Report on New Patented Drugs

Pulmozyme

PMPRB

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

Brand Name:	Pulmozyme
Generic Name:	dornase alfa recombinant
DIN:	02046733 2.5 mg/ampul
Patentee:	Hoffmann-La Roche Canada Ltd.
Indication (as per product monograph):	For the management of cystic fibrosis patients to reduce the frequency of respiratory infections requiring parenteral antibiotics and to improve pulmonary function.
Notice of Compliance:	December 1993
Date of First Sale:	August 1994 In most cases, patents are issued before the drugs come to market. In this case, the first patent pertaining to Pulmozyme was issued on February 5, 2002 and it came under the PMPRB's jurisdiction at that time.
ATC Class:	RO5CB13 *Cough and Cold Preparation, expectorants, excluding combinations with cough suppressants, mucolytics*

Application of the Guidelines

Summary:

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The seven countries listed in the *Patented Medicines Regulations, 1994*, for purposes of price comparison are France, Italy, Germany, Sweden, Switzerland, United Kingdom and the United States.

The introductory price of Pulmozyme was found to be within the Guidelines because the Canadian price did not exceed the median of the prices for the same drug in the seven countries listed in the *Patented Medicines Regulations, 1994* (Regulations). The price of Pulmozyme continued to be within the Guidelines in 2002 when it came under the PMPRB's jurisdiction.

Scientific Review:

Pulmozyme is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) reviewed it as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines.)

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the Anatomical, Therapeutic, Chemical (ATC) System that are clinically equivalent in addressing the approved indication.

The other medications in the same fourth level ATC as Pulmozyme include Mucomyst (N-acetylcystine) and Uromitexan (mesna). However, neither of these agents share the same indication as Pulmozyme nor is there any evidence supporting the use of these agents for the treatment of cystic fibrosis. Consequently, the HDAP recommended no comparators for the conduct of a TCC for Pulmozyme.

The Guidelines provide that when it is inappropriate or impossible to conduct a TCC, the primary weight will be given to the median of the international prices. The price will be presumed excessive if it exceeds the median of the prices of the same drug in the seven countries listed in the Regulations. See the PMPRB's Compendium of Guidelines, Policies and Procedures for a more complete description of the Guidelines and the policies on International Price Comparisons.

Price Review:

The Canadian price of Pulmozyme was within the Guidelines as it did not exceed the median of the prices for the same drug in those countries in which it was being sold. As shown in the following table, the price of Pulmozyme in Canada continued to be below the median international price in 2002.

Country	$ CDN price per 2.5 mg/amp
Canada	$35.00
France	$42.17
Germany	$40.74
Italy	$35.88
Sweden	$44.93
Switzerland	$33.47
UK	$41.26
US	$50.32
Median	$41.26

Sources

Canada: Liste des médicaments, Régie de l'assurance maladie du Québec, 2002
France: Sempex, February 2002
Germany: Rote Liste, January 2002
Italy: L'Informatore Farmaceutico, March 2002
Sweden: Prislista, May 2002
Switzerland: Medwin, September 2002
UK: MIMS, March 2002
US: AWP, Drug Topics Red Book, March 2002; FSS Price, 2002

Evidence/ References:

The references are available on the PMPRB website, under Other Publications; Patented Medicines; Reports on New Patented Drugs; Pulmozyme.