

SUBMISSION FOR PMPRB CONSULTATION
ON DRAFT GUIDELINES



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Introduction

The Canadian Health Coalition (CHC) is a non-profit organization that works to protect, improve and expand public health care in Canada. We are made up of health care workers, unions, community organizations, faith-based organizations, seniors and academics, as well as affiliated coalitions in the provinces and one territory.

The CHC welcomes this opportunity to comment on the PMPRB's new Draft Guidelines which operationalize the recent amendments to the *Patented Medicines Regulations*. The CHC strongly supports both the new Guidelines and the amended Regulations. These long-awaited reforms will help make patented medicines more affordable for Canadians. However, to ensure that everyone in Canada can access the medicines they need, these changes must be accompanied by the adoption of a universal, public pharmacare program. The modernization of the PMPRB's regulatory framework is an important first step in the implementation of this new program.

Rising Drug Costs in Canada

Canada's rapidly rising drug costs are unsustainable. Canada currently spends more on prescription medication than it does on physicians.¹ Our spending on medication per capita is higher than all other OECD countries except for the United States and Switzerland. Among OECD countries, Canada pays the third highest prices for patented medicines.² Since 2006, the number of patented medicines in Canada that cost over \$10 000 per year has more than tripled. In 2017, these medicines accounted for over 40% of patented medicine sales compared to 7.6% in 2006.³ In 2017, Canadians with drug costs of \$10 000 or more represented 2% of beneficiaries but accounted for more than one-third of public drug spending.⁴

Given these high drug costs, many Canadians can't afford to take their medication as prescribed. In 2016, nearly one million Canadians had to choose between food and heat and buying their medication.⁵ Among eleven high-income countries, Canada has the second highest rate of cost-related non-adherence.⁶

The CHC welcomes the PMPRB's proposed Guidelines which will help tackle these issues by ensuring that Canadians are protected from excessive prices for patented medicines.

¹ Canadian Institute for Health Information. National Health Expenditure Database - 2019.

² Patented Medicine Prices Review Board. Annual Report 2017, Figure 21, p.42.

³ Patented Medicine Prices Review Board. Annual Report 2017, p.30.

⁴ Canadian Institute for Health Information. Prescribed Drug Spending in Canada, 2018: A Focus on Public Drug Programs, p.5.

⁵ Law M et al. The consequences of patient charges for prescription drugs in Canada: a cross-sectional survey. *CMAJ Open*. 6:1, E63-E70 (2018).

⁶ Morgan S & Lee A. Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries. *BMJ Open*. 7:e014287 (2017).

Comments and Questions: Draft Guidelines

Given the number of acronyms used in the Guidelines, it would be helpful to include a List of Acronyms at the beginning of the document for ease of reference.

It appears that the PMPRB will no longer be looking at the therapeutic value of new medicines. The loss of this information will make it much more difficult to determine how therapeutically useful new patented medicines introduced onto the Canadian market are.

Point 7 of the Guidelines states that “Every reasonable effort will be made by the PMPRB to assist patentees in understanding the Guidelines and their application.” Given the highly technical and complex nature of the Guidelines, it is essential that the PMPRB makes comparable efforts to assist parties other than patentees, such as consumer groups, in understanding the Guidelines and their impact.

Point 8 states that the “Guidelines do not provide an exhaustive description of all steps that may be taken or all issues that may arise in the context of a price review.” It’s important that the PMPRB Staff and Board maintain the discretion to use any other appropriate methods or tests when assessing the excessiveness of drug prices.

Point 27 states that ad hoc audits of patentee filings may be conducted by PMPRB staff. Are there criteria that Staff will use to determine when to conduct an ad hoc audit?

Point 31 states that the PMPRB staff will “normally” conduct price reviews using the methods and tests set out in the Guidelines. What other ways will the PMPRB use to conduct price reviews?

Point 49: Category I prices don’t take into account the therapeutic value of a product except indirectly through the Incremental Cost-Effectiveness Ratio (ICER). It is not clear what the effect of not considering the therapeutic value will be.

Point 63 states that a reassessment may be conducted if “a Category I medicine’s cost-utility analysis is updated.” Will the PMPRB be reliant on either CADTH or INESS producing an updated cost-utility study?

Comments and Questions: Backgrounder Document

Risk-based approach to price regulation (Question 4, p.4)

The Guidelines are focused on medicines that are at the highest risk of excessive pricing, but they only vaguely outline criteria for which medicines this risk applies to. Several criteria could be considered:

- a) Medicines that may help with the most serious medical conditions;
- b) Relatively low-priced medicines that are prescribed very frequently;
- c) Medicines with a very high price.

Market size (Question 8, p.6)

How will anticipated market size be calculated? Will the PMPRB be solely relying on the manufacturer's estimate?

Cost-effectiveness threshold (Question 10, p.7)

The Guidelines say that the cost-effectiveness threshold will be recalculated periodically. What does "periodically" mean in practice?

Net budget impact (Question 11, p.8)

The Guidelines state: "An average national net budget impact can be calculated for each new patented medicine that would absorb the budget envelope available for all new spending on patented medicines within the GDP growth estimate." However, new patented medicines can be line extensions or new active substances (NAS). What are the implications on the net budget impact when there are a smaller or larger number of NAS compared to the 5-year average?

Maximum use (Question 14, p.10)

If pharmacoeconomic studies are not available from either CADTH or INESS, why wouldn't the PMPRB commission one from an external, independent source?

How accurate have manufacturers' estimates of maximum use been in the past? Are estimates from manufacturers the best way of estimating maximum use?

Adjusting the Maximum List Price (Question 23, p.13)

The document states that the Maximum List Price (MLP) for medicines may be adjusted by the Consumer Price Index (CPI) in certain circumstances. In what circumstances would this take place?

Guidelines Modernization and Evaluation Process (Question 25, p.13)

The document states that the Guidelines Modernization and Evaluation Process (GMEP) report will be published after at least a full year of post-implementation data are available. Will the GMEP report be an internal PMPRB report or will it involve input from outside sources? In the latter case, which outside sources will be involved? Will the final GMEP report be made public?

Implications of Lower Prices Resulting from the Guidelines

Since the Guidelines will only affect drugs approved after the proposed Guidelines come into effect, any changes in total expenditures and total revenue for manufacturers will only occur gradually. For example, according to the PMPRB's 2017 Annual Report, drugs introduced in the previous 10 years only accounted for 51.6% of sales.⁷ If this trend continues and the proposed Guidelines come into effect in mid-2020, only about 50% of sales will be affected by the Guidelines by 2030.

The effect of lower prices on whether and/or how quickly new drugs are introduced into the Canadian market is important to patients for drugs that represent a significant therapeutic improvement over existing medicines. Only 10.8% of new active substances marketed in Canada between 1995 and 2016 represented significant improvements.⁸ None of the studies that look at how quickly companies introduced new drugs into different markets break down their analyses by the therapeutic value of drugs. It is therefore unknown whether delayed marketing will affect the treatment that patients receive.

The effect of lower prices on the introduction of orphan drugs is not known. Between Canada and Australia, which has had an orphan drug policy since the 1990s, there is no difference in the number of orphan drugs introduced on the market or how long their introduction is delayed.⁹

There is a question about whether lower prices will lead to fewer clinical trials being undertaken in Canada. A study asked thirty-four European senior pharmaceutical company executives from 14 research-based pharmaceutical and biotech companies about factors influencing their decisions in choosing sites for research and development (R&D) in general and clinical trials in particular.¹⁰ Among the factors they were asked about were the quality of the science in the country, the intellectual property regime, the spread of facilities (different sites for different research activities to take advantage of local scientific expertise), public funding for basic research, cost factors (including R&D tax credits and capital grants) and regulatory factors. For the sites for R&D in general, by far the most important driver was a location where one can do good science by accessing world-leading scientists. Cost factors were relatively unimportant. As for clinical trials, it was important to locate them in major commercial markets in order to familiarize key opinion leaders with the new products being tested. In addition, they sought places where clinical trials were cost-efficient to run and patient recruitment was timely.

Opponents of the proposed Guidelines have not explained whether countries that currently have lower median prices compared to Canada have trouble attracting clinical trials, have fewer

⁷ Patented Medicine Prices Review Board. Annual Report 2017. Figure 7, p.27.

⁸ Lexchin J. Health Canada's use of expedited review pathways and therapeutic innovation, 1995-2016: Cross-sectional analysis. *BMJ Open*. 2018; 8:e023605.

⁹ Lexchin J & Moroz N. Does an orphan drug policy make a difference in access? A comparison of Canada and Australia. *Int J of Health Services*. 2019; <https://doi.org/10.1177/0020731419886526>.

¹⁰ Bramley-Harker E et al. Key factors in attracting internationally mobile investments by the research-based pharmaceutical industry. London: 2007. NERA Economic Consulting.

therapeutically important new drugs introduced, have the introduction of these products delayed, or do not see the introduction of orphan drugs. This analysis has not been done in the six new PMPRB11 countries that currently have lower median prices compared to Canada (Spain, Netherlands, Belgium, Norway, France and Australia).

Opponents argue that the new PMPRB11 group of countries will lead to median Canadian prices being about 80% of their current level and that the proposed Guidelines will drive prices even lower. However, the available prices in the PMPRB11 countries are list prices, not prices based on secret discounts. The argument that Canadian prices will eventually end up below those in the PMPRB11 is therefore not supported. Furthermore, as noted above, lower prices in Canada will only take effect gradually since the proposed Guidelines will only apply to drugs approved after the Guidelines have come into effect.

Whether or not lower prices resulting from the implementation of the PMPRB Guidelines will delay or stop the launch of new drugs in Canada (as claimed by PDCI Market Access)¹¹ is questionable for several reasons. There is a greater percentage of first-wave launches in the UK (61%) than in Canada (50%) despite prices in the UK being 83% of those in Canada. PDCI uses a study of external reference pricing (ERP) by Kanavos et al.¹² to make several claims about the possible effects of lower prices resulting from ERP. They claim that the availability of pharmaceuticals, equitable access to medicines and the stimulation of industrial policy can be undermined. They claim that the impact of ERP on the affordability of medicines is ambiguous. They also claim that ERP creates price instability which leads to launch delays and that manufacturers are unwilling to launch in low-price countries.

However, in their conclusion, Kanavos et al. point out the limitations of their study: “We have identified studies, the majority of which rely on weak non-experimental study designs and conduct post-only analysis. To some extent, therefore, the results identified above need to be interpreted with caution as it is not possible to make inferences about the impact of ERP on individual policy variables and its overall impact within countries...Despite its obvious limitations, ERP should not be altogether dismissed as improvements can clearly be made in the way it is implemented.” Furthermore, in its critique of the new Guidelines, PDCI relies on reports from Cutting Edge Information and SAS that are not publicly available and therefore cannot be independently analyzed.

A paper by Cockburn et al. is sometimes used to argue that lower prices (and weaker patents) will delay or stop launches.¹³ However, since this study relies on data ending in 2002, its relevance to the current situation is unclear. Moreover, the authors’ conclusion that “price regulation delays launch, while longer and more extensive patent rights accelerate it” is significantly attenuated when just looking at the sample of high-income countries.

¹¹ PDCI Market Access. Overview, Impact and Implications of PMPRB 2019 Price Reforms. Dec 2019.

¹² Kanavos P et al. Does external reference pricing deliver what it promises? Evidence of its impact at national level. *European Journal of Health Economics*. 2019; <https://doi.org/10.1007/s10198-019-01116-4>.

¹³ Cockburn I et al. Patents and the global diffusion of new drugs. *American Economic Review*. 2016; 106:136-64.

Overall, none of the arguments opposing the Guidelines based on their lowering of Canadian drug prices can be substantiated.

Conclusion

The CHC strongly supports the reforms to the PMPRB system, which will give the PMPRB the tools to protect Canadians from excessive prices and make patented medicines more affordable. Health Canada estimates that these reforms will save Canadians \$13 billion over the next decade.¹⁴ These reforms are long overdue, but they are only one part of a larger solution to make medications more affordable. To ensure that everyone in Canada can access the medications they need, these reforms must be accompanied by immediate action to implement a national public pharmacare program. Universal, public pharmacare will build on the PMPRB reforms to further reduce medication costs by using consolidated market power to negotiate lower drug prices. The PMPRB reforms lay the foundation for a national pharmacare program that will ensure equitable access to medications for Canadians from coast to coast to coast.

¹⁴ Government of Canada. Government of Canada Announces Changes to Lower Drug Prices and Lay the Foundation for National Pharmacare (9 Aug 2019).