

26 June 2017

The Honourable J. Philpott  
Minister of Health  
Health Canada

Dear Minister Philpott

### **Re Proposed Amendments to the Patented Medicines Regulations**

Health Canada has asked for comments on its regulatory proposals on protecting Canadians from excessive prices for pharmaceuticals. I applaud Health Canada for its efforts in reviewing the Regulations, and offer the following comments on my own behalf.

I am Professor of Economics at the University of Calgary. In 2003-4, I held the TD MacDonald Chair in Industrial Economics at the Competition Bureau, Industry Canada, in Ottawa. Since approximately 1998, my research has focused mainly on pharmaceutical markets. I have also consulted in the pharmaceutical industry for manufacturers, industry associations, and government, mainly with respect to issues in Canada. I have acted as an expert witness in numerous cases relating to pharmaceutical patents. I have also participated as a Member of a Working Group for the Patented Medicine Prices Review Board. My comments are made purely on my own behalf, and do not indicate the position of my employer the University of Calgary or any other party.

I hope that the following comments will assist the Government.

#### **Proposal 4a: Pharmacoeconomic evaluation**

The proposal to include cost-effectiveness as a criterion to be evaluated by the PMPRB is appropriate. In my view, if a drug offers good value for money, then its price should not be considered excessive, regardless of any other considerations. However, I recognize that determining cost-effectiveness is very challenging. In addition, even if the cost-effectiveness is somehow known, there is a second challenge in deciding on an appropriate threshold for cost-effectiveness.

To address the second challenge, it will be necessary for the PMPRB to commission research on the appropriate threshold, probably following the seminal work of Claxton et al in the UK.<sup>1</sup> While pharmacoeconomic evaluation can be useful, its application in practice can be exceedingly complex, and it typically involves many assumptions and a great deal of inference.

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<sup>1</sup> Claxton, K., Martin, S., Soares, M., Rice, N., Spackman, E., Hinde, S., Devlin, N., Smith, P. C., and Sculpher, M. (2015). Methods for the estimation of the national institute for health and care excellence cost-effectiveness threshold. Health technology assessment, pages 1542.

Generally, I note that the language on “cost utility analysis” is somewhat restrictive. It would be helpful to obtain other analyses that may be related, but would more generally be considered cost-effectiveness analysis or cost-benefit analyses.

I do not believe that obtaining information on cost-utility in other countries would be helpful, since the relevant costs are generally different and may have very limited comparability.

#### **Proposal 4b: The size of the market**

The proposed information requirements are unclear to me. First, the discussion and heading for this section appear to imply that the patentee should provide information on the size of the market in other countries as well as Canada. I do not believe that information would be particularly useful, and indeed the proposal for the information to be provided does not appear to include that explicitly.

Second, the proposed information indicates that the patentee should provide information about the size of the market “without restraint on utilization.” I am not sure of the exact meaning of this. There are many possible restraints on utilization, including whether a drug is included on a formulary, and whether it is approved with or without conditions. Even price may be a “restraint” on the amount sold. Which restraints, exactly, are relevant? And if the patentee expects that, for example, insurers will somehow limit the volume, would that not be relevant when forecasting the market size?

The language of the proposal is also obscure. The proposal suggest that patentees should provide information on the “uptake” of the product. This could mean almost anything.

Suppose that the goal is to use the information to help set the price, on the basis that a given price may lead to excessive revenues. Then *anticipated or actual revenues* in Canada may be used.<sup>2</sup> However, if the firm wishes to make a case that its revenues need to be high because of high costs of making or marketing its product, it should in addition provide that information. I do not see any need to add to this requirement additional information about the size of the market in other countries or to consider hypothetical revenues in the absence of actual restraints on utilization. Thus I suggest that the information requirements of the firm be described as revenues in Canada of the product in prior years and anticipated revenues in the current year (incorporating all indirect or direct payments or other compensation to or from buyers or insurers).

I note further that the discussion around this point on page 10 of the consultation document states that “Seeing that firms are assumed to set their introductory prices at a profitable level to recoup initial investment...” This is an incorrect assumption. Firms set their prices to maximize

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<sup>2</sup> For an example of how to use revenues, see Fellows, GK, and A. Hollis, “Funding innovation for treatment for rare diseases: adopting a cost-based yardstick approach.” *Orphanet Journal of Rare Diseases* 2013, 8:180.

their profits, as indeed they are responsible to their shareholders. The profit-maximizing price in general bears no relationship to the investment that was made to develop and bring the product to market. While it may be a proper goal for the PMPRB to ensure that firms are, *on average*, properly compensated for their investments, we should not expect that firms have such a goal, or that for individual products revenues will just be enough to recoup investments.

#### **Proposal 5: Indirect Price Reductions**

In some cases, there may be other indirect price modifiers that are not reductions. I suggest rewording to include both price increases and price decreases.

#### **Additional Factor: Extension of Monopoly Pricing through Section 6 of the PM(NOC) Regulations**

An important criterion for “excessive pricing” should be that of having extended a monopoly by virtue of a patent that is ultimately found invalid or not infringed. Under Section 6 of the PM(NOC) regulations, a patentee may “apply to a court for an order prohibiting the Minister [of Health] from issuing a notice of compliance [to a generic drug] until after the expiration of a patent.” Under Section 7, this application may be overturned if the Court finds the patent invalid or not infringed. Under Section 8, the generic company may seek compensation from the patentee for any loss suffered because of the application by the patentee, if the patent is found invalid or not infringed. Notably, the patentee does not have to compensate the losses of payers or consumers who paid the brand price based on the assertion of a patent that the court ultimately finds invalid or not infringed. This is despite the fact that the patentee is deemed by the court to have “improperly” kept a competitor out of the market. (See for example *Teva v Pfizer*, 2017 FC 526, at 18).

There have been many cases before the courts under Section 8 of the PM(NOC) regulations, for drugs with significant sales. The table below shows estimates of the effect of having brand prices, rather than generic prices, for five important drugs for which generic entry was delayed because of an application under Section 6 of the PM(NOC) Regulations:

## Delays to Generic Entry Caused by Patents shown in NOC Proceedings to be invalid or not infringed

DRUG NAME	EARLIEST FEASIBLE DATE GENERIC COULD HAVE RECEIVED NOC	ACTUAL DATE OF GENERIC ENTRY	DAYS DELAY	LOST SAVINGS TO PAYERS
RAMIPRIL	26 APR., 2004	12 DEC., 2006	960	\$0.5BN
ATORVASTATIN	MAY 15, 2007	MAY 19, 2010	1,100	\$1.8BN
AMLODIPINE	20 OCT., 2004	9 JUL, 2009	1,723	\$1.0BN
PANTOPRAZOLE	26 APR, 2004	5 MAR, 2008	362	\$0.2BN
VENLAFAXINE	10 JAN., 2006	2 AUG., 2007	569	\$0.3BN

Source: Hollis A and Grootendorst P. Tendering Generic Drugs: What are the risks? Paper commissioned by the Canadian Generic Pharmaceutical Association, October 2012.

There have been various other S.8 proceedings on a variety of drugs, some of which have yet to be decided by the courts, with substantial periods of delay to generic entry. It is difficult to think of a clearer case of “excessive” pricing, than monopoly pricing based on assertion of a patent which a court finds to be invalid or not infringed. I therefore propose that the PMPRB should use as one of its new factors, that prices be deemed excessive when they are based on exclusion of an generic competitor under the terms described in Section 8(1) of the PM(NOC) Regulations.<sup>3</sup> The quantum of excessive pricing is relatively easily calculated in such cases, being the difference between the total actual cost of purchasing the drug less the expected cost of purchasing the drug but for the assertion of the patent under the regulations.

I note that I have served as an expert witness in some of the above cases (and others) on behalf of generic companies, which have sought to be compensated for their losses in being kept out of the market. The losses to consumers and payers are entirely separate, and there is no obvious gain to generic manufacturers from the proposal I make above. I have not been asked to make this submission by any party.

### **Additional Factor: Time since market entry**

Normally, we expect that price should decline with competition and that costs would fall over time as the firm benefits from “learning by doing”. If anything, this should result in prices falling over time. In addition, firms can potentially benefit from reduced need to support promotion as the product becomes better known in the market. The current model of limiting price increases to inflation is therefore inappropriate. It would be reasonable to impose a real price decrease that became more restrictive over time. This could be particularly important for drugs that are able to use a series of patents to obtain exclusivity longer than average. In general, this strategy

<sup>3</sup> I note that the PM(NOC) Regulations are themselves in flux because of Bill C-30. However, I expect that they will be fully clarified in the next month or so.

would somewhat even the playing field between drugs that had longer and shorter exclusivity periods. It would also be consistent with many of the comparator countries in the new PMPRB-12 that impose price reductions periodically.

A real price decrease could be designed as, for example, as allowing prices to change up to inflation minus 2.5% annually. If inflation were greater than 2.5%, this would imply a nominal price increase, and if inflation were less than 2.5%, this would imply a nominal price decrease.

I hope that these comments will be helpful to the Government and would be pleased to provide further information as required.

Yours truly,

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