Report on New Patented Drugs – Azilect

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:	Azilect
Generic Name:	*(rasagiline mesylate)*
DINs:	02284650 (0.5 mg tablet) 02284642 (1 mg tablet)
Patentee:	Teva Neuroscience G.P.-S.E.N.C.

Indication – as per product monograph:

For the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as adjunct therapy to levodopa

Date of Issuance of First Patent Pertaining to the Medicine:	August 25, 1998
Notice of Compliance:	August 17, 2006
Date of First Sale:	September 14, 2006
ATC Class:	N04BD Nervous System; Anti-Parkinson Drugs; Dopaminergic Agents; Monoamine oxidase B inhibitors

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Azilect were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and did not exceed the range of prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations (*Regulations) in which Azilect was sold.

Scientific Review

Azilect is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Azilect be classified 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 drug product 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 recommended Comtan (*entacapone)* as an appropriate comparator to Azilect. It offers comparable level of clinical efficacy in patients with advanced Parkinson's disease.

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 Azilect and the comparable drug product were based on their product monograph and supported by clinical literature.

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 prices of all of the comparable drug products based on the TCC test or if it exceeds the range of prices of the same medicine sold in the seven countries listed in the Regulations.

The introductory price of Azilect 1 mg tablet was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicine as shown in the table below.

Introductory Period (September to December 2006)

Trade Name (generic name)	Strength	Dosage Regimen (Daily)	Unit Price	Treatment Cost (Daily)
Azilect (*rasagiline mesylate*)	1 mg	1 tablet	$7.0000(1)	$7.0000
Comtan (*entacapone*)	200 mg	8 tablets	$1.4000(2)	$11.2000

Sources:
(1) PPS Pharma Buyers Guide. Ontario Edition. January 2007.
(2) Régie de l'assurance maladie du Québec, Février 2006.

Due to the lack of standardized dosing and titration, a Reasonable Relationship (RR) test was conducted for Azilect 0.5 mg tablet and the result indicated that the introductory price of $7.0000 was within the Guidelines.

In 2006, Azilect 0.5 mg tablet and Azilect 1 mg tablet were being sold in one (United States) and five (Germany, Sweden, Switzerland, United Kingdom, and United States) countries, respectively, listed in the Regulations. In compliance with the Guidelines, the prices of Azilect in Canada did not exceed the range of prices in those countries. The price of the 0.5 mg tablet was the lowest and the price of the 1 mg tablet was the second highest above the median of the international price.

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process 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 – Azilect

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