Report on New Patented Drugs – Hepsera

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: Hepsera

Generic Name: (*adefovir dipivoxil*)

DIN: 02247823 10 mg/tablet

Patentee: Gilead Sciences Inc.

Indication - as per product monograph:

For the treatment of chronic hepatitis B in adults with compensated and decompensated liver disease with evidence of active viral replication, and either evidence of histologically active disease or elevation in serum aminotransferases (ALT or AST).

Date of Issuance of First Patent Pertaining to the Medicine: August 21, 2003

Notice of Compliance: August 27, 2003

Date of First Sale: July 13, 2006

ATC Class: J05AF08
Antivirals for Systemic Use, Direct Acting Antivirals, Nucleoside Transcriptase Inhibitors

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Hepsera was found to be within the Guidelines as the price in Canada did not exceed the median of the prices of the same drug product in those countries listed in the *Patented Medicines Regulations, 1994* (Regulations) in which it was sold.

Scientific Review

Hepsera is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Hepsera be reviewed as a category 3 new medicine (provides moderate, little or no improvement).

The HDAP further recommended that lamivudine (Heptovir), peginterferon alpha-2a (Pegasys) and entecavir (Barraclude) are appropriate comparators to Hepsera for purposes of a Therapeutic Class Comparison (TCC) test. These agents are indicated and used for the treatment of chronic hepatitis B and may be considered clinically equivalent in the management of HBV; none eradicate or fully cure HBV.

The HDAP did not make a recommendation regarding a comparable dosage regimen. Recent data suggest that if the patient has responded to peginterferon, the benefit is maintained for up to one year or more, without further drug therapy. Since the length of therapy required for the treatment of HBV with lamivudine (Heptovir), entecavir (Baraclude) and adefovir (Hepsera) is not yet known, and the duration of benefit accrued from peginterferon in patients who respond to it after a 48-week treatment course has not been established, a comparable dosage regimen could not be derived.

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 prices of all of the comparable drug products based on a TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines 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.

As comparable dosage regimens could not be determined for purposes of conducting a TCC test, the price of Hepsera was considered within the Guidelines as it did not exceed the median of the international prices identified in an IPC test.

Introductory period (July to December 2006)

Country	Price per tablet (CDN$)
Canada	$23.2100[1]
France	$23.7584[2]
Germany	$27.6119[3]
Italy	$22.1080[4]
Sweden	$27.8924[5]
Switzerland	$26.7104[6]
United Kingdom	$22.4930[7]
United States	$18.5684[8]
International Median	$23.7584

Source:
(1) Canada: No publicly available price at introduction (2006). MEDIS May-July 2007
(2) France: Sempex, August 2006
(3) Germany: Rote Liste, January 2006
(4) Italy: L´informatore farmaceutico, December 2006
(5) Sweden: Prislista, November 2006
(6) Switzerland: Medwin Website, July -December 2006
(7) United Kingdom: Mims, December 2006
(8) United States: Average prices of Thomson Micromedex Wholesale Acquisition Cost (WAC) and prices available on the US Department of Veterans Affairs Website

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 - HEPSERA

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