October 2006

Report on New Patented Drugs - Vfend

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:	Vfend
Generic Name:	*(voriconazole)*
DIN:	02256487 200 mg vial 02256460 50 mg tablet 02256479 200 mg tablet
Patentee:	Pfizer Canada Inc.
Indication - as per product monograph:	For the treatment of invasive aspergillosis.
Date of Issuance of First Patent(s) Pertaining to the Medicine:	January 18, 2000
Notice of Compliance:	August 20, 2004
Date of First Sale:	November 15, 2004
ATC Class:	J02AC03 *Antiinfectives for Systemic Use, Antimycotics for Systemic Use, Triazole Derivatives*

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Vfend 200 mg vial 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 and the price did not exceed the prices of the same drug in the comparator countries where Vfend 200 mg vial was sold.

The introductory prices of Vfend 50 mg and 200 mg tablets were found to be within the Guidelines as their prices in Canada did not exceed the median of the prices of the same drug in the comparator countries in which they were sold.

Scientific Review

Vfend is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Vfend be classified 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 Abelcet (amphotericin B lipid complex), Ambisome (liposomal amphotericin B), Cancidas (caspofungin acetate), and Fungizone (amphotericin B) as comparable medicines to Vfend 200 mg vial. These agents share the same indication and are clinically equivalent in addressing the approved indication of Vfend 200 mg vial.

The HDAP did not identify any comparable medicines for a TCC test for Vfend 50 mg and 200 mg tablets as presently there is inconclusive data that intravenous antifungal therapies or Sporanox (itraconazole) oral tablets are clinically equivalent to the two strengths of Vfend oral tablets.

The recommended comparable dosage regimens for Vfend 200 mg vial and the comparable medicines 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 prices of the same medicine sold in the countries listed in the *Patented Medicines Regulations* (Regulations). The Guidelines further state that when it is inappropriate or impossible to conduct a TCC test, the Board will give primary weight to the median of the international prices identified in an International Price Comparison test.

The introductory price of Vfend 200 mg vial was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparable medicines.

Introductory Period (November to December 2004)

Name	Strength	Dosage Regimen (12 weeks)	Unit Price	Cost per Treatment
Vfend	200 mg/vial	237 vials	$140.0000[1]	$33,180.0000
Abelcet	5 mg/mL	5880 mL	$9.9200[1]	$58,329.6000
Ambisone	50 mg/vial	588 vials	$210.0000[2]	$123,480.0000
Cancidas	50 mg/vial	84 vials	$440.0000[3]	$36,960.0000
Fungizone	50 mg/vial	176 vials	$37.3500[4]	$6,573.6000

1 Publicly available price as per the Patented Medicines Regulations
2 PPS Pharma, July 1, 2004
3 Liste des médicaments, Régie de l'assurance maladie du Québec, October 2003 and October 2005
4 Ontario Drug Benefit Formulary, January 30, 2003 and September 27, 2005

The introductory prices of Vfend 50 mg and 200 mg tablets were within the Guidelines as they did not exceed the median of the prices in the seven comparator countries. The prices in Canada were the lowest of these countries.

Introductory Period (November to December 2004)

Country	CDN price for 50 mg tablet	CDN price for 200 mg tablet
Canada	$11.8800	$47.5000
France	$15.7628	$63.3823
Germany	$20.4079	$77.6265
Italy	$16.7912	$67.1665
Sweden	$15.1486	$60.5934
Switzerland	$15.2209	$62.2312
United Kingdom	$19.7027	$78.8119
United States	$9.1951	$36.7792
Median	$15.7628	$63.3822

Sources:
Canada: Publicly available price as per the Patented Medicines Regulations
France: Semprex, November 2004
Germany: Rote List, July 2004
Italy: L'informatore farmaceutico, December 2004
Sweden: Prislista, November 2004
Switzerland: Medwin website, December 2004
UK: Mims, December 2004
USA: Federal Supply Schedule (FSS), December 2004, Redbook Direct Price (DP), December 2004, and Redbook Wholesale Acquisition Cost (WAC), October 2004

In 2004, Vfend 200 mg vial was being sold in six of the seven countries listed in the Regulations, namely France, Germany, Italy, Sweden, United Kingdom, and the United States. In compliance with the Guidelines, the price of Vfend 200 mg vial did not exceed the range of the prices of the same medicine sold in those countries. The price of Vfend 200 mg vial in Canada was the second lowest of those countries, below the median international price.

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.

References – Vfend

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