Report on New Patented Drug – Pristiq

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products by Board Staff, for purposes of applying the Board's pre-2010 Guidelines for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Pristiq

Generic Name: (*desvenlafaxine succinate)*

DINs: 02321092 (50 mg tablet)
02321106 (100 mg tablet)

Patentee: Wyeth Pharmaceuticals

Indication – as per product monograph:

For the symptomatic relief of major depressive disorder.

Date of Issuance of First Patent Pertaining to the Medicine: October 17, 2006

Notice of Compliance: February 4, 2009

Date of First Sale: March 5, 2009 (DIN 02321092)
March 6, 2009 (DIN 02321106)

ATC Class: N06AX23
Nervous system; Psychoanaleptics; antidepressants, Other antidepressants.

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Pristiq were found to be within the pre-2010 Guidelines because the cost of therapy did not exceed the cost of therapy of existing drug products in the therapeutic class comparison and did not exceed the range of prices of the same drug products in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Pristiq was sold.

Scientific Review

Pristiq is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Pristiq be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products).

The Therapeutic Class Comparison (TCC) test of the pre-2010 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 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 "up to 2009"* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended venlafaxine (Effexor XR), trazodone (Desyrel), mirtazapine (Remeron RD), buproprion (Wellbutrin) and duloxetine (Cymbalta) as the appropriate comparators to Pristiq. They all share the same 4th level ATC class and the same indication as Pristiq. There were no comparative trial data to support the inclusion of drug products outside the 4th level ATC.

The pre-2010 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 Pristiq and the comparable drug products were based on the respective product monographs and supported by clinical literature.

Price Review

Under the pre-2010 Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the TCC test or if it exceeds the range of prices of the same drug product sold in the seven countries listed in the Regulations.

The introductory prices of Pristiq were within the pre-2010 Guidelines as the cost per treatment did not exceed the cost per treatment of the comparable drug products as shown in the table below.

Introductory Period – Pristiq 50 mg per tablet and 100 mg per tablet - (March to June 2009)

Brand Name (generic name)	Strength	Dosage Regimen (per day)	Unit Price	Cost per Treatment (per day)
Pristiq (desvenlafaxine succinate)	50 mg/tablet	1 tablet	$2.5700 (1)	$2.5700
Desyrel Dividose (trazodone HCl)	150 mg/tablet	2 2/3 tablets	$0.5812 (2)	$1.5499
Remeron RD (mirtazapine)	45 mg/tablet	1 tablet	$1.1700 (2)	$1.1700
Wellbutrin SR (bupropion)	150 mg/tablet	1 tablet	$0.8260 (2)	$0.8260
Wellbutrin XL (bupropion)	150 mg/tablet	1 tablet	$0.5190 (2)	$0.5190
Effexor XR (venlafaxine)	75 mg/ capsule	3 capsules	$1.6110 (2)	$4.8330
Effexor XR (venlafaxine) + Effexor XR (venlafaxine)	150 mg/ capsule + 75 mg/ capsule	1 capsule + 1 capsule	$1.7039 (2) + $1.6110 (2)	$3.3149
Cymbalta (duloxetine)	60 mg/ capsule	1 capsule	$3.5600 (2)	$3.5600
Pristiq (desvenlafaxine succinate)	100 mg/tablet	1 tablet	$2.5700 (1)	$2.5700
Desyrel Dividose (trazodone HCl)	150 mg/tablet	4 tablets	$0.5812 (2)	$2.3248
Remeron RD (mirtazapine)	30 mg/tablet	2 tablets	$0.7800 (2)	$1.5600
Remeron (mirtazapine)	30 mg/tablet	2 tablets	$1.2400 (2)	$2.4800
Wellbutrin SR (bupropion)	150 mg/tablet	2 tablets	$0.8260 (2)	$1.6520
Wellbutrin XL (bupropion)	300 mg/tablet	1 tablet	$1.0380 (2)	$1.0380
Cymbalta (duloxetine)	60 mg/ capsule	1 capsule	$3.5600 (2)	$3.5600

Remeron RD (mirtazapine) + Remeron RD (mirtazapine)	45 mg/tablet + 15 mg/tablet	1 tablet + 1 tablet	$1.1700 [2] + $0.3900 [2]	$1.5600
Effexor XR (venlafaxine)	150 mg/ capsule	2 capsules	$1.7039 [2]	$3.4078

(1) PPS Pharma, 2010.
(2) Association Québécoise des pharmaciens propriétaires, 2009.

In 2009, both strengths of Pristiq were sold in one country listed in the Regulations, namely, the United States. In compliance with the Guidelines, the prices of Pristiq in Canada did not exceed the prices of the same drug product in this country.

The publication of the Summary Reports is part of the PMPRB's commitment to make its price review 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 drug products 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 product if it has reason to believe it is being sold at an excessive price.

In Summary Reports under the pre-2010 Guidelines, the PMPRB refers to the publicly available prices of comparators, provided that such prices are not more than 10% above a non-excessive price in which case no price will be made available. Publication of these prices is for information purposes only and should not be relied upon as indicating the public prices are considered within the pre-2010 Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than that stated and is not to be interpreted as an endorsement, recommendation or approval of any drug product, 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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