Commission on the
Future of Health Care
in Canada

Commission sur
l'avenir des soins de santé
au Canada

DISCUSSION PAPER

Pharmacare in Canada

MAY 2002

This paper is one of a series of nine public discussion documents designed to help Canadians make informed decisions about the future of Canada's healthcare system. Each of these research-based papers explores three potential courses of action to address key healthcare challenges. Canada may choose to pursue some, none, or all of these courses of action; in addition, many other options are available but not described here. These research highlights were prepared for the Commission on the Future of Health Care in Canada, by the Canadian Health Services Research Foundation.

Thank you for your interest in shaping the future of Canada's healthcare system.

This discussion document and survey on Pharmacare is one of a series of nine such documents the Commission on the Future of Health Care in Canada has developed in partnership with the Canadian Health Services Research Foundation. They were designed to enable Canadians to be better informed about some of the key challenges confronting their health care system and to express their preferences on proposed solutions. We have worked hard to summarize relevant, factual information and to make it as balanced and accessible as possible.

Each of our nine documents follows an identical format. We begin by briefly summarizing a particular health issue. Next, we identify three possible courses of action to address the issue and their respective pros and cons. Last, we ask you to complete a brief survey relating to the courses of action.

To make it easier to provide us with your responses, the survey questions are included on the final pages of this document. Please detach and forward these pages to us by fax at: (613) 992-3782, or by mail at:

Commission on the Future of Health Care in Canada
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Ottawa, Ontario
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You can also complete the survey on-line through our interactive website at: www.healthcarecommission.ca.

There are no "right" or "wrong" answers, and the results are intended to be informational only. They are designed to illustrate how each person's response fits within the context of others who have responded, not to have scientific validity in and of themselves. The survey results are only one of many ways the Commission is studying and analyzing this issue. To order other titles in this series, please write to us at the address above, or call 1-800-793-6161. Other titles include:

- Homecare in Canada
- Access to healthcare in Canada
- Sustainability of Canada's healthcare system
- Consumer choice in Canada's healthcare system
- The Canada Health Act
- Globalization and Canada's healthcare system
- Human resources in Canada's healthcare system
- Medically necessary care: what is it, and who decides?

We are grateful for your contribution to shaping Canada's healthcare system and hope that this document will be as informative to you, as we know your survey responses will be valuable to us.

Sincerely,

Roy Romanow

Pharmacare in Canada

Many of us have had our lives, or those of people we love, radically changed by prescription drugs. Here, a grandparent has been kept alive by a heart medication; there, a child has lived into his teens because of breakthroughs in the treatment of cystic fibrosis. Vaccination and antibiotics have prevented untold deaths. Pain is eased, more normal lives made possible, chronic conditions dealt with. There is hope that someday new drug therapies may be as effective in treating diseases such as cancer and AIDS. No surprise, then, that in a poll released in late 2001, 86 percent of Canadians said they believe prescription drugs play an important role in improving the quality of healthcare.

At the same time, the drug costs are continuing to rise, and many Canadians are concerned that this may not be sustainable. Spending on drugs is increasing faster than all other healthcare spending. The budget for prescription drugs grew by 344 percent between 1985 and 2000, when Canadians spent $11.3 billion on prescription drugs.

How much we should spend, what portion of that should be paid by the taxpayer, and what limits we might have to put on drug therapies are very complex issues, and there are many ways to approach them. However, this paper focuses on three of the many potential courses of action for Canada. They are:

I. Streamlining the regulatory approval process for new drugs. Should Canada make it faster and easier for drug companies to bring new drugs onto the market, and for patients to access these drugs? Patients eagerly anticipate new drugs, and hope these drugs will fulfill the high expectations they have for them, but what are the trade-offs for speeding up drug approval?

II. Creating a national pharmacare program to pay for prescription drugs. Many Canadians can't afford to take medications once they make it to market. Some new drugs can cost hundreds or even thousands of dollars for a course of treatment. Many people have drug coverage provided as part of their employee benefits, while others are covered by government drug plans. Some Canadians, however, have no drug coverage at all. Should we create a national pharmacare plan that pays for the drugs Canadians take?

III. Dealing with the rising cost of drugs. Drug budgets continue to increase every year. Should Canada try new ways of keeping drug costs down?

As we consider the future of our healthcare system, we may choose to pursue these courses of action separately, in combination with each other, or not at all.

Access to new drugs

It takes a long time to bring a drug to market in Canada. Drug companies estimate that a drug can spend more than a decade in a development process that takes it from basic laboratory research to clinical trials, where drugs are tested on people.

After this testing, the drug company must apply to Health Canada for a review if it wants to sell the drug in Canada. The company files a submission that includes information on the drug's safety, quality, efficacy and side effects. Health Canada staff assess whether the potential benefits of the drug outweigh the risks; if the data suggest they do, or the risks can be mitigated, the manufacturer can sell the drug in Canada.

The industry often criticizes Health Canada for not approving drugs fast enough. And patients sometimes join them in asking the government for faster approvals. In particular, people with HIV were effective in lobbying the government to speed up approvals of experimental drugs during the 1990s. Other patient groups (sometimes with funding from the drug companies that want to sell their products) have also started lobbying the government for faster approval of certain drugs.

A major reason for the delays at Health Canada is that while the number of proposed new drugs requiring review is increasing every year, the number of reviewers is not. As a result, there is a backlog at Health Canada and it can now take up to six months for a reviewer to even begin looking at an application.

Course of action: Government should streamline the regulatory approval process for drugs

There are several ways that Health Canada could shorten the time it takes to approve a drug in Canada. It could increase funding to Health Canada's drug approval branch so it can hire more staff, and complete more reviews. The money could come from the government, or from user fees charged to the industry. Such user fees could also be used to finance a separate agency to review drugs. Or Canada could co-operate with other countries that review drugs, either by sharing information and resources, or simply adopting the results of drug reviews from other countries.

Arguments For

Canada is slower than other countries in approving drugs. That means that Canadians may not be able to take a new drug until long after residents of other countries. Drug reviews take anywhere from a few hundred days to over 2,000 days at Health Canada. One study found the average time is about 608 days — longer than Australia (538 days), the United States (496 days), Sweden (360 days), and the United Kingdom (344 days). On average, it takes Canada 3.5 months longer to approve a drug than it takes the U.S.

If Health Canada had more funding, it could hire more people to review drugs and approve drugs faster. In the 1990s, the United States and the United Kingdom increased funding through user fees charged to drug companies, and have shortened approval times.

If other countries are also approving the same drugs at the same time, often using the same process, Canada should share resources with them. The European Union, for example, has a procedure where a drug company can apply for drug approval in any country, and all other countries belonging to the EU recognize the results of the review.

In fact, Health Canada already uses the same process as the United States. Canada could just approve the work of the Americans, and allow Canadians to access drugs at the same time. Canada could retain the right to ask drug companies for more evidence when we have reservations.

Arguments Against

Health Canada already fast-tracks approval of drugs for life-threatening and serious illnesses. One program allows patients with life-threatening illnesses to use experimental drugs before they have been approved. In addition, Health Canada tries to approve some drugs in less than 200 days, when they are for a condition for which there is no treatment, or they appear to be much better than treatments currently available.

Most new drugs are not better than treatments currently available. Many medications are not real breakthroughs, so a faster process doesn't necessarily mean better drugs will be available. One French journal that reviews the evidence behind new drugs concluded that over 65 percent of the drugs it had reviewed from 1981 to 2000 were either "nothing new" or "not acceptable."

There are better things Health Canada could pay for than hiring more people to review drugs faster. Funds could instead be spent on better monitoring the safety of drugs after they are on the market, for example. This would allow Health Canada to discover more quickly when drugs have serious side effects, and take them off the market. In April 2002, Health Canada announced a new directorate with responsibilities in this area.

An international partnership is only as strong as its' weakest link. If countries share reviews, drug companies might only submit applications to countries they know will approve them faster. That's OK most of the time, but if even one country is willing to compromise the quality of a review to win business from a drug company, negative effects on public health could be widespread. In addition, Canada should be careful about going too far down any path that could compromise its ability to make its own laws.

Faster drug approvals can compromise public safety. One study released in 1990 by the investigative arm of the U.S. Congress showed a greater tendency to find post-approval risks in drugs that had been approved faster. However, it is true that another study found that overall risks have not increased since the U.S. has shortened approval times.

Survey Questions

Please refer to page 11 for the survey questions for this section.

II Drug Coverage

Just because a drug has been approved in Canada does not mean all Canadians are able to use it. Drugs are expensive, and not all Canadians have insurance that will pay for them.

Drug insurance in Canada is a patchwork of plans with different rules and coverage. The best estimate is that about 62 percent of Canadians have private drug insurance, often provided through their employer. About 19 percent are covered by a government drug plan, usually operated by provincial governments, and seven percent of the population probably has coverage from both a public and a private plan.

However, about 12 percent of Canadians have no drug coverage at all, so when their doctor gives them a prescription, they have to pay the whole cost out of their own pocket. That can be a real financial burden for some people. In all, private insurance plans and Canadians paying direct account for about 54 percent of spending on prescription drugs in Canada. Federal and provincial governments pay the other 46 percent.

Some government plans provide coverage only for certain groups, such as seniors, people on income assistance, and those suffering from specific illnesses with very high drug costs, such as AIDS and cancer. Some provinces have plans that provide coverage to all residents, but they usually have deductibles, so people have to pay a certain amount annually before government coverage kicks in.

In Quebec, drug insurance has been mandatory for every resident of the province since 1997. Employers must provide insurance to employees, and anyone who is not eligible for employer coverage must buy insurance from the government.

Course of action: Canada should create a national pharmacare program that would pay for all prescription drugs

One of the defining characteristics of medicare is that when Canadians visit a doctor's office or hospital, they do not receive a bill for services that are considered "medically necessary" under the Canada Health Act. Government pays the full cost.

It is hard to think of drugs as not being medically necessary as well, but they are not included in the Canada Health Act. A number of commissions and expert inquiries over the years have called for that to change and have told the government to come up with a way to ensure that all Canadians have drug coverage.

Several different approaches to creating a national plan have been suggested. At a minimum, a national plan could be designed to fill the gaps in current coverage, providing drug insurance to the 12 percent of Canadians who don't currently have it. Or it could be inclusive, providing drug coverage for everyone, but permitting deductibles and user fees to be charged to patients. The plan would not come under medicare, so there could be some private involvement in the plan's operation. Thirdly, we could create a plan where drugs were defined as medically necessary under the Canada Health Act, so that drug coverage in Canada would be similar to medicare.

Proposals for national pharmacare tend to follow this third option, where the federal government would legislate universal coverage for pharmaceuticals. In this scenario, the provinces would provide complete coverage, and share the cost with the federal government.

ARGUMENTS FOR

It's fair. Right now, people on income assistance, such as welfare or public pensions, are usually covered by government plans and people who work for larger companies get drug coverage as part of their benefit package. However, people who work for small businesses and the working poor often have no coverage. This situation — many payers, no standard coverage, and high out-of-pocket payments — looks a lot more like the American healthcare system than medicare.

There would be economies of scale. Larger government drug plans in Canada are already the most efficient. In Ontario and Quebec, for example, administrative costs represent about two percent of the cost of the plan. A national pharmacare plan could replace the 14 federal, provincial and territorial plans, billing structures, and processes for deciding whether a drug should be funded.

A publicly-run system would provide more services for patients, and less overhead. Lessons can be learned from the American way of doing things. Research has found that between 20 and 24 percent of all healthcare spending in the U.S. goes to administration, but in Canada, administration is only eight to 11 percent of spending. A drug plan run like medicare could be just as efficient with taxpayers' dollars.

A large drug plan can negotiate better prices. If the provincial drug plans combined their buying power in a national pharmacare plan, they could negotiate better prices with pharmaceutical companies and keep drug costs down. In Australia for example, the government pays approximately 75 percent of the cost of prescription drugs outside hospitals. As of 1993, Australia had been able to keep its drug prices more than 30 percent lower than the other 29 countries in the Organization for Economic Co-operation and Development. At that time, Canada's were almost 30 percent above the OECD average.

ARGUMENTS AGAINST

It would be very expensive for taxpayers. Costs would be shifted from individuals taking drugs to government. It is hard to see how government could avoid turning to the public for funds to cover the 54 percent of prescription drug costs currently paid privately. In a 1997 study, it was estimated that this system would increase government spending on drugs by $4.3 billion.

The administrative savings may not be that large. Administrative costs in the Ontario and Quebec drug plans are low at two per cent, but they are higher in other provinces — up to 13 per cent in the smaller Atlantic provinces.

Standardization has its drawbacks. With a single national plan, residents of some provinces will get much better drug coverage than they have currently. However, the effect could be minimal for residents of provinces where drug plans are more generous.

A public/private partnership would cost government less. One 1997 study found that models that involved a certain degree of public/private partnership would have far less impact on government spending, though it would not control the overall cost of drugs.

SURVEY QUESTIONS

Please refer to page 11-12 for the survey questions for this section.

III Cost Control

The budget for prescription drugs increased by 344 percent in Canada between 1985 and 2000. It's tempting to blame cost increases on the impact of Canada's aging population, but studies show this may be exaggerated. Some say doctors are prescribing more drugs than they should. Others say the increase in spending is because new medications are more expensive than older treatments.

Some prescription drugs have helped make people's lives better, and undoubtedly saved some lives as well. But they cost an enormous amount of money and that has governments worried. They also want to be sure that they are paying for the right drugs and not for those which have a negligible effect. That's also why they require that a company demonstrate a drug's cost-effectiveness before it is added to the formulary.

In addition, the government drug plans all use some form of cost sharing, with individuals either paying a certain percentage of the cost of a drug, a portion of the dispensing fee, or an annual deductible that must be paid before public drug insurance kicks in.

Cost sharing limits how much provincial governments spend by shifting part of the costs to patients. Co-payments and deductibles, while they may cause some grumbling, don't cause many people to avoid taking a drug. But vulnerable patients, particularly seniors and people with mental illnesses, are much more sensitive to cost sharing. When these groups stop taking their medications, they are much more likely to get sick and end up in hospital, thereby increasing overall healthcare costs.

Despite cost-sharing programs across Canada, drug costs have continued to rise, for both consumers and governments.

Course of action: Instead of shifting drug costs onto patients with co-payments and deductibles, government should pursue other approaches to control the cost of drugs.

There are options for policies that focus on sharing drug costs between governments and consumers. Governments can reduce the overall amount they spend on drugs by setting up a national formulary that would not cover all drugs, but only those that are the most cost-effective. Another policy would be a system of reference-based pricing, in which the formulary would restrict what the government will pay to the price of the least expensive option, unless there is a good medical reason, such as bad side effects.

Another approach is to work with doctors on the way they prescribe medicines. Some doctors may prescribe expensive medications when cheaper choices are available, or give them to patients who may not need them. Government could influence how doctors prescribe, either by setting limits, or by educating them about better prescribing.

Canada could also do more to regulate drug prices. Currently, we regulate the maximum prices drug companies can charge wholesalers but not the price charged to consumers, after wholesalers and retailers have added markups. Canada could make changes to ensure it negotiates better prices with the drug industry and do more to control the price consumers pay for drugs.

Arguments For

Formularies work. Every hospital has a formulary committee that chooses drugs according to their effectiveness and price. Often the hospital can negotiate lower prices by having drug companies compete against each other to get on the formulary.

Why pay for more expensive drugs, when in most cases, the cheaper drugs will work just as well? Since 1995, the British Columbia drug plan has used reference-based pricing for some groups of drugs. When two drugs appear to do an equally good job, the government will only pay for the cheaper drug — unless there is a good reason, such as the more expensive drug will have fewer side effects for the patient. The policy is saving the government millions of dollars every year.

Educating doctors can work — in the right circumstances. When educational outreach to doctors is planned carefully and offered in the right setting, it can help doctors prescribe better and save costs, although there is no single approach that works in all circumstances.

If government played a larger role, it could more effectively control the prices paid for drugs. Look to New Zealand, which has a government-sponsored organization that purchases drugs for the entire population covered by national health insurance. Drug companies lower their prices to win a sale to the organization, and therefore gain access to the entire country's market.

Canada could just set a limit on how large a drug company's profits can be. This is already being done elsewhere. For example, the United Kingdom has set limits on the drug industry's rate of return on investment.

Arguments Against

New drugs may be more expensive, but they may save costs to the system as a whole. In some cases, newer drugs may cost more than older drugs, but they may have fewer side effects or decrease the need for other healthcare services.

Lower drug costs can mean trade-offs in other areas. Drug companies do not tend to conduct research and development activity in countries where they are not profitable. Canada is not a major centre for R&D, but governments want this to change, and some recognize they may have to pay more for drugs for this to happen.

R&D funding has to come from somewhere. The drug industry needs money to research and develop new drugs, and Canada should pay its fair share of the cost. If we don't, it weakens our position in the international community.

Doctor education doesn't always work. Educational outreach to doctors can work in some circumstances, but in other cases it can fail miserably. Simply writing and distributing guidelines to doctors does not work. And a more carefully structured education program for doctors can cost more than the savings it generates.

Limits on profits encourage the drug industry to become less efficient. True, the United Kingdom has set limits on how much of a return on investment drug companies can make. However, under this system there is little incentive for the industry to become more efficient in its operations — and do a better job of developing drugs.

Survey Questions

Please refer to page 12 for the survey questions for this section.

Acknowledgements

This document was produced by the Canadian Health Services Research Foundation, in partnership with the Commission on the Future of Health Care in Canada. The topics and courses of action reflect key issues raised frequently in the Commission's consultations to date, for which the Foundation was able to find relevant research evidence to help inform the debate.

This document has been reviewed by the following experts for accuracy and fairness, but final responsibility lies with the Canadian Health Services Research Foundation:

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A complete bibliography of the research used to prepare these documents can be found at www.healthcarecommission.ca.

SURVEY INSTRUCTIONS

Please detach the following page and forward to us by fax at:
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For information:
Call toll free at 1-800-793-6161
www.healthcarecommission.ca

Thank you

Survey Questions

For each of the following questions, please indicate your opinion by selecting the appropriate box.

Access to New Drugs

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Creating a national pharmacare program that ensures that all Canadians have some type of prescription drug insurance will improve healthcare in Canada.	❑	❑	❑	❑	❑

2. Do you believe that Canada should concentrate more resources on speeding up our own drug approval process, or that Canada should pool resources and work more closely with other countries on drug approvals?

Strongly Agree more resources on our own approval process	Agree more resources on our own approval process	Neutral	Disagree work more closely with other countries	Strongly Disagree work more closely with other countries
❑	❑	❑	❑	❑

3. In general, do you believe that it is more important to have access to new drugs as quickly as possible, or that it's better to wait extra months or years until we can be sure a new drug is safe for everybody over the long term?

Strongly Agree it's important to have drugs quickly	Agree it's important to have drugs quickly	Neutral	Disagree it's important to wait extra months to be sure of safety	Strongly Disagree it's important to wait extra months to be sure of safety
❑	❑	❑	❑	❑

4. In addition to safety, please rank the importance of these principles for a Canadian drug approval process. Rank these three factors with 1 being most important and 3 being least important.

	Most Favoured		Least Favoured
Speed of approval — getting safe drugs approved as fast as possible	❑ 1	❑ 2	❑ 3
Canadian control — ensuring that Canadians have full control over what drugs are approved for sale in Canada	❑ 1	❑ 2	❑ 3
Affordability — ensuring that the drug approval process does not consume a lot of resources	❑ 1	❑ 2	❑ 3

Drug Coverage

1. If the federal government were to introduce a national pharmacare program, do you believe that it should be designed to fill in the gap for the 12% of Canadians who do not currently have drug insurance, or do you believe that all Canadians should be covered under one national pharmacare program?

Strongly Agree fill the gap for 12% who have no coverage	Agree fill the gap for 12% who have no coverage	Neutral	Disagree all Canadians should be covered under one national pharmacare program	Strongly Disagree all Canadians should be covered under one national pharmacare program
❑	❑	❑	❑	❑

2. If the federal government were to introduce a national pharmacare program, do you believe that it should be part of medicare, with no cost to the user at the point of service or outside of medicare, which would allow user fees (such as co-payments or deductibles)?

Strongly Agree part of medicare	Agree part of medicare	Neutral	Disagree outside of medicare	Strongly Disagree outside of medicare
❑	❑	❑	❑	❑

3. If the federal government were to introduce a national pharmacare program, do you believe that the best way of funding it would be mainly through general tax revenues or through a separate mandatory premium-based insurance plan?

Strongly Agree fund through general tax revenues	Agree fund through general tax revenues	Neutral	Disagree fund through mandatory insurance plan	Strongly Disagree fund through mandatory insurance plan
❑	❑	❑	❑	❑

Cost Control

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Controlling the cost of drugs through means other than shifting drug costs onto patients with co-payments and deductibles will improve healthcare in Canada.	❑	❑	❑	❑	❑

2. Which should be the highest priority?

   Decreasing the cost of drugs to governments and consumers.

   OR

   Encouraging more research and development into new drugs by drug companies in Canada.

Strongly Agree only medically necessary services covered	Agree only medically necessary services covered	Neutral	Disagree social support services should be covered	Strongly Disagree social support services should be covered
❑	❑	❑	❑	❑

3. Do you agree or disagree with each of the following ways of controlling drug costs?	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Introducing a formulary or referenced-based pricing which would only pay for the cheapest (but still effective) version of each drug.	❑	❑	❑	❑	❑
Educating doctors about prescribing cheaper versions of drugs and only to prescribe drugs when they are really necessary.	❑	❑	❑	❑	❑
Having governments use their purchasing power to negotiate better prices for drugs with the companies that make them.	❑	❑	❑	❑	❑

Analysis Information

Please complete the following information for analysis purposes. Thank you.

Gender: ❑ Male ❑ Female

Age: ❑ under 18 ❑ 19-29 ❑ 30-49 ❑ 50-65 ❑ over 65

Province or Territory in which you reside: _____

Continued ...

Your annual household income from all sources before taxes is: (Optional)

Choose one:

❑ Less than $20000

❑ $20000 to $39999

❑ $40000 to $59000

❑ $60000 to $79000

❑ $80000 to $99000

❑ More than $100K

The highest level of schooling you have completed is: (Optional)

Choose one:

❑ Elementary School or less

❑ Secondary School

❑ Community College/CEGEP/Trade School

❑ Prof./Trade Certification

❑ Bachelor Degree

❑ Graduate Degree

Are you a healthcare professional? (Optional)

❑ Yes ❑ No

Approximately how many times in the last year have you personally used the healthcare system? (eg. seen a doctor or specialist, spent time in the hospital, received care in a hospital emergency room, etc.) (Optional)

Choose one:

❑ 0-3

❑ 4-6

❑ 7-9

❑ More than 10

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