I am pleased to offer the following comments and suggestions with respect to the changes proposed by the PMPRB with respect to the CPI Guideline and the reporting requirements under the *Regulations*.

Background

I am the President and Principal Consultant of PDCI Market Access Inc. (PDCI), an Ottawa based pricing and reimbursement consultancy. I worked with the PMPRB in various capacities between 1988 and 1994 and was directly involved in policy development and development of the Excessive Price Guidelines including the original CPI Guideline as well as the changes to the CPI Guideline in 1993 which came into effect in 1994. I also developed the first Patentee's Guide to Reporting in 1988 that outlined the filing requirements under the *Regulations*. Since leaving PMPRB, I have provided advice and consulting services to pharmaceutical manufacturers with respect to the PMPRB Guidelines and the associated legislation, regulations, policies and procedures. In addition, I have been qualified by the Federal Court of Canada in various patent litigation cases as an expert with expertise in market access, reimbursement policies and pricing regimes of the Canadian pharmaceutical marketplace.

Disclaimer

The views expressed below are my own. I have not received input, direction or any financial assistance from any third party with respect to these opinions.

A. CPI Guideline

> *Initiative #1: Eliminate the Use of Forecast CPI and Transition to the use of Actual Lagged CPI as part of the CPI Adjustment Methodology*
>
> *Proposal for Consideration: Maintain current CPI Adjustment Methodology for existing drug products, except replace the use of the forecast CPI with actual CPI in calculating the CPI Adjustment Factor for the forecast period.*[1]

The original CPI Guideline implemented in 1989 allowed manufacturers (referred to as "patentees" by the PMPRB) to increase the price of a patented medicine by the cumulative change in CPI since introduction of the medicine. Under this original CPI Guideline, a manufacturer could take annual CPI increases each year or "bank" any unused CPI for price increases at some later time.

In 1993, the PMPRB conducted consultations on proposed amendments to the Guidelines including the CPI Guideline. The proposed changes were based on the (unfounded) fear that because manufacturers were not taking the maximum CPI allowable each year under the Guidelines, significant price increases would eventually occur as manufacturers would want to make use of the "banked" CPI.

There was no evidence or basis upon which to support this concern, nevertheless, the result in 1994 was an early version of the current three year CPI methodology that includes a one year "cap". Over the years there were changes including how and when the forecast CPI (based on the federal budget) and actual CPI (as reported by Statistics Canada) were factored into the calculations. Although the changes

[1] PMPRB Notice and Comment: http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1747&mp=1746

were typically minor in concept, in practice, they added significantly to the level of complexity of the calculations and created considerable confusion and frustration on the part of manufacturers that couldn't understand why prices appeared to be outside the Guidelines when they believed that they had increased their prices by no more than CPI. Moreover, the current methodology is difficult to communicate clearly and often requires extensive spreadsheet models to take into all the factors necessary to calculate accurately the non-excessive price (to four decimal places) as required by the PMPRB methodology.

Proposed "Lagged" CPI

The Notice and Comment refers to use of a lagged CPI but does provide any information with respect to the lag itself (e.g., 6 months, 12 months). In addition the PMPRB is seeking input from stakeholders regarding transitional measures.

The concept of a lagged CPI is not new and is the basis of price increases in some multi-year contracts for blood products and public health vaccines. These lagged increases are often based on the actual change in CPI in the past calendar year applied to prices as April 1 of the current year (e.g., the 2012 over 2011 increase in CPI applied as of April 1, 2013).

This approach works well for contracts with individual purchasers (e.g., CBS, PWGSC) and for products that are not also funded through provincial drug plans. However, many patented medicines are listed on provincial drug benefit plans and manufacturers must consider both PMPRB and provincial price increase policies. A lagged CPI will most likely not be consistent with provincial price increase policies and the greater the lag the more likely the inconsistency between the PMPRB CPI and the provincial policy. Moreover the lag would need to be at least 9 – 12 months to accommodate the provincial price increase application process (manufacturers must apply in advance for price increases in some provinces). Furthermore, patented hospital products and cancer drugs supplied to cancer agencies may be subject to multi-year contracts with price increase provisions. A lagged CPI may provide some certainty for next year but not beyond.

There is a better, more predictable approach which can apply to all patented medicines and provide predictability to all stakeholders.

The 2% solution

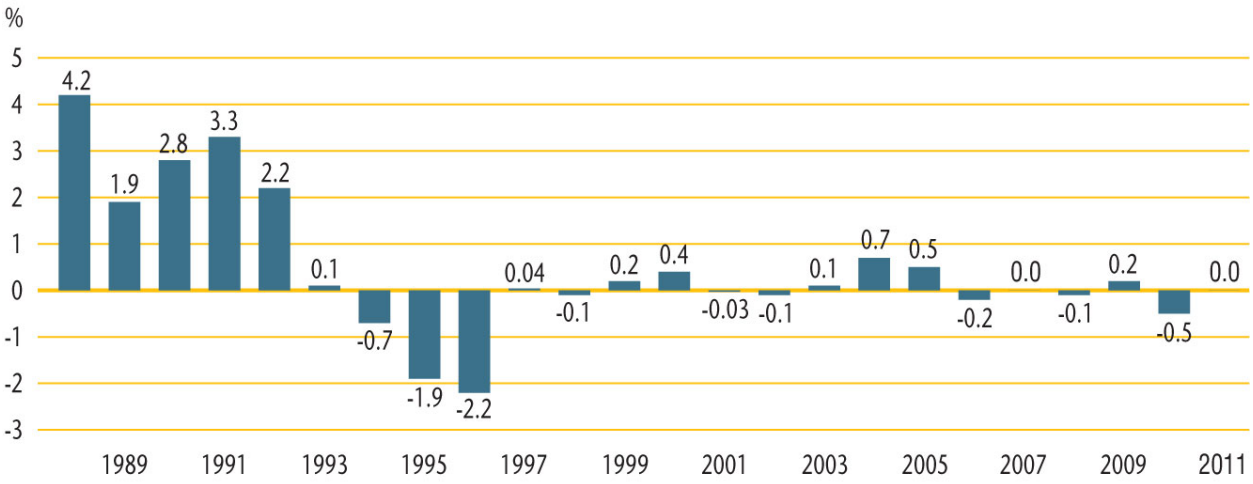
It is proposed that the PMPRB establish a fixed CPI rate of 2% annually (maximum of 6.01% over 3 years, 4.00% over two years) with a fixed "cap" of 3% increase in any one year.

The Federal Government and Bank of Canada have a long established (since 1995) target of maintaining inflation (as measured by CPI) at 2%, the midpoint of the control range of 1% to 3%.[2] The 2% target is consistent with the PMPRB's analysis that over the last 12 years actual CPI has increased by 2.07% (forecast CPI by 2.03%).[3] Moreover, despite CPI averaging 2%, average price increases of patented medicines from 1993 to 2011 have never exceed 1% in any given year and in nine years prices actually decreased on average as outlined in the graph below (extracted from the PMPRB 2011 Annual Report).

[2] Bank of Canada Backgrounder, "Inflation Control Target", http://www.bankofcanada.ca/wp-content/uploads/2010/11/inflation_control_target.pdf

[3] PMPRB Notice and Comment May 2013 http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1747&mp=1746

FIGURE 3 Annual Rates of Price Change, Patented Medicines Price Index (PMPI), 1988–2011



Source: PMPRB

The 2% approach has the advantage of predictability, certainty as well as consistency with federal government policy. More importantly, the 2% approach will greatly simplify the calculations required for applying the CPI methodology and make the CPI Guideline far more accessible and understandable for all. This will help promote compliance by manufacturers, reduce the number of investigations resulting from inadvertent transgressions of the CPI guideline, which in turn should provide efficiencies and cost savings for the PMPRB.

Some stakeholders (payers, consumers) may have concerns that in some years the actual CPI may be less than 2% and manufacturers will take advantage. However, in the 25 years PMPRB has been in existence, increases in the prices of patented medicines have always been less than that permitted by the CPI and there is no reason to expect that to change in the future.

Some manufacturers may be concerned that they are foregoing possible increases in years where actual CPI is greater than 2%. However as noted above most manufacturers do not take the full CPI and as history has shown, the actual CPI should average out to 2%. In addition, a patentee can always seek a hearing before the Board in the event it believes that the 2% CPI is not appropriate in a particular situation.

Finally there may be concern that the 2% is not the actual CPI in a given year and that paragraph 85 (1) (d) of the *Patent Act* requires the Board to consider "changes in the Consumer Price Index". However the *Act* is not specific nor is it restrictive with respect to the interpretation and application of this excessive price factor. In the past, PMPRB has relied on a forecast CPI and is now considering a lagged CPI – all proxies for the actual CPI. The 2% approach can also be considered a reasonable proxy for actual CPI and is supported by historical trends as well as government fiscal and monetary policies. In the event the Government and Bank of Canada change the inflation target (the 2% is in place until at least 2016) PMPRB can review and revise the CPI Guideline at that time.

Transitional Measures. It is proposed that the 2% approach be phased in beginning in 2013 and take full effect by 2015. The CPI forecasts for 2013 and 2014 were already established at 2% (over the previous year) with the two and three year forecasts adjusted for actual CPI in the base years. Therefore, for purposes of transition, given that the 2% is already a component of the forecasts these figures should be considered the "final CPI" for purposes of the updated methodology. That is, no upward adjustment of NEAPs in the event the actual CPI in 2013 or 2014 is higher or lower than the 2% forecast (this removes any uncertainty for 2013 and 2014). Accordingly, the CPI factors announced for 2013 and 2014 in the PMPRB Newsletter would remain as final with the full 2% approach taking effect as of 2015 as outlined in the table below:

CPI Adjustment	2013[4]	2014[5]	2015	2016	2017
3 Year	1.072	1.049	1.061	1.061	1.061
2 Year	1.041	1.033	1.040	1.040	1.040
1 Year	1.020	1.020	1.020	1.020	1.020

Under the 2% approach the, "1 year Cap" would always be 3%.

B. Annual (instead of semi-annual) Form-2 Filings

Initiative #2: Reduction of Regulatory Filing Requirements

Proposal for Consideration – Existing Patented Drugs: For existing drug products, to replace the semi-annual regulatory filing of Form 2- Information on the identity and prices of the medicine by an annual filing.[6]

Under the Regulations, manufacturers are required to file price and sales data for their existing patented medicines on a semi-annual basis. However the PMPRB price review process considers average prices on an annual basis only. Therefore, on its face, the PMPRB proposal makes good sense and would reduce regulatory burden for manufacturers and should provide efficiencies for the PMPRB staff who would no longer need to process, verify and analyze the extensive mid-year price and sales data required under the Regulations.

It should be noted however that many manufacturers rely on the mid-year compliance report as an early warning system that highlights any prices that may be falling outside the Guidelines. This early warning can provide sufficient lead time to make price adjustments such that prices at the end of the year (for the full 12 months) are back within Guidelines. The early warning has been necessary in that there is often considerable uncertainty with respect to the Non Excessive Average Price (NEAP) that would prevail in a given year due in part to the complexity of the CPI guidelines (actual vs. forecast CPI), and

[4] PMPRB April 2012 Newsletter: CPI-Based Price-Adjustment Factors for 2013 http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1619&mid=1526
[5] PMPRB April 2013 Newsletter: CPI-Based Price-Adjustment Factors for 2014 http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1744&mid=1668
[6] PMPRB Notice and Comment http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1747&mp=1746

the fluctuation in exchange rates and foreign prices that form the basis of the Highest International Price Comparison (HIPC) Guideline.

The CPI uncertainty is largely addressed by the first initiative above. The HIPC issue has not been addressed and is an important concern as shifts in exchange rates and/or local prices in other markets can create the perception of excessive Canadian prices even in cases where prices in Canada have not changed. The mid-year compliance review helps manufacturers identify some of these potential cases and allows them to take appropriate action in a timely manner. Accordingly, should PMPRB decide to proceed with amendments to the *Regulations* to eliminate the mid-year Form-2 filing, it should, in parallel, adopt measures that provide manufacturers with greater certainty with respect to the HIPC guideline. Possible options include:

- Applying the HIPC guideline only at time of introduction
- Freezing exchange rates for each drug to the rates prevailing at time of introduction
- Make use of a lagged exchange rate (e.g., lagged by one year)

Summary

The comments and proposals outlined above have been offered in the context of reducing regulatory burden, improving the efficiency of the PMPRB price review process and providing manufacturers and other stakeholders greater certainty and clarity with respect to the application of Guidelines and the PMPRB's mandate to ensure prices of patented medicines are not excessive.

I will be pleased to discuss the comments and proposals outlined above and provide additional information if warranted.