care system and today have become one of the most widely used interventions in medicine. They are used for prevention of disease, for symptom control to enhance quality of life, and for improvements in health outcomes overall. Drugs can replace more invasive forms of treatment such as surgery and can reduce costs in other health care sectors, for example through reductions in hospital lengths of stay. They can provide dramatic benefits as breakthrough therapies, as they have in the treatment of HIV/AIDS and some forms of cancer.

There are down sides as well. Some new drugs provide minimal added value, being similar to existing drugs or providing only marginal health benefits. Worldwide there is recognition that drug costs are becoming a major concern and are increasingly unaffordable. Recent attention focused on adverse drug reactions highlights the risks associated with drug therapy. As well, poly-pharmacy (patients taking many drugs) is increasing, and with it, the risk of complications related to drug interactions.

(b) Pharmaceuticals in Canada

(i) The Canada Health Act

The *Canada Health Act* (CHA) of 1984 includes five program criteria that provinces and territories must observe to allow them to receive federal funding for health care: public administration, comprehensiveness, universality, portability, and accessibility (Health Canada 2004). The CHA mandates public coverage for physician services and hospital care, including pharmaceuticals used while in hospital. However, outpatient prescriptions are not included under the CHA. Many people believe pharmaceuticals should be a fully insured service and advocate for a national publicly-funded pharmacare program. Currently, the majority of pharmaceutical funding and policy development occurs on a jurisdictional, rather than a national level.

(ii) Overview of drug costs

The Canadian Institute for Health Information (CIHI) reports that total spending on drugs in Canada was almost $20 billion in 2003, up from $16.7 billion in 2001. Approximately 80 per cent of these costs are for prescription drugs (as distinct from non-prescription or over-the-counter drugs). The average annual rate of growth of these costs over the past 20 years has been 9.7 per cent, well in excess of inflation and population growth. Of total health expenditures, the proportion spent on drugs is growing relentlessly: it was 9.5 per cent in 1985 and is projected to reach 16.2 per cent in 2003. Of all costs in the health care sector, spending on drugs now exceeds spending on physician services and is second only to spending for hospital services (CIHI 2004). Growth in drug expenditures is attributed not only to the introduction of new, more expensive drugs, but also to increased utilization (more people taking more drugs) (Willison 2002).

(iii) Jurisdictional variation

There are 19 publicly-funded drug plans in Canada: 10 provincial, three territorial, and six federal. The six federal programs are operated by Health Canada and serve specific populations across the country: (1) First Nations, Inuit, and Innu people; (2) members of the Department of National Defence; (3) some veterans and their families through Veterans Affairs Canada; (4) members of the RCMP; (5) some incarcerated individuals in federal correctional facilities; and (6) some individuals eligible through Citizenship and Immigration.[1]

Each of the 19 plans has its own definitions of eligible populations, coverage policies, formularies for included drugs, co-payments, deductibles, out-of-pocket caps, and so on.[2] Each plan has its own system for dealing with catastrophic costs (drug expenses so high that they could threaten a person's financial security), some protecting all residents and some protecting only limited groups of people. There are disease-specific plans in many of the jurisdictions as well; these provide public funding for the drugs associated with rare and/or high-cost conditions such as cystic fibrosis, multiple sclerosis, HIV/AIDS, and cancer. In these cases, a patient's disease determines his or her drug coverage, as does the province of residence.

The absence of a national approach to the funding of pharmaceuticals has led to discrepancies among the provinces and territories. Some jurisdictions have comprehensive programs providing protective coverage for their beneficiaries, but other programs have a number of coverage gaps. For disease-specific drug funding, coverage differences may be significant enough to cause people to move from one jurisdiction to another in order to be protected against high drug expenses. While access to medically necessary drugs, outside of hospitals, does not fall under the jurisdiction of the *Canada Health Act*, consistency of access may be attained through the implementation of a pan-Canadian standard for catastrophic drug coverage.

With respect to interprovincial differences, various perspectives can be taken. For example, MacDonald and Potvin found a large degree of variation when they examined coverage of drugs by six provincial plans[3] based on chemical subgroup level (CSG) as defined by the World Health Organization. (CSG is one level up from the individual drug level.) They found that BC and NS provided access to the greatest number of full-listing CSGs (336) in contrast to the other extreme, the 268 listed by Manitoba. The authors comment that this variation has therapeutic implications for patients. In conclusion they promote the need to provide comprehensive and equitable access to publicly-funded drugs across the country (MacDonald 2004).

[1] The six federal plans share a common advisory committee.

[2] Definitions of terms (as per Fraser Group, 2002):

- Co-payment: the proportion of the cost of each prescription that must be paid by an individual; may take the form of a percentage of the cost or a specific dollar amount per prescription.
- Deductible: the initial amount of drug expense that must be paid by an individual before a drug plan reimburses any expense, generally computed on a yearly basis.
- Out-of-pocket cap: plan provisions that restrict the total amount of deductibles and co-payments that will be imposed on an individual; either a fixed dollar amount, or an amount determined by family income.

[3] Plans compared were those of BC, Alberta, Manitoba, Ontario, Quebec, and NS.

The details of each plan are well described in the appendix of the Canadian Institute for Health Information (CIHI) report *Drug Expenditures in Canada 1985-2003* (CIHI 2004). For example, CIHI data reveal:

- There is considerable variation in the level and growth of drug expenditure across the provinces. In 2001, estimated total drug expenditure per capita ranged from $444 per person in BC to $584 in PEI.[4]
- In 2001, the proportion of prescribed drugs out of total drug expenditures ranged from 75.8 per cent in BC to 84.6 per cent in Quebec.
- The proportion of prescribed drugs financed by the public sector in 2001 varied across the provinces, from a low of 30.8 per cent in PEI to a high of 53.3 per cent in BC.

(iv) How patented drugs enter the market

To market a new patented drug in Canada, a manufacturer must apply for a Notice of Compliance (NOC) from the Therapeutic Products Directorate (TPD) at Health Canada, the federal authority that regulates pharmaceutical drugs and medical devices for human use. A manufacturer must present scientific evidence supporting a product's safety, efficacy, and quality, as required by the *Food and Drugs Act and Regulations*, in order to receive an NOC (TPD 2003). Drugs considered include new chemical entities (NCEs), drug combinations, line extensions, and generics.

With the granting of an NOC, a manufacturer may market the drug and physicians may prescribe it – however, a system for public payment will not be in place. To approach a drug plan regarding coverage of the drug, a manufacturer must prepare particular materials supporting the clinical effectiveness and cost effectiveness of the product, according to specifications laid out by the drug plan. Not all drugs are approved for coverage. According to a recent analysis (Applied Management 2004), from 1999 to 2003 an average of 23 NOCs were issued for new drugs each year (range 18 to 31) and federal/provincial/territorial (FPT) drug plans ultimately approved between 18 per cent (PEI) and 68 per cent (Quebec) of these for public coverage.

The time span between NOC and approval for coverage varied significantly – from 253 days (Quebec) to 877 days (PEI). However, this measurement may not be meaningful because manufacturers often take weeks or months to finalize product information following NOC. It may be more meaningful to adopt a quality-oriented measure such as whether it has a clinical or economic advantage in comparison with currently available drugs. This would be evaluated by the Common Drug Review process established by the F/P/T Ministers.

(v) Price regulation

[4] The term "total drug expenditure" is comprehensive, covering prescription drugs (about 80 per cent of the total) and non-prescription drugs, which in turn include over-the-counter medications and personal health supplies (bandages, thermometers, feminine hygiene products, etc.) This categorization reflects the term as defined by CIHI's National Health Expenditure Database, including both public and private expenditures.

Canada enacted the *Patent Act* in 1969, requiring licensing of generic drugs. The Act was rewritten in 1985. Subsections have been updated since, including in1989 when patents were extended from 10 years to 20 years, bringing Canada into line with international standards (Department of Justice 1985). In return for extended patents, drug manufacturers committed to increases in Canadian drug research and development (R&D); initially R&D spending was to equal 10 per cent of drug sales (to 1996) (Office of the Auditor General 1998).

Since 1987, under the Patent Act, manufacturers' prices for patented drugs have been regulated and reported by the Patented Medicines Prices Review Board (PMPRB), an arms-length organization reporting to Parliament through the federal Minister of Health. The stated mission of the PMPRB is to "protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patent medicines are not excessive." PMPRB has a role in regulating the pricing of patent medicines, but also in reporting trends in drug research and sales, in initiatives related to drug utilization, and in tracking Canada against its peers internationally. For example, in 2003, PMPRB reported that growth in pharmaceutical sales in Canada has exceeded levels in the US, UK, Germany, Italy, and France (PMPRB 2003).

The PMPRB has established voluntary guidelines for the setting of drug prices in Canada. In cases where the guidelines are not observed, the PMPRB first encourages voluntary compliance and, if this fails, has the power to take "remedial action." For example, in 2002, of 60 drugs reviewed by the PMPRB, 46 were priced within the PMPRB's guidelines and 14 were priced at levels outside the guidelines, triggering investigations (PMPRB 2003). In 2003, the PMPRB reviewed the prices of 70 of the 71 new patented drug products reported that year; 58 were found to be within the PMPPRB guidelines and 12 were investigated (PMPRB 2004).

The PMPRB maintains that this management has controlled the prices of patented medicines in Canada which, over the past 10 years, have remained 5 per cent to12 per cent below the median of prices in other industrialized countries, a trend which started in 1993. At the same time, total spending on drug R&D and basic research in Canada has increased. Currently, the PMPRB does not regulate the price of non-patented drugs (including generic drugs) and this gap may have cost implications; a recent report states that Canadian prices for generics are higher than those in the US and internationally (Skinner 2004).[5]

In 1998, the PMPRB was audited by the Auditor General of Canada to determine whether drug price regulation by the PMPRB was occurring in accordance with relevant legislation and whether Parliament was receiving sufficient information in those areas monitored by PMPRB. The audit was generally favourable although PMPRB was instructed to ensure its price review decisions were clear and transparent, to identify its own cost-effective means to check the accuracy of price information submitted by patentees, to work with Statistics Canada to improve the reporting of drug price trends information filed by patentees, and to ensure information submitted by industry on R&D spending was accurate.

[5] Many provinces have policies related to generic drugs, e.g. Ontario controls generic expenses by setting a ceiling price for first entry generics (70 per cent of the brand name price) and second entry (90 per cent of the price of the first generic drug); Quebec has legislation that requires obtaining the best price in the country.

(vi) Adverse drug reactions and adverse events

Complications resulting from drug therapy, termed adverse drug reactions (ADRs), appear to be escalating. In 2003, the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) received 9209 reports of suspected ADRs, of which 70 per cent (6404) were classed as serious. This was a 7.5 per cent increase in reports over the previous year, a trend consistent over the previous five years (CADRMP 2004). There is significant under-reporting of ADRs, and there are initiatives are underway to make an impact on this. One approach is to consider systems to make physician reporting of ADRs mandatory rather than voluntary, although this would not be easy to design and implement. Another is to pass legislation requiring reporting of all "critical incidents", as Saskatchewan has done (Saskatchewan Executive Council 2004). A trend that may assist is the increasing interest in post-marketing surveillance to monitor the performance of a drug once it is being used by many (thousands or millions) of people, a population much larger than the group studied in the initial clinical drug trials where rare ADRs will not be captured (Trontell 2004).

ADRs are one form of a larger collection of unexpected and unfortunate results of health care treatment, generally termed adverse events (AEs). The issue of AEs in hospitals in Canada has recently been closely examined through a project funded by CIHI and the Canadian Institutes of Health Research (CIHR) and led by Drs. Ross Baker and Peter Norton. For this study, AEs are defined as "unintended injuries or complications resulting in death, disability, or prolonged hospital stay that arise from health care management." Many of these AEs involve pharmaceuticals (Baker 2004).

Four hospitals in each of five provinces were randomly selected for review of their medical charts. In these hospitals, researchers found that 7.5 per cent of hospital admissions were associated with AEs, of which 37 per cent were judged to be preventable and 21 per cent lethal. When causes of AEs were examined, drug-related events formed part of the second highest category, causing 85 of 360 AEs (surgery was first, causing 123 of 360). Overall, the data gathered in the study extrapolated to 185,000 annual hospital admissions being associated with an AE, 70,000 of which were deemed potentially preventable (Baker 2004). The 7.5 per cent AE rate found in Canadian hospitals was compared with published AE rates in other countries which ranged from 2.9 per cent to 16.6 per cent.

The need to monitor the ongoing risks associated with drug therapy is being pursued by the Canadian Patient Safety Institute, established in Edmonton in late 2003 (Health Canada 2003). The Institute was a response to one of the recommendations of the National Steering Committee on Patient Safety, an initiative led by the Royal College of Physicians and Surgeons of Canada. Altogether, this committee made 19 recommendations in five areas: establishment of a patient safety institute leading to a national integrated patient safety strategy, improvement in legal and regulatory processes, improvement in measuring and evaluation processes, establishment of educational and professional development programs, and improvement in information and communication processes. The committee's 2002 report provides examples of the use of a patient safety framework, one scenario being proactive review of drug safety (National Steering Committee on Patient Safety 2002).

(vii) Payment for drugs: public and private funding

Payment for pharmaceuticals in Canada is a mixture of public and private funding. Some Canadians have the benefits of both public and private funding of prescriptions, some have one or the other, and some have neither. CIHI reports that 46 per cent of spending on prescribed drugs was financed by the public sector in 2001, 34 per cent by private insurers, and 20 per cent by households as out-of-pocket expenses. The high proportion of private insurance coverage of drugs makes Canada unusual among those Western countries with national health insurance (Willison 2002). Canada, Mexico, and the US are the only OECD countries that do not provide universal[6] prescription drug insurance plans for their citizens (Flood 2002).

Although private insurance plans do not received significant attention in the literature, consultant and author Marg French points out that private employer plans face the same cost pressures as public plans. At $5 billion to $6 billion per year, prescription drugs make up 70 per cent of the cost of the health benefits in employer plans. For those employers providing private insurance for their employees, significant considerations are: (1) private plans often pay for new and expensive drugs which public plans do not cover; (2) insurers can withdraw coverage with 30 days notice, leaving employers vulnerable, as they have committed coverage to their employees; and (3) private plans must also insure retirees who can constitute up to half of a plan's client base (French 2004). Costs for private plans can be considerable as well: Brogan Inc. found the top five per cent of claimants covered by private drug insurance in Canada accounted for 40 per cent of private drug costs in 1997 and almost two-thirds (63 per cent) were still in the top five per cent of claimants three years later (Brogan 2002).

Just under 10 per cent of the Canadian population – or 2.4 million people (2000 data) – have 100 per cent coverage for drug expenses and in total about one-third of Canadians have some type of protective cap on out-of-pocket drug expenses. The remainder of those with private plans (45 per cent of those covered by the plans or eight million people) have substantial but incomplete coverage from severe drug expenses (Fraser Group 2002).

Private and public plans differ in their structure: public plans generally have ceilings on what their beneficiaries must pay while private plans have limits on the amount paid by the plan. Many private plans emulate the provincial plans in their formularies. An additional complexity is the interface among multiple plans as each one attempts to be the payer of last resort.

[6] It should be noted that universal drug plans do not provide first-dollar or free drug coverage; citizens pay out-of-pocket through a mixture of deductibles and co-payments, and these costs can be high. However, in a universal system, no citizens are without some type of coverage.

(viii) Pharmaceutical data sources

Adequate and high-quality data are integral to any analysis of pharmaceutical issues and trends. A number of Canadian organizations provide data and information sources for pharmaceuticals, although there are many areas where information is not available.

Some Canadian data sources (listed alphabetically):

Drug information sources

- *Canadian Institute for Health Information (CIHI)* (www.cihi.ca) maintains the National Health Expenditure Database which contains data back to 1960. From these data, CIHI regularly publishes the report *Drug Expenditure in Canada*. The document reports on drug utilization and expenditures, including provincial and international comparisons.

- *Federal/provincial/territorial (FPT) drug plans* collect significant amounts of information on prescription drugs provided to their beneficiaries (31 per cent to 53 per cent of residents, depending on the jurisdiction) (CIHI 2004). Much of this material is available publicly.

- *Patented Medicines Prices Review Board (PMPRB)* (www.pmprb-cepmb.gc.ca) is an independent quasi-judicial body with a mandate to ensure that the prices charged by manufacturers of patented medicines in Canada are not excessive. PMPRB collects data and reports trends in pharmaceutical use.

- *Private organizations* such as IMS Health (www.imshealthcanada.com), Brogan Inc. (www.broganinc.com), and Rx&D (www.canadapharma.org) collect pharmaceutical information from a number of sources and maintain drug databases, producing both public and commissioned reports.

- *Statistics Canada* (www.statcan.ca) collects pharmaceutical data within several of its periodic surveys: the Survey on Household Spending (n=20,000+ households), the National Population Health Survey (n=15,000), and the Canadian Community Health Survey (n=130,000).

Drug policy sources

- *Academic and policy organizations* contribute significantly to the field, e.g. the BC Therapeutics Initiative in Vancouver (www.ti.ubc.ca), the Institute for Research in Public Policy in Montreal (www.irpp.org), and the Institute for Clinical Evaluative Sciences in Toronto (www.ices.on.ca).

- *Canadian Life and Health Insurance Association (CLHIA)* (www.clhia.ca) is a voluntary non-profit trade association which includes 97 per cent of the life and health insurance associations in Canada. CLHIA collects data and also commissions reports related to pharmaceuticals.

- *Professional organizations* such as the Canadian Pharmacists Association (www.pharmacists.ca) and the Canadian Medical Association (www.cma.ca) collect information and generate a number of policies and reports.

2. What have governments promised?

(a) The 2003 Health Accord: two commitments

In February 2003, the First Ministers announced the Health Care Renewal Accord, committing to a plan to improve access to quality health care for all Canadians. Under the Accord, the federal government provided $34.8 billion over five years, in part for a new Health Reform Fund for primary care, home care, and catastrophic drug coverage. Within the details of the Accord were the following two commitments related to pharmaceuticals:

A. Catastrophic drug coverage
"First Ministers agreed that no Canadian should suffer undue financial hardships for needed drug therapy. Accordingly, as an integral component of these reforms, First Ministers will take measures, by the end of 2005/06, to ensure that Canadians, wherever they live, have reasonable access to catastrophic drug coverage."

B. Pharmaceutical initiatives
"As a priority, First Ministers agree to further collaborate to promote optimal drug use, best practices in drug prescription and better manage the costs of all drugs including generic drugs, to ensure that drugs are safe, effective and accessible in a timely and cost-effective fashion."

(b) Catastrophic drug coverage: introduction and definitions

The term "catastrophic drug coverage" is frequently used with respect to payment for pharmaceuticals. However, the phrase and its individual terms are seldom officially defined. For the purposes of this report, the following concepts will be employed:

- *Catastrophic* defines the upper limit beyond which payment would constitute a financial hardship, although the hardship would vary depending on the financial situations of individuals and families. Some experts see this limit as a fixed dollar figure, others as a percentage of income, and others propose a blend of the two. Some new drugs are so expensive that requirement for even one drug for one person represents a catastrophic expense which can cost tens of thousands and even hundreds of thousands of dollars.

  The Commission on the Future of Health Care in Canada (the Romanow Report) provides this interpretation of the phrase catastrophic drug coverage:
  … $1,500 per person per year [is] the point at which drug expenses for an individual would be considered "catastrophic"…[T]his threshold is roughly equivalent to the deductibles in many of the provinces' drug plans and would cause the least amount of disruption to existing drug insurance plans. (Romanow 2002)

  The report of the Standing Committee on Social Affairs, Science and Technology (the Kirby Report) covers the issue of catastrophic coverage as well, though does not provide a specific definition of the phrase. The report draws a parallel between catastrophic costs and very high or severe costs: *Particular attention is*

devoted to the absence and insufficiency of coverage for very high prescription drug expenses…[There is a] need for enhanced protection against severe or "catastrophic" prescription drug expenses. (Kirby 2002)

- *Drugs* can be prescription or non-prescription (over-the-counter). For those drugs that are prescribed, only a subset (3,500 to 4,000) are listed on a provincial formulary, which means they are eligible for coverage. Many drugs are only used in institutional environments; for example, injectable drugs are mostly used in hospitals. For the purposes of this report, drug means those available on prescription and used primarily for outpatients.

- *Coverage* can refer to a range of possibilities, from first-dollar (where costs are paid or reimbursed for the full cost of the drug) to last-dollar (where an individual pays out-of-pocket up to a pre-determined amount, above which costs are paid or reimbursed by a third party). Between these extremes is a wide range of coverage with varying co-payments and deductibles. Ultimately, the term "coverage" is used to mean those pharmaceuticals a drug plan pays for.

(c) Pharmaceutical management initiatives in Canada: introduction and concepts

Many challenges related to the management of pharmaceuticals have been identified. For example, the rapidly escalating cost of drugs, high deductibles, lack of analysis of utilization patterns, and industry influence on prescribing were noted by Ken Fyke, in the 2001 Commission on Medicare in Saskatchewan (Fyke 2001). Some feel the primary driver of drug utilization in Canada (and elsewhere) is the pharmaceutical industry, operating on a for-profit basis. In addition, there is the challenge in Canada of managing public and private drug plans within multiple jurisdictions, and the public pressure that can occur when one province or territory covers drugs not covered by its neighbours.

A number of complex considerations are necessary to assure high quality management of pharmaceuticals. These considerations include examination of access and equity, efficacy and effectiveness, cost-effectiveness, safety, and utilization. Worldwide, initiatives have been developed to streamline the management of pharmaceuticals. A number of these are underway in Canada and are discussed in Section 3(b) below.

(d) Interlinking of the two commitments

Drug plans cannot be managed without managing the drugs, and clinical choices must be considered in relationship to the investment. Merely managing the beneficiary structure of drug coverage ignores the vital importance of clinical evaluation of prescription drugs listed for public coverage.

(e) The national pharmacare debate and the 2004 Health Care Summit

A national pharmacare program for Canada has been proposed a number of times. In 1997 the National Forum on Health stated: *Because pharmaceuticals are medically necessary and public financing is the only reasonable way to promote universal access and to control costs, we believe Canada should take the necessary steps to include drugs as part of its publicly funded health care system.* (National Forum on Health1997). A number of organizations and experts support comprehensive coverage of

pharmaceuticals under the *Canada Health Act*, though they all acknowledge that implementation will be complex (Forêst 2004, IRRP 2000, Romanow 2002).

The issue emerged in the summer of 2004 prior to the First Ministers' Health Care Summit when Premier Gordon Campbell of BC suggested that the federal government initiate a national pharmacare program. Public responses both supported and opposed the idea. For example, the Canadian Medical Association (CMA) appeared to have reservations, issuing instead a "Seven Point Plan for a National Pharmaceutical Strategy":

(1) focus on the uninsured and underinsured,
(2) fund a program to promote optimal pharmaceutical drug therapy,
(3) expedite the drug review process,
(4) create an arm's length drug regulatory authority,
(5) explore the feasibility of a national drug formulary,
(6) explore potential savings via bulk purchasing of pharmaceuticals, and
(7) harmonize tax policy to support health policy (CMA 2004).

The Canadian Pharmacists Association (CPhA) was also opposed to the idea of national pharmacare, stating that increasing access by more people to more drugs must be balanced by ensuring appropriate drug use. Drug benefit plans must be part of an integrated approach to health care reform. The CPhA recommendations were to establish federal standards and link these to best practices, while assuring access by uninsured, underinsured, and those facing catastrophic costs (CPhA 2004).

Once the summit was underway the focus turned to waiting lists, access, and other system concerns and away from a debate about a national pharmacare program (Sibbald 2004). However, by the end of the summit on September 15, 2004, a 10-year plan "to strengthen health care" had been released (Office of the Prime Minister 2004). With respect to drugs, a National Pharmaceutical Strategy was proposed, to be led by a Ministerial Task Force and to report by June 30, 2006. (Quebec will maintain its own pharmacare program.) The task force was mandated with 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 drugs and vaccines;
- enhance action to influence the prescribing behaviour of health care professionals so 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.

In addition to the items under the National Pharmacare Strategy, pharmaceutical issues arose in several other areas outlined in the 10-year plan. In particular, first dollar coverage is to be in place by 2006 for (1) short term acute home care including intravenous medications related to the discharge diagnosis, and (2) palliative-specific pharmaceuticals required at the end of life. Health Ministers are to report progress in implementation to First Ministers by December 31, 2006.

3. Current initiatives and concerns

(a) Catastrophic drug coverage

(i) The situation in Canada

There are a number of reasons why lack of adequate coverage of drugs may cause ill health for Canadians (Kirby 2002):

- People with no cost protection may not be compliant with their medications and their health may suffer; these patients may end up in hospital as a result.
- Cheaper but less effective alternative drugs may be used.
- People may be discouraged from seeking work and may stay on social assistance to maintain drug coverage.
- Prohibitive expenses for private plans may cause sponsoring employers to discontinue or reduce coverage for their employees.

The implications of reductions in public funding of drugs were investigated in Quebec after a 1996 expansion of the provincial drug plan introduced co-insurance and cost-sharing for previously insured beneficiaries (senior citizens and those receiving income security). Analysis revealed that the patients studied reduced their use of both essential and less essential medication. In turn, reductions in the use of essential drugs were associated with an increase in the rate of emergency visits and adverse health events (Tamblyn 2001).

About 25 per cent of Canadians are covered by public drug plans (Sketris, 2003) and these plans cover about 39 per cent of all drug costs (prescription plus non-prescription) (CIHI, 2004). As discussed earlier in Section 1(b), each province and territory in Canada has its own public drug insurance program and each of the 19 plans has its own design, formulary (drugs eligible for coverage), groups of beneficiaries, eligibility requirements, cost-sharing arrangements, and methods of pharmacist reimbursement. All jurisdictions operate drug plans for seniors and social assistance recipients. Within some of these plans, however, there is variation based on income (Applied Management 2003).

Some public drug plans have set maximum annual co-payments or “caps” and some have not set such limits. For jurisdictions with these maximums, policies differ depending on the reasons for drug plan eligibility and income. For example, in BC, a sliding scale is in place. For all eligible seniors, those with incomes under $33,000 will pay up to 1.25 per cent of their incomes, those with incomes from $33,000 to $50,000

will pay two per cent, and those with incomes over $50,000 will pay three per cent. In Quebec, this annual cap is a fixed amount, varying from $16.66 to $69.92 per month, depending on eligibility class and income. In Alberta, for those under age 65 not otherwise covered by a private or public plan, enrollment in "Alberta Blue Cross Group 1" is possible, with income-dependent annual premiums ranging from $344 to $492 (CIHI 2004). Other jurisdictions (in particular, the Atlantic region) have not established maximum payments or percentages, leaving people vulnerable to high drug expenses if ill health should require expensive treatments. This is also true for some private drug plans which require co-payments on all prescriptions with no maximum to be paid out-of-pocket.

Catastrophic expenses were examined in a 2000 report conducted for Health Canada (Applied Management 2000).[7] Catastrophic coverage was defined as the amount of reimbursement an individual would receive on the last $1,000 of a $50,000 annual drug bill – for example, 100 per cent coverage would mean reimbursement of the last $1,000. Province of residence was found to be the major factor in degree of catastrophic coverage, with five provinces supplying full reimbursement at this high level of expense (BC, Manitoba, Ontario, Quebec, and Saskatchewan).

In the Atlantic provinces (NL, NB, NS, and PEI), many people were exposed to catastrophic costs. Alberta's mix of insurance plans also left some residents vulnerable. According to the last-dollar model used by Applied Management, the five provinces with full reimbursement covered 100 per cent of drug expenses between $49,000 and $50,000, whereas the degrees of coverage in the remaining five provinces were: Alberta, 64 per cent; NL, 53 per cent; NB, 50 per cent; NS, 54 per cent; and PEI, 53 per cent.

This 2000 study was updated in 2002 using new data, more sophisticated methodology, and more information from private sector drug plans (Fraser 2002). Key points include:

- More than 100,000 Canadians require prescription drugs costing over $5,000/year; some have drug coverage protection but some do not.
- Public and/or private plans cover 89 per cent of Canadians, leaving 11 per cent inadequately covered. Of the 11 per cent, nine per cent are considered under-insured and two per cent uninsured.
- The under-insured nine per cent have drug coverage plans without protective caps, meaning out-of-pocket costs may be 20 per cent of the total with no maximum cost.
- The two per cent uninsured extrapolates to at least 600,000 Canadians. All live in the Atlantic provinces where 24 per cent to 30 per cent of residents have no drug plan coverage, public or private.
- Of the 98 per cent of people with some type of coverage (including those considered under-insured), 53 per cent are covered by public plans, 58 per cent by private plans, and 13 per cent by both public and private plans.
- In all provinces, low income seniors have drug coverage including caps on out-of-pocket costs. However, for seniors who are not considered to be low income, not all provinces cap costs.

[7] Changes have occurred in FPT drug plans since this report was released, although probably not enough to change the conclusions of these analyses.

- In all provinces, social assistance recipients are covered against catastrophic costs with minimal or no personal financial costs.

A simulation model was developed by Coombs et al. at the University of British Columbia, in response to the 2003 Health Care Accord proposal for a program to ensure catastrophic drug coverage for all Canadians. The model used a representative set of 4,860 Canadian households – differing in size, age distribution, income, and drug expenses – and applied to this sample the cost-sharing rules of each jurisdictional drug plan (as they were in August 2003) to determine the proportions of households which would face out-of-pocket payments exceeding catastrophic levels. Results showed drug plans varied considerably. The greatest protection was offered by the plans of BC, Saskatchewan, Manitoba, and Ontario, which limit out-of-pocket expenditures to a certain level of income. The plans in the Atlantic provinces offered the least protection. Alberta and Quebec were in the middle, offering reasonable coverage but exposing some people to significant burdens when premiums and co-payments were combined. Alberta was the least favourable of these two provinces with no upper limit on contributions for non-seniors. The three most influential elements of a drug plan's design were determined to be: eligibility rules, premiums, and maximum out-of-pocket contributions (Coombs 2004).

In the fall of 2002, two thoughtful and comprehensive reviews of Canadian health care were released. In October 2002, *The Health of Canadians: the Federal Role* was published, authored by Senator Michael Kirby and the Standing Senate Committee on Social Affairs, Science and Technology. A few weeks later in late November 2002, *Building on Values: The Future of Health Care in Canada* was issued by Roy Romanow. Both documents cover many issues including the need for a catastrophic drug coverage program for Canadians, albeit with different approaches.

Senator Kirby and colleagues started with two objectives: (1) to ensure no Canadian is exposed to financial hardship as a result of prescription drug costs, and (2) to ensure long-term sustainability of drug coverage programs. They proposed a detailed plan which took into account both public and private drug plans (Kirby 2002).

- All funding for the new initiative would come from the federal government and would be managed by individual jurisdictions.
- In order to be eligible for federal funding, provincial/territorial (P/T) governments would guarantee that residents would never pay more than three per cent of their family incomes out-of-pocket for prescription drugs (no dollar figure maximum was set).
- If this condition was met, the federal government would then agree to pay 90 per cent of prescription drug expenses over $5,000 when an individual's combined cost (out-of-pocket plus provincial contribution) was over $5000 per year. The P/T government would pay the remaining 10 per cent.
- Private drug insurance plans would be eligible for federal funding provided they guaranteed that no member paid over $1,500/year out-of-pocket. Over $5,000, the federal plan would pay 90 per cent and the plan would pay the remaining 10 per cent. Private plans would be responsible for costs between $1,500 and $5,000. This means people covered by private plans would never pay more than $1,500 or three per cent of their family income, whichever is lower.

- Funding would be transferred to the P/T or private drug plan, not to individuals, and federal payments would be made at regular pre-determined intervals to P/T plans or private plans based on claims, subject to audit.
- The projected cost to the federal government was approximately $500 million per year.

Senator Kirby's proposed plan has been explored for feasibility by others. For example, experts from McMaster University and the University of Toronto (Crossley 2003) built several economic models to examine catastrophic drug coverage using the Kirby framework (three per cent of household income or $1,500 per household member). With 2001 Statistics Canada data, they examined, by province, how a program would assist different types of households, depending on the means and age of beneficiaries. Results showed 5.8 per cent of households would qualify for catastrophic drug coverage (range: PEI 12.8 per cent; Ontario 3.4 per cent). Most of these households (88 per cent) would qualify based on household income versus the individual $1,500 cap, and the mean transfer would be $713 per household (median $330). However, the top one per cent of beneficiaries would receive over $5,450. Low income households and seniors would account for the greatest proportion of program costs, but their mean household benefit would be smaller than non-seniors, some of whom face ruinous costs without a program. Program costs were estimated at $461 million (excluding implementation and administration), assuming provincial programs do not change and drug consumption does not increase due to the program.

Romanow's plan was termed a "catastrophic drug transfer" and was less detailed (Romanow 2002). It proposed integrating drugs into the health care system, not building an insurance system to pay for them.

- Romanow noted that access to necessary prescription drugs should not be determined by where in Canada a person lives.
- At the outset, catastrophic was defined as being greater than an annual $1,500 out-of-pocket prescription cost per person. This was the dollar figure seen as being the least disruptive to existing plans and the most acceptable to society.
- Romanow felt that first-dollar coverage did not appear to be of interest to the Canadian public and also some outlay was seen as making drug costs a shared responsibility (assuming disadvantaged people have this waived).
- The proposed federal transfer would be targeted funding to reimburse 50 per cent of P/T drug insurance costs above a threshold of $1500/person/year.
- P/T governments would therefore have funds freed up to expand access through their drug plans by reducing deductibles or co-payments and/or covering those not already covered by the plan.
- The plan would be developed through co-operation between the federal and P/T governments.
- The estimated annual cost of the program would be $749 million to $1 billion.

It should be noted that the costs of implementing the initiatives designed by Kirby and Romanow may only be costs to the federal government. The provincial governments would likely be required to pay additional costs from their own funds, making the programs more costly than the estimates quoted.

(ii) Canada compared to other countries

A number of authors have compared Canada to other countries in the areas of health care and drug plan coverage, although these comparisons do not focus specifically on catastrophic drug coverage.

Catastrophic health expenditures overall were examined in 59 countries by the WHO (Xu 2003). Catastrophic expenditures on health were defined as members of a household spending over 40 per cent of their income (after meeting subsistence needs) on the health system. Canada fared very well, being among the most favourable nine, along with the Czech Republic, Denmark, France, Germany, Slovakia, Slovenia, South Africa, and the UK. In this study it was determined that in Canada only nine in 1,000 households (0.09 per cent) deal with such a cost, as compared with the two least favourable countries examined, Brazil and Vietnam, where over 10 per cent of households shoulder this burden.

CIHI routinely compares Canada to other countries in the Organisation for Economic Co-operation and Development (OECD), but cautions that data may be inconsistent across countries due to variations in reporting, inclusion, and classification of health expenditures, as well as socioe-conomic status and service delivery models (CIHI, 2004). Twelve countries have supplied 2001 data to the OECD to allow recent comparisons (Australia, Canada, Denmark, France, Germany, Hungary, Japan, Korea, the Netherlands, Switzerland, the UK, and the US). These data show that Canada ranks fifth in GDP per capita ($34,573), but third in total drug expenditures per capita ($541), and fourth in total health expenditures per capita ($3,350).[8] When total drug expenditures are reported as a percentage of total health expenditures, Canada ranks fourth at 16.2 per cent, after Hungary (30.7 per cent), France (21 per cent), and Japan (18.7 per cent).

Catastrophic drug costs are not independently examined in the CIHI reports. However, the comment is made that in OECD countries, outside of North America, the entire population has some coverage for prescription drugs through public insurance. Most countries have cost-control measures in place as well, such as restrictive formularies, and they impose cost-sharing through deductibles, co-payments, and additional insurance. At least half of the OECD countries for whom data were available in 2001 reported that public funding covers over 50 per cent of pharmaceutical costs. Despite ranking third in total drug expenditure per capita, Canada ranked seventh in public drug expenditure per capita ($196), after France ($425), Germany ($341), Japan ($323), Switzerland ($265), Australia ($223), and Hungary ($208). The gap is due to the significant role played in Canada by private drug insurance programs.

Outpatient pharmaceutical policies for seniors (age 65+) were examined in seven countries, including Australia, Canada, Germany, Japan, New Zealand, the UK, and the US (Freund, 2000). All but Canada and the US included access to prescription drugs through their national health plans. Data from 1998 or 1999 show annual out-of-pocket maximum payments:

- Australia: costs are capped at US $100.

[8] All in Canadian dollars.

- Germany: co-payments are capped at ≤2 per cent of patient income.
- Japan: drugs are free for age 70+, otherwise dependent on income, assets, etc.
- NZ: drugs are covered for "high users" (use of 20+ listed drugs per year).
- UK: all prescribed pharmaceuticals on the formulary are covered.
- US: most plans have a maximum benefit and patients pay over and above this.

The authors of this paper note that all countries studied appear to use the same mix of policy tools for cost containment (e.g. formularies, practice guidelines, generic prescribing, reference pricing, and cost-sharing with patients) but the results of these policy tools are quite varied. They also observed several common themes among the countries studied: a move toward coverage of inpatient prescription drugs and last-dollar coverage for outpatient prescription drugs. Canada currently funds inpatient prescriptions but has not traditionally covered outpatient prescriptions.

The Conference Board of Canada published a July 2004 report (sponsored by Alberta Health and Wellness) which examined Australia, France, NZ, Spain, Sweden, and Switzerland to provide insights on performance, productivity, and management practices for the benefit of Canadian decision-makers. Some points made in the report:

- The share of total health spending on drugs ranged from seven per cent (Sweden) to 22 per cent (Spain) versus 16 per cent in Canada.
- Annual drug cost increases ranged from three per cent (NZ) to 11 per cent (Australia, Spain, and Switzerland) versus nine per cent in Canada.
- Policies in specific countries:
    - ⇒ NZ controls drug prices through bulk purchasing and reference pricing.
    - ⇒ France and Sweden have introduced generic drug use policies.
    - ⇒ Sweden monitors physician prescribing practices.
    - ⇒ Spain regulates pricing, supply, and distribution of drugs and also publishes a "negative list" of drugs not eligible for public funding; however, patients pay 40 per cent of drug costs.
    - ⇒ Australia has universal drug coverage with subsidized prices, generic use and a safety net cap.
    - ⇒ Switzerland has suffered significant increases in drug costs perhaps due to support of the local drug industry and absence of regulation.

    (Conference Board of Canada 2004)

In international comparisons, the US is usually an outlier with respect to the lack of national health and drug programs for its citizens. This is true even for seniors in the US covered by Medicare, a national plan without an outpatient prescription drug program. The needs of seniors in the US may be met through employer-sponsored plans, privately-purchased plans, Medicaid, health maintenance organizations (HMOs), and some state programs, but gaps remain. A recent analysis revealed that these coverage gaps resulted in decreased use of essential medications (18 per cent versus 10 per cent for controls); patients also shopped around for the best price, switched medications, and used medication samples (Tseng 2004).

In the US, national Medicare programs have been proposed but have not gone forward due to cost. Researchers from RAND developed several models which estimated the cost of a no-deductible program for Medicare beneficiaries to be US $11-14 billion. The cost would be half this ($5 billion in 2001) if only catastrophic coverage is provided, with a $10/month deductible and "substantial protection" provided for expenses over $3000 (Goldman 2002).

In late 2003, President Bush introduced a new prescription drug benefit plan for seniors. According to Canadian experts Hurley and Morgan (2004): *The plan employs a "doughnut" design intended to make it sufficiently tempting to patients with modest drug costs and provide coverage against truly catastrophic costs, while limiting the government's financial exposure. A typical beneficiary's out-of-pocket costs would include a monthly premium of $35, a $250 annual deductible, 25 per cent of the next $2,000 in drug costs, 100 per cent of the next $2850 (the hole in the insurance doughnut), and 5 per cent of costs above $5,100.* Hurley and Morgan see this as a "lump of coal," as the plan will help the very poor and very sick but will also mean substantial costs for many seniors including some who will be worse off than they were before. Overall, these authors see the new plan having two winners: the drug companies and private insurers.

As stated earlier, Canada is unusual with respect to the prominent role played by private drug plans (Willison 2002). In most countries, private health insurance is available and purchased by a subset of the population, but is generally applied to health care services such as hospitals and physicians, and less so for drugs. For example, in Australia, private insurance only pays for 0.5 per cent of prescriptions, versus 25 per cent in Canada (Flood 2002). Private insurance is held by 10 per cent of people in the UK but used for supplementary health costs, not prescribed drugs -- these have been covered by the National Health Service since 1948 (Freund 2000).

(b) Pharmaceutical management initiatives

(i) Initiatives underway in Canada

There are two ways to manage drug expenditures: manage the drugs or manage the beneficiaries. Management of drugs extends coverage to a larger percent of the population without increasing costs and with greater potential for positive outcomes. For example, assessing inappropriate use of high-cost drugs and instituting simple mechanisms to exempt high-risk patients could maximize savings and minimize harm (Soumerai 2004). Following are snapshots of selected initiatives; future reports will describe these further.

Accountability initiatives

- *Outcome measures and performance indicators:* Outcomes of medical interventions, including pharmaceuticals, are the ultimate measure of benefits and harms. With an increasing climate of accountability, outcome measures and performance indicators are gaining recognition. Pharmaceutical outcome measures can be developed to determine impact on both patients and on the health care system. With respect to system impact, for example, Statistics

Canada reports annually on prescription drug spending as a percentage of income in its Survey of Household Spending (Statistics Canada 2002). With respect to patient outcomes, a number of measures or indicators have been proposed. One framework is a classification according to economic, clinical, and humanistic outcomes (the ECHO model) (MacKinnon 2002). The drug industry has also proposed indicators linking in to the larger themes of access, quality, and sustainability. Examples are: percentage of the population exceeding X dollars or Y percent of their income on prescription drugs (an access measure); and percentage of Canadians with selected chronic conditions who receive optimal drug therapy (a quality issue) (Rx&D 2003).

Data gathering initiatives

- *National Prescription Drug Utilization Information System (NPDUIS):* To allow comparisons to be made across the various public drug plans in Canada, standardized information is required. In 2002, NPDUIS developed as a Health Canada-funded collaboration between CIHI and PMPRB; it is a collection of databases which will allow detailed examination of drug utilization across the country. Areas to be addressed will be utilization comparisons; optimal drug spending; strategies to control costs; and differences in access, prescribing, and outcomes. NPDUIS products will be web-based reports available to authorized users. In future, the initiative may also capture information from private drug plans. (For further information on NPDUIS, see http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=indicators_drug_e.)

Initiatives promoting evidence-based practice

- *Academic detailing:* The drug industry spends a great deal of money educating physicians about its products through office visits made by drug company representatives. This form of promotion presumably leads to increased sales and profitability for the drug industry, as the tradition is well established. Academic detailing follows the same rationale but the visiting educator is a health care professional (generally a pharmacist) with an evidence-based approach and impartial information. A growing number of provinces have initiated programs in academic detailing, including BC, Alberta, Saskatchewan, Manitoba, and NS, with a program underway in London, Ontario, as well. Evaluation of such programs has shown benefit in influencing prescribers and saving money (Silversides 1997, Sketris 2003).

- *Canadian Coordinating Office for Health Technology Assessment (CCOHTA):* Since 1989, CCOHTA has supported health care decision-makers through the production of unbiased, reliable information about health technologies, focusing on clinical effectiveness and cost-effectiveness; about 50 per cent of publications appraise pharmaceuticals. CCOHTA also houses the staff of two important drug-related initiatives, the CDR and COMPUS (see below). (For further information on CCOHTA, see www.ccohta.ca.)

- *Canadian Optimal Medication Prescribing and Utilization Service (COMPUS):* Launched in March 2004 as a Health Canada-funded service and housed at the offices of CCOHTA, COMPUS aims to "promote and facilitate best practices in drug prescribing and use among health care providers and patients/consumers"

(CCOHTA website). The goal of COMPUS is to improve health outcomes and quality of life as well as to promote the cost-effective use of medications. It is hoped these ends can be met through influences on the attitudes, knowledge, skills, and behaviors of health care providers and patients. Initiatives will include collecting, evaluating, and disseminating information on best practices. COMPUS is modelled after the Australian National Prescribing Service (NPS) – described in more detail below. (For further information on COMPUS, see www.ccohta.ca/entry_e.html.)

- *Cochrane Collaboration:* A worldwide, not-for-profit organization established a decade ago, the Cochrane Collaboration prepares, promotes, and maintains comprehensive reviews of health care interventions, including pharmaceuticals, following a standardized rigorous approach. The Cochrane Library currently contains 2,074 such reviews authored by 7,000 volunteer experts. Reviews include consumer synopses written in lay language as well. The Library is available by paid subscription although 10 countries have obtained national licenses so that electronic access is free for all their citizens. (Canada is not among these, with the exception of the province of Saskatchewan.) Cochrane has also allowed free access to those living in countries classified as low- or middle-income by the World Bank (Grimshaw 2004). (For further information on the Cochrane Collaboration, see www.cochrane.org.)

- *Critical appraisal:* Traditionally, the formularies across Canada have used the techniques of evidence-based medicine to varying extents for the background material they use for decision-making. One well-established example is the Therapeutics Initiative (TI) in BC. The TI is an independent organization, established at the University of British Columbia in 1994 to "provide physicians and pharmacists with up-to-date, evidence-based, practical information on rational drug therapy." The TI supplies evidence-based reviews of pharmaceuticals to the BC PharmaCare program on request. (For further information on the BC TI, see www.ti.ubc.ca). A related process can be found in Ontario's Drug Quality and Therapeutics Committee (DQTC), founded in 1968. The primary role of DQTC is to "provide independent, expert advice to the Ontario Ministry of Health and Long-Term Care (MOHLTC) on drug-related matters, such as the evaluation of new drugs, and the monitoring and evaluation of current formulary listings." (For further information on Ontario's DQTC, see www.health.gov.on.ca/english/public/pub/drugs/dqtc.html.)

- *Drug Effectiveness Review Project (DERP):* DERP is "a collaboration of organizations (mostly public) that have joined together to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same class, and to apply the information to public policy and related activities." The majority of participating organizations are US states and HMOs but Canada is participating in both governance and funding through CCOHTA. Each participating organization contributes an equal amount to the financing of the project. The drug classes to be studied are determined collaboratively and evidence is compiled through comprehensive, updated, systematic reviews conducted by Evidence Based Practice Centers (EPCs) in the US.

- *e-Therapeutics:* $8.8 million over 27 months has been provided by Health Canada's Primary Care Health Transition Fund to develop a system to provide

point-of-care access to current evidence-based Canadian drug and therapeutic information aimed at physicians, pharmacists, and nurses. e-Therapeutics tools will be delivered using a web portal. Downloadable content will come from the CPhA, Health Canada (e.g. drug safety notices, ADR reports), provincial formularies, clinical practice guidelines, disease management information, CCOHTA, among others. Stakeholders from health professions, government, Canada Health Infoway, and others are involved, and IBM Canada is developing the technical aspects. (For further information on e-Therapeutics at the College of Pharmacy, see www.pharmacists.ca/content/about_cpha/whats_happening/cpha_in_action/pdf/CPhA_AGM_e-TherapeuticsMay04.pdf.)

- *Evidence-based clinical practice guidelines (CPGs):* CPGs are pathways describing the ideal steps to be followed in determining a patient's diagnosis and/or treatment plan. To optimize physician prescribing of drugs, it has been hoped that CPGs could be widely and effectively taken up and put into practice. Thousands of CPGs have been developed by professional organizations, governments, the pharmaceutical industry and others; in fact there are many databases of guidelines and also guidelines for guidelines. This field continues to evolve as the implementation of CPGs has presented challenges from the start. However, new strategies are constantly being developed to increase their uptake and use (Sketris 2003). In Canada, the CMA has been a leader with its CMA Infobase, a database of evidence-based Canadian CPGs which includes physician summaries and patient guides (For further information, see http://mdm.ca/cpgsnew/cpgs/index.asp.)

Pharmaceutical listing initiatives

- *Common Drug Review (CDR):* Traditionally, each of the 19 public drug plans in Canada had its own process for evaluating the benefits of the new pharmaceuticals coming to market, and these processes varied considerably. In part as a result of this variation, drug plan formulary decisions for coverage also varied widely. In 2002 Health Canada established the CDR to allow a single drug evaluation process, with submissions from drug manufacturers coming in to one point for appraisal. The CDR conducts systematic reviews of clinical and economic information on new drugs approved by Health Canada and, through its Canadian Expert Drug Advisory Committee (CEDAC), provides formulary listing advice. CEDAC recommendations are available publicly. Using this advice, individual drug plans make independent listing decisions. The first CDR reviews were performed in late 2003 and an estimated 24 new drugs (NCEs) will be assessed per year (18 were assessed in the first year of operation). The CDR/ CEDAC process is seen by some as a first step towards a national formulary. (CDR offices are housed at CCOHTA: for further information the CDR, see www.ccohta.ca/entry_e.html.)

- *Drug formularies:* Formularies are defined lists of drugs eligible for coverage and are used by hospitals, public drug plans, and some private drug plans. The purpose is to provide funding for those drugs determined to be effective and to deny coverage for those not determined to provide additional value. Only a subset of all drugs on the market are contained on most formularies. Formularies are developed using the advice of experts, often on well-established Pharmacy and Therapeutics (P&T) Committees who may consider drug safety,

efficacy, effectiveness, and cost-effectiveness. In addition to regular drug listings on a formulary, there may be a special access stream that allows coverage of additional non-formulary drugs under certain pre-defined conditions.

- *Generic substitution policies:* As a cost containment measure, drug plans have developed processes for determining which generic drugs are considered equivalents of brand-name drugs. Supporting information for substitution processes is obtained in part from Health Canada's Therapeutics Products Directorate. Although this initiative makes sense, generic substitution can be controversial (Sketris 2003, Skinner 2004).

- *Reference drug pricing (RP):* Categories of compounds can be established which are therapeutically equivalent, though not chemically equivalent. Within these categories, the price of the least expensive drug can serve as the reference, meaning a more expensive drug will not be fully reimbursed. In Canada, this initiative was first introduced in BC in 1995 as a cost-control measure, and ultimately five classes of drugs were referenced (Sketris 2003). Savings can result but the magnitude of savings depends upon the category of the drugs, i.e. reference pricing programs are most effective when there are significant differences in the prices of the drugs under consideration. However, the program has not been without controversy; some feel drug substitution results in higher costs in other areas of the system, even though the drugs included in these programs are from the same drug class. For example, one opinion is that the program "has shifted the cost of drugs to patients and has not contained the growth of prescription drug spending" (Graham 2003). Others contend that cost shifting does not occur unless there is no therapeutic reason for the switch. If there is a reason, the program covers drug costs.

  A number of rigorous, academic reviews of the BC program have been carried out, one published by Schneeweiss and colleagues in 2002. Their findings were: (1) RP resulted in moderate to large savings in drug expenditures; (2) savings were largest in drug classes in which a frequently used drug was priced substantially above the average price of competitor drugs; (3) substitution of more costly medications from another class for RP drugs was not substantial; (4) there appeared to be no increase in the rate of drug discontinuation; (5) there was a modest implementation cost, because physicians monitored patients more closely; (6) no severe negative effects (e.g., hospital admissions, mortality) could be attributed to the RP policy; (7) an authorization process allowing physicians to request RP exemptions appears to have lessened resistance to RP; and (8) requesting authorization for RP exemptions involved significant administrative costs for Pharmacare and paperwork for physicians.

  Grootendorst examined three drug categories referenced by the BC PharmaCare program and estimated annual drug plan savings of $7.7 million (3.6 per cent of the annual cost of drugs funded for seniors in 1997) (Grootendorst, 2001). RP of angiotensin-converting enzyme (ACE) inhibitors was examined recently and again savings were found: During the first year of implementation, savings were $6.2 million, mainly achieved through utilization changes but also by cost-shifting to patients (approximately 17 per cent of costs) (Schneeweiss 2004).

(ii) Initiatives underway in other countries

- *Management of Medicines (UK):* Medicines management is defined as the "clinical, cost-effective, and safe use of medicines to ensure that patients get the maximum benefit from the medicines they need, while at the same time minimizing potential harm." The UK has been a leader in many areas of health care organization and management. A recent initiative has been the development of National Service Frameworks (NSFs) for the management of specific chronic conditions with an emphasis on the use of evidence. Involvement of patients and their carers is a major feature of the NSFs. (For further information on the UK initiative called Management of Medicines, see www.dh.gov.uk/assetRoot/04/08/87/55/04088755.pdf.)

- *National Prescribing Service (NPS) (Australia):* The NPS was established in 1998 as a non-profit company with 36 member agencies, publicly funded but arms-length from both government and the pharmaceutical industry. The vision of NPS is to be "the most trusted source of independent information about medicines for Australians." Working with health professionals, government, industry, and consumers, the NPS aims to improve the health of all Australians through critical analyses of current evidence on drugs. Multiple services are provided to health professionals (academic detailing, audits, group discussions, medical school teaching, documents, conferences, telephone advice about drug interactions and safety, etc.) and consumers (pamphlets and telephone advice) (For further information on the NPS in Australia, see www.nps.org.au.)

- *Physician-directed financial incentives (UK, Germany, NZ):* According to Freund et al. (2002), physicians in these three countries are allotted prescribing budgets. In the UK, physicians collectively hold "hard" budgets for pharmaceuticals that are combined with their budgets for other services. In NZ, primary care organizations have prescribing budgets as well, with any financial savings being split between the organization and government. (Apparently these supply significant income for the organizations.) A similar initiative in Germany has been resisted by physicians.

4. Key messages arising from this report

1. *Lack of drug insurance/under-insurance:* At a minimum, two per cent of Canadians are uninsured and nine per cent are under-insured for drug coverage, therefore a number of citizens could face significant financial hardship if certain types of ill health occur. Most of these Canadians live in the Atlantic provinces. A program for catastrophic drug coverage must address this to ensure there is a safety net protecting all Canadians against extreme drug expenses.
2. *Management of the system:* The management of prescription drug use involves a complex interplay between patients, health care providers, governments and private insurance. Patients have a major role to play, in both their own health care and the operation and funding of the health care system. A number of programs across the country and internationally are developing systems to streamline management and to ensure accurate and comparable data are available to allow efficient management.

3. *Evidence-base:* Drug plan expenses must be managed through rigorous, evidence-based drug evaluations and policies. An approach employing multiple initiatives, such as those described in Section 3(b) of this report, will be the most effective. A strong evidence base should underlie all work in this area.
4. *Quality management programs:* Investment must go into programs that improve the quality of drug use, rather than simply paying for the drugs themselves. Excellent programs exist, but they are relatively insignificant and have limited reach, in comparison to the marketing activities of manufacturers. Reducing the cost of drugs is one approach, as is reducing drug dependence through prevention and alternative types of treatment. Again, a number of initiatives are underway which will mature and expand with adequate support.

The 10-year plan arising from the September 2004 First Ministers' Summit is an excellent starting point for further discussions, refinements, and improvements in all four of these areas. It is hoped that sufficient resources will be provided to support programs and initiatives such as those described throughout this report. Among substantive yet attainable goals is the establishment of a national drug formulary and fiscally supportable universal drug coverage in Canada.

5. Some gaps, emerging issues, and challenges

(a) Catastrophic drug coverage

- Collection of accurate and comparable data to determine Canadians' coverage needs;
- Beneficiary coverage in Atlantic Canada.

(b) Pharmaceutical management initiatives

- Lack of independent (non-industry sponsored) drug information about new drugs and their role in contemporary medicine.

6. Concluding ideas

(a) Catastrophic drug coverage

- Define minimum standards for drug coverage;
- Establish a process for formulary review;
- Establish a process for consolidation of the top 10 therapeutic groups of drugs by patient cost;
- Identify drugs that cost more than $5,000/patient/year and review their status across the public plans; establish common listing status for these drugs across Canada.

(b) Pharmaceutical management initiatives

- Invest in the development of drug information for physicians, pharmacists, and patients, available in a timely fashion and free of industry influence;
- Commission research papers to answer some key questions for Canadians, e.g. How many drugs are truly breakthrough innovations? What percentage of R&D is really invested in advancing therapy versus expanding markets?

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8. Abbreviations

ACE	Angiotensin-converting enzyme (inhibitors)
ADR	Adverse drug reaction
AE	Adverse event
BC	British Columbia
CADRMP	Canadian Adverse Drug Reaction Monitoring Program
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CDR	Common Drug Review
CEDAC	Canadian Expert Drug Advisory Committee
CSG	Chemical subgroup level (as per the WHO)
CIHI	Canadian Institute for Health Information
CIHR	Canadian Institutes of Health Research
CLHIA	Canadian Life and Health Insurance Association
CMA	Canadian Medical Association
COMPUS	Canadian Optimum Medication Prescribing Utilization Service
CPG	Clinical practice guideline
CPhA	Canadian Pharmacists Association
DERP	Drug Effectiveness Review Project
DQTC	Drug Quality and Therapeutics Committee (Ontario)
EPC	Evidence-based Practice Centers
FPT	Federal / provincial / territorial
HMO	Health maintenance organizations (US)
MOHLTC	Ministry of Health and Long-Term Care (Ontario)
NB	New Brunswick
NCE	New chemical entity
NL	Newfoundland & Labrador
NOC	Notice of Compliance
NPDUIS	National Prescription Drug Utilization Information System
NPS	National Prescribing Service (Australia)
NS	Nova Scotia
NSF	National Service Frameworks (UK)
NZ	New Zealand
OECD	Organization for Economic Co-operation and Development
PEI	Prince Edward Island
PMPRB	Patent Medicines Prices Review Board
P/T	Provincial / territorial
P&T	Pharmacy & Therapeutics (Committee)
RCMP	Royal Canadian Mounted Police
RP	Reference drug pricing
R&D	Research and development
Rx&D	“Canada’s Research Based Pharmaceutical Companies”
TI	Therapeutics Initiative (BC)
TPD	Therapeutic Products Directorate (Health Canada)
UK	United Kingdom
US	United States
WHO	World Health Organization