Report on New Patented Drugs – Champix

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: Champix

Generic Name: (*varenicline tartrate*)

DIN: 02291177 (0.5 mg tablet)
02291185 (1 mg tablet)

Patentee: Pfizer Canada Inc.

Indication - as per product monograph:
Smoking cessation

Date of Issuance of First Patent(s) Pertaining to the Medicine: December 7, 2004

Notice of Compliance: January 24, 2007

Date of First Sale: April 12, 2007

ATC Class: N07BA
Nervous System; Other Nervous System Drugs; Drugs Used in Addictive Disorders; Drugs used in nicotine dependence.

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Champix were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing comparable medicines in the therapeutic class comparison and the prices did not exceed the range of prices in other comparator countries where Champix was sold.

Scientific Review

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

The two strengths of Champix are used in combination for smoking cessation. The product monograph sets out that treatment with Champix is for a twelve -week period and is initiated with the 0.5 mg once daily for the first three days. Day four to seven the 0.5 mg should be taken twice daily and day eight to end of treatment the 1 mg is taken twice daily. Patients should set a date to stop smoking and Champix dosing should start 1-2 weeks before this date.

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 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 bupropion (*Zyban and Wellbutrin SR*) and nicotine replacement products (Habitrol, *Nicoderm, Nicotrol, Prostep, Nicorette Gum and Nicorette Inhaler*) as the most appropriate comparators for Champix. They share the same 4th level ATC class, and all these drug products are used and/or approved for smoking cessation therapy and are considered standard therapy.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. Comparative dosage regimens for Champix and the comparators are based on product monographs, guidelines and published clinical trials.

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 based in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations, 1994* (Regulations*).*

The Guidelines also provide that the PMPRB reserves the right to exclude from the TCC test any drug product it has reason to believe is being sold at an excessive price. At the time of this review the price of Nicoderm (nicotine) was subject to a Notice of Hearing; it was excluded from the TCC test. No publicly available prices were found for Prostep (nicotine) and it was also excluded from the TCC test.

The prices of Champix were within the Guidelines as the cost of treatment did not exceed the cost of treatment of the comparable medicines and did not exceed the range of the prices of the same medicine in the countries listed in the Regulations.

Introductory Period (April to June 2007)

Brand Name (generic)	Strength	Dosage Regimen (12 Weeks)	Unit Price	Cost per Treatment (12 Weeks)
Champix (varenicline tartrate) + Champix (varenicline tartrate)	0.5 mg tablet + 1 mg tablet	11 tablets + 154 tablets	$1.6850[1] + $1.6850[1]	$18.5350 + $259.4900 $278.0250
Habitrol (nicotine) + Habitrol (nicotine) + Habitrol (nicotine)	21 mg patch + 14 mg patch + 7 mg patch	42 patches + 21 patches + 21 patches	$2.6786[2] + $2.6786[2] + $2.6786[2]	$112.5012 + $56.2506 + $56.2506 $225.0024
Nicorette Gum (nicotine)	4 mg piece	1008 pieces	$0.2883[2]	$290.6064
Nicorette Inhaler (nicotine)	10 mg dose	1008 cartridges	$0.7500[3]	$756.0000
Nicotrol (nicotine) + Nicotrol (nicotine) + Nicotrol (nicotine)	24.9 mg/ 30 sq cm + 16.9 mg/ 20 sq cm + 8.3 mg/ 10 sq cm	56 patches + 14 patches + 14 patches	$3.3700[3] + $3.3700[3] + $3.3700[3]	$188.7200 + $47.1800 + $47.1800 $283.0800
Wellbutrin SR (bupropion)	150 mg tablet	165 tablets	$0.8162[2]	$134.6730
Zyban (bupropion)	150 mg tablet	165 tablets	$0.8000[2]	$132.000

Sources :

(1) PPS, July 2007
(2) Liste de médicaments publiée par la Régie de l'assurance maladie du Québec, April 2007
(3) Association québécoise des pharmaciens propriétaires, Juillet 2007

In 2007, Champix was being sold in France, Germany, Italy, Sweden, Switzerland, United Kingdom and the United States. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries; the prices of Champix in Canada were the lowest.

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 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.

References – Champix

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