Submission to PMPRB

in response to the

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By

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Introduction

The discussion paper issued by PMPRB is comprehensive and outlines the main issues very clearly. This is a very difficult subject – the regulation of a monopoly, particularly one that combines health, intense emotional involvement with the unique situation where those that choose and those that pay are (almost) always different. Any thought of regulation being based on "supply & demand" has to be essentially suspended. As outlined in the paper there is the critical need to balance an appropriate return to the patentee (to encourage continued research and innovation as well as continuity of supply) with an appropriate price that ensures the long term sustainability of "the system" in total (public, private and patients); its ability to pay and meet public policy needs to provide access – not just for a specific drug but for the whole universe of effective drugs, now and in the future.

I have chosen to focus on one area that appears not to have been directly addressed in the paper, the other areas raised are all equally important but have been addressed by the paper and the questions it poses.

Q10 – The impact of "Indication Expansion" on pricing

This is an area that the policy paper itself does not directly address but which I think is crucial to consider in any modernization of the PMPRB – the impact of an increase in volume due to a new indication for an existing drug (especially where the new indication is applicable to a population which is significant in comparison to the population for the original indication). When this happens it is likely that any calculation to support an appropriate price made at original review by PMPRB is no longer valid given the change in (expected) volume. Such "indication Expansion" may either be formal through a Health Canada approval or informal through "off-label" use. In either case the volume of a drug dispensed will rise, potentially very significantly such as the history of Remicade.

The issue of expanding indications has two key and influential impacts on what may be excessive pricing for this particular drug and potentially for future drugs:

- A cost that may have seemed reasonable over a small population may become excessive when the drug is prescribed for a much larger population
    - the current system (almost) ensures that there is no price benefit when volumes increase
    - much of the cost of a drug is the recovery of fixed R&D costs for both this and other failed drugs; a sudden expansion in the population of those taking the drug means that those fixed costs could be spread over a larger volume but with a fixed price the result is that only the patentee gains
- The cost that may have been reasonable for one therapeutic class may not be reasonable for another
    - Section 85(1) factors include a reference to "the prices at which other medicines in the same therapeutic class have been sold in the relevant market", so an expansion to a new therapeutic class sets a new reference price in that new class

- If the price was relevant to the volume of the original indication but is excessive for the new due to the greater population you have now baked in an unreasonable higher cost for that new indication

Potential solutions

One way to address this is for PMPRB to review pricing when new indications are approved by Health Canada. However, this would have to be considered in light of any disincentive created to seek formal expansion of indications but to rely on "off-label" use. Such avoidance by the patentee would at least not create a new reference price for the new therapeutic area.

Another approach, and one that may be easier to implement, is that a review to see if pricing is excessive is triggered when actual volumes increase by a specific percentage.

A combination of both would allow

- The system to benefit from economies of scale while retaining an incentive to the patentee
- The avoidance of creating a high reference price in a therapeutic are a with a larger population

Conclusion

In the review of the PMPRB guidelines an area that should not be ignored is the impact of volume on whether a drug price is reasonable (or "not excessive"). Volumes can change over time particularly with the formal or informal use of the drug for new indications. Either significant volume increases or new approved indications or both should trigger a price review of a drug by PMPRB.

1. About Gary Walters

Gary has worked in the employee benefits industry for almost 30 years, working for major insurance and reinsurance companies until becoming an independent consultant in 2016.

Most recently Gary set up and led the Canadian Group division of a major international reinsurer. Prior to that he was responsible for the financial functions at several leading Canadian Group insurers, including product development, pricing and valuation, accounting and LTD claim best practice departments. Gary also led the small group profit centres at two companies, where his responsibilities included marketing, business development, underwriting, administration, pricing and product development.

He is very active in the insurance industry and actuarial profession. He is a frequent speaker at industry and actuarial conferences. Gary was also a member of the Canadian Life & Health Insurance Association's (CLHIA) Group Committee. He chaired the CLHIA working group that developed the CLHIA Industry Drug Pooling Agreement.

2. About Cedar Hill Group Inc

In 2016, bringing almost 30 years of experience in the Group Insurance and Reinsurance industries and a passion for the issues of the Industry, particularly Drug and Disability insurance, Gary decided to form Cedar Hill Group Inc (CHG). In particular, as a consultant to the Insurance and Group Benefits industry, Provincial governments and the Pharmaceutical industry on strategies to manage drug and other healthcare costs and create a greater understanding of the interactions between, and impact on, public and private medical coverage. The overarching objective of Gary's work is to improve the sustainability of the entire healthcare system as well as the financial sustainability of each part. Further, to work towards a greater understanding between the industry players and between the industry and governments, pharmaceutical industry, pharmacy and other players to make such improvements possible.