March 2006

Report on New Patented Drugs - Levitra

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: Levitra

Generic Name: (*vardenafil*)

DIN:

02250462	5 mg tablet
02250470	10 mg tablet
02250489	20 mg tablet

Patentee: Bayer, Inc.

Indication - as per product monograph:

For the treatment of erectile dysfunction (difficulties or the inability to achieve or maintain penile erection sufficient for satisfactory sexual performance).

Date of Issuance of First Patent(s) Pertaining to the Medicine: December 3, 2002

Notice of Compliance: March 17, 2004

Date of First Sale: March 17, 2004

ATC Class: G04BE09

Genitourinary System and Sex Hormones; Urological: Other Urological, including antispasmodics; Drugs Used in Erectile Dysfunction (ED)

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of the Levitra drug products 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 the prices did not exceed the range of prices in other comparator countries where Levitra is sold or did not do so by an amount sufficient to trigger any of the investigation criteria under the *Compliance and Enforcement Policy*.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Levitra be reviewed as a category 3 new drug product (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.

Erectile dysfunction affects 26% to 52% of men (depending on ages surveyed). Levitra inhibits the enzyme phosphodiesterase type 5 (PDE5) in the corpus cavernosum which ultimately leads to penile erection. The HDAP identified two other PDE5 inhibitors in the same 4th level ATC that are clinically equivalent for the treatment of erectile dysfunction; Viagra (*sildenafil*) and Cialis (*tadalafil*).

The PMPRB's 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 Levitra and the comparators are based on the respective product monographs and supported by clinical literature.

Price Review

Under the Guidelines, the introductory price for 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 *Patented Medicines Regulations*.

Levitra 10 mg and 20 mg tablets

The prices of Levitra 10 mg and 20 mg were within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicines.

Introductory Period (March to June 2004)

Name	Strength	Price per tablets[1]
Levitra	10 mg tablets 20 mg tablets	$11.25 $11.70
Viagra	50 mg tablets 100 mg tablets	$11.25 $11.70
Cialis	10 mg tablets 20 mg tablets	$11.70 $11.70

[1] PPS, July 2004

In 2004, both strengths of Levitra were also sold in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. In compliance with the Guidelines the price in Canada for the 10 mg tablet and the 20 mg tablet strengths did not exceed the range of prices in those countries.

Levitra 5 mg tablets

The price of Levitra 5 mg tablet did not exceed the prices of the comparable medicines in the TCC test. In 2004, Levitra 5 mg tablet was also sold in France, Germany, Switzerland, Sweden, the United Kingdom and the United States. The Canadian price for Levitra 5 mg tablet exceeded the range of prices in those countries but by an amount which did not trigger the criteria for commencing an investigation. As a result, the benchmark price for review in future periods is established by the International Price Comparison test.

References - Levitra

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