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and Long-Term Care

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PATENTED MEDICINE PRICES REVIEW BOARD
2005 MAY 9 PM 3 50
CONSEIL D'EXAMEN DU PRIX DES MEDICAMENTS BREVETES

MAY 0 9 2005

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Secretary of the Board
Patented Medicine Prices Review Board
Standard Life Centre
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To Whom It May Concern:

This is in reference to the framework questions described in the discussion paper on Price Increases for Patented Medicines as noted in the Patented Medicine Prices Review Board (PMPRB) Notice and Comment publication dated March 2005.

As noted in your report, Canada's patented drug prices are currently at the median of the C7 countries as a result of PMPRB pricing rules and its application to allowable price increases. The guidelines were established with a concurrent commitment by the brand pharmaceutical industry to a Canadian research and development to sales ratio of 10 per cent in exchange for longer patent protection.

Provincial drug reimbursement policies have also had a significant role in curbing patent drug price increases. In Ontario, there has been a price freeze in effect since 1994. At this time, the price freeze is still in effect but the ODB program will only accept price increases if the manufacturer provides price reductions for other products so that the net impact is cost-neutral to Government.

There is significant pressure from the brand pharmaceutical industry to remove the price freeze policy which in part is driven by the differential in Canadian and United States prices. PMPRB's discussion paper notes that in 2004 manufacturers of about 35% of the patented medicine products implemented price increases. The elimination of the price freeze would mean potential annual price increases up to the Consumer Price Index (CPI) under the current guidelines. For example, if the ODB allowed a 1% increase for patented products in 2004/05 there would be an estimated impact of $21 million. The total impact would depend on the allowable CPI increases. Ontario's private insurance sector would experience similar impacts.

A key reason cited by the manufacturers is that price increases are needed to level the price differentials between the USA and Canada. However many have reported that, if one looks at the issue carefully, the price differentials between the countries are not that large. This is due to that

fact that in the U.S., Federal and State authorities, who pay for a large portion of the drug expenditures, enter into contracts with manufacturers and Pharmacy Benefit Managers (PBM) that involve considerable rebates and discounts. As a result, the effective price (price paid by payers) of drugs are considerably lower than what is listed for cash paying customers. We would recommend that PMPRB complete an analysis comparing Canadian prices to different types of US payers which takes into consideration the impact of exchange rates.

Manufacturers, in effort to get the maximum value from a product during its life cycle, may attempt to increase its price as the product nears patent expiration. The adverse impact of such a price increase is that, it will set a higher price for the relevant therapeutic category.

In the last few years, there has been considerable consolidation in the pharmaceutical industry, resulting in a handful of firms controlling most of the market. A price increase in this environment will further strengthen oligopoly power of these firms.

ODB does not support across the board price increases. Such price increases can significantly affect ODB's budget, especially if the increase applies to a small group of single source drugs. Since a handful of single source drugs make up significant portion of ODB's expenditure, a relatively minor price increase for any of these drugs can have a large budgetary impact. For instance a 4% increase in the price of Lipitor in 2004 could add $7.8M to ODB's budget.

Our experience in price increases for older pre-patent expiry products indicates that such increases results in higher ODB expenditures and loss for the pharmacists. ODB has a mechanism in place (known as cost-to-operator claims) for cases where a pharmacist can receive the acquisition cost when the price of a drug exceeds ODB price plus pharmacy markup. In recent years however, the frequency of such cases have increased dramatically. A review of oral solids in 2004 indicates that price increases resulted in an increase ODB expenditure of $21 9M.

The discussion paper outlines three framework models for price increases. We support the "framework 3" model in which patentees would be required to apply to the PMPRB in advance of any price increase and that the manufacturer would be required to provide justification of the increase and the extent of the increase. Prior notification allows PMPRB to provide proactive guidelines which provincial and the private sector can use in setting their reimbursement and/or /formulary policies. We also recommend that PMPRB collect additional information from manufacturers such as ingredient cost and patent expiration date.

Under this proposed framework, PMPRB will need to have clear criteria established to assess cost increase requests. Based on our discussions within the ministry we have had significant difficulty in determining discrete variables to measure price increases against. Some example could include a significant increase in raw material costs or changes in production costs directly related to that product. Similar work has been done in Australia and we would recommend that PMPRB review and assess the price increase policy that has been developed in that country. Alternatively, price increases could be linked to the amount and/or type of research and development that is invested in Canada. If the increases are based on meeting specific criteria, then the frequency of increases do not need to be defined in the guidelines.

The increases could continue to be based on CPI guidelines but there is a possibility of building in variables on the increases. If the costs increases for production or materials are below the CPI level then the price increase should not be based on a maximum CPI increase. The CPI increases could be considered to evaluate price increases that are related to performance based measures such as company specific research and development investments. Price increases, up

to a maximum of CPI, could be based on a company's research and development to sales ratio which is considerably higher than the current 10% and compared to other pharmaceutical companies e.g., ratio is 15 to 20%. There should also be an emphasis on basic or pre-clinical research.

Cost-effectiveness is a key principle for reimbursing drugs under the Ontario Drug Benefit (ODB) program. One determinant of cost-effectiveness is the price of the product and ongoing effectiveness should be considered when the product is first introduced to the Canadian market and as prices are updated. Price is a reflection of the drugs value in terms of efficacy, safety, side effects, dosing convenience, and risk of adverse interactions with other medications. Any increase in the price should coincide with evidence that shows increased value in terms of these factors.

Thank you for the opportunity to comment. If you require clarification on any of the points noted above, please contact myself at (416) 327-8095 or Brent Fraser at (416) 327-8118.

Sincerely,

Susan Paetkau
Director
Drug Programs Branch