Report on a New Patented Drug — Myozyme

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 in Canada after January 1, 2002.

Brand Name: Myozyme (50 mg/vial)

Generic Name: alglucosidase alfa

DIN: 02284863

Patentee: Genzyme Canada Inc.

Indication – as per product monograph: For use in patients with Pompe disease (GAA deficiency)

Date of Issuance of First Patent(s) Pertaining to the Medicine: April 29, 2008

Notice of Compliance: August 14, 2006

Date of First Sale: January 9, 2007

ATC Class: A16AB07
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 Myozyme exceeded the Excessive Price Guidelines (Guidelines) because the price in Canada slightly exceeded the median of the prices of the same drug product sold in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Myozyme was sold. However, the investigation criteria were not triggered and excess revenues were offset in the following year.

Scientific Review

Myozyme is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Myozyme be classified as a category 2 new medicine (breakthrough or substantial improvement). The HDAP did not recommend any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

Price Review

Under the Guidelines, the introductory price of a category 2 new drug product will be presumed to be excessive if it exceeds the higher of the prices of all comparable drug products based on the TCC test or 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: http://www.pmprb-cepmb.gc.ca/CMFiles/comp08-e38NBY-3182008-1638.pdf.

No comparators were identified for purposes of conducting a TCC test. The introductory price of Myozyme was just slightly above the median of the international prices identified in an IPC test. Myozyme was sold in five country listed in the Regulations.

Introductory Period (January to June 2007)

Country and Median	Price (in Canadian dollars)
Canada	$840.3100 per vial
France	Not sold
Germany	$840.3099 per vial
Italy	$840.3099 per vial
Sweden	$856.2828 per vial
Switzerland	Not sold
United Kingdom	$823.5171 per vial
United States	$734.9248 per vial
Median	$840.3099 per vial

Sources:
Canada, Germany, Italy, Sweden, United Kingdom and United States: Publicly available price as per Regulations.

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 test any drug product it has reason to believe 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.

This report, including the references, is available on our Web site under Regulatory; Patented Medicines; Reports on New Patented Drugs for Human Use; Myozyme. ■