Under its transparency initiative, the Board is to make publicly available the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's price Guidelines. It is an important initiative which we hope will provide another valuable source of information about new patented drugs. The Board looks forward to feedback on this initiative.

Report on New Patented Drugs – Cerezyme

Brand Name (generic): Cerezyme (imiglucerase)

DIN: 02230694 - 200 unit/vial
02241751 - 400 unit/vial

Patentee: Genzyme Canada Inc.

Indication (as per the product monograph): Cerezyme is indicated for long-term enzyme replacement therapy for patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: anaemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.

Notice of Compliance: February 12, 1997 - 200 unit/vial
February 23, 2000 - 400 unit/vial

Date of first sale: 1997 - 200 unit/vial
2000 - 400 unit/vial

The first patent pertaining to Cerezyme was issued on May 22, 2001 and it came under the PMPRB's jurisdiction at that time.

ATC Class: A16ABO2: *Other Alimentary Tract and Metabolism Products, Enzymes*.

Application of the Guidelines

Scientific Review: The PMPRB's Human Drug Advisory Panel recommended that Cerezyme be reviewed as a category 2 new drug (breakthrough or substantial improvement) based on the following information:

- Cerezyme is the first drug product to be approved and sold in Canada which has been demonstrated to be effective as a long-term enzyme replacement therapy for patients with confirmed diagnosis of Type 1 Gaucher disease.
- Ceredase (alglucerase), another medicine supplied by the same manufacturer, had been identified as a possible comparator for Cerezyme. Ceredase was supplied in Canada under the Special Access Program (SAP) until it was phased out as patients were switched to Cerezyme. Ceredase is no longer available and consequently, Cerezyme is the only drug approved and sold in Canada for this indication.

Price Review: Under the Guidelines, the price of a new drug in category 2 should not exceed the higher of the prices of other drugs that treat the same disease (therapeutic class comparison, or TCC test) and the median of the prices of the same drug in the seven countries listed in the *Patented Medicines Regulations*. It was not possible to conduct a TCC test for Cerezyme as the HDAP did not identify any comparable medicines.

	200 unit/vial	400 unit/vial
Canada	**$1,160.0000**	**$2,320.0000**
Germany	$1,352.1802	$2,781.5752
France	—	—
Italy	$965.5091	—
Sweden	$1,427.2996	$2,854.5304
Switzerland	—	—
UK	—	—
US	$1,098.8034	$2,197.6068
Median	$1,225.4918	$2,781.5752

An International Price Comparison (IPC) test was conducted on each strength of Cerezyme. The Canadian price of each strength was found to be within the Guidelines as it did not exceed the median of the prices for the same drug in those countries in which it is being sold.

The *Patented Medicines Regulations* require that patentees file publicly available prices in the seven countries listed therein (see ss. 4(1)(g)).

Evidence/ Reference considered by HDAP:

Available on the PMPRB website, under Publications; Patented Medicines; Reports on New Patented Drugs; Cerezyme.

Sources:

Germany: Rote Liste, November 2001*

Italy: L'Informatore Farmaceutico, June 2001*

Sweden: Prislista, June 2001*

US: "Direct Prices," Drug Topics Red Book, 2001

* Derived from publicly available formulary price using regulated wholesale mark-ups set out in PMPRB Study Series S-0215

Schedule 3 of the Compendium of Guidelines, Policies and Procedures sets out the methodology to conduct an IPC test. The Regulations and the Compendium are both available on our website under Legislation, Regulations, Guidelines.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner. ■

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