July 10, 2016

To: Patented Medicine Prices Review Board

Thank you for the opportunity to comment on the PMPRB Guidelines Modernization Discussion Paper. While I will answer some of the individual questions at the end of the document I also feel that it is necessary to make some general comments.

To begin with, the paper characterizes the PMPRB as a "consumer protection pillar" but the paper does not recognize that controlling prices of individual products alone does not control overall spending on pharmaceuticals which is a combination of a number of factors including the mix of drugs prescribed, the number of prescriptions per person, the size and age distribution of the population and the prices of individual products. Nor does it recognize that the level of spending does not reflect therapeutic benefit since many drugs are being misprescribed. While these various factors do not necessarily directly impact on the PMPRB Guidelines they should be acknowledged in order to give the various parties a perspective about the impact that the PMPRB can have on overall drug spending in Canada.

The PMPRB itself recognizes that the way that Canada sets prices for patented medicines has not encouraged companies to invest in R&D in Canada because a number of other factors are much more important. Moreover, even if prices were successful in incentivizing R&D, because the Patented Medicine Prices Review Board (PMPRB) allows companies to price new drugs up to the level of existing products in the same therapeutic category, it is likely that what we would get is more me too drugs rather than drugs for unmet medical needs (1). Regulations governing how the PMPRB sets maximum prices should be changed so that new entries into existing therapeutic classes are only priced to the level of generic drugs in that class, unless the new product offers a proven therapeutic improvement. External reference pricing, i.e., setting Canadian prices based on what other countries allow, is fraught with difficulties because it assumes that these countries have accurately assessed the value of new drugs. Moreover, drug companies typically introduce new drugs into the American and German markets first (2) because of the relative lack of price controls in those countries that allow them to charge high prices (3). Companies then use American and German prices as benchmarks for prices in other countries. Moving beyond the 7 countries that the PMPRB currently uses and incorporating a wider range of countries would lower Canadian prices.

A more basic question is whether or not the PMPRB should continue to use external reference pricing as a means of establishing the price of patented medicines or whether the PMPRB should be abandoned and replaced by another means of controlling prices. Other methods are operating in different countries or have been proposed, but they would have to be carefully assessed to see if they are suitable for Canada. New Zealand probably has the most aggressive mix of tools to control drug prices, including internal reference based pricing but covering a much wider range of drug groups. It also uses multi-product agreements whereby companies agree to lower the price on a drug already covered in order to get a new one listed, tendering for drugs no longer under patent to generate price competition among companies, and expenditure caps that limit spending when there is uncertainty and potential risk around the likely uptake of the medicine (4). Without PHARMAC, the agency that manages the New Zealand drug budget, expenditures were projected to grow from NZ $517 million in 2000 to NZ $2.336 billion in 2012, but instead were only NZ $777 million (5).

In answer to some of the specific questions asked in the paper here are my responses.

Question 1

The question of what is an “excessive” price should be determined based on a combination of factors including the cost of R&D and manufacturing, the therapeutic value of the product and the overall level of profit of the company. Since therapeutic value (benefit to harm ratio) cannot accurately be determined when new drugs are introduced into the market it should be re-evaluated at regular intervals and the price adjusted either upwards or downwards. Similarly, manufacturing costs may change and this should be reflected in the price of drugs.

Question 3:

The PMPRB should require that companies disclose R&D and manufacturing costs.

Question 4 (and 12):

The PMPRB should revise the set of countries that it uses for price comparison to reflect those countries where the pharmaceutical industry more closely mirrors the Canadian situation, i.e., no domestic large multinational companies. Countries to consider would be Australia, New Zealand and Norway among others.

Question 5:

As the PMPRB has acknowledged factors such as pricing are not important in attracting R&D and therefore the level of R&D should not be a factor in setting prices.

Question 6:

The pharmaceutical industry typically argues that its prices are justified based on therapeutic benefit, e.g., the prices of the new medications for Hepatitis C are justified because they cure patients and therefore avoid the need for treatment for liver cancer or liver transplants. Therefore, I advocate for the PMPRB to continue to consider therapeutic benefit as a factor in setting prices. (Of course, this rational about therapeutic benefit ignores arguments that on this basis we should be paying huge amounts for clean, safe drinking water since the availability of good water quality keeps people from getting diseases such as cholera.)

Question 7:

Without knowing how the PMPRB would determine the risk of excessive pricing this question is very difficult to answer. Also there is the obvious question - what is an “excessive” price?

Question 9:

One of the fundamental normative features of Canadian health policy is that all residents of Canada should be treated equally and this should apply to how much people, collectively or individually, pay for their medications. In most other countries there is no discrimination in prices based on geography.

I would be happy to meet with representatives of the PMPRB to elaborate on my answers.

Sincerely,

Joel Lexchin MD
Emeritus Professor
York University
and
Emergency Physician
University Health Network
E mail: jlexchin@yorku.ca
Tel: 416-209-4885

References

1. Husereau D, Jacobs P. Investigation and analysis of options to enhance Canada's patented medicine price ceiling regulatory regime. 2013.
2. Office of Fair Trading. Annexe D: global overview of the pharmaceutical industry. 2007.
3. Patented Medicine Prices Review Board. Annual report 2013. Ottawa: 2014.
4. Pharmaceutical Management Agency. Purchasing medicines Wellington: PHARMAC; nd [Available from: http://www.pharmac.health.nz/assets/purchasing-medicines-information-sheet.pdf.
5. Pharmaceutical Management Agency. Annual review 2012. Wellington: 2013.