Patented
Medicine Prices
Review Board

PMPRB Notice and Comment

March 2005

The Patented Medicine Prices Review Board is a quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

# Price Increases for Patented Medicines: Discussion Paper

## Executive Summary

Established in 1987 through amendments to the *Patent Act* (the *Act*), the Patented Medicine Prices Review Board (PMPRB) reviews manufacturers' prices of patented medicines sold in Canada to ensure that they are not excessive. Since the introduction of price controls, price inflation of patented medicines has been reduced significantly and average prices of patented medicines sold in Canada are now in line with other comparable countries.

During 2004, the PMPRB had been advised that manufacturers of a significant number of patented medicines had informed customers of proposed price increases. While price increases in line with changes to the Consumer Price Index (CPI) are permitted under the *Excessive Price Guidelines* (the Guidelines), the PMPRB is concerned that it may be seeing the beginning of a change in patented medicine prices.

The recent reports of price increases raise the question of whether Canada is on the verge of experiencing a major shift in pricing, bringing the past decade of price stability to an end. Currently, pharmaceutical costs are taking up increasingly larger chunks of Canada's health care budgets at a time that, as in most of the world, Canada's federal, provincial and territorial governments are looking for ways to ensure continued access to pharmaceutical products. However, at the same time as these proposed increases are occurring in Canada, other countries are placing further controls on pharmaceutical prices for their citizens.

In response to these reports of price increases, the PMPRB is initiating a dialogue with stakeholders, beginning with this Discussion Paper. This paper explores the evolution of the Guideline for price increases of patented medicines, historical price trends and the observations that suggest that we may be seeing the first signs of a change in patented medicine pricing stability in Canada. The PMPRB is not making specific proposals regarding price increases. Instead it is looking to engage stakeholders in a discussion of the issue. We are asking the questions in the context of our mandate under the *Act* to ensure that prices of patented medicines in Canada are not excessive.

## 1.0 Introduction

The Patented Medicine Prices Review Board (PMPRB) was established in 1987 through amendments to the *Patent Act* (the *Act*). Its mandate is two-fold: to ensure that the prices of patented medicines sold in Canada are not excessive, and to contribute to informed decisions and policy making by reporting on pharmaceutical trends and the R&D spending of pharmaceutical patentees.

The PMPRB is a quasi-judicial tribunal that carries out its mandate independently of other bodies such as Health Canada, which approves drugs for safety and efficacy, and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.

The *Patent Act* lists factors for the PMPRB to consider in determining whether the prices of patented medicines are excessive. For the purpose of promoting voluntary compliance with the *Act*, the PMPRB has developed the *Excessive Price Guidelines* (the Guidelines). The Guidelines are based on the factors in the *Act* and were developed in consultation with stakeholders, including consumer groups, provincial ministries of health and the pharmaceutical industry.

The PMPRB periodically reviews and amends the Guidelines as required to ensure that they continue to be effective and responsive to changes in the environment. As per the *Patent Act*, any changes to the Guidelines are made in consultation with stakeholders. The last major amendments to the Guidelines were made in 1994.

Last fall, the PMPRB announced that it would review its Guidelines in regard to price increases.[1] During 2004, the PMPRB had been advised that manufacturers of a significant number of patented medicines had informed customers of price increases. While price increases in line with changes to the Consumer Price Index (CPI) are permitted under the current Guidelines, the PMPRB is concerned that it may be seeing the beginning of a change in the price stability of patented medicines in Canada that has been in place over the last decade.

In response, the PMPRB is initiating a dialogue with stakeholders, beginning with this Discussion Paper. This paper explores the evolution of the Guidelines for price increases of patented medicines, historical price trends and the observations that suggest that we may be seeing the first signs of a change in patented medicine pricing stability in Canada.[2] The PMPRB is not making specific proposals at this time, but is seeking input from stakeholders on this issue. The PMPRB has chosen to consider these questions now as part of our mandate under the *Act* to ensure that prices of patented medicines in Canada are not excessive.

In a separate initiative, as part of a larger amendment package that was published in the January 2005 NEWSletter, the PMPRB is engaged in a consultation process on changes to the *Patented Medicines Regulations, 1994* (the *Regulations*) which set out patentee's filing requirements. One proposed amendment would require that patentees notify the PMPRB of planned price increases in advance of their implementation. It is required to ensure that the PMPRB has sufficient information to determine if specific price increases are within the Guidelines. By receiving the information in advance, the PMPRB will be in the position to notify patentees sooner of any potential pricing issues, with administrative benefits for both. It should be noted that the proposed amendment does not call for prior approval of a price increase, but rather seeks to ensure that the PMPRB has sufficient information between reporting periods on the

1 See *The Future of Price Controls – Maintaining the Balance*, by Dr. Robert G. Elgie, PMPRB Chairperson in a speech to PHARMAC 2004, available at **http://www.pmprb-cepmb.gc.ca/english/View.asp?x=373&mp=122**.

2 Detailed background information on the federal regulation of patented medicine prices and the PMPRB's Guidelines can be found on the PMPRB's website as an appendix to this document, under Publications; Notice and Comment; Price Increases for Patented Medicines.

state of prices. The consultation on changes to the *Regulations* is a separate process and independent of the purpose of this discussion paper. For further information concerning this proposed regulatory amendment, along with other proposed changes, please refer to the PMPRB, *Notice and Comment*, January 2005.[3]

## 2.0 Background

Established as an integral part of the 1987 amendments to the *Patent Act*, the PMPRB was given the mandate of regulating the prices of patented medicines sold in Canada and ensuring that prices are not excessive. The *Patent Act* identifies factors for the Board to consider in determining whether the price of a patented medicine is excessive. While designating the factors to be considered, the *Act* gives the PMPRB significant latitude to determine how these factors will be applied.

The factors in the *Act* have been operationalized in the PMPRB's Guidelines to provide clear and simple criteria for pricing, on the part of manufacturers, and for reviewing prices, on the part of the PMPRB.[4]

### Excessive Price Factors in the *Patent Act*

The *Patent Act* lists factors for the PMPRB to consider in determining whether the price of a patented medicine is excessive.

85. (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(a) the prices at which the medicine has been sold in the relevant market;

(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.

3 Copy of *Notice and Comment*, January 2005 is available on the PMPRB website under Publications. http://www.pmprb-cepmb.gc.ca/CMFiles/jan05notice-e15OAH-272005-2828.pdf

4 The Guidelines can be found in the PMPRB´s Compendium of Guidelines, Policies and Procedures (Compendium) and are available on the website http://www.pmprb-cepmb.gc.ca/english/View.asp?x=150&mp=135.

## 2.1 Excessive Price Guidelines

The PMPRB reviews the pricing information for all patented medicines sold in Canada on an ongoing basis to ensure that the prices charged by patentees are within the Guidelines. The Guidelines limit the prices of patented medicines as follows:

- prices for most new patented medicines are limited such that the cost of therapy for the new medicine does not exceed the highest cost of therapy for existing medicines used to treat the same disease in Canada;
- prices of breakthrough patented medicines and those which bring a substantial improvement are generally limited to the median of the prices charged for the same medicine in other industrialized countries listed in the *Regulations* (France, Germany, Italy, Sweden, Switzerland, U.K. and U.S.);
- price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI); and
- the price of a patented medicine in Canada may at no time exceed the highest price for the same medicine in the comparator countries listed in the Regulations.

## 2.2 Evolution of the Guidelines for Price Increases

The inclusion of changes in the CPI in the pharmaceutical pricing provisions of the *Patent Act* as a factor for consideration by the PMPRB must be viewed in the context of the era in which the amendments were drafted. At the time in 1984, when legislators had begun studying possible changes to the existing *Patent Act*, the country was just coming out of an era of high inflation both for prices in general and patented medicines in particular. After a long period of extensive study and deliberation, beginning with the establishment of a Commission of Inquiry on the Pharmaceutical Industry in Canada (the Eastman Commission), concerns were raised that pharmaceutical prices were continuing to grow at an amount higher than what they would have had they been restricted to changes in CPI.[5] By 1987, legislators arrived at a policy that struck a balance between needed changes to pharmaceutical patent policy and the interests of on-going consumer protection.

The Guidelines, developed to operationalize the new pharmaceutical provisions of the *Act*, sought to develop a methodology for applying the CPI factor that was both easy to implement and understand, and that balanced the interests of all parties. The resulting CPI Guidelines allowed patentees to take annual price increases to the full extent of changes in the CPI, which at the time were still considerable, while protecting Canadians from any potential excessive price increases that may have resulted from extended patent protection for manufacturers. To facilitate compliance, the PMPRB developed a transparent process, based on a standardized methodology and annually published the CPI forecast for the up-coming year, that would assist manufacturers in planning their pricing strategies for the up-coming year.

By 1992, the environment had changed. The rate of inflation had begun to decline. Faced with new concerns related to the Canadian prices of patented medicines in comparison to world prices and a realization that the initial CPI Guideline may result in large price increases, accumulated over time, being applied in a single year, the PMPRB moved to amend the Guidelines. It was out of the extensive consultations that took place in 1992-93 that the current CPI Guidelines were developed: price increases were limited to the cumulative change in the CPI over three years, and any price increase in a given year could not exceed 1.5 times the forecast change in the actual CPI. At that time, changes were also made to various aspects of the international price comparison Guidelines.

5 Harvie André, Opening Remarks to the Legislative Committee on Bill C-22, December 16, 1986.

# CPI-Adjustment Methodology

## 1. The Guideline

1.1 The price of an existing drug product during the year under review will be presumed to be excessive if it exceeds the benchmark price of the DIN adjusted for the cumulative change in the Consumer Price Index (CPI) from the benchmark year to the year under review (CPI-adjusted price).

1.2 In addition, one year price increases may not exceed 1.5 times the forecast change in the annual CPI.

1.3 In periods of high inflation (over 10%), the limit will be five percentage points more than the forecast change in the annual CPI.

## 2. Terminology

2.1 Forecast Period: The forecast period is the year for which prices are being set.

2.2 Benchmark year:

a. For patented drug products first marketed in Canada more than three years prior to the forecast period, the benchmark year is the calendar year three years proceeding the forecast period. For example, for 1999, the corresponding benchmark year is 1996.

b. For patented drug products first marketed three years or less prior to the forecast period, the benchmark year is the year in which the drug product was introduced in Canada.

### *2.3 CPI in Federal Statutes*

The use of the CPI as a statutory factor for consideration in federal programs is not unique to the pharmaceutical pricing provisions of the *Patent Act*. The Government of Canada has used the CPI in a number of areas as a way to index, escalate or adjust money values of certain benefits or expenditures made by its departments and agencies. The most well known application of CPI is found in pension legislation (e.g. *Old Age Security Act*) as a way of ensuring that benefits stay in line with changes in inflation. In addition to its use in the *Patent Act*, CPI has been used in such measures as to ensure that insurance guarantees remain in line with inflation or to set limits on election contributions. The use of an amount less than the full year-over-year change in CPI has been used in a few cases to limit the growth of expenditures. For example in the *Parliament of Canada Act*, sessional allowances paid out to Members of Parliament are indexed at an amount of one percent less than the lesser of either the CPI or the Industrial Aggregate.[6]

While Federal Statutes usually set out in detail how the CPI, or some portion of it, will be applied, the *Patent Act* differs in that it only provides in general terms that the Board shall consider changes in the CPI in the process of determining if the price of a patented medicine is excessive. It is up to the discretion of the PMPRB to determine in a particular case and for the purpose of its Guidelines, the precise manner in which changes in CPI should be considered and the weight to put on that factor.

6 The Industrial Aggregate, published by Statistics Canada, measures the average weekly wages and salaries in Canada

Despite the fact that the PMPRB's Guidelines have always allowed price increases in line with full annual increases in the CPI, the *Act* makes no such provision. In a speech to the Legislative Committee considering Bill C-22 in 1986, the then Minister of Consumer and Corporate Affairs, Harvie Andre, stated that:

> *"using the CPI does not mean that medicine prices can be raised by CPI each and every year. The Board has the power to demand an explanation of every increase and will not automatically accept an increase equal to the CPI"* [7]

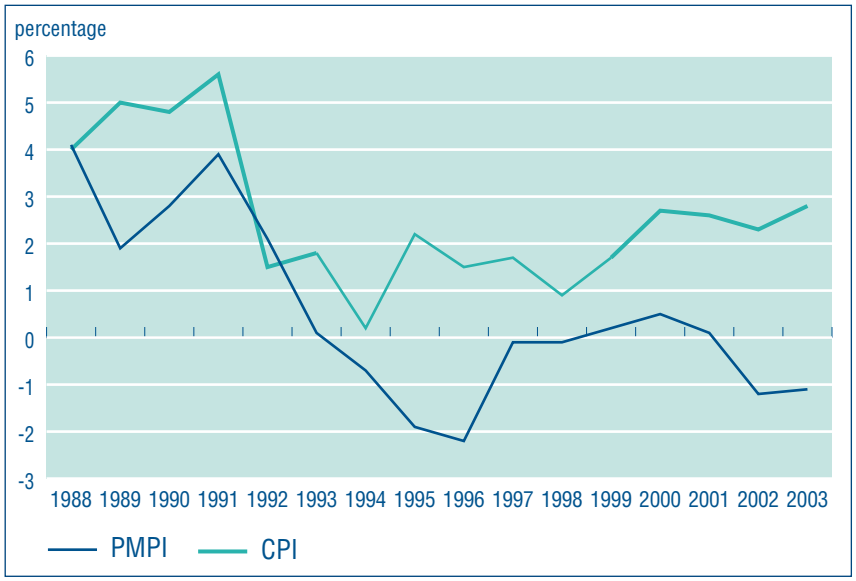
From the beginning, the policy of limiting the maximum price increase for existing patented medicine products to changes in the CPI has effectively brought price inflation in the market under control. In fact, the implementation of the PMPRB's Guidelines, as they currently stand, has contributed to a trend in which the average increase has remained below the index. The transformation of the pricing trend for patented medicines is even more remarkable after 1994. That year, changes were made to the Guidelines both with respect to price increases and international price comparisons. The combined effect of these changes, in conjunction with cost containment policies of the provincial drug plans, introduced around the same time, have resulted in more than a decade of price stability for patented medicines in Canada.

## 3.0 Price Stability in The Last Decade

Since the creation of the PMPRB, manufacturers' price increases for patented medicines, on average, have been below changes in the CPI. Apart from federal price regulations, cost containment policies adopted by provincial and territorial drug programs that include mandatory generic substitution, limits on the products to be reimbursed, reference based pricing and price freezes, to name a few, also have had a significant impact on overall drug prices in Canada in the last decade.

The PMPRB maintains the Patented Medicines Price Index (PMPI) that measures average year-over-year changes in manufacturers' prices of patented medicines in Canada.[8] Figure 1 shows that CPI-inflation has exceeded increases in patented medicine prices, as measured by the PMPI, in almost every year since 1988.

### Figure 1 Year-over-Year Changes in the PMPI and CPI, 1988-2003




Source: PMPRB

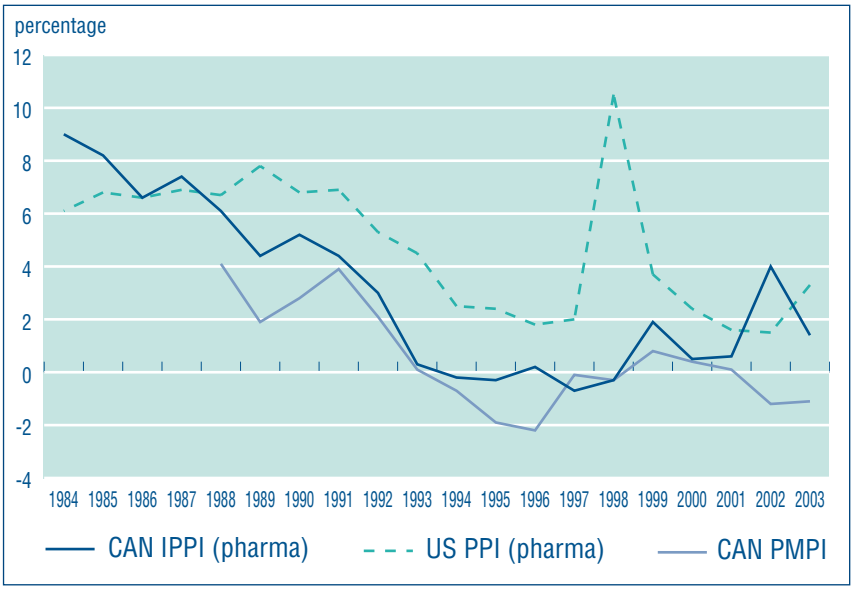
7 Harvie Andre, "Notes for opening remarks to Legislative Committee on Bill C-22" December 16, 1986.

8 The PMPI measures the overall change in prices of existing patented drug products. See the PMPRB's *A Description of the Laspeyres Methodology Used to Construct the Patented Medicine Price Index (PMPI)*, March 1997, revised June 2000, for a detailed explanation of the PMPI.

That increases in the PMPI have been consistently less than CPI-inflation is not surprising. This outcome reflects a component of the PMPRB's Guidelines that requires price increases over any three-year period to be not greater than CPI-inflation. This requirement, applied to patented medicines on a product-by-product basis, has the effect of establishing CPI-inflation as an upper bound on PMPI growth over any period of three years or more.[9]

From 1987, the PMPRB's regulatory activities have contributed to bringing price inflation for patented medicines under control. Comparing the year-over-year change in the pharmaceutical component of the Canadian Industrial Product Price Index [IPPI (Pharma)] with the U.S. Product Price Index [U.S. PPI(Pharma)] in Figure 2, one sees that, before 1987, the growth of pharmaceutical prices in Canada as indicated by the IPPI (Pharma) was consistently greater than in the US.[10] Since 1987 (with the exception of 2002), changes in the IPPI (Pharma) and the PMPI have consistently been below the U.S. PPI (Pharma).

## Figure 2 Year-over-Year Changes in Pharmaceutical Price Indices, Canada and the U.S.




Source: PMPRB; Statistics Canada; U.S. Bureau of Labor Statistics

Figure 3 shows the relationship between Canadian prices and the corresponding median price among the seven comparator countries listed in the *Patented Medicines Regulations* over the period 1987 to 2003.[11]

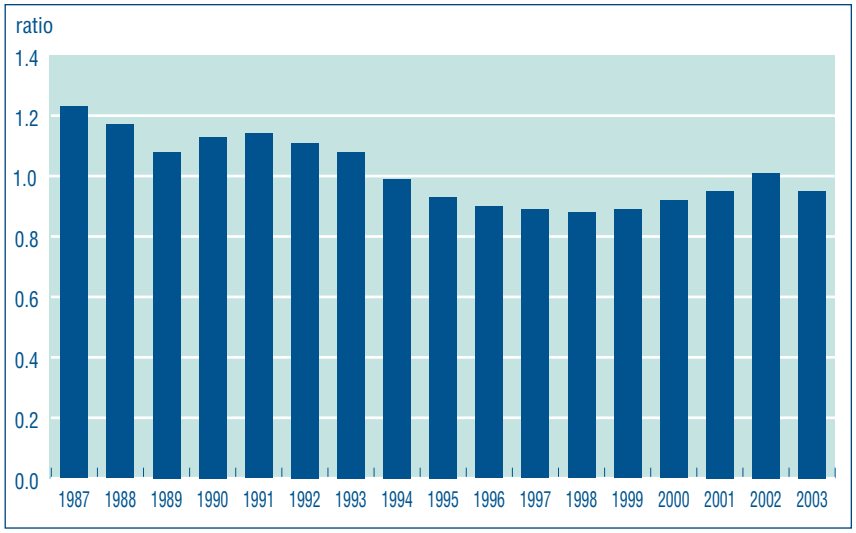
Canadian prices were on average 23% higher than the median international prices in 1987. This ratio declined and Canadian prices remained relatively stable at levels 5% to 12% below the median from 1994 to 2003, with the exception of 2002 when Canadian prices, on average, were 1% above the median.

9 The PMPRB's Guidelines also impose a cap on year-over-year price increases equal to one-and –one-half times the rate of CPI-inflation for the year in question.

10 The Canadian IPPI and the American PPI contain the prices received by producers for their goods and services. In the case of the pharmaceutical industry these indices include both patented and non-patented drugs as well as products destined for export and domestic consumption.

11 The seven countries are: France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.

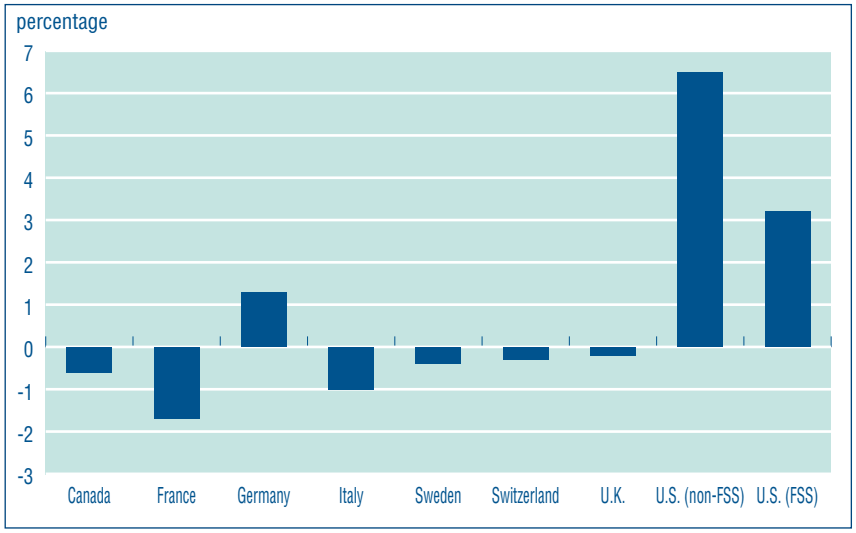
## Figure 3 Ratio of Canadian Prices of Patented Drugs to Median International Prices, 1987-2003




Source: PMPRB

Figure 4 shows the average annual rates of change in prices for patented medicines for Canada and each of the seven comparator countries. With the notable exception of the US, all countries had stability in overall patented medicine prices over the period 1988 to 2003. For 1998-2003 the average change in Canadian patented medicine prices falls squarely within the range observed in the comparator countries, except the US.

## Figure 4 Average Annual Percent Change,Patented drug Prices: 1998-2003




Source: PMPRB

## 4.0 Current Environment

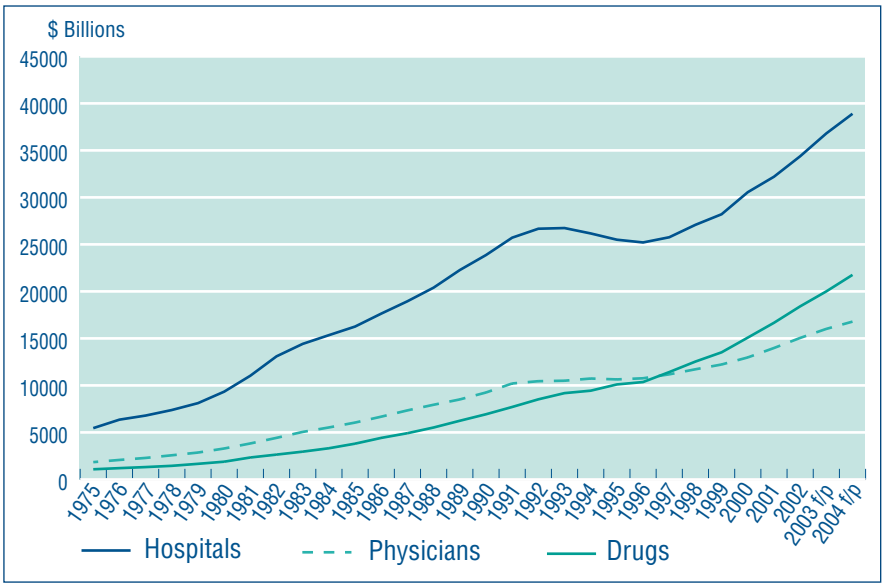
Over the past decade then, Canada has been able to achieve a level of price stability, due in large part to efforts of the PMPRB, and the cost-containment strategies of the provinces and territories. This fact, however, has not eliminated the challenges faced by all levels of government to ensure that Canadians have access to important medical treatments at a price that will not cause undue hardship. Currently the federal government is working with its provincial and territorial partners to develop a strategy to guarantee that the Canadian health care system remains sustainable. This is the same challenge faced by governments world-wide as they attempt to find a balance between increased pressure on health care budgets and the need to protect the interests of their citizens. Given the relative success of our comparator countries in limiting, or even reversing, the escalation in pharmaceutical prices, the PMPRB is concerned that, should reported price increases materialize, the close relationship of average Canadian prices relative to the international median may change.

### *4.1 Increases in Pharmaceutical Expenditures*

Despite the moderating influence of prices, total retail spending on drugs by Canadians has grown rapidly in recent years. According to the Canadian Institute for Health Information (CIHI), retail spending grew by 10.5% in 2002 to $18.4 billion. CIHI forecasts a growth of 8.7% in 2003 to $19.6 billion and 8.8% in 2004 to $21.7 billion.

As shown in Figure 5, drug expenditures overall have surpassed physician spending since 1997. In recent years drug spending has been the fastest growing component of total health care spending creating pressures on the entire health care system and generating concerns about its sustainability.

### Figure 5 Total Health Expenditure, Selected Uses of Funds, Canada, 1975 to 2004



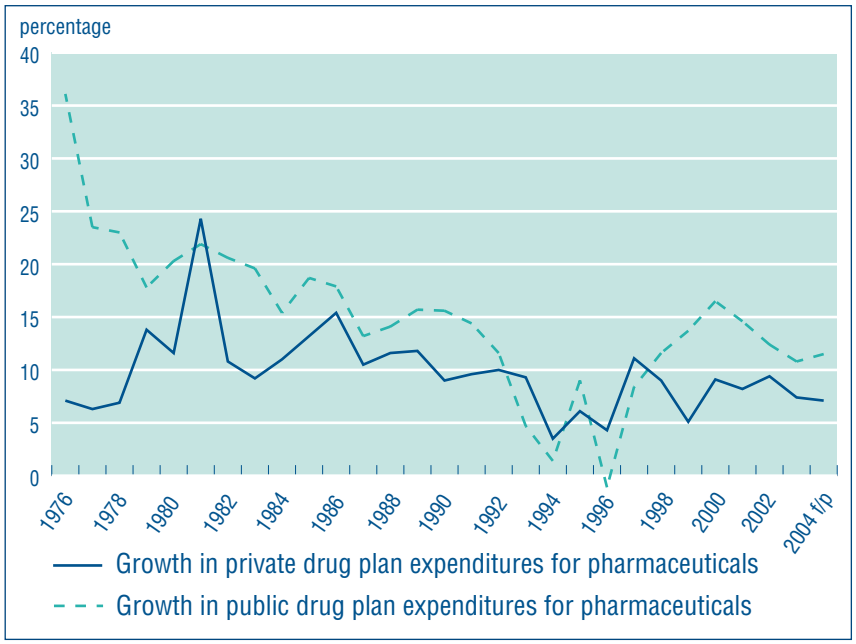

Source: CIHI, National Health Expenditure Trends 1975-2004

Studies conducted by the PMPRB on behalf of the F/P/T Ministers of Health, demonstrated that increases in drug expenditures can largely be attributed to increases in the rate of utilization of existing drugs and the reimbursement of newer, often higher-cost drugs.[12] Other factors such as an aging society, changes in treatment regimes and increased public expectations have also contributed to the increased role of pharmaceutical products in Canada and many health care systems.

12 *Provincial Drug Plans Overview Report: Pharmaceutical Trends 1995/96* – 1999/00; F/P/T Working Group on Drug Prices; 2003

This rate of growth in overall drug spending in Canada is being felt acutely by both public and private sectors. Public drug plans, in particular, have experienced double-digit growth in expenditures in recent years. As illustrated in Figure 6, public sector pharmaceutical expenditures grew 12.4%, and private sector expenditures grew by 9.4% in 2002. Forecasts for 2004 suggest additional public sector growth at a rate of 11.5%, and private sector by 7.1%.

## Figure 6 Growth in Public and Private Drug Plan Expenditures for Pharmaceuticals




Source: CIHI, National Health Expenditure Trends 1975-2004

### *4.2 F/P/T Collaboration and Pharmaceuticals Management*

The importance of pharmaceuticals in the health care system continues to be validated in the collaborative efforts on the part of all levels of government in pharmaceuticals management. A number of important collaborative initiatives have been implemented by the federal, provincial and territorial governments in recent years. These include: the Common Drug Review (CDR), which reviews and makes recommendations on the listing of new chemical entities for reimbursement by participating drug plans; the National Prescription Drug Utilization Information System (NPDUIS), which will increase analytical capacity on drug cost, utilization and other trends; and the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), which identifies and shares best practices in pharmaceutical prescribing.

In addition to these existing collaborative initiatives, in September 2004, Canada's First Ministers announced their commitment to develop a National Pharmaceuticals Strategy (NPS) as part of a 10 year plan to strengthen health care. In agreeing to the NPS, First Ministers confirmed their commitment to the principle that "no Canadians should suffer undue financial hardship in accessing needed drug therapies. Affordable access to drugs is fundamental to equitable health outcomes for all our citizens."[13] An F/P/T Ministerial Task Force has been established to lead the development and implementation of the NPS and report progress by June 30, 2006. The agenda is an important one, particularly in an era when evidence shows that pharmaceutical utilization is a major cost driver in the health care system. As such, it is more important than ever to review policies governing price increases, to ensure that they continue to be appropriate and relevant to the current environment.

13 *A 10 Year Plan to Strengthen Health Care*, First Ministers Meeting September 13-16, 2004 communiqué, available at: http://www.scics.gc.ca/cinfo04/800042005_e.pdf .

## 4.3 Signs of Change in Price Stability

At the same time as we are seeing an increased importance being placed on ensuring affordable access to important pharmaceutical treatments, the PMPRB has become aware of a number of recent events that suggest price stability could be under some strain. These events include:

- It has come to the Board's attention that manufacturers of approximately 35% of the patented medicine products under its jurisdiction have informed the trade of price increases in 2004. This has resulted in a number of inquiries about whether these price increases are within the Guidelines;
- The PMPRB has also received reports of price increases for some non-patented drugs. In some cases the price increase was much higher than the CPI. Reports regarding non-patented drug price increases have been forwarded to Health Canada as they are looking into non-patented drug pricing in Canada for consideration in the work related to the NPS;
- Reports from media, usually linked to cross-border sales into the U.S., have raised considerable public concern and speculation over the possibility of drug shortages in Canada and price hikes to a level at par with the U.S.;
- As a result of an unprecedented number of requests for price increases that were not consistent with its policies, Quebec delayed the issue of a new formulary over the past year, releasing a new formulary only recently, on February 9, 2005. Also recently, Quebec's Minister of Health, Philippe Couillard, released a discussion paper that recommends changes that would allow price increases, but entrench limits on the extent of any increases. Prices would be locked in for the first five years that a drug is listed on the provincial formulary after which the average price increase across all the products in a manufacturer's line would be limited to a maximum rate defined as the increase in the provincial CPI minus half of a percentage point. Further, any increase for an individual product would be limited to no more than 1.5 times the defined maximum rate.[14]

Given these reports, are we seeing signs that the price stability of the past decade is starting to weaken?

## 4.4 Proposed Amendments in the Current Regulatory Framework

The above reports have been particularly difficult to deal with because there is no requirement in either the *Act* or the *Regulations* for manufacturers to notify the PMPRB in advance of price increases. Currently patentees file sales and price information with the PMPRB every six months following the introduction in Canada of a new patented medicine. As a result, the PMPRB learns about price increases after the fact. Between each of the six-month reporting periods then, the PMPRB must rely on external reports, such as media, trade notices and communications with stakeholders for information on any potential price increases. Such information is generally insufficient to accurately determine if the price increase would be within the Guidelines, particularly when information comes from sources other than manufacturers.

As noted earlier, the PMPRB has embarked upon a series of Regulatory Amendments, aimed at supporting a more efficient and timely price review process, including provisions that would require notification of a proposed price increase in advance of its application. It should be noted that this proposed amendment does not call for prior approval of a price increase, but rather seeks to ensure that the PMPRB has sufficient information between reporting periods on the state of prices.

14 For precision on how this factor will be applied see the Pharmaceutical Policy Consultation Paper available on the Santé et Services Sociaux Quebec website. http://ftp.msss.gouv.qc.ca/publications/acrobat/f/documentation/2004/04-708-04A.pdf

After a decade of price stability, any reported increase, even those within the Guidelines, raises questions. Why now? What has changed to justify these increases? Does this signal the onset of a new reality of price inflation? In its consumer protection role, the PMPRB has the obligation to monitor these developments and be prepared to act.

## *4.5 Looking Beyond Canada: International Policies towards Pharmaceutical Price Increases*

Under the current Guidelines, manufacturers are allowed an automatic entitlement to increase prices every year in accordance with the PMPRB's Guidelines for price increases. Given the importance the PMPRB places on ensuring that on average Canadian patented medicine prices remain in line with the median of international prices, it would be useful to look at how the other countries, used for price comparison purposes, are addressing this issue.

Canada is not alone in its interest in controlling drug price increases. Governments in other countries have taken steps to limit, either directly or indirectly, the extent that manufacturers can increase pharmaceutical prices. With the exception of the United States, where there is no control over price inflation for the general public, all the remaining comparator countries (the six European countries) used by the PMPRB have shown some success in achieving price stability (refer to Figure 4, p.8.)

As in Canada, all of these countries have concerns about the impact of growing health care spending on national budgets. According to the OECD, the higher cost of drugs has resulted in pharmaceutical spending taking on an increasing share of overall health care budgets in most member countries. In the ten years between 1992 and 2002, the per capita expenditure on pharmaceuticals in the OECD increased about 87%, at a rate 1.3 times faster than total health care expenditures.[15]

Many countries, including those that are currently being used by the PMPRB as comparator countries, have taken steps to strengthen their cost-containment efforts. In some cases these efforts have gone further than to limit price increases, and in fact resulted in price roll backs. For example, in 2004, the Italian medicines agency made changes to its reimbursement list, which would see price cuts to almost 300 of the country's highest selling products.

In November 2004, the UK announced changes to the country's Pharmaceutical Price Regulation Scheme following negotiations with its pharmaceutical industry. Under the new scheme, effective for five years starting January 1, 2005, manufacturers with sales to the National Health Service (NHS) in excess of £1 million are required to lower the price of their products by 7% across the board (a previous five year agreement negotiated in 1999 saw prices rolled back by 4.5%). In addition, no price increases will be permitted for a period of 12 months until December 31, 2005, except in cases in which a corresponding price decrease in another product offsets the increased costs to the NHS.

Given the regulatory changes currently taking place internationally to control health care budgets, some of which target pharmaceutical prices, how would a period of price inflation in Canada, after years of stability, affect its place in relation to our comparator countries? Some of the amendments made to the Guidelines in 1994 were part of an attempt to bring Canadian prices in line with international price trends. Will Canada be returning to a period in which its prices exceed the median international price?

15 Organization for Economic Cooperation and Development, *OECD Health Data 2004* (Paris: OECD, 2004).

## 5.0 Questions for Stakeholders to Consider

While the combination of federal and provincial restraints on drug prices have resulted in stability over the last decade or so, the reports of price increases last year that have come to the PMPRB's attention raise concerns that perhaps we might be seeing the first signs of a change. Assuming that recent trends of manufacturers increasing prices for existing medicines continues, is there the potential that consumers in Canada will be adversely affected if the PMPRB does not take immediate action? Or, is a 'watchful waiting' position warranted instead to allow time to further study reports of price increases?

At this time, the PMPRB has no set positions or proposals for changes to the Guidelines with respect to price increases. As we continue to study and monitor these reports of price increases, it is important to hear from stakeholders what their views are on these issues.

In preparing a response to the following questions, stakeholders are asked to consider the following three frameworks which highlight the spectrum of different hypothetical regulatory systems.

### *Framework 1*

Currently, the Guidelines allow patentees to take an automatic price increase in a given period (i.e. annually) for each product up to a predetermined maximum established by the Guidelines. The PMPRB reviews these price changes only after the fact, requiring a readjustment of the price if found to be excessive.

### *Framework 2*

As in Framework 1, patentees would be allowed to take a price increase in a given period up to a maximum limit established by the Guidelines. However, patentees would be required to apply to the PMPRB in advance, allowing a review of the proposed price increase before it is implemented to ensure that the new price remains within the Guidelines. Patentees would be allowed to implement the price increase only after receiving approval from the PMPRB.

### *Framework 3*

As in Framework 2, patentees would be required to apply to the PMPRB in advance of any price increase. In addition, patentees would be required to provide both a justification for the proposed increase and the extent of that increase. The PMPRB would then make a determination on both the appropriateness of the increase and then on the extent of the increase allowed up to a non-excessive maximum. The criteria that may be used in a patentee's rationale, the methodology used by the PMPRB in making its determination and the maximum limit allowable would be established in the Guidelines.

In considering the above frameworks, stakeholders are asked to consider the following questions with respect to the PMPRB's Guidelines:

1. Should they continue to allow for automatic (i.e. without prior approval) price increases?
2. Are there considerations other than, or in addition to, the CPI that should be used to review price increases?
3. How often should price increases occur? (e.g. every year, once every 3 - 5 years, only after a certain introductory period, when justified)
4. If justification is required, what criteria should be considered?
5. Given that the CPI is established in the *Patent Act* as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future Guidelines?

## 6.0 Next Steps

Stakeholders are encouraged to consider the above questions and submit comments forwarded to the Secretary of the Board, no later than **May 9, 2005**, at the following address:

Box L40
Standard Life Centre
333 Laurier Avenue West
14th floor
Ottawa, Ontario
K1P 1C1; or
By fax (613) 952-7626; or
By e-mail: sdupont@pmprb-cepmb.gc.ca

In the meantime, the PMPRB will continue to monitor the situation and will report back to stakeholders on the outcome of the submissions later in the year.