

Report on New Patented Drugs — Tysabri

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products conducted by Board Staff for purposes of applying the Board's pre-2010 Guidelines for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Tysabri

Generic Name: natalizumab

DIN: 02286386 (20 mg/mL)

Patentee: Biogen Idec Canada Inc.

Indication – as per product monograph: Indicated as monotherapy (i.e., single disease-modifying agent) for the treatment of patients with the relapsing–remitting form of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability. Tysabri is generally recommended in MS patients who have had an inadequate response to, or are unable to tolerate, other therapies for multiple sclerosis.

Date of Issuance of First Patent Pertaining to the Medicine: June 29, 2004

Notice of Compliance: September 28, 2006

Date of First Sale: November 21, 2006

ATC Class: L04AA23

*Antineoplastic and Immunomodulating Agents; Immunosuppressants; Immunosuppressants;
Selective immunosuppressants*

Application of the Guidelines

Summary

The introductory price of the Tysabri was found to be within the pre-2010 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 Tysabri was sold.

Scientific Review

Tysabri is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Tysabri be classified as a category 3 new medicine (provides moderate, little or no therapeutic over comparable drug products). The HDAP did not recommend any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

Price Review

The TCC of the pre-2010 Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drug products that are clinically equivalent in treating the same disease or

condition. Comparators are generally selected from among existing drug products in the same 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) Classification System. However, 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 Board's *Compendium of Guidelines, Policies and Procedures "up to 2009"* for a more complete description of the Guidelines and the policies on TCCs.

As no comparators were identified for purposes of conducting a TCC test, an IPC test was conducted. The introductory price of Tysabri was considered within the pre-2010 Guidelines as it did not exceed the median of the international prices identified in the IPC test. Tysabri was sold in six countries listed in the Regulations, namely, Germany, Italy, Sweden, Switzerland, United Kingdom and the United States.

Introductory Period (November to December 2006)

Country and Median	Price (in Canadian dollars)
Canada	(1)
France	Not sold
Germany	\$185.7471 per mL ⁽²⁾
Italy	\$184.2120 per mL ⁽²⁾
Sweden	\$172.3649 per mL ⁽²⁾
Switzerland	\$178.2805 per mL ⁽²⁾
United Kingdom	\$168.8668 per mL ⁽²⁾
United States	\$179.1648 per mL ⁽²⁾
Median	\$178.7227 per mL

Sources:

- 1 No public price available until 2008. La Régie de l'assurance maladie du Québec, 2008, listed a price of \$159.1876/mL.
- 2 Publicly available price as per the *Patented Medicines Regulations*.

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 Summary Reports under the pre-2010 Guidelines, the PMPRB refers to the publicly available prices of comparators, provided that such prices are not more than 10% above a non-excessive price, in which case no price will be made available. Publication of these prices is for information only and should not be construed as indicating that the public prices are considered to be within the pre-2010 Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than 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.

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