Report on New Patented Drug — Relistor

The PMPRB publishes the results of the reviews of new patented drug products 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: Relistor

Generic Name: *methylnaltrexone bromide*

DIN: 02308215 (20mg/vial)

Patentee: Wyeth Pharmaceuticals

Indication – as per product monograph: For treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, Relistor should be used as an adjunct therapy to induce prompt bowel movement.

Date of Issuance of First Patent Pertaining to the Patented drug product: April 6, 1993

Notice of Compliance: March 28, 2008

Date of First Sale: May 22, 2008

ATC Class: A06AX
Alimentary Tract and Metabolism; Laxatives; Laxatives; Other Laxatives

Application of the Guidelines

Summary

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

Scientific Review

Relistor is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Relistor be classified as a category 2 new patented drug product (a breakthrough or a substantial improvement over comparable existing drug products). 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 and the median of the international prices identified in the International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines.

As no comparators were identified for purposes of conducting a TCC test, the introductory price of Relistor was considered within the Guidelines as it did not exceed the median of the international prices identified in the IPC test. Relistor was sold in one country listed in the Regulations.

When an IPC test is being conducted to determine the median price, an interim median international price will be used in cases when the drug product is sold in fewer than five countries at the time of its introduction. Unless it is excessive, the introductory price will be treated as the interim benchmark price. The interim benchmark price may be reviewed at the end of three years or when the drug product is sold in at least five countries, whichever comes first.

Introductory Period (May to June 2008)

Country and Median	Price (in Canadian dollars)
Canada[1]	$38.00 per vial
France	Not sold
Germany	Not sold
Italy	Not sold
Sweden	Not sold
Switzerland	Not sold
United Kingdom	Not sold
United States[2]	$39.8634 per vial
Median	$39.8634 per vial

Sources:
1 PPS, July 2008
2 Federal Supply Schedule, June 2008 and Direct Price, Red Book, July 2008

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 drug products 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 indicating the public prices are considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than that stated and is not to be interpreted as an endorsement, recommendation or approval of any drug product, 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 Drug Products; Reports on New Patented Drugs for Human Use; Relistor. ■