

Canadian Pharmaceutical Strategy
Discussion Paper

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Good pharmaceutical policy should enhance access to effective new medicines in order to improve patient outcomes and promote the quality, efficiency and cost-effectiveness of an integrated healthcare system. Healthcare policy decisions, at whatever level they are made, ultimately affect patients' lives. For those Canadians who rely on publicly funded drug plans, there is a reasonable expectation that governments will judiciously make decisions about the treatment options that are available for the care of individual patients.

The following discussion paper lays out a vision for a pharmaceutical strategy for Canada that focuses on catastrophic drug coverage and improved access to medications to improve outcomes. This paper also discusses health outcomes and recognizes that managing chronic diseases and their risk factors must be an essential feature of an effective pharmaceutical strategy. It also examines issues related to patient centered health care such as engaging patients in the management of their own health. The purpose of the discussion paper is to serve as a foundation for discussion and debate and as a tool for developing consensus.

Background

The September 15 2004 First Ministers meeting on *The Future of Health Care* produced a shared agenda to renew health care in Canada, focusing on a consensus to ensure Canadians have access to the care they need, when they need it. Prime Minister Paul Martin announced \$41 billion of new federal funding to support 'a 10-year plan to strengthen health care'. This money is made available through the Canada Health Transfer and, in part, will begin to address the issue of national pharmacare. An additional \$500 million was allotted to help advance catastrophic drug coverage and home care. A task force was mandated to develop and implement a national pharmacare strategy.

The ministerial task force is charged with developing a pharmaceutical strategy for implementation by June 30, 2006. The areas of focus include: catastrophic drug coverage, national drug formulary, drug approval process, safety surveillance, buying strategies, prescribing procedures, electronic health records, non-patented drug access, and cost analysis.

Health ministers met for a second time to discuss in detail the goals outlined during the First Ministers meeting in September. The provinces have agreed to focus on studying bulk-buying, and are committed to seeing a 10 year plan to improve health care come to fruition. Additional action items that were reviewed at the Health Ministers' meeting include: wait time reduction, improving access, home care, primary care reform, access to care in the north, prevention and health promotion, innovations, accountability and dispute resolution.

Concerns with the current National Pharmaceutical Strategy (NPS) initiative

Canadians have a number of concerns about the development of the proposed strategy as it is currently presented. The following represents an overview of some of the most frequently cited issues for patients, health care providers, and others.

Lack of transparency:

A persistently heard criticism is that the current NPS initiative appears to be shrouded in secrecy. Since September 2004, almost no new information has been forthcoming from any level of government, and it has turned a deaf ear to requests for updates from patients and providers: "Since then, Health Canada and its provincial counterparts, excluding Quebec, which is not involved in the process, have met behind closed doors, providing few hints of what they're planning for this summer's deadline."¹

Lack of consultation:

Another complaint that has been noted in the press, in position papers, and in updates from health care groups involves the lack of consultation on the governments' part with ANY of the stakeholders who are most involved: "Almost two years after its launch, a federal-provincial task force charged with drawing up a strategy for a national drug plan had yet to talk to the very people who know most about drugs: the doctors who prescribe them, pharmacists who distribute them, the people who take them."²

A joint statement issued by the Canadian Medical Association, the Canadian Nurses Association, the Canadian Pharmacists' Association, the Canadian Healthcare Association, and the Health Action Lobby describes the problem in this manner: "Given the ongoing growth of drug costs, concerns about drug safety and gaps in care, the need for a National Pharmaceutical Strategy is vitally important...yet to date, the extent to which we have seen effective consultation with health care providers has been limited and overall progress appears slow."³

Lack of stakeholder engagement:

Hand in hand with a lack of consultation, lies a lack of stakeholder involvement. Not only have the most affected individuals not been consulted on their views, their involvement in the process of developing a national strategy is not welcome.

"A proposed national pharmaceuticals strategy based on its current list of nine priorities is doomed to fail unless changes are made and far more input is allowed into its development, say Canada's physicians, pharmacists and patient advocacy groups."⁴

"Canadian patients, as healthcare consumers must be part of the decision process that fundamentally affects every aspect of their lives, stemming from their health state."⁵

¹ Kohler, Nicholas *The silent treatment: We're supposed to be getting a drug plan strategy. Too bad no one's been consulted.* Macleans Magazine, April 3, 2006.

² *ibid*

³ *Hope runs high, confidence runs low one year into the 10-year plan to strengthen health care* Press Release, HEAL, September 15, 2005

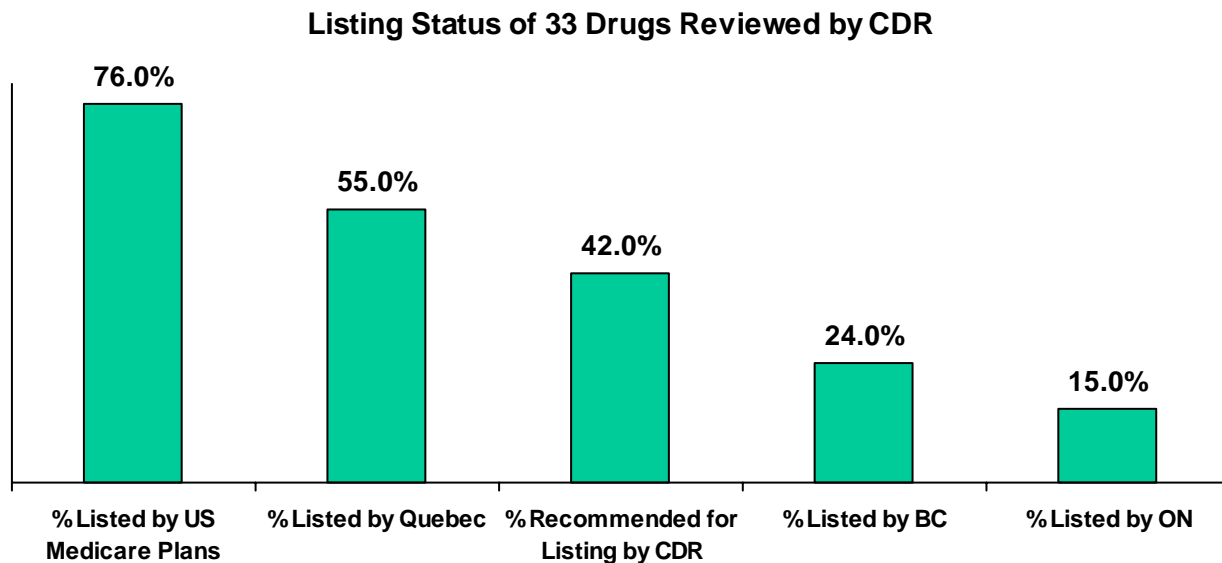
⁴ Borselino, Matt *Pharmaceutical strategy should also promote drug adherence/accessibility and improved electronic health records* Medical Post, April 4 2006.

⁵ National Pharmaceutical Strategy Position Paper, Best Medicines Coalition

Cost Containment Focus:

The evidence of the past few years clearly indicates that drug review and approval in Canada is focused on cost containment rather than on getting the right medication to the right patient at the right time. The institution of the Common Drug Review (CDR) is a telling example of this problem. Under the guise of reducing duplication and taking advantage of scarce resources, the CDR has become an extra layer of bureaucracy, whose decision makers look almost exclusively at the costs of a drug – rather than it’s benefits - when making recommendations to the provinces regarding whether a drug should be listed or not.

Since the inception of the CDR, only 42% of the 33 drugs reviewed by the CDR have been recommended for listing, and on average, only 21% of these drugs has been listed for reimbursement by participating provincial drug plans (Quebec does not participate in the CDR). Access to publicly funded drug benefits is now better in the United States than in Canada⁶:



The CDR and its provincial counterparts are not only focused on cost containment but primarily on cost containment with respect to patented drugs, even though Canadian prices for innovative drugs are low by international comparison. Where there has not been sufficient focus is on the cost containment of generic drugs whose prices in Canada are very expensive by international comparison. If governments are intent on getting value for taxpayers’ money then the price of generic drugs in Canada should be closely examined for cost savings.

⁶ Chart Sources: Canadian Information based on data from iMAM Brogan Inc. December 2005. U.S. Information based in data from U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Formulary Finder accessed March 19, 2006.

Input from Canadians

There has been ample input in the past that identifies what patients want, and what providers need. The government has commissioned a number of studies including those by Romanow and Kirby. Numerous organizations have created their own position paper on the National Pharmaceutical Strategy including: The Canadian HealthCare Coalition, the Best Medicines Coalition, The Canadian Healthcare Association, Health Charities Coalition of Canada, Canadian Union of Public Employees, and Canada's Research Based Pharmaceutical Companies (Rx&D) to name just a few.

There are consistent themes that emerge from disparate sources. For example, Canadians affected by a national pharmaceutical policy want to be consulted on the NPS. They want a process and a strategy that is open and transparent – consistent with the current government's messaging. They want a system that is based on putting the patient first – giving patients access to necessary medications when they need them:

"...A new model that is consistent with societal values and fiscal realities, that is timely and transparent, and is flexible enough to allow patients to receive drugs they are prepared to pay for in a safe environment as close to home as possible."⁷

Cancer Care Ontario

"Universal first dollar coverage for cost-effective, safe drugs will save money and lives."⁸
Canadian Health Coalition

"It should be a patient-centered or patient-focused system that strives to meet the needs of patients – treatment, care, improved quality of life, and ultimately improved health outcomes."⁹

Best Medicines Coalition

"Canadian Healthcare Association believes that a national drug formulary should support timely and equitable access to pharmaceuticals. The process of listing drugs on a formulary should be transparent and administratively efficient and should be based on a rigorous review of evidence showing therapeutic effectiveness."¹⁰

Canadian Healthcare Association

⁷ Sullivan T, Sawka C, Cancer Care Ontario, Letter to the Toronto Star

⁸ Connors, K, Chair Canadian Health Coalition, as quoted in the Globe and Mail *Improved Management and use of Medication* Andre Picard, Feb. 23, 2006.

⁹ National Pharmaceutical Strategy Position Paper, Best Medicines Coalition

¹⁰ Canadian Healthcare Association, *Policy Positions Regarding Issues addressed by the National Pharmaceuticals Strategy*, February 2006.

Groundwork for Debate

The following synthesizes some key principles for a pharmaceutical strategy for Canada that have been embraced by a variety of stakeholders. The major themes that surface repeatedly are described below and should be considered a starting point for debate.

Patient Centered:

The patient should remain at the center of any debate concerning access to drugs. As those most affected by decisions made regarding access to treatments, patients must be consulted and must remain the focus of any national drug program. Patients across the globe are demanding an increased role in the delivery of their care – in part because they see cost containment exercises eroding the level of health care delivered in their countries. It is clear that the public purse has limits and costs must be considered, but a program that focuses mainly on cost containment is both unfair and short sighted. In fact, a study by researchers from New Zealand found that the shift towards cost containment and severely restrictive drug formularies had contributed to a negative shift in population health in New Zealand.¹¹ When considering whether to reimburse a drug, it is important that so-called ‘societal’ factors such as the effect on a patients’ quality of life or long term health be taken into account.

Protection from individual catastrophic drug costs:

The Canada Health Act (the Act) states no Canadian should suffer hardship for needed care. However, the Act was created at a time when drugs weren’t a prominent and integral component of health care delivery. When looked at in the light of the realities of health care delivery today, it can be argued that drugs should be part of our national health care plan. Government commissioned studies arrive at the same conclusions: both the Kirby and Romanow reports recommend a publicly-funded catastrophic drug program to protect Canadians from drug costs. The Canadian Health Charities Coalition recommends “There should be, at a minimum, consistent standards that ensure that all Canadians are protected from undue financial hardship due to high prescription costs.”¹²

As the Canada Health Act has attempted to remove individual financial barriers to medically necessary care, the CDR has created a systemic fiscal barrier to the same care. A “democratic deficit” is being created by Canada’s healthcare decision-making institutions, such as the CDR, that are not directly accountable to the electorate.

Transparency:

To date, the National Pharmaceutical strategy has operated in a near vacuum of information. In fact, in a recent survey performed by the Best Medicines Coalition, 90 percent of respondents felt that the government has not done a good job of informing Canadians about the proposed strategy and plans¹³. This must be rectified. The Canadian Healthcare Association agrees: “The most important step is to ensure accountability and transparency in the use of increased dollars and to make measurable progress. Federal investments must be linked to provincial and territorial initiatives

¹¹ ¹¹ Sundakov, A and V, *New Zealand Pharmaceutical Policies*, Castalia Strategic Advisors, August 2005

¹² Health Charities Coalition of Canada Roundtable, November 15, 2005

¹³ Kovacs Burns, K *Under Public Scrutiny: A Preliminary Study on the Public’s View of the NPS*, CHSPR Conference, Vancouver, February 2006.

targeting pan-Canadian objectives to broaden the care continuum and reduce wait times.”¹⁴

Universality & Portability:

The program must provide the coverage across the country regardless of income, social strata, age, or province of residence. The program must also be transferable between provinces. Addressing the issues of universality and portability should ensure that access barriers are removed and that the NPS proposed idea of a “National Formulary” does not result in access deterioration as provinces subscribe to the lowest common denominator.

Timeliness:

A National Pharmacare program has the ability to help speed access to needed new medications through a reduction in the number of review and approval processes. The most recent estimates indicate that Health Canada takes on average close to 750 days to review a new drug. The drug then spends another half year at the Common Drug Review before provinces begin their own review. Furthermore, at many of the levels, reviews are duplicated unnecessarily. All this time patients are waiting for access to potentially life-saving or life-altering medication. Opportunities to determine acceptable wait times for access to new medicines should be discussed in the same way that wait times for other medical treatments have been developed.

Post approval surveillance system:

Patients and providers have long been advocating for a more robust post-approval surveillance system within Canada. The Health Charities Coalition of Canada (HCCC) suggests “Health Canada should develop an arm’s length post-marketing surveillance system – a way of tracking and monitoring adverse reactions to a drug after it reaches the marketplace – co-funded by government and industry.”¹⁵

A post approval surveillance system could also retroactively provide Canadians the much needed longitudinal data often missing where drugs developed for orphan or rare disorders are concerned. Currently such drugs are being routinely turned down by the CDR for approval. Conditional approvals could be given pending the collection of such post approval data.

Protection of the physician-patient relationship:

Included among the stated NPS objectives is the desire to influence the prescribing behaviour of health care professionals. Physicians will be asked to prescribe the medication that is proven the most cost effective. This type of thinking is completely at odds with current thinking on Chronic Disease Management and Patient-Centered Care. Physicians must be allowed to prescribe the drug that they consider to be the most effective for their patient. According to The Best Medicines Coalition, “The NPS policies must be patient-focused or centered, guided by principles of physician choice, patient access and needs based on scientific evidence in clinical practice guidelines, and containing drug costs by providing the best treatments and medicines as preventative

¹⁴ *Meeting the Healthcare Needs of Canadians* The Canadian HealthCare Association

¹⁵ Health Charities Coalition of Canada Roundtable, November 15, 2005

measures for complications, which improve health outcomes and in turn, reduce the need for extra doctors' visits or visits to the emergency department, or hospitalization."¹⁶

Appropriate Cost Sharing:

Canadian patients recognize that health care costs are high, and that some forms of cost sharing and restrictions are likely to be necessary. *Appropriate* income-based cost sharing can be instituted that still protects those Canadians with low incomes as well as those with catastrophic drug costs.

¹⁶ Best Medicines Coalition, NPS Position Paper

Complementary Concepts

Along with the above mentioned principles, there are certain concepts that are currently being investigated that provide innovative solutions for health care delivery. A few that could complement a national pharmaceutical strategy are described below.

Chronic Disease Management:

Chronic Disease Management (CDM) can be defined as a systematic, population-based approach to identify persons at risk, intervene with specific programs of care, and measure clinical and other outcomes. Effective CDM programs contain health costs by reducing the need for acute and often more costly health care interventions. Chronic disease management helps individuals keep as healthy as possible and maintain their independence, through prevention, early detection, and proper management of symptoms and chronic conditions, such as congestive heart failure, asthma, diabetes, hypertension, osteoporosis and other chronic illnesses.¹⁷ Others have described CDM as “a cultural shift that focuses on patient and carer as central in managing their chronic disease, supported rather than directed by a health and social care team. The patient as a passive recipient of care is no longer viable in this approach to care delivery.”¹⁸

British Columbia’s Department of Health has instituted a variety of CDM programs and has been very successful in helping patients attain greater control over their conditions, while saving resources at the same time. BC has programs for a number of diseases, including diabetes, asthma, chronic renal disease and heart disease. Taking asthma as an example, “partners from across BC’s health care system have been working to provide the information and support people need to effectively manage their asthma. For example, asthma care guidelines have been developed and distributed to family physicians and many community pharmacists are providing asthma education. As well, the BC Lung Association and BC health authorities have made asthma programs and educational resources available in many communities across the province. These combined efforts are working as BC statistics indicate a 50% decrease in asthma hospitalizations over the past four years.”¹⁹ Decreasing hospitalizations means that more asthma patients are living happier lives with their disease under control. However, it also means that the healthcare system is saving money from avoided hospitalizations.

Patient Centered Health Care:

Patients are taking an active role in their own care, and are beginning to demand that they have input in how their health care is delivered. The emergence of organizations such as the International Alliance of Patients’ Organizations (IAPO), and the World Alliance for Patient Safety, which are committed to the concept of patient centered health care, are indicators of the movement towards increased consumer involvement in health.

At its recent World Congress, IAPO asserted that “One of the key events of the week was the launch of IAPO’s Declaration on Patient-Centred Healthcare. It is the first

¹⁷ Ontario Pharmacists Association, *OPA Today* <http://www.opatoday.com/ChronicDiseaseManagement.asp>

¹⁸ Astin, F, Closs SJ, Lascelles M, *A 21st Century Approach to chronic disease management in the UK: Implications for nurse educators* Contemporary Nurse, Vol 20, No 2 December 2005

¹⁹ BC Health Chronic Disease Management Newsletter, June 2004
<http://www.hlth.gov.bc.ca/cdm/research/updatejun04.pdf>

globally accepted definition of patient-centred healthcare developed by and representing the global patients' movement. The Declaration contains five principles which, if followed, will result in patient-centred healthcare: Respect; Choice and Empowerment; Patient Involvement in Health Policy; Access and Support; and Information.”²⁰

A current example that combines elements of Chronic Disease Management and Patient-Centered Care is the Asheville Project.

The Asheville project began as an experiment that was intended to last 6 months to determine if increased input from pharmacists could have an impact on both patient health and health costs. Pharmacists were trained in counselling patients with diabetes and began helping them manage their disease. A group of pharmacists initially coached forty-six patients in managing their diabetes (700 patients are now in the program). After six months, 75 percent of patients showed at least some improvement in blood sugar. Sixty-three percent of them showed blood sugar in the optimal range, compared to 38 percent of patients before the intervention. In the final evaluation, total medical costs decreased by \$1,622 to \$3,356 per patient per year. More of the money was spent for preventive medications and less on emergency-room and hospital care. There were also signs that employees of the city of Asheville were more productive; every year from 1997 to 2001, their days of sick time taken decreased.

Today, the project has expanded to include three other chronic diseases — high cholesterol, high blood pressure, and asthma.²¹ Asthma results have just been released and participants saw significant improvements in all measures of asthma control over a five year period. Emergency department visits and hospital visits declined significantly, and direct medical cost savings averaged \$725 per patient per year. Indirect costs associated with missed or non-productive workdays were estimated to decline by \$1230 per patient per year.²²

Create Covenants (Heal Health Care)²³

The idea of creating covenants to heal healthcare is the policy advanced by Dr. Glenna M. Crooks, the president of Strategic Health Policy International Inc. Dr. Crooks suggests that healthcare needs a fundamental culture shift in order for the sector to be 'healed', and that responsibility lies not only with governments, but with all players in the health care arena: “Too many policy debates occur in political settings and politics, by its nature, is hard-wired for conflict...Conflict may well be a necessary part of politics, but it is not the best way to resolve the important decisions of the day in an enterprise of healing.”

Dr. Crooks describes the historic patient-healer encounter as one that was held sacred by the healer, the patient, and the community because they had a covenant with each other, rather than a contract. According to Dr. Crooks the concept of a “covenant” meant

²⁰ International Alliance of Patients' Organizations, <http://www.patientsorganizations.org/showarticle.pl?id=649&n=605>

²¹ Angela Spivey, The Asheville Project, Endeavors <http://research.unc.edu/endeavors/win2004/asheville.html>

²² Barry A Bunting and Carol W. Cranor, *The Asheville project: Long-Term Clinical, Humanistic and Economic Outcomes of a Community-Based Medication Therapy Management Program for Asthma*. Journal of the American Pharmacists Association, March/April 2006.

²³ Crooks, Dr. Glenna *Create Covenants. Heal Health Care* Strategic Health Policy International.

that the relationship would be permanent, or nearly so. It meant that the deity, or deities, had blessed the healer, that neither the healer nor the patient would benefit to the detriment of the other, and that the community would do its part to create healthy environments and pay for care.” She postulates that as our health care systems become more complex, we have lost sight of the covenant concept, and have layered them with contracts. “To heal health care, we need to step outside our conflicts and contracts and enter into covenants.”

Dr. Crooks’ recommended solution involves three steps. First, all healers must embrace covenants of caring. Healers now include not only those we would traditionally view as healers (physicians, nurses and pharmacists) but also insurance company executives, legislators and parliamentarians, regulators, health care company staffs, pharmaceutical company sales representatives and so on. Secondly, patients should be invited into these covenants of obligation and be called upon to be better managers of their own health. Finally, communities should be called into the covenant as well, by asking that they better support healing through funding and better public policy choices for safe and healthy communities.

Summary

Canadians used to boast that their healthcare was the best in the world. It may have been at one time but the evidence would suggest it is no longer, especially in the area of pharmacare when compared to the United States, many European Union countries, Japan and Australia. The need for a national pharmaceutical strategy to redress this imbalance is clear. The current hodgepodge of federal, provincial and territorial drug plans and review structures is not serving Canadians well anywhere in the country. The national pharmaceutical strategy that is finally developed needs to be:

- Transparent
- Consultative
- Patient-outcome focus
- Centred on improving access to drugs for rare and orphan disorders
- Universal and portable
- Grounded in the value that therapeutic decisions are made between patient and physician
- Inclusive of a chronic disease management model of care
- Funded as needed through income-based cost-sharing
- Supportive of a post approval surveillance system
- Much more timely and expeditious in providing access to new drugs
- Inclusive of catastrophic drug coverage, and
- Designed to improve the value for money that Canadians receive from generic drugs.