

Report on New Patented Drugs – Emend

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the Board's *Excessive Price Guidelines* (Guidelines) for all new active substances introduced after January 1, 2002.

Brand Name: Emend

Generic Name: (*aprepitant*)

DIN: 02298791 (80 mg capsule)
02298805 (125 mg capsule)
02298813 (1 X 125 mg and 2 X 80 mg capsules)
(tri-pack)

Patentee: Merck Frosst Canada Ltd.

Indication – as per product monograph:

In combination with a 5-HT₃ antagonist class of antiemetics and dexamethasone is indicated for the: 1. prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy and 2. prevention of nausea and vomiting in women due to treatment with a moderately emetogenic cancer chemotherapy consisting of cyclophosphamide and anthracycline.

Date of Issuance of First Patent

Pertaining to the Medicine: March 21, 2006

Notice of Compliance: August 24, 2007

Date of First Sale: September 24, 2007

ATC Class: A04AD
Alimentary Tract and Metabolism; Antiemetics and Antinauseants; Antiemetics and Antinauseants; Other antiemetics

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Emend 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 countries listed in the *Patented Medicines Regulations* (Regulations) in which Emend was sold.

Scientific Review

Emend is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Emend be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing medicines).

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new medicine cannot exceed the prices of other comparable drugs that treat 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 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 did not recommend any comparators for the conduct of a TCC test.

Price Review

Under the Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on a TCC test or if it exceeds the prices of the same medicine sold 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.

It was not possible to conduct a TCC test as the HDAP did not identify any comparator drug products. At introduction, the prices of Emend were within the Guidelines as they did not exceed the median of the international prices identified in an IPC test as shown in the tables below.

Introductory Period (September to December 2007) Emend 80 mg capsule

Country and Median	Price (in Canadian dollars)
Canada	\$30.1800
France	\$31.3732
Germany	\$31.2314
Italy	--
Sweden	\$32.1146
Switzerland	--
United Kingdom	\$33.4849
United States	\$98.2475
Median	\$32.1146

Emend 125 mg capsule

Country and Median	Price (in Canadian dollars)
Canada	\$30.1800
France	\$18.8134
Germany	\$30.3121
Italy	--
Sweden	\$30.7438
Switzerland	--
United Kingdom	\$33.4864
United States	\$121.4452
Median	\$30.7438

Emend 80 mg and 125 mg capsules (tri-pack)

Country and Median	Price (in Canadian dollars)
Canada	\$30.1800
France	\$31.2503
Germany	\$31.6880
Italy	\$27.8822
Sweden	\$29.7112
Switzerland	\$30.0902
United Kingdom	\$33.4874
United States	\$107.5926
Median	\$31.2503

Source: Publicly available prices as per the Regulations

The publication of the Summary Reports is part of the PMPRB's commitment to make its price review 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 medicines sold in Canada to ensure that such prices are not excessive.

The PMPRB reserves the right to exclude from the therapeutic class comparison list any drug if it has reason to believe it 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 being considered within the 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 nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

References - Emend

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