Session II: Pharmacare

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The three papers presented in this session make important contributions to the policy discussions in Canada today surrounding the National Pharmaceuticals Strategy. I would like to describe the context of those discussions and suggest some additional considerations that are likely to impact drug policy in the coming years.

Drugs are the fastest growing component of health care, increasing from about $4 billion in 1985, or 9.5% of health care spending, to an estimated $22 billion in 2004, or 16.7% of total spending.[1] There is good reason to believe that growth in drug spending may continue to outpace growth in total health spending in the foreseeable future.

The title for the session, "Pharmacare," is an optimistic choice. We do not have pharmacare in Canada. We have a hodgepodge of public plans with uneven coverage across the country. Although public funding accounts for 73% of total health expenditures in Canada, it represents only 38% of drug expenditures, well below the OECD average of 60%.[2] Canada ranks second lowest, above the United States which reports 20%. By comparison, public funding accounts for 67% and 75% of total spending in France and Germany, respectively.

Our hodgepodge pharmacare system is a result of decisions taken in the past to exclude outpatient drugs from the Canada Health Act. Since then, pharmaceuticals have taken on a growing importance in health care – both as an important tool in treating disease and in improving health outcomes, but also as a cost-driver. Over time, provincial governments found it necessary to supplement medicare with programs to provide drug coverage for the more vulnerable in society. While these programs have been effective, the uncoordinated nature of our system has resulted, as both Romanow and Kirby have pointed out, in serious gaps in coverage across the country and has created challenges to ensuring the most effective utilization of drugs in health care.

Governments have turned their attention to this issue. In September 2004, Canada's First Ministers agreed on a 10-year plan to strengthen health care.[3] This initiative included a significant package of measures to develop a National Pharmaceuticals Strategy for Canada recognizing that "affordable access to drugs is fundamental to equitable health outcomes for all our citizens." Government leaders gave their ministers of health an aggressive timetable to develop and implement the strategy and asked them to report on their progress by June 30, 2006.

What has happened in the past year? When Canada's Health Ministers met a few weeks ago, most of the media attention focused on the issue of wait times. But their press release showed that they also talked about drugs and that they "reaffirmed their commitment to the National Pharmaceuticals

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[1] "Drug Spending to Reach Almost $22 Billion in 2004, Reports CIHI," Canadian Institute for Health Information, April 5, 2005, http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_05apr2005_e CIHI. The Patented Medicine Prices Review Board has reported that sales of all drugs by manufacturers in Canada increased over 400% from $3.7 billion in 1990 to $15.9 billion in 2004. For most years, total sales increased by over 10% per annum.

[2] "Drug spending in OECD countries up by nearly a third since 1998, according to new OECD data," June 8, 2005, http://www.oecd.org.

[3] "A 10-year plan to strengthen health care," September 16, 2004, http://pm.gc.ca/eng/news.asp?category=1&id =260.

Strategy."[4] They stated that the strategy must protect Canadians from catastrophic drug costs if it is to be a success and they asked that work on that file be accelerated. They looked at an emerging issue, expensive drugs for rare diseases, and committed to research programs on two specific diseases.

On the issue of what I have called the hodgepodge of public drug programs, health ministers committed to "better align their regulatory and reimbursement regimes to ensure the best possible outcomes for Canadians," and as a start:

- To expand the Common Drug Review to all drugs, to work towards a national formulary, and more consistent access to medicines by Canadians.[5]
- To expand the powers of the federal Patented Medicine Prices Review Board (PMPRB) to monitor and report on non-patented drug prices.[6]
- To work together on collecting, integrating and disseminating information on the real-world risks and benefits of drugs.

The papers presented today make an important contribution to these initiatives. Steve Morgan's study of equity in British Columbia's Fair Pharmacare program provides useful evidence of the performance of an income-based program that should help governments in studying approaches to catastrophic drug coverage and in aligning public reimbursement programs. One of the biggest challenges in addressing expensive drugs for rare diseases is how to balance the assessment of cost-effectiveness with the goal of providing incentives for new research. Aidan Hollis has suggested a novel approach in the case of such orphan drugs to take into account the degree of innovation involved. In his paper on "reference pricing", Sebastian Schneeweiss reminds us that a reference drug policy is a reimbursement policy, not a pricing policy. Policymakers looking at aligning reimbursement programs and encouraging the cost-effective utilization of medicines will benefit from the research he reports.

As work proceeds on the National Pharmaceuticals Strategy, there are some additional challenges that must be kept in mind. One of these is the globalization of the pharmaceutical market. We must be careful not to develop policies in isolation. In many respects, the pharmaceutical market is an international market. The innovative pharmaceutical industry is a multinational industry. Intellectual property protection for drugs is largely determined through international trade agreements. The costs of developing new drugs are global costs; decisions regarding basic research and the manufacture of new drugs are largely global decisions. And, more and more, decisions regarding the pricing of new drugs have a world-wide dimension.

Canada needs to think about its policies on pharmacare, drug pricing, and framework policies in the global context. In particular, we need to be aware of the interests of our largest trading partner. The U.S. market represents close to half of the world market for drugs and major policy changes in that market, such as the introduction of the Prescription Drug Benefit under Medicare in 2006, can impact Canada. The potential impact of the U.S. market on our country has been brought home

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[4] http://www.scics.gc.ca/cinfo05/830866004_e.html.

[5] The Common Drug Review makes recommendations to public plans, based on therapeutic criteria and cost-effectiveness, on which new drugs to cover. (https://www.ccohta.ca/entry_e.html) The expansion of the CDR would extend its coverage to all drugs and enhance a national coordinated approach to drug review for reimbursement purposes.

[6] This move is significant in several respects. Studies by the PMPRB and others have shown that prices for non-patented drugs, including single source drugs supplied by brand name companies, and generic drugs, are priced higher in Canada than in many other countries. The monitoring and reporting is presumably intended to give governments more ability to use moral suasion to influence the prices of these drugs in future. But if not, the press release also reported that provinces will consider delegating to the federal PMPRB, through legislation, responsibility to regulate the prices of those drugs.

dramatically in recent years with the internet pharmacy issue. Over the past decade, our policies have protected Canadians by ensuring that prices for brand name medicines are in line with most developed countries, but the U.S. remains an outlier, with much higher prices for many Americans, especially the uninsured. The demand to source lower-priced drugs from Canada has created a significant policy debate in the U.S. about drug prices in that country. In Canada, as Health Minister Dosanjh has put it, the internet pharmacy issue has raised potential questions regarding the supply of affordable prescription medications in Canada;[7] it has also increased the incentives for some to raise challenges to our pricing system. We need to be vigilant and prepared to defend our policies and to marshal support from other countries in international fora.

The second challenge is the nature of drug development and discovery today. We need only look at the headlines. Last week, the *Globe and Mail* reported the challenges facing brand name companies as products representing 15% of their sales, or an estimated $80 billion annually, will go off patent by the end of the decade.[8] The Centre for Medicines Research (CMR), has reported that spending on R&D by the pharmaceutical industry has not been keeping pace with the growth in sales in recent years and there has been a continuing decline in the introduction of new drugs. According to the CMR, the number of New Molecular Entities (NMEs) launched in world markets has been declining since 1997; in fact the number of new launches has dropped almost 50% from 46 NMEs in 1997 to 24 in 2004, the lowest number in over 20 years.[9]

The newer drugs often offer real potential to treat disease and to target therapy to those who will benefit the most. But they also often carry a high price tag. Aidan Hollis has presented some ideas to address questions about allocating resources to expensive drugs for *rare* diseases. But what about expensive drugs for *not-so-rare* diseases? In recent years, important new drugs have come to market for multiple sclerosis, rheumatoid arthritis, some forms of cancer, and other diseases at an annual cost per patient of $20,000 or more. These new treatments add pressures on the funding of pharmaceutical therapy and the tools available to make the tough choices as a society about how best to allocate scarce health care resources. The trend in new drug development towards more specialized high cost drugs reinforces the importance of the National Pharmaceuticals Strategy – we need to find ways to ensure affordable access to necessary drugs by Canadians.

The third challenge follows directly from these points. As the development of public policy becomes more complex in a global context and as we face tougher decisions about allocating resources, patients and consumers are demanding a seat at the table. Health systems in many developed countries are making efforts to provide a greater voice for consumers in the system. We have to do so too, not only to respond to the growing numbers demanding it, but because it will strengthen the legitimacy and acceptance of the decisions that are made.

Much work has been done on the National Pharmaceuticals Strategy, but there has been little public consultation to date. In their communiqué last month, health ministers confirmed their commitment to the strategy and to report real progress next June. They also made this commitment: "Key to this report will be further consultations with stakeholders." Canadians expect no less.

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[7] Health Canada, News Release, "Minister Dosanjh announces federal strategy to protect Canadians' supply of safe and affordable prescription drugs," June 29, 2005.

[8] "Pharma's Big Headache," Leonard Zehr, *Globe and Mail*, November 12, 2005.

[9] "Innovation on the wane?" Centre for Medicines Research, http://www.cmr.org/; personal communication.