PMPRB Advisory Note

Rezulin - Parke Davis

May 1999

This Advisory Note provides information on the PMPRB price review process and the patented medicine Rezulin.

Patented Medicine Prices Review Board

- The PMPRB is a quasi-judicial tribunal with the mandate to protect consumer interests and contribute to Canadian health care by ensuring that the prices charged by manufacturers of patented medicines are not excessive.

- The Board has no authority to approve drugs for sale, to authorize their use nor to take drugs off the market. It is required to review the prices being charged by manufacturers of patented drugs for compliance with the *Patent Act*. If, following a public hearing, the Board finds that a price is excessive, it may order a reduction in the price to a non-excessive level.

Price Review Process

- In accordance with the *Act*, the Board has established price guidelines in consultation with provincial ministers of health, consumer groups, the pharmaceutical industry and other stakeholders. The Guidelines are based on factors specified by Parliament in the *Act*. The effect of the Guidelines is to limit the prices of most new patented drugs so that they cannot exceed the price of the most expensive drug on the market that treats the same condition or disease; in the case of a breakthrough drug, the price in Canada may not exceed the median of the prices for the same drug in seven other industrialized countries.

- The Board has followed a policy of voluntary compliance which has been supported by all stakeholders, including the pharmaceutical industry. In fact, most manufacturers ensure that they set prices that comply with the Guidelines. The Board has completed a hearing on only one occasion, in a matter involving ICN Canada Ltd. and the drug Virazole. In that case, the Board found that the price of the drug was excessive and ordered a price reduction and other remedies. In 14 other cases since 1993, the Board has approved voluntary undertakings from manufacturers to make adjustments in order to comply with the *Act*.

Parke-Davis

- Parke-Davis is a division of Warner- Lambert Inc., an American company, which has the rights to sell Rezulin in North America. In May 1997, it received approval to sell Rezulin from Health Canada, but it has never brought the drug to market.

- Parke-Davis is free to sell Rezulin at any time pursuant to the authorization from Health Canada. The PMPRB has no authority to approve drugs for sale, to authorize their use nor to take drugs off the market.

Rezulin

- According to public sources, Rezulin is only being sold in the United States and Japan at this time. In 1997, it was approved for sale in the United Kingdom and was sold by another company under the brand name Romozin for a brief period of time, but was then ordered off the market by the authorities due to safety concerns. It is not being sold anywhere in Europe. Issues related to the safety of Rezulin have continued to be under review by the Food and Drugs Administration in the United States.

- The price of Rezulin in the United States is reported to be $4.74 ($US), approximately $7.11 ($CAN) per 400 mg tablet (average wholesale price listed in Drug Topics Red Book May 1999).

- It was also reported that the price in the United Kingdom (as listed in the Monthly Index of Medical Specialties, October 1997) was approximately $2.00 ($CAN) for the 400 mg tablet when the drug was sold in that country.

- In applying the Board's Guidelines, the staff rely on the recommendations of an independent panel of scientists, the Human Drug Advisory Panel, as to the therapeutic merits and appropriate comparators for price review purposes. Based on their advice, it would appear that the prices of comparable drugs to Rezulin in Canada do not exceed about $1.85.

- Under the Board's compliance policy, Board staff, at the request of a patentee, will provide advice as to the application of the Guidelines. It has not been the practice of the Board to report on that advice unless the patentee has done so. The Board's price review process is currently under review by a working group representing stakeholders.

- If a patentee disagrees with the advisory opinion from Board staff, there are a number of vehicles available to it to attempt the resolve the matter:

  - Under the *Act*, a patentee can apply to the Board for an Advanced Ruling Certificate with respect to the proposed price. This procedure can only be initiated by the patentee, not by the Board.

  - The patentee can provide supporting information, if it exists, to justify why its proposed price should not be considered excessive under the *Act* or Guidelines.

  - The patentee can begin selling the drug in Canada and be prepared, if necessary, to defend its price before the Board in a public hearing. The *Act* and the laws of Canada ensure the patentee a right to be heard and a fair hearing.

- The matter of Rezulin has never been referred to the Board itself and the Board has made no finding or determination of what might be an excessive price for purposes of the *Patent Act*.

Availability of Rezulin in Canada

- Patients who wish to obtain more information about the availability of Rezulin should contact their physician and pharmacist.