Report on New Patented Drugs – Macugen

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: Macugen

Generic Name: (*pegaptanib sodium injection*)

DIN: 02267225 (0.3 mg/90 µL syringe)

Patentee: Pfizer Canada Inc.

Indication – as per product monograph:
For the treatment of subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration.

Date of Issuance of First Patent(s) Pertaining to the Medicine: February 14, 2006

Notice of Compliance: May 2, 2005

Date of First Sale: August 26, 2005

ATC Class: S01XA17
Sensory Organs; Ophthalmologicals; Other Ophthalmologicals

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Macugen was found to be within the PMPRB's Guidelines because 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

Macugen is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that it be classified as a category 2 new medicine as it provides a substantial improvement in the treatment of subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration, where current standard of care provides insufficient therapy options for patients who have minimally classic or occult

lesions with no classic morphology. This recommendation is based on two randomized phase III clinical trials (reference #7), in which patients treated with Macugen exhibited favourable results in all subtypes (classic or occult) of wet (CNV).

Loss of visual acuity is a major cause of incapacity and considerably reduces quality of life. The possibility to stop the progression of the disease while treating a greater spectrum of patients with Macugen, combined with the relative ease of administration and medically manageable side effects, remains very relevant in this patient population.

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test for Macugen as there are no comparators that can be considered clinically equivalent.

Price Review

Under the Guidelines, the introductory price of a new category 2 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 the median of the international prices identified in an International Price Comparison (IPC) test. As no comparable drug products could be identified for purposes of conducting a TCC test, the introductory price of Macugen was considered within the Guidelines as it did not exceed the median of the international prices identified in the IPC test. Macugen was sold in only one other country (United States) of the seven countries listed in the Regulations at the time of introduction to the Canadian market.

Introduction Period (August to December 2005)

Country	Price per 0.3 mg/90 µL pre-filled syringe
Canada	$995.0000[1]
France	—
Germany	—
Italy	—
Sweden	—
Switzerland	—
UK	—
US	$1222.8725[2]

Source: 1. No publicly available price at introduction (2005) or in 2006. PPS Pharma January 2007.
2. Publicly available price as per the *Regulations*.

The Guidelines provide that when a medicine is sold in fewer than five countries at the time of its introduction, the introductory price will be treated as the interim benchmark price. Board Staff will review at the end of three years or when the medicine is sold in at least five countries, whichever comes first.

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 - Macugen

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