Report on New Patented Drugs - Cialis

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: Cialis

Generic Name: *(tadalafil)*

DIN: 02248088 10 mg/tablet
02248089 20 mg/tablet

Patentee: Eli Lilly Canada Inc.

Indication - as per product monograph:

For the treatment of erectile dysfunction.

Date of Issuance of First Patent(s) Pertaining to the Medicine: May 28, 2002

Notice of Compliance: September 17, 2003

Date of First Sale: November 28, 2003

ATC Class: GO4BE08
Urologicals; Drugs Used in Erectile Dysfunction

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Cialis 10 mg/tablet and Cialis 20 mg/tablet were not in excess of the triggers for commencing an investigation under the Guidelines in the introductory sale period (November to December 2003) because their costs of therapy did not exceed by 5% or more the maximum non-excessive (MNE) price (or have excess revenues of $25,000.00 or more) based on the cost of therapy of existing drugs in the therapeutic class comparison. In addition, the prices of Cialis in Canada did not exceed the prices of the same medicines in the other comparator countries listed in the *Patented Medicines Regulations* (Regulations) where they were sold.

For information on the Criteria for Commencing an Investigation, please see Schedule 5 of the Compendium of Guidelines, Policies and Procedures, as posted on our Web site under Legislation, Regulations and Guidelines.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Cialis be reviewed 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 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 Viagra (sildenafil) as the most appropriate comparator for Cialis, as it shares the same 4th level ATC classification and is clinically equivalent in addressing the approved indication of Cialis.

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 Cialis and the comparator are based on their respective product monographs, available comparative clinical trial information 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 prices of all of the comparable drug products in the TCC test by a margin greater than or equal to the triggers for commencing an investigation in the introductory period, or if it exceeds the prices of the same medicine in the seven countries listed in the Regulations. The prices of Cialis 10 mg/tablet and Cialis 20 mg/tablet did not exceed the triggers as their costs per treatment did not exceed the costs per treatment of the comparator medicine by an amount that triggered the investigation criteria. The prices were subsequently within the Guidelines.

(Introductory Period (November to December 2003)

Name	Strength	Dosage Regimen	Cost per Treatment*
Cialis	**10 mg tablet**	**10 mg**	**$11.7000**
Viagra	**50 mg tablet**	**50 mg**	**$11.2500**
Cialis	**20 mg tablet**	**20 mg**	**$11.7000**
Viagra	**100 mg tablet**	**100 mg**	**$11.2500**

*Sources: for Viagra, PPS, July 2003; for Cialis, publicly available prices as per the *Patented Medicines Regulations, 1994*

In 2003, Cialis 10 mg/tablet and Cialis 20 mg/tablet were being sold in six of the seven countries listed in the Regulations (not sold in Switzerland). In compliance with the Guidelines, the prices of Cialis 10 mg/tablet and Cialis 20 mg/tablet in Canada were lower than the highest price prevailing in those countries. The prices of Cialis 10 mg/tablet and Cialis 20 mg/tablet were the second highest of those countries, above the median 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.

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 - Cialis

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