Report on New Patented Drugs - Aptivus

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: Aptivus

Generic Name: (*tipranavir*)

DIN: 02273322 (250 mg capsule)

Patentee: Boehringer Ingelheim (Canada) Ltd.

Indication - as per product monograph:

Aptivus co-administered with low dose ritonavir, indicated in combination with anti-retroviral treatment of human immunodeficiency virus-1 (HIV-1) infected adult patients with evidence of viral replication, who are treatment experienced and have HIV-1 strains resistant to multiple protease inhibitors.

Date of Issuance of First Patent(s) Pertaining to the Medicine: November 21, 2006

Notice of Compliance: November 21, 2005

Date of First Sale: January 9, 2006

ATC Class: J05AE09
Antiinfectives for Systemic Use; Antivirals for Systemic Use; Direct Acting Antivirals; Protease inhibitors

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Aptivus was found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing comparable drugs in the therapeutic class comparison and the price did not exceed the prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Aptivus was sold.

Scientific Review

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

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other 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) 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 identified Fuzeon (*enfuvirtide*) as a comparator to Aptivus. Fuzeon has also been studied in the treatment-experienced of HIV patients. Protease inhibitors were not considered appropriate comparators since Aptivus is indicated for patients who have failed protease inhibitor treatment.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Aptivus and the comparator Fuzeon are based on respective product monographs and comparative clinical trial data as well as guidelines relevant to the subject matter.

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 price of all of the comparable drug products in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the Regulations.

The price of Aptivus 250 mg capsule was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicine.

Introductory Period (January to June 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost per Treatment (per day)
Aptivus (*tipranavir*) + Norvir (*ritonavir*)	250 mg capsule + 100 mg capsule	4 capsules + 4 capsules	$8.2500[(1)] + $1.3354[(2)]	$33.0000 + $5.3416 $38.3416
Fuzeon (*enfuvirtide*)	108 mg vial	1 vial	$39.7600[(2)]	$39.7600

Sources:
(1) Publicly available price as per the Regulations
(2) Liste de médicaments, Régie de l'assurance maladie du Québec, Février 2006

In 2006, Aptivus was being sold in six of the seven countries listed in the Regulations, namely France, Germany, Sweden, Switzerland, United Kingdom and the United States. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries. The price of Aptivus in Canada was the lowest of those countries.

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 - Aptivus

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