Report on New Patented Drugs - Alimta

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: Alimta

Generic Name: *(pemetrexed disodium)*

DIN: 02253437 500 mg vial

Patentee: Eli Lilly Canada Inc.

Indication - as per product monograph:

As first line therapy, Alimta is indicated in combination with cisplatin for the treatment of patients with malignant pleural mesothelioma (MPM) whose disease is unresectable or who are otherwise not candidates for curative surgery.

Date of Issuance of First Patent(s) Pertaining to the Medicine: July 25, 2000

Notice of Compliance: May 21, 2004

Date of First Sale: July 29, 2004

ATC Class: L01BA04
Antineoplastic and Immunomodulating Agents –Folic Acid Analogues

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Alimta 500 mg vial was found to be within the Guidelines because its price in Canada did not exceed the prices in the other comparator countries where Alimta 500 mg vial was sold. Although Alimta represents a category 3 new medicine under the Guidelines, it was not possible to identify comparator drug products for purposes of conducting a Therapeutic Class Comparison (TCC) test under the Guidelines, and therefore the median of the International Price Comparison (IPC) test was used in determining the maximum non-excessive (MNE) price of Alimta.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Alimta be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

The HDAP further recommended that, as there is no standard therapy for the treatment of MPM, and since no comparative clinical studies on combination therapies are available, it was not possible to identify comparator drug products for purposes of conducting a TCC test under the Guidelines.

Price Review

Under the Guidelines, in circumstances where it is not possible or appropriate to conduct a TCC test for a new category 3 drug product, the MNE price is determined with reference to the median of the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations, 1994* (Regulations). The price of Alimta 500 mg vial was within the Guidelines in the first 30-day sales of the medicine from July 29, 2004, as its price in Canada did not exceed the price of Alimta 500 mg vial in the only other country in which it was then sold, the United States. Alimta 500 mg vial was subsequently introduced for sale in two other countries listed in the Regulations during the last months of 2004 (Germany and Sweden). The following table identifies the prices of Alimta 500 mg vial in relation to those countries in which it was then sold:

Country	**Price per vial (CDN$)**
Canada	**$2750.0000**
Germany	$2163.8000
Sweden	$2145.4800
United States	$2865.1400
International Median	$2163.8000

Source: Publicly available prices as per the *Patented Medicines Regulations, 1994.*

In 2005, when Alimta 500 mg vial was sold in all of the seven countries listed in the Regulations, its price in Canada did not exceed the median price of those countries, and was therefore within the Guidelines. The following table sets out the prices of Alimta 500 mg vial in relation to the other listed countries:

Country	**Price per vial (CDN$)**
Canada	**$2,115.6900**
Germany	$2,295.8600
Sweden	$2,289.6800
France	$1,907.9100
Italy	$2,297.4500
Switzerland	$2,239.4600
United Kingdom	$1,880.1500
United States	$2,698.1200
International Median	**$2,289.6800**

Source: Publicly available prices as per the *Patented Medicine Regulations, 1994.*

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 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 - Alimta

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