Report on New Patented Drugs - Baraclude

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: Baraclude

Generic Name: *(entecavir)*

DIN: 02282224 0.5 mg tablet
02282232 0.05 mg/mL

Patentee: Bristol-Myers Squibb Canada Inc.

Indication - as per product monograph:

For the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Date of Issuance of First Patent(s) Pertaining to the medicine: May 29, 2001

Notice of Compliance: June 16, 2006

Date of First Sale: June 21, 2006

ATC Class: J05AF10
Antiinfectives for Systemic Use; Antivirals for Systemic Use; Direct Acting Antivirals; Nucleoside and nucleotide reverse transcriptase inhibitors

APPLICATION OF THE GUIDELINES

Summary

The prices of Baraclude 0.5 mg tablet and Baraclude 0.05 mg/mL 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*, *1994* (Regulations) in which Baraclude was sold.

Scientific Review

Baraclude is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Baraclude be classified as a category 3 new medicine (provides moderate, little or therapeutic advantage over comparable medicines).

The HDAP identified Heptovir (*lamivudine*) and Pegasys (*peginterferon*) as comparable drug products but concluded that comparable dosage regimens could not be derived since the length of therapy required for treatment of HBV with Heptovir and Baraclude was not yet known, and the duration of benefit accrued from Pegasys in patients who respond to it after a 48-week course has not been established.

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 of the comparable drug products, based on a Therapeutic Class Comparison (TCC) test, or if 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.

The price of Baraclude 0.5 mg tablet was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test.

First 30-day sales (June to July 2006)

Country	Price per 0.5 mg tablet
Canada	$22.1213
France	--
Germany	--
Italy	--
Sweden	$28.0365
Switzerland	--
U.K.	$27.1316
U.S.	$28.8592
Median	$28.0365

Sources:
Canada: Publicly available price as per the Regulations
Sweden: Prelista, November 2006
U.K.: Mims, December 2006
U.S**.:** Average of Thomson Micromedex Wholesale Acquisition Cost (WAC), October 2006, and Federal Supply Schedule (FSS), July – December 2006

The price of Baraclude 0.05 mg/mL was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test.

Period (June to July 2006)

Country	Price per 0.05 mg/mL
Canada	$2.2121
France	--
Germany	--
Italy	--
Sweden	--
Switzerland	--
U.K.	$4.5219
U.S.	$2.5020
Median	$3.5120

Sources:
Canada: Publicly available price as per the Regulations
U.K.: Mims, December 2006
U.S.: Average of Thomson Micromedex Wholesale Acquisition Cost (WAC), October 2006, and Federal Supply Schedule (FSS), July – December 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 – Baraclude

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