Report on New Patented Drugs – Replagal

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the Board's *Excessive Price Guidelines* (Guidelines) for all new active substances introduced after January 1, 2002.

Brand Name: Replagal

Generic Name: *agalsidase alfa*

DIN: 02249057 (3.5 mg/vial)

Patentee: Shire Human Genetic Therapies

Indication – as per product monograph:

Long term enzyme replacement therapy in patients with confirmed diagnosis of disease (alfa-galactosidase A deficiency)

Date of Issuance of First Patent(s) Pertaining to the Medicine:
June 26, 2007

Notice of Compliance: NOC/c on February 6, 2004

Date of First Sale: July 2004

ATC Class: A16AB03
Alimentary Tract and Metabolism; Other Alimentary Tract and Metabolism Products; Other Alimentary Tract and Metabolism Products; Enzymes

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Replagal was found to be within the Guidelines because the price in Canada did not exceed the median of the prices of the same drug in those countries listed in the *Patented Medicines Regulations* (Regulations) in which Replagal was sold.

Scientific Review

Replagal is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Replagal be classified as a category 2 new medicine (provides a breakthrough or substantial improvement). It is a breakthrough medicine as it is the first one to be sold in Canada that treats effectively a particular illness or addresses effectively a particular indication, i.e. the management of Fabry disease.

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

Price Review

Under the Guidelines, the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the price of all of the comparable drug products based in the TCC test, and the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines.

It was not possible to conduct a TCC test as the HDAP did not identify any comparator drug products. At introduction, the price of Replagal was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test. Replagal was sold in six of the seven countries listed in the Regulations. The table below does not include prices for Canada and some of the countries in which Replagal was sold in the introductory period as there were no publicly available sources for the prices.

Introductory Period (July – December 2004)

Country	Price per 3.5 mg/vial
Canada	no public price available
France	$2,840.4358*
Germany	$3,040.0173*
Italy	$2,693.1091*
Sweden	$2,820.6223*
Switzerland	No public price available
United Kingdom	no public price available
United States	not sold
Median	$2,830.5290

*Derived based on methodology set out in Verification of Foreign Patented Drug Prices (2000), PMPRB Study Series S-0215

Sources:

France: Sempex, August 2004
Germany: Rote Liste, July 2004
Italy: L'informatore farmaceutico, September 2004
Sweden: Preslista, September 2004

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by 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 PMPRB reserves the right to exclude from the therapeutic class comparison list any drug product if it has reason to believe it is being sold at an excessive price.

In its Summary Reports, the PMPRB will also refer to the publicly available prices of comparators provided such prices are not more than 10% above a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information purposes only and should not be relied upon as being considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than stated 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.

References – Replagal

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