Report on New Patented Drugs - Vantas

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: Vantas

Generic Name: (*histrelin acetate*)

DIN: 02278383 (50 mg subdermal implant)

Patentee: Paladin Labs Inc.

Indication - as per product monograph:
For the palliative treatment of hormone-dependent advanced prostate cancer (Stage M1 [TNM] or Stage D2 [AUA]).

Date of Issuance of First Patent(s) Pertaining to the Medicine: May 28, 1996

Notice of Compliance: March 10, 2006

Date of First Sale: July 14, 2006

ATC Class: H01CA03
Systemic Hormonal Preparations, Excluding Sex Hormones and Insulins; Pituitary and Hypothalamic Hormones and Analogues; Hypothalamic Hormones; gonadotropin-releasing hormones.

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Vantas 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 did not exceed the range of prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Vantas was sold.

Scientific Review

Vantas is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Vantas be classified as a category 3 new medicine (provides moderate, little or no therapeutic 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 World Health Organization (WHO) 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 recommended Eligard PFS (*leuprolide acetate*), Lupron Depot PFS (*leuprolide acetate*), Suprefact Depot (*buserelin acetate*), Zoladex (*goserelin acetate*) and Zoladex LA (*goserelin acetate*) as comparator drug products to Vantas. Although these agents do not share the same 4th level ATC as Vantas, they are indicated and used to treat the same indication as Vantas.

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 Vantas and the comparable drug products were 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 based on the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the Regulations.

The introductory price of Vantas was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicines.

Introductory Period (July to December 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost per Treatment (12 months)
Vantas	50 mg	1 implant	$3,564.00[(1)]	$3,564.00
Eligard PFS	7.5 mg	12 vials	$343.58[(2)]	$4,122.96
Eligard PFS	22.5 mg	4 vials	$891.00[(2)]	$3,564.00
Eligard PFS	30 mg	3 vials	$1,285.20[(2)]	$3,855.60
Eligard PFS	45 mg	2 vials	--- [(3)]	--- [(3)]
Lupron Depot PFS	7.5 mg	12 vials	$387.97[(2)]	$4,655.64
Lupron Depot PFS	22.5 mg	4 vials	$1,071.00[(2)]	$4,284.00
Lupron Depot PFS	30 mg	3 vials	$1,428.00[(2)]	$4,284.00
Suprefact Depot	6.3 mg	6 vials	$670.00[(2)]	$4,020.00
Suprefact Depot	9.45 mg	4 vials	$990.00[(2)]	$3,960.00
Zoladex	3.6 mg	13 vials	$381.75[(2)]	$4,962.75
Zoladex LA	10.8 mg	4 vials	$1,087.98[(2)]	$4,351.92

Sources:
(1) Publicly available price as per the Regulations
(2) Ontario Drug Benefit Formulary, June 2006
(3) The price of Eligard PFS 45 mg is under investigation

In 2006, Vantas was being sold in one of the seven countries listed in the Regulations, namely the United States. In compliance with the Guidelines, the Canadian price was not the highest 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.

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