



Patented  
Medicine Prices  
Review Board

Conseil d'examen du  
prix des médicaments  
brevetés

## **Drug Pricing: A Comparison between Canada and Other Countries**

Notes for an Address by

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to

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## **Introduction**

Thank you very much for your kind invitation to participate in today's discussions. Let me also thank Hugh Segal and the Institute for Research on Public Policy for organizing this timely conference. It will help to underscore the important work of the Romanow Commission and the other consultations on the future of health care in this country and it will contribute to public understanding of the significance of pharmaceuticals in Canadian health care.

When we surveyed our major stakeholders last year as part of our environmental scan, they told us they are concerned about "the rising price of drugs" and their contribution to increasing health costs. They are concerned that the increased costs will impact the availability of medicines to people who really need them. But they also recognize the need for research and development into new drugs.

Any discussion on a national strategy towards drug insurance requires a discussion about the assumptions we make about drug costs and the likely trends in those costs. Therefore the question of drug prices becomes critical to discussions about strategies for drug insurance.

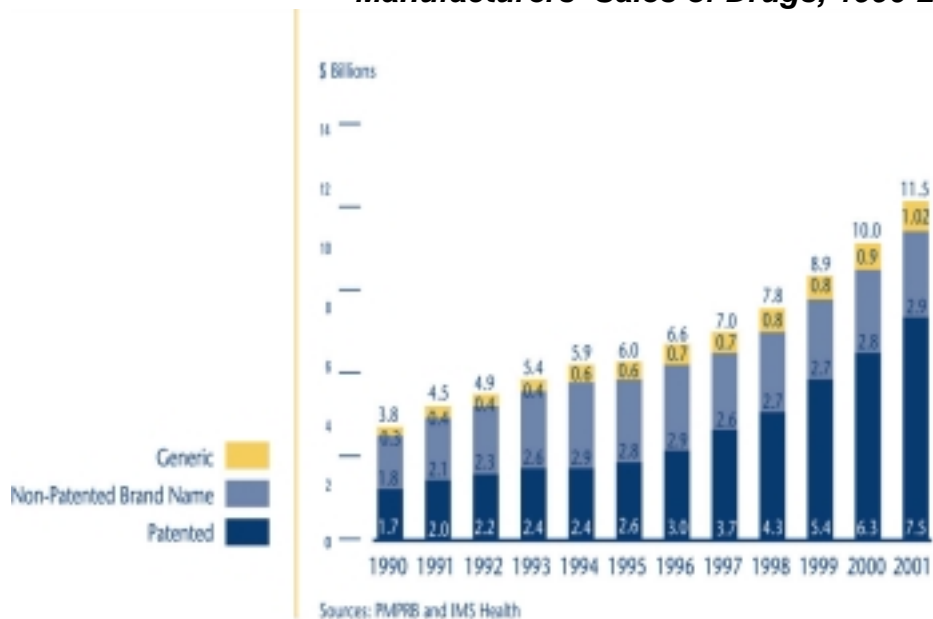
This conference is also timely as the PMPRB prepares for our Symposium 2002 which will take place next month in Ottawa. That Symposium will be focused on issues related to drug price regulation in Canada and other countries and I am looking forward to the appropriate linkages between the discussions today and in that conference.

## **Trends in Drug Prices and Expenditures in Canada**

Throughout our public consultations, and in the discussions about drug expenditures, I have often noted a confusion about the terms drug "prices" and drug "costs." These terms are sometimes erroneously used interchangeably, but there is an important distinction between them.

Drug **costs** refer to our total expenditures on drugs - how much we spend on medications. The evidence is clear that these expenditures have been increasing at significant rates in recent years.

### Manufacturers' Sales of Drugs, 1990-2001



Last year, manufacturers' sales of all drugs in Canada increased by 15%, \$11.5 billion. And this increase was in line with what we have seen over the past five years. By the way, it is interesting to note that sales of patented drugs have been going up even faster, by 19% in 2001. As a result, patented drugs now represent 65% of total drug sales, up from 45% just a few years ago.

These sales increases are, of course, reflected in the continuing double-digit growth in drug plan spending. Québec's drug costs have increased by 16.6% per annum over the last four years. The Ontario Drug Benefit Program is projecting its long-term growth to be 15% per year, a projection it describes as "modest" and which "will be higher if there is significant scientific discovery."

But the trends in drug *prices* have been different. By price, I am referring to the actual price of a specific quantity of a particular drug. On average, the prices of individual patented drugs have not been going up year over year but rather have been stable for most of the past decade.

### ***Year-over-Year Changes in the PMPI, 1988-2001***

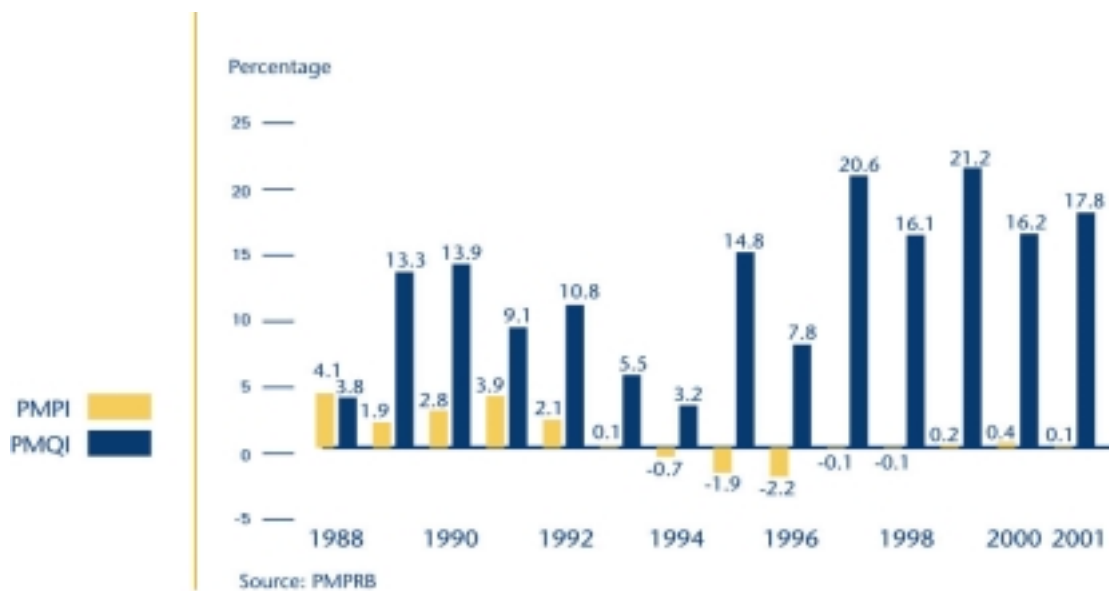


As shown in this graph, the Patented Medicine Price Index, which measures the annual changes in prices of patented drugs, has, on average, increased only slightly in recent years and, in some years, has even declined. This is not by accident. The PMPRB's price guidelines, based on factors in the *Patent Act*, provide that prices for existing patented drugs cannot go up by more than the Consumer Price Index. In addition, a number of provincial governments have imposed price freezes or other policies that restrain prices for drugs covered under provincial plans, such as mandatory generic substitution and reference-based pricing.

The PMPRB's Guidelines also place limits on the introductory prices of new patented drugs. The prices of most new drugs, those that provide moderate or no improvement, may not exceed the highest-priced existing drug that treats the same disease or condition. The price of a breakthrough or substantial improvement drug can be higher, provided it does not exceed the median of the prices in seven other industrialized countries.

So if the prices of drugs are restrained by government policies, why have drug costs been going up? There are many reasons but two major ones stand out. First, the utilization of drugs has been increasing significantly.

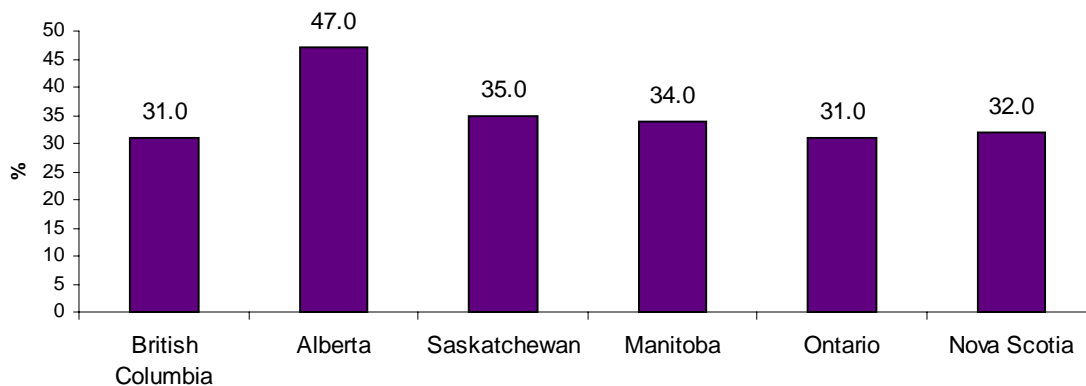
### Year-over-Year Changes in the PMPI and the PMQI, 1988-2001



As shown in our Patented Medicine Quantity Index, most of the increase in sales of patented drugs each year has been accounted for by increases in the quantities of drugs sold as opposed to changes in the price. Canadians are using more drugs more often to treat diseases and this is a significant factor in increasing total drug expenditures or drug costs.

A second important factor has been the increasing use of new drugs. Even though the prices of new patented drugs are limited to ensure they are not excessive, there may still be an incremental cost to the health care system in using them. If a breakthrough drug is used where no pharmaceutical treatment had previously been available, there will be an increase in the drug bill. If a new drug is used in place of a less expensive one, such as a generic copy of an older drug, we should expect to see an increase in total drug costs.

### Pharmaceutical Expenditures on Newer Drugs, 1999-2000



Source: PMPRB

In studies conducted for F/P/T governments, we found that approximately 30% of the spending by some of the major drug plans is accounted for by new drugs added to the formulary within the previous five years. It would appear that the speedy take-up and use of newer drugs is making a significant contribution to our total drug bill.

None of this is to say that these increases are necessarily inappropriate. More work is required to determine if we are allocating resources efficiently in the area of pharmaceuticals to promote improved outcomes.

### **Drug Price Trends in Other Countries**

Let us turn now and examine how trends in drug prices and expenditures in Canada compare with trends in other countries.

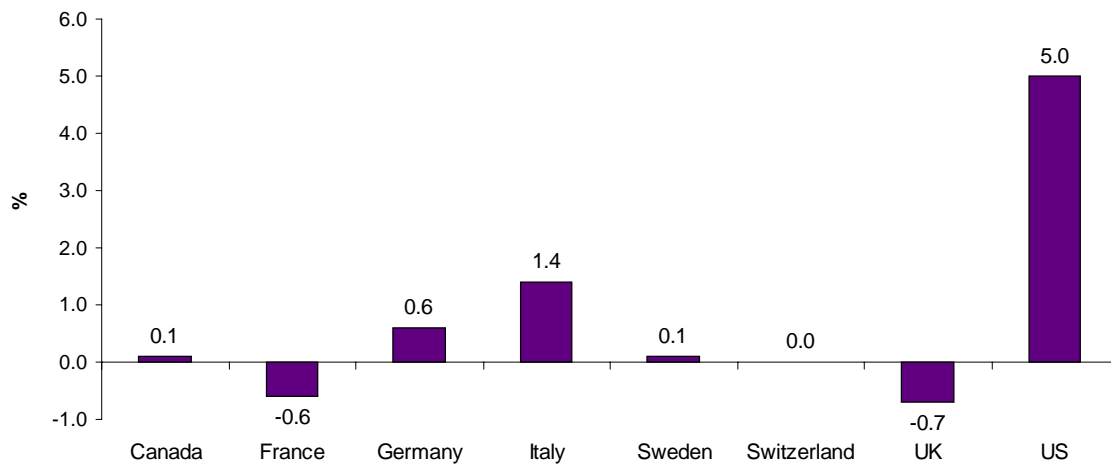
#### ***Growth in Retail Pharmacy Sales of Drugs, 2001***



Last year, it is estimated that the increase in retail pharmacy sales in Canada was second to the US, although higher than Italy, Germany, the UK and France. Elsewhere, it has been reported that drug expenditures in Australia have increased by 14% per annum over the past decade, a rate in line with the increases in many public drug plans in this country. All countries, except the US, control drug prices and costs in some manner; how do the price trends in Canada compare to other countries?

To give us a better handle on this question, we are currently completing a study of the trends in prices of patented drugs in the countries we are required to use for comparison purposes: France, Germany, Italy, Sweden, Switzerland, the UK and the US. These countries have traditionally had a significant pharmaceutical industry and research and development activity and have also traditionally been considered to comprise a range of higher- and lower-priced countries.

***Average Annual Rate of Change in Patented Drug Prices, 1996-2001***



Source: PMPRB

With the exception of the US, these countries have experienced small increases or even declines in the prices of patented drugs over the last five years.

The trend in Canada appears to be in the mid-range of the European countries. From 1996 to 2001, the average annual increase in prices in Canada was 0.1% compared to 1.4% in Italy and an average decline of 0.7% in the UK. During the same period, annual price increases in the US averaged 5%.

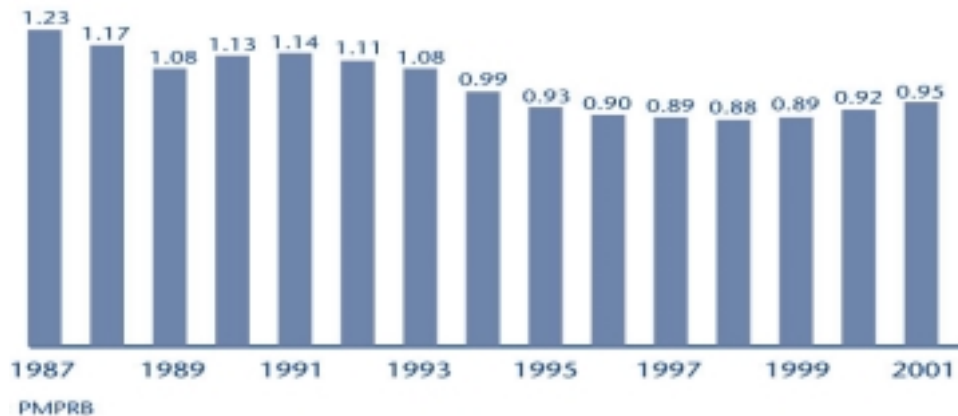
Recall that I am referring here to changes from year to year in prices of the same drugs and not to the overall increase in total drug expenditures.

In summary, all of the countries that have publicly-funded health care systems – in other words, all developed countries except the US – appear to have been able to control the rate of inflation in the prices of existing drugs and to limit the prices of new drugs.

## **Comparing Drug Prices in Canada and Other Countries**

Measures of price change do not tell the entire story. It is also important to know how the level of prices compares from one country to another. In the case of the PMPRB's mandate to determine if the price of a patented medicine is excessive, the *Patent Act* requires that we take into account the prices of the same drug in other countries.

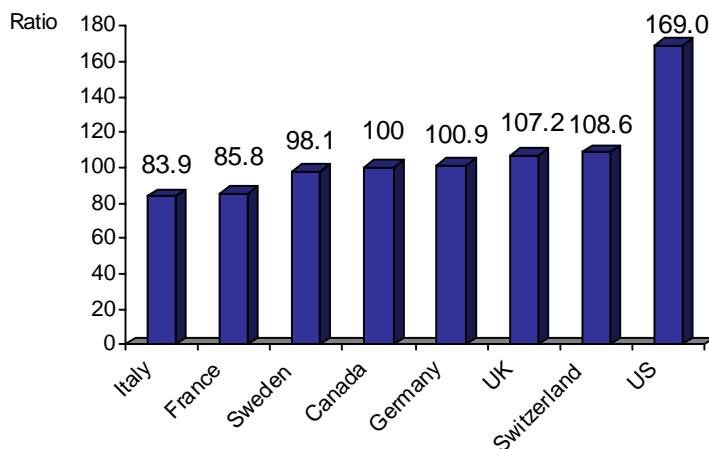
### ***Ratio of Canadian Prices of Patented Drugs to Median International Prices, 1987-2001***



As shown in this graph, Canadian prices for patented drugs on average declined from a level 23% above the median of foreign prices in 1987 to fall below the median as of 1994. Canadian prices have remained below the median prices since then. Last year, prices here were 5% below the median for the same group of drugs.

When we do a country by country comparison, we see a similar trend.

### **Average Foreign to Canadian Price Ratios, Patented Drug Products, 2001**



Source: PMPRB

In 1987, prices for patented drugs in Canada were second-highest in the basket of seven countries that we compare ourselves to, but our prices have declined relative to the other countries since then.

Last year, Canadian prices for patented drugs were well below prices in the US and put us in the mid-range of the European countries. As shown in this graph, Canadian prices on average were below those in Switzerland, the UK and Germany but higher than in Sweden, France and Italy. The differences between the highest and lowest priced countries in this group are not as significant as the difference between this group and the United States which continues to have the highest prices overall.

I would like to come back to the issue of American drug prices in a few minutes, but let me note a methodological point. Comparing drug prices is always a difficult task but it becomes even more difficult when we include the United States. Unlike the other countries that have universal health care and publicly-funded drug plans, there are no public formularies that effectively set national prices in the US and there is considerable price differentiation between different customers. The variation in prices and the lack of transparency makes it more difficult to calculate a US price for comparison purposes. For our price review purposes at the PMPRB, and following an extensive public consultation with stakeholders, we apply a methodology to calculate a US price for comparison purposes that represents a simple average of the publicly-available prices for the drug reported by the manufacturer and the price listed on the Federal Supply Schedule. The FSS lists the prices available to the US federal government and agencies.

The foreign price trends I have reported today are generally in line with other studies. For example, last year the Australian Productivity Commission published a study comparing prices for drugs in Australia and a number of OECD countries including Canada and the US.

In general, that study reported similar trends in terms of comparisons for brand-name drugs; Canadian prices tend to be in the mid-range of the European countries in our basket and well below those in the US.

The Australian study also concluded that Canadian prices for drugs are considerably higher than prices in Australia but that the biggest differences are for generic drugs and to a lesser extent, for brand-name “me-too” drugs. According to the study, the prices of “innovative” drugs in Australia appear to be more in line with the prices in Canada and our European basket.

### **Patented vs. Non-patented Drugs**

Another message I try to communicate to our stakeholders is the difference between patented and non-patented drugs. By definition, the difference is straight-forward: A patented drug is one to which a Canadian patent pertains. Most new drugs are protected by patent and fall into this category, but not all do. Unfortunately, the question of whether a patent pertains to a medicine is one of the issues that creates a field day for the lawyers hired by drug companies and it has been known to drag out our cases. The law however is very clear that a drug falls under our jurisdiction if there is even the slightest thread of a connection between a patent and the drug and the PMPRB has been consistent and vigorous in defending that interpretation.

Another aspect to this question comes as a surprise to some observers: Not all non-patented drugs have generic alternatives; some of these non-patented drugs are single source and escape both the discipline of market competition and the oversight of the PMPRB.

F/P/T governments have asked us to compare the prices of these non-patented single-source drugs in Canada with other countries. What we have found is that, on average, they are higher in Canada than in all other countries except the US. In fact, in 1999, the prices in Canada for these drugs were estimated to be 28% higher than the median of prices in the countries we use for comparison purposes; in contrast, the prices of patented drugs were 5% below the median foreign price last year.

### **Developments in the US**

Governments throughout the world have found it necessary to intervene in the pharmaceutical market for many reasons. These interventions recognize that consumers do not make the choice of whether to use a drug and, if so, which one

- physicians make those decisions - and, because drugs are so important in health care, society believes they should be accessible regardless of an individual's capacity to pay.

Although the pharmaceutical industry often complains about drug price controls, the fact is that direct or indirect price regulation has existed in most developed countries for many years. What is particularly noteworthy today is that we are seeing more pressure on pricing in the US.

As Americans struggle to address the issue of prescription drug coverage for seniors, there appears to be a growing concern about the pricing practices of the pharmaceutical industry in that country. Among other things, many states have developed plans to regulate prices, in particular the prices charged under state programs.

In the Congress, proposals to allow the re-importation of drugs from Canada, to permit what is known in Europe as "parallel trade" in drugs, are again moving through the legislative process.

At the recent BIO 2002 conference in Toronto, US Health and Human Services Secretary Thompson warned the pharmaceutical industry that it should exercise more voluntary restraint in pricing or face greater pressure for government intervention in the US.

These pressures in the US arise, in part, because of increased awareness of the disparity in drug prices between the US and other countries, including Canada. Although we can take some comfort in knowing that our approaches have resulted in drug prices in line with most of our trading partners, we must recognize that the disparity with the US continues and may even be growing.

The pressures on drug pricing in the US coincide with other challenges to the pharmaceutical industry. The expected loss of market exclusivity on blockbuster drugs as patents expire and the absence of new blockbusters have encouraged manufacturers to seek ways of extending market exclusivity and to increase sales for existing drugs. The growth in direct-to-consumer advertising in the US, for example, has been well-documented.

In 2001, the US represented 42% of the world market for pharmaceuticals, or approximately 20 times the Canadian market. If pharmaceutical manufacturers are concerned about the possible re-importation of drugs from Canada, they are probably even more concerned about the possible importation of policies and ideas that might limit their current flexibility in pricing and marketing their products in the US.

These concerns may well result in efforts to put upward pressure on prices in Canada and efforts to open the doors for increased promotion of drugs.

Left unchecked, these actions may cause even greater increases in drug expenditures and put more pressure on private and public drug plans.

Canadian consumers and policymakers must continue to be vigilant in such an environment.

### **Conclusion**

I have covered a lot of ground in a short time, so let me attempt to summarize the key points:

- Countries that have publicly-funded health care systems have lower and more stable drug prices.
- Prices for patented drugs in Canada have consistently been in the mid-range of prices in major European countries since the mid-1990s.
- On the other hand, prices for non-patented single source drugs are higher.
- Overall, drug prices are lower in Australia. The gap between prices in Canada and Australia appears to be much wider for generic drugs and so-called “me-too” drugs than for “innovative” drugs.
- The higher price of drugs in the US is a factor in the debates in the US on how to improve drug coverage for seniors. We should expect to see increased pressure to narrow that gap.
- In spite of efforts at limiting prices, expenditures on drugs continue to increase at significant rates due to increased utilization and use of newer and more costly drugs.