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Thank you for the opportunity to take part in the PMPRB consultation process. Below please find my responses to the questions posed by the Board.

Options for Possible Changes to the *Patented Medicines Regulations*, 1994 and the Excessive Price Guidelines

Any Market Price Review

The timing of when the Board should examine the price in different markets is important but equally important is which market the Board should devote the most attention to. Affordability can be looked at from either a collective or an individual viewpoint. A collective basis would be whether a province or a hospital has the resources to pay for the drug while an individual basis is whether drugs are priced out of reach of a significant number of individual patients. There are obviously differences in the resources available to collectives (hospitals, provinces) but in general they tend to have greater resources and greater bargaining power than individual patients. Therefore I would suggest that the Board have guidelines for different classes of purchasers and pay special attention to the prices that individuals without insurance have to pay for medications, i.e., what is the average transaction price in pharmacies. This price should be reviewed on a regular basis to ensure that drugs remain affordable to the most vulnerable group of individuals – those not covered by either a provincial public plan or private insurance.

Re-Setting the MNE Price

1. When the MNE price can be shown to not cover the patentee's cost of making and marketing the drug

I do not have an opinion on the timing of when the MNE price could be reset, however all of the options that the Board puts forward involve determining the costs of "making and marketing" the product involved. Up until now the Board has not considered these costs and the document distributed by the Board states that it has yet to determine what activities and costs would be considered under the definition of making and marketing.

However, in my opinion without an adequate a priori definition of what these costs are and whether or not they could realistically be derived it is premature to look at the question of resetting the MNE price based on "making and marketing" costs. Once the Board's work in this area has been completed it may be appropriate to re-examine this question.

2. When the scientific information/evidence available at the time the medicine was first introduced was not sufficient to determine with confidence its category of therapeutic improvement, or when new post-market evidence suggests the initial categorization was inappropriate

In re-examining evidence regarding the therapeutic value of medications the Board need to be cognizant that research produced through funding from the pharmaceutical industry is much more likely to show positive results compared to research funded from any other source. This conclusion applies to randomized clinical trials, pharmacoeconomic studies and meta-analyses and has been recently summarized by Sismondo (Contemporary Clinical Trials 2008;29:109-13). Therefore, in considering postmarketing evidence about the value of drugs the Board needs to look at the source of the evidence.

3. When the Median of the International Price Comparison is the pivotal test and the medicine is sold in too few countries at introduction

The question of how many countries the drug should be sold in is important because of the variability in prices in the different countries that the Board uses in determining prices in Canada. In some countries prices are usually higher than those in Canada and in some they are lower. If the number of countries that are used is too small then the sample may be biased. If the Board proposes to use 3 countries then it needs to do research to show that, in general, that prices in the first 3 countries where a product is marketed reflect a range of prices.

The time at which prices should be re-evaluated should be dependent on the stability of prices in the comparison countries. If prices are relatively stable over the time that the drugs are marketed then an earlier time period is reasonable. However, if prices are unstable then a fixed time period may capture prices when they are in flux and lead to Canadian prices being out of sync with those in other countries. The Board should produce research looking at how stable prices are in the comparison countries before changing its current practices. In addition, prices in other countries should take into account any discounts or rebates that are received and that are not reflected in the published prices.

Options to Address Issues Arising from the Federal Court of Canada Decision

A. Regulatory Options

The option of excluding drugs provided for free from price calculations seems reasonable

on the surface but this free provision is provided at the discretion of the companies and can be withdrawn at any time. If medications provided for free are subsequently sold that would affect the average sale price. Therefore, if medications that are provided for free are to be excluded then either the companies must commit to continuing to provide the drugs for free to the group that is currently receiving them or else the average price should be recalculated when the company stops the free provision.

The Board notes that if samples continue to be included in the average price that companies may stop the distribution of samples. The lack of free samples may have a negative impact on some patients but in general the research that has been done has shown that the use of samples has a negative impact on the quality of prescribing and that the use of samples leads to overall higher prescribing costs. (See: Journal of General Internal Medicine 2000;15:478-83; Family Medicine 2002;34:729-31; American Journal of Medicine 2005;118;881-4). Therefore, the discontinuation of the provision of free samples may have an overall positive effect and should not be a consideration in how the Board decides to treat samples in its calculations of the average price.

Under Option 5 the Board states that the code developed by Rx&D prohibits the provision of gifts and that therefore this is unlikely to occur. In fact the Rx&D guidelines continue to allow companies to provide meals to doctors as well as “service-oriented items”, moreover compliance with the Rx&D code is not proactively monitored but relies on complaints to ensure compliance. Therefore, the extent of the provision of gifts and their value may be significantly underestimated. Finally, the Rx&D code allows companies to subsidize medical education through independent third parties and these third parties may offer the CME at locations where expensive meals are provided. The Board should therefore continue to include the value of gifts in its calculations.

B. Guidelines Options

Both of the options presented rest on the assumption that the current method of determining the introductory MNE price is appropriate. Since the Board is re-examining its methodology to calculate this price any proposal to change the guidelines with regard to the CPI adjustment methodology for determining the MNE price should await the conclusion of that work.