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May 9, 2005

Patented Medicine Prices Review Board
Secretary of the Board
Box L40
Standard Life Centre
333 Laurier Avenue West
14th floor
Ottawa, On
K1P 1C1

Subject: Abbott Laboratories' response to "Price increases for Patented Medicines: Discussion Paper"

Dear Secretary of the Board,

Following PMPRB's invitation to participate in the discussion regarding Price Increases, Abbott Laboratories is please to respond with our responses to the "Questions for Stakeholders" in the Discussion paper.

Please let me know if you have any questions on our responses. We appreciate the opportunity to respond.

Sincerely,

Laurie Dotto

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Abbott Laboratories Comments:

The PMPRB was established to ensure that patented medicines are available to Canadians at a price that is not excessive. Within the Patent Act, numerous factors have been established to determine if the price of patented medicines is excessive. These factors are (as stated in the Price increases for Patented Medicines: Discussion Paper):

a) The prices at which the medicine has been sold in the relevant market;
b) The prices at which other medicines in the same therapeutic class have been sold in the relevant market;
c) The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
d) Changes in the Consumer Price Index; and
e) Such other factors as may be specified in any regulations made for the purposes of this subsection.

In addition to these factors, the Excessive Price Guidelines offer regulation on how a price increase on patented medicine can be determined using the CPI Guidelines. In the CPI Guidelines price increases are limited to the cumulative change in the CPI over three years, and any price increase in a given year may not exceed 1,5 times the forecast change in the actual CPI.

Position on Price Increase Discussion Paper

It is Abbott Laboratories' position that the PMPRB, in its current framework, has had much success in attaining the goals that it was established to achieve, namely ensuring that patented medicines prices are not excessive and ensuring price stability. If we look at where Canadian patented medicine prices were in 1987 (23% higher than the median international comparative prices) and where they have been recently (5% to 12% under the median international comparative prices between 1994 and 2003) price stability has been put in place in Canada by the Guidelines and monitored efficiently by the PMPRB.

Abbott Laboratories therefore sees no reason to change the Guidelines or its application by the PMPRB.

Response to Frameworks

Question 1

Should they continue to allow for automatic (i.e. without prior approval) price increase?

Abbott Laboratories is comfortable with the efficiency of the current process of reporting a price increase once it has been established. The current process allows for flexibility of adjusting pricing strategies at the last minute, if necessary, without having to seek prior approval by the PMPRB and face potential delays associated with such a process.

Moreover, Abbott Laboratories is reluctant to divulge any sensitive competitive information such as a price increase prior to its implementation. The ramifications of a competitor, wholesaler, distributor or customer obtaining this type of competitive information prior to implementation could lead to an adjustment in their strategy, buying pattern, etc... This would put us at a disadvantage and negate the effect of strategic decisions.

In addition, prior approval of a price increase by PMPRB would also have the potential of duplicating the workload associated with filing and re-filing adjustments to price increases, during the planning process, prior to actually putting the increase in place.

A change to advance notification requirements for new products or planned price changes will result in the following:

- Increased regulatory burden for both the manufacturers and the PMPRB
- Inefficiencies in the price review process. The current average PMPRB pricing review timelines are considered too long. This review time needs to be brought into the 60 - 120 day timeframe that has been suggested.

Other considerations:

- Change to Patent Act would be required
- Current "Excessive Price Guidelines" apply to "Average selling price" not to "List price"
- Manufacturers do not receive advance notification of NOC date from Health Canada for new products. A requirement to submit pricing 60 days in advance of first sale is therefore not practical and would only lead to the delay of new medicine introduction to market by an additional 60 days.
- Failure to allow for price increases may lead to the widening of a gap between Canadian and US pricing and the further development of cross-border trade in pharmaceuticals. This in turn may result in product shortages or a reduction in the commercialization of innovative treatments and products for Canadians.

Question 2

Are there considerations other than, or in addition to, the CPI that should be used to review price increases?

Abbott Laboratories recognizes and supports the need to maintain a sustainable healthcare system in Canada. The use of CPI as part of the PMPRB "Excessive Price Guidelines" calculation has been stable over the past 10 years (ref: PMPRB discussion Paper, March 2005) while inflation has increased by 21,6% over the same period.

It is Abbott Laboratories' position that the CPI remains the corner stone to the calculation of an acceptable price increase on a yearly basis, as it is a recognized and simple measure of the Canadian economic environment.

Question 3

How often should price increases occur? (e.g. every year, once every 3- 5 years, only after a certain introductory period, when justified)

Timing of a price increase should not matter provided it falls within the Guidelines and therefore is not excessive.

As is the case presently, patentees should not be constrained to a fixed date to implement a price increase. The appropriate timing of any price increases will vary depending on the product. For example, the timing of price increases is important for cyclical or seasonal products. Having flexibility to increase price, as the market requires is a competitive necessity.

Moreover, there is no evidence that patentees have abused the price increase flexibility available to them by putting in place numerous price increases in a short. In its current format, the Guidelines, by limiting the total price increase for each year, controls by the same token the limits the number of price increases that a manufacturer will want to take in a year.

Over the past year several provincial reimbursement agencies have advised us that they are prepared to accept price increases at various times during the year. Therefore, it would be very complicated for the PMPRB to establish fixed dates for price increases that would take in to account all of the dates required by each provincial formulary.

Question 4

If justification is required, what criteria should be considered?

As long as price falls within the current PMPRB Guidelines and does not exceed the Excessive Price Guidelines, no other justification should be required.

Justification should only be required in cases where the price increase exceeds the CPI Guidelines and brings the price of the patented medicine at an excessive level in comparison to market comparator and international median as defined in the Guidelines.

In addition to the CPI, the indexed prices at which other medicines in the same therapeutic class have been sold and the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada should be considered in the calculation of acceptable price increase to reflect the economic environment of the products.

There is no need to over-regulate a process that works well at the present time and that reaches the goals it was set to attain.

Question 5

Given that the CPI is established in the Patent Act as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future Guidelines?

The CPI was incorporated in the Guidelines as a methodology to establish price increase boundaries that were both easy to implement and understand. This is exactly what the CPI Guideline has achieved, clear and precise direction that is easy to incorporate in a patentee's pricing strategy.

Abbott Laboratories recommends keeping the present utilization of the CPI in future Guidelines as the main reference of price increase calculations and also add the CPI to the prices of comparator drugs when comparing the price increase to other drugs.

Conclusion

In summary, Abbott Laboratories believes that a sustainable healthcare system and an environment for innovation can both be maintained in Canada. The ability for manufacturers to introduce price increases and establish competitive pricing for innovative pharmaceutical treatments is paramount to the "health" of the industry and the patients in this country. Data collected by the PMPRB over the past decade demonstrates that the current system for price assessment is working. Changes to this approach will result in increased administrative burden for both manufacturers and the PMPRB. Longer pricing reviews and approval times and the delay of innovative treatments for the Canadian public.

In addition, we believe that the application of any proposed changes will require amendments to the Patent Act.