Comments on Draft Revised Guidelines for Patented Medicine Prices Review Board

Submitted by:
Don Hamilton, Pharmacist

Oct 6, 2008

I am writing to provide some feedback on the Notice and Comment document (Aug 08) circulated by the PMPRB.

I would like to commend the PMPRB for putting together the process of consultation and invitation of stakeholder comment. If I may comment on the process, it is interesting to me that there does not seem to be any input from politician group sanctioning the operating principles which form the basis for comparisons of the responses and perspectives. While we all have our own perspectives, this type of leadership might be invaluable in weighting the potentially opposing interests or priorities of the various stakeholders. I understand this to be a difficult task, but when providing comment on specifics it is useful to know the intended operating principles that should be adhered to. This is particularly important with this type circumstance which is one of the most crucial interfaces between a publicly run health system and free enterprise system (drug manufacturers).

Having said that, I would like to make a few comments on the proposed draft for consideration by the Board from my perspective as a pharmacist employed in a hospital setting.

1. Underlying principles:
   I think the inclusion of the principle that Canada should pay its Fair Share is inappropriate. I do not know what is "fair" in a payment system. It seems to me that the pharmaceutical companies would not have an operating principle that would state that they should be mindful of charging a "fair" price. I seems to me that the price would be dictated by what the market would bear (how it could be maximized) and the relevant legislative controls. We are talking about the perspective of controlling "excessive" prices, and I suggest that the principle of "Fair Share" should not apply. It seems the notion of fair share and excessive are obvious and do not need to be put into operating principles. Again, perhaps this is a case for political leadership as the buck stops at there in this system. It is obvious that this issue would be viewed differently by different stakeholders.

2. I am in agreement with the new categories and use of Oxford Center of evidence-based Medicine. It is useful to point out how the evidence is controlled, released, reviewed, and added to over time. Once on the market, the rigor of the evidence required to make decisions that would relate price appropriateness appears to be complex and difficult to obtain. There are obvious issues with evidence, such as

when there are major uses of a drug that are off-label or in populations not approved (e.g. pediatrics).

3. I understand the difficulty in International Therapeutic Class Comparison, but think this should still be considered at beginning. The weight of such a consideration might be attenuated with the similarity or differences in alternatives in each country. It is perhaps not the most sensitive at present, but should be continued as a minor component with the option of increasing importance as the world becomes more similar than different (globalization).

4. Generic Drug Products: I am not clear as to why the generic manufacturers should be compared to the reference Brand price. I may be mistaken, but the price considerations for an innovator brand product appear to be more complex than those of the generic (off patent) manufacturing and licensing of a product. The initial development and risk associated with bringing a product to market do not appear to be the same as producing a generic product which is off patent and has a current role in clinical care. I suggest the Board pay particular attention to this aspect of the guidelines as it seems that this is an opportunity to use the actual manufacturing costs as a yardstick for consideration on what is excessive. There may be good logic that would encourage competition on actual manufacturing costs (I sense this is a complex issue) that would result in significant price reductions.

5. Benefits: ALL benefits should be included in the cost of the drug. I think the Board should proceed very carefully when considering the arguments for any exceptions when entertaining these concepts. If the drug is sold at a particular price and the "benefit" is included in the price, this is a decision by the manufacturer and the legal system to comply. It seems that the charging of a high price and providing a subsequent "rebate", would favor the manufacturer in that this would still be the list price in terms of international and other comparisons. Thus, there may be a possible historical advantage to the industry in keeping the "official" price elevated. Again, this is the interface of a public health system and free enterprise and the purpose of this Board it to act on behalf of the public system to be able to identify and control "excessive" prices on behalf of the public system. Any consideration of the company perspective does not seem appropriate in deliberating on this topic. I do not agree with any system that permits a "rebound" to a previous non-excessive price. The rule of CPI adjustment seems to be appropriate and can be planned for by the manufacturer. It may be that more information and data on individual circumstances is needed by the Board prior to speculating on the potential for this occurrence and impact on manufacturers. I think this is a complex issue and there may be other considerations at play that impact a low price (e.g. willingness to accept loss leader penetration into one market to provide increased market share into another market, as possibly in hospital vs community scenario where a patient I started on a chronic therapy in hospital).

6. Any Market Price: I think this legislation is national and should apply nationally to any market. I agree that the Board may find it difficult to monitor comparisons on markets. It seems that systems need to be in place for mandatory reporting of prices within the public health system. As part of all health care funding is by federal public funds, this should be a reason to require disclosure. It is interesting that the costs of larger markets are generally advantaged vs smaller markets. While this makes some sense from a purely business perspective, it does not seem to be in keeping with one of the basic principles of the Canada Health Act…that of universal access. I propose the Board collect data on prices in various markets and make the database submissions mandatory. The Board would then have information to field regular reviews or comparison data for when a "complaint" in registered.

7. Re-setting the MNE Price: I agree that this issue should be discussed further by the Board and reviewed on a case-by-case basis in the interim.

Other

In providing these comments, my perspective is that of a member of the public health care system. I am pleased that the Board is trying to understand and deal with the issue of excessive pricing and feel strongly that controls on pricing of such important items as pharmaceuticals is an important issue that needs careful diligence. Again, I would like to see the issue of clearer expectation and representation of the public through clearly stated political direction. The public position should be to minimize the cost of drugs, including minimizing the ceiling for "excessive" as is the mandate of the Board. Personally, I am disappointed that the Board has not given more time to a consideration of analysis of the generic manufacturer and excessive pricing. The Board has an opportunity at the present time to create an environment of true competition on generic prices vs the comparison to the Brand product, which does not seem logical to me.

While I do not share all the history of the legislation and the Board on this issue, I how these comments from my perspective are of some use in the review of this draft.

Thank you for the opportunity to have input.