Report on New Patented Drugs - Sativex

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: Sativex

Generic Name: *(delta-9-tetrahydrocannabinol & cannabidiol)*

DIN: 02266121 52 mg/mL (27 mg/mL & 25 mg/mL)

Patentee: Bayer Inc.

Indication - as per product monograph:

May be useful as adjunctive treatment for the symptomatic relief of neuropathic pain in multiple sclerosis (MS) in adults.

Date of Issuance of First(s) Patent Pertaining to the Medicine: April 25, 2006

Notice of Compliance: April 15, 2005

Date of First Sale: June 22, 2005

In most cases, patents are issued before the drug comes to market. In this case, the first patent pertaining to Sativex was issued on April 25, 2006 and it came under the PMPRB's jurisdiction at that time.

ATC Class: N07DA
Nervous System; Other Nervous System Drugs

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Sativex was 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. Sativex was not sold in any of the other comparator countries.

Scientific Review

Sativex is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Sativex be classified as a category 3 new medicine (provides moderate, little or 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 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 selection of the Guidelines and the policies on TCCs.

The HDAP identified Cesamet (*nabilone*) and Marinol (*dronabinol*) as the most appropriate comparators for Sativex. These agents are utilized for the symptomatic relief of neuropathic pain in MS patients and are clinically equivalent in addressing the approved indication of Sativex.

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 Sativex and the comparators are based on the respective product monographs and supported by clinical literature.

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 the price in Canada exceeds the range of prices of the same medicine sold in the countries listed in the *Patented Medicines Regulations* (Regulations).

The introductory price of Sativex was within the Guidelines as the weekly cost per treatment did not exceed the weekly cost per treatment with the comparator medicines.

Introductory Period (July to December 2005)

Name	Strength	Dosage Regimen	Unit Price	Cost per Week
Sativex	52 mg/mL	1.5 mL	$22.7182[1]	$34.0773
Cesamet	1 mg capsule	10 capsules	$6.2052[1]	$62.0520
Marinol	5 mg capsule	5 capsules	$3.8200[2]	$19.1000
Marinol + Marinol	5 mg capsule + 10 mg capsule	1 capsule + 2 capsules	$3.8200[2] + $7.6400[3]	$3.8200 + $15.2800 $19.1000

Sources:
(1) Publicly available price as per the *Patented Medicines Regulations*
(2) Ontario Drug Benefit Formulary, August 2006
(3) Liste de médicament d'exception, Régie de l'assurance maladie du Québec, Octobre 2005

Sativex was not sold in any of the seven countries listed in the Regulations at the time of its introduction on the Canadian market in 2005. In compliance with the Guidelines, at such time as it may be sold in any of the seven countries listed in the Regulations, the price in Canada cannot exceed the range of prices in 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.

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