Report on New Patented Drug – Zelnorm

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 Price Guidelines for all new active substances introduced after January 1, 2002.

Brand Name:	Zelnorm
Generic Name:	*(tegaserod hydrogen maleate)*
DIN:	02245566 6 mg tablet
Patentee:	Novartis Pharma Canada Inc.
Indication - as per product monograph:	For the symptomatic treatment of irritable bowel syndrome with constipation (IBS-C) in female patients whose main symptoms are constipation and abdominal pain and/or discomfort.
Notice of Compliance:	March 12, 2002
Date of First Sale:	June 4, 2002
Date of Issuance of First Patent(s) Pertaining to the Medicine:	March 15, 2005
ATC Class:	A03AE02 *Alimentary Tract and Metabolism, Drugs for Functional Gastrointestinal Disorders, Drugs for Functional Bowel Disorders, Drugs Acting on Serotonin Receptors*

Application of the Guidelines

Summary

The introductory price of Zelnorm 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 it was sold.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Zelnorm 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 Dicetel (*pinaverium bromide*), Modulon (*trimebutine maleate*), Levsin *(hyoscyamine sulfate*) and Bentylol (*dicyclomine HCl*) as appropriate comparators as they treat a variety of symptoms related to irritable bowel syndrome with constipation. However, as these agents are dosed on an as needed (prn) basis versus the daily compulsory dosing of Zelnorm, the HDAP could not identify a comparable dosage regimen.

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 Regulations. The Guidelines further state that when it is inappropriate or impossible to conduct a TCC test, Board Staff will give primary weight to 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.

As the HDAP did not recommend a comparable dosage regimen in this case, in accordance with the Guidelines, primary weight was given to the median of the international prices.

Introductory period (July to December 2002)

Country	Price per tablet (CDN$)
Canada	$ 2.0000
Switzerland	$1.0068
United States	$3.0495
International Median	$2.0282

Canada: PPS July 2002
Switzerland: Medwin Web site, December 2002
United States: Federal Supply Schedule (FSS), December 2002

The Guidelines provide that when a medicine is sold in fewer than five countries at the time of its introduction, 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 medicine is sold in at least five countries, whichever comes first. At introduction, Zelnorm was sold in two countries. Zelnorm continued to be sold in two countries at the end of three years and the price continued to be within the Guidelines.

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. ■

Summary Reports are available on our Web site under Regulatory; Patented Medicines; Reports on New Patented Drugs for Human Use.

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