Report on New Patented Drugs - Somavert

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 in Canada after January 1, 2002.

Brand Name: Somavert

Generic Name: *(pegvisomant)*

DIN:

02272199	10 mg/vial
02272202	15 mg/vial
02272210	20 mg/vial

Patentee: Pfizer Canada Inc.

Indication - as per product monograph:

For the treatment of acromegaly in patients who have had an inadequate response to surgery, and/or radiation therapy, and other medical therapies, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum IGF-1 levels and to improve clinical signs and symptoms.

Date of Issuance of First(s) Patent Pertaining to the Medicine: April 1, 2003

Notice of Compliance: October 17, 2005

Date of First Sale: January 24, 2006

ATC Class: H01AX01
Systemic Hormonal Preparations, Excluding Sex Hormones and Insulins; Pituitary Lobe Hormones and Analogues, Other Anterior Pituitary Lobe Hormones and Analogues

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Somavert were found to be within the Guidelines because the prices in Canada did not exceed the median of the prices of the same drug in those comparator countries listed in the *Patented Medicines Regulations* in which Somavert was sold.

Scientific Review

Somavert is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Somavert be classified as a category 3 new medicine (provides moderate, little or 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 selection of the Guidelines and the policies on TCCs.

The HDAP did not identify any comparable medicines for Somavert. It has been granted a restricted indication for patients who have failed surgery and treatment with somatostatin analogues, a population for which there is no current drug therapy. Somatostatin analogues will likely remain first-line therapy as they target growth hormone levels; Somavert has a clinical profile which is distinctly different from somatostatin analogues and therefore the HDAP did not consider Somavert to be clinically equivalent to somatostatin analogues.

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 price of all of the comparable drug products in the TCC test, or if the price in Canada exceeds the range of the prices of the same medicine sold in the countries listed in the *Patented Medicines Regulations* (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.

As no comparators were identified for purposes of conducting a TCC test, the prices of Somavert were within the Guidelines as they did not exceed the median of the international prices identified in an IPC test.

Introductory Period (January to June 2006)

Country	10 mg vial	15 mg vial	20 mg vial
Canada	**$113.3600**	**$169.8700**	**$226.3800**
France	$115.5812	$173.2738	$233.6251
Germany	$123.9284	$185.2148	$245.8234
Italy	$119.4412	$179.1620	$238.8826
Sweden	$124.8670	$187.3033	$249.7225
Switzerland	$120.3365	$178.9816	$239.0460
United Kingdom	$110.3084	$165.4627	$220.6177
United States	$93.7786	$140.6645	$187.5571
Median	$119.4412	$178.9816	$238.8826

Sources:

Canada:	Publicly available price as per the *Patented Medicines Regulations*
France:	Sempex, February 2006
Germany:	Rote List, January 2006
Italy:	L'informatore farmaceutico, June 2006
Sweden:	Prislista, June 2006
Switzerland:	Medwin Web site, January – June 2006
UK:	Mims, June 2006
USA:	Federal Supply Schedule (FSS), January – June 2006 Thomson Micromedex Wholesale Acquisition Cost (WAC), April 2006

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 – Somavert

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