June 06

Report on New Patented Drugs - Remodulin

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

Brand Name: Remodulin

Generic Name: *(treprostinil sodium)*

DIN: 02246554 5.0 mg/ml

Patentee: Northern Therapeutics Inc.

Indication - as per product monograph:

For the long term, subcutaneous treatment of pulmonary arterial hypertension in NYHA Class III & IV patients who did not respond adequately to conventional therapy.

Date of Issuance of First Patent(s) Pertaining to the Medicine: August 19, 2003

Notice of Compliance: October 4, 2002

Date of First Sale: October 7, 2004

ATC Class: Not yet classified in the WHO ATC index.

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Remodulin 5.0 mg/ml was found to be within the Guidelines because the daily cost of therapy did not exceed the daily cost of therapy of existing drugs in the therapeutic class comparison and the price did not exceed the prices in the other comparator countries where Remodulin 5.0 mg/ml was sold.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Remodulin 5.0 mg/ml be reviewed 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. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP identified Tracleer (*bosentan*) and Flolan (*epoprostenol*) as the most appropriate comparators for Remodulin as they share the same indication as Remodulin and are clinically equivalent at addressing the approved indication of Remodulin.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Remodulin and the comparators are based on their respective product monographs and supported by clinical literature.

Price Review

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*. The price of Remodulin 5.0 mg/ml was within the Guidelines as the daily cost of treatment did not exceed the daily cost of treatment with the comparator medicines.

Introductory Period (October to December 2004)			
Name	**Strength**	**Dosage Regimen**	**Cost per Day**
Remodulin (treprostinil sodium)	**5.0 mg/ml**	**22 ng/kg/min**	**$99.9000** [1]
Flolan (epoprostenol)	1.5 mg/vial	27 ng/kg/min	$ 63.3500 [1]
Tracleer (bosentan)	125 mg/tablet	125 mg bid	$128.3572 [2]

1. Association québécoise des pharmaciens propriétaires (AQPP), October 2004
2. Liste des médicaments, Régie de l'assurance maladie du Québec, October 2003

In 2004, Remodulin 5.0 mg/ml was being sold in two of the seven countries listed in the Regulations that are Germany and the U.S. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries; the price of Remodulin 5.0 mg/ml in Canada was the lowest of those countries, below the median international price.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the 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.

References – Remodulin

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