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Thank you for the opportunity to respond to the Patented Medicine Prices Review Board's discussion paper on price increases for patented medicines.

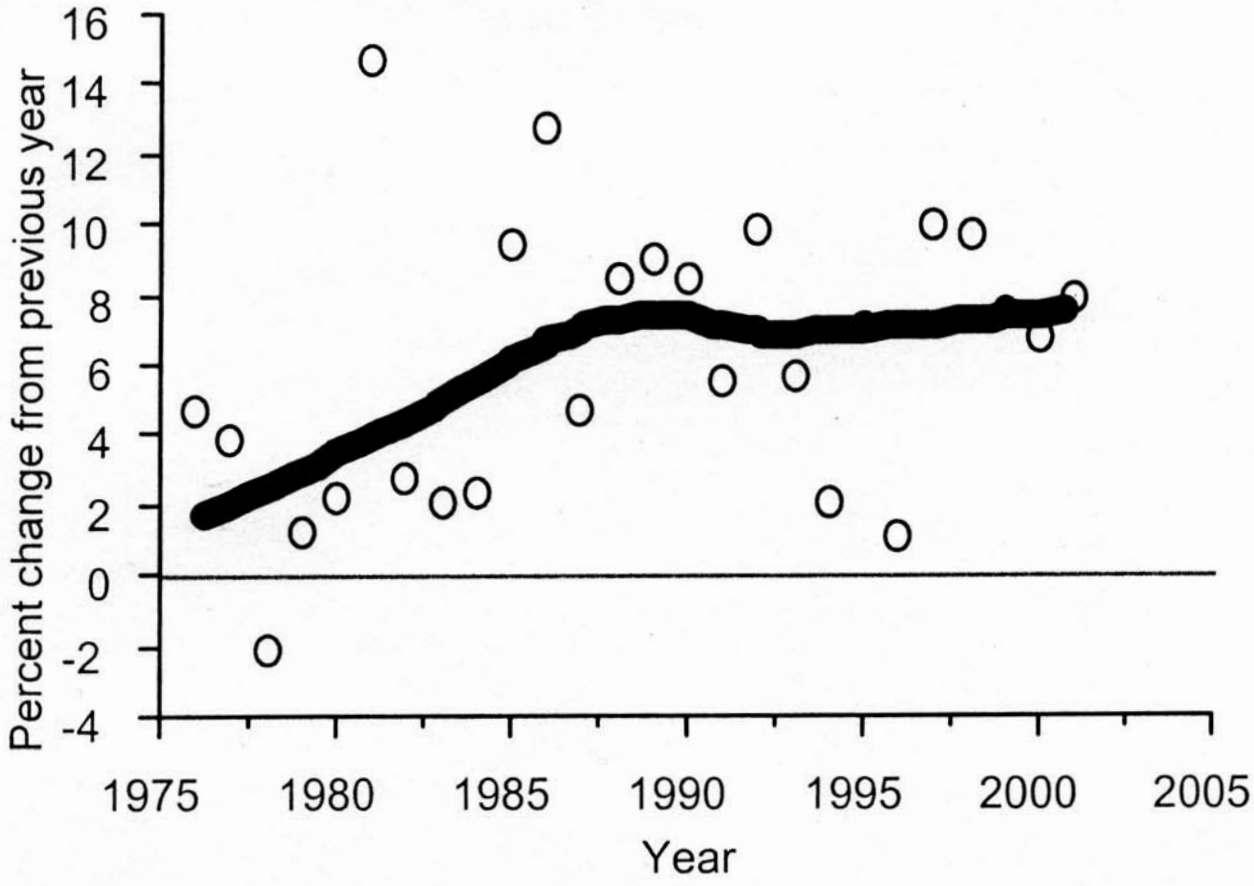
Before commenting specifically on the questions that the Board raised I want to review the reason for the existence of the Board and its success this far in achieving its goals. The Board's mandate is "to ensure that the manufacturers' prices of patented medicines sold in Canada are not excessive." The reason for this mandate is simple – to protect Canadian consumers from undue hardship in being able to access patented medications.

To the extent that the Board has controlled the prices for individual medications it has been successful in fulfilling its mandate but to confine the analysis to drug prices is to engage in a very restrictive interpretation of the reason for the existence of the Board. Regulating prices for individual products is necessary for ensuring access but not sufficient as the Board itself recognizes in its Discussion Paper of March 2005. Rising overall drug expenditures is endangering access to medications to consumers whether their medications are paid through private or public insurance. Especially at risk are the roughly 12% of Canadians who do not have any insurance and pay for drugs out-of-pocket. This point can be illustrated by a study from the Hospital for Sick Children in Toronto that found that a significant number of children lacked timely access to necessary medications because of economic problems (1).

Even after adjusting for inflation overall retail spending for medications has been going up at 7-8% for well over a decade as shown by Figure 1 on the next page. This year over year increase in spending is 3-4 times the rate of inflation. Previous research by the Board, and others, has identified the main reason for this continued increase as the substitution of newer, more expensive medications for older, less expensive ones without any proof that these newer drugs offer an incremental value in terms of improved effectiveness or safety. Indeed, research from the Board, the United States (2) and France (3) indicates that at a maximum only 15% of new drugs offer substantial therapeutic gains over existing products.

One of the main reasons why doctors are willing to use these newer more expensive medications is the intensity of the promotion that accompanies their release. To give one example, in 2000 Merck spent over $6,000,000 in Canada promoting rofecoxib (Vioxx®) resulting in 48,000 visits to doctors' offices by sales representatives and over 1 million samples being left behind.

Figure 1: Percent change in retail prescription drug expenditures in Canada, 1975-2001 (constant dollars, 1992 = 100)



Sources: Canadian Institute for Health Information. National health expenditure trends, 1975-2001, report. Executive summary.
Bank of Canada. Inflation calculator. Available at http://www.bankofcanada.ca/en/inflation_calc.htm

The Board does not have any direct power to control promotion but indirectly it could take promotion into account when setting the introductory price for a new patented medication. There are five criteria listed in the *Patent Act* that the Board is allowed to taken into account when determining the introductory price: (a) prices of the medicine in Canada, (b) prices of other medicines in the same therapeutic class in Canada, (c) prices for the medicine and other medicines in the same therapeutic class outside Canada, (d) Consumer Price Index, and (e) other factors that may be specified by regulation.
The Board has never chosen to ask for "other factors" to be specified in the regulations despite the fact that its strategy of controlling individual drug prices has not been successful in ensuring that Canadians can access patented medications. The Board should

enter into serious discussions with the government about taking into account promotional expenditures in setting introductory prices. Strategies to consider could include a lower introductory price if promotion exceeds a certain level of sales.

The Board also needs to recognize that its guidelines are part of the reason why introductory prices can be set at levels not justified by the value of the product. The Board currently allows companies to set prices up to the highest cost of therapy for existing medicines used to treat the same disease. Research has established that when drugs go off patent the company marketing the brand-name product does not attempt to compete with generics on price and maintains the price that existed when the product was on patent (4). Keeping higher prices for brand-name products enables new entrants into the same therapeutic market to charge higher prices. These high-priced new drugs then contribute to the climbing overall expenditures. The Board needs to urgently review its policies around the criteria used for introductory prices.

Finally, the Board needs to move beyond just comparing drug prices in different countries as a measure of its success in achieving its objective of protecting consumer welfare. In its international comparisons the Board should be looking at how well Canada does against other countries in metrics such as changes in per capita drug spending and rate of rise in total expenditures.

Recommendations:

1. **The Board should enter into discussions with the government to modify the regulations to allow it to consider the amount spent on promotion when setting a maximum introductory price.**
2. **The Board should modify its guidelines with respect to allowing new patented medications to be priced up to the highest cost of therapy for existing medications used to treat the same disease.**
3. **The Board should adopt additional metrics when it compares drug prices and spending in Canada to that in other countries.**

Questions with respect to the Board's Guidelines:

1. **Should they continue to allow for automatic (i.e. without prior approval) price increases?**

In light of the fact that current Board policies have not been successful in controlling drug expenditures and thereby ensuring access by Canadians to medications, automatic price increases should not be allowed.

2. **Are there considerations other than, or in addition to, the CPI that should be used to review price increases?**

The Board should be looking at promotional expenditures as a percent of sales in reviewing price increases. The board could construct a formula that would link allowable

price rises to levels of promotion, the higher the level of promotion the lower the price increase that would be allowed.

Drugs that show significant improvements in effectiveness and/or safety can offer both health benefits and economic savings since they may decrease the need for hospitalizations, visits to physicians and additional testing and imaging. The only way that such improvements can be adequately demonstrated is through comparative clinical testing. Therefore, in considering price increases the Board should be looking at the amount of clinical R&D that a company has committed to comparative drug trials and establish a formula relating the amount spent to allowable 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)**

The goal is not just to control drug prices but overall expenditures. Therefore, looking at intervals between price increases is not the optimum approach to establishing when price increases should occur. Instead, the Board should establish maximum levels for increases in total sales of current patented medications for each company. If sales exceed that maximum no price increases in individual products should be allowed. Maximum allowable increases in sales could be computed in a manner similar to that presently used by the Board in deciding upon allowable increases for individual products.

4. **If justification is required, what criteria should be considered?**

See the answer to questions 2 and 3 above.

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?**

The CPI should be retained for use in conjunction with the other factors that I have recommended.

References

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