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Attn: Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue, West
Suite 1400
Ottawa, Ontario
K1P 1C1

Re: Notice and Comment on Proposed Amendments

Dear Mme Dupont,

The Notice and Comment document notes that the PMPRB Stakeholder Working Group on Price Review Issues expressed concerns about the timeliness of the review process. As a former industry representative on the Working Group, I've been interested to see how the Timelines Project would address those concerns. Unfortunately it seems to me that the proposed amendments will merely serve to further complicate the price review process with unforeseen and unintended consequences, and new, unproductive compliance issues. The net effect will be to exacerbate rather than improve the timeliness of the review process.

I would also note that the proposed amendments on price notification amount to changing the PMPRB's mandate from price review to price control. As such, they are inconsistent with the spirit and intent of the Patent Act, and possibly beyond its scope.

Notification of Proposed Price 60 Days Prior to First Sale

While the Patent Act allows the Board the discretionary power that it may ask for proposed price information, by Board order, it does not require that the Board must ask for prior notification of prices of products which are not yet being sold in Canada. The Patent Act gives the Board the specific mandate to review actual selling prices as distinct from pre-screen or pre-approve proposed or hypothetical prices.

Given that the Board already has substantial powers to review prices after actual sales transactions, and to take remedial action if prices are proven to be excessive, the onus should be on the Board to demonstrate why it needs the additional authority to screen prices prospectively.

The 60 day notification appears arbitrarily chosen and completely ignores the operational realities of new product launches. Compliance will be difficult for patentees because in actual practice pricing options and scenarios are reassessed right up to the date of NOC and date of first sale. It is often necessary to change a planned price in the light of new clinical, commercial or competitive information in the last few days prior to launch.

In addition, prior notification places an unfair burden on the patentee by the creation of an entire new category of potential compliance violations relating to future pricing intentions. In the interest of transparency, when the Board creates new potential compliance violations it should also clearly indicate what penalties it proposes to apply to instances of non-compliance.

Far from improving efficiency as the Board suggests, the 60 Day price notification would create new regulatory questions:

- Is the patentee subject to a penalty for changing a pre-notified price?
- If the patentee's changed price turns out, on review to be within Guidelines what would be the basis for a penalty for deviating from the notified price?
- Would the patentee be required to re-notify the Board each time it reassessed the planned price and would justification be required?
- Would the Board establish a time limit beyond which no further notification would be accepted, or does it expect manufacturers to delay product launches to accommodate its the 60 day notice period?
- If the patentee is still assessing pricing options in the final 60 days before sale will it be permissible to file a notification that price is yet to be determined?

Underlying all this is the question of what claim can the Board legitimately make on a manufacturer for an administrative omission connected with this new notification requirement, absent proof that the product is actually being sold at an excessive price.

Notification of Proposed Price Increase

Again, this proposal appears to exceed the intent of the Patent Act by creating a mandate for PMPRB to screen or pre-approve future prices rather than reviewing actual transaction prices.

This proposed amendment, like the proposed prior notification of new product pricing creates an entire new category of potential compliance violations without indicating proposed penalties that would apply in the event non-compliance. As with the other proposal, there is no evidence presented as to why the Price Review Board needs to become a Price Control Board screening future prices when it already has substantial power to act where it deems that actual transaction prices are excessive.

The 120 day notification period like the 60 day period for new drug prices appears to have been arrived at arbitrarily without any regard for the operating realities of commercial businesses - and without regard as to new compliance issues that the new notification requirement would create or what the Board would propose as penalties for non-compliance.

As with the other notification proposal, instead of the increased efficiency the Board claims, the advance price notification would create a new regulatory quagmire of unnecessary and unproductive compliance “issues”.

For instance, what if a manufacturer's notification is received less than 120 days prior to implementation or if a manufacturer declines for proprietary commercial reasons to provide any customer or third party with advance notice of a price change?

- Is the increase disallowed or delayed for late filing?
- What would be the basis of the Board's disallowance if the new price was within guidelines and therefore non-excessive.
- Would the Board order a roll-back of a price which is otherwise non-excessive due to non-notification?
- If the manufacturer refuses to roll back the non-excessive price would the Board call a public hearing into a price which is non-excessive under their own guidelines?

The rationale for this measure states that in between its six month reporting periods the PMPRB has to rely on trade notices and complaints for information on price changes. All customers have to rely on trade notices for information on product and price changes; but unlike them, the Board has the authority to review transaction prices in detail and to punish prices deemed to be excessive. Given such powers, where is the demonstrated need for this additional reporting requirement?

Details on Calculation of Net Prices and Net Revenues

The proposed amendment to require patentees to identify on their sales reports how average prices were calculated does not provide any indication of how this would change the current reporting format. The lack of specifics as to how this proposal would impact the existing reporting process makes it possible to respond only in general terms.

The current reporting format requires up to forty lines of data for each pack size of each patented medicine sorted by four trade classes into ten provinces. Providing a reason for the average selling price of each of those forty lines is not a small task. The additional work would represent a substantial increase in the time required to prepare reports and would inevitably compromise the ability of many patentees to file their six month Canadian sales and international price reports within 30 days of the end of the reporting period as currently required.

In view of the increased regulatory burden this proposal would generate the Board should consider a further amendment allowing patentees 60 to 90 days to file their six month reports if it intends to implement these changes.

Conclusion

The proposed amendments on prior notification of new product prices and price increases on existing products appear to be incompatible with the spirit and intention of the Patent Act. The Board should never forget that one of the key objectives of the Patent Act was to create a policy framework that would encourage pharmaceutical research and development in Canada. The Board would do well with any proposed change to ask itself whether the result will be to enhance or impede productivity.

I appreciate the opportunity to provide these comments and trust that they will be given due consideration.

Sincerely,

Peter Kaldas,
P.S.Projects