Report on New Patented Drugs – Trelstar

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: Trelstar

Generic Name: (*triptorelin pamoate*)

DIN: 02240000 (3.75 mg/vial)

Patentee: Paladin Labs Inc.

Indication - as per product monograph:

For the management and relief of chronic pain associated with endometriosis.

For the palliative treatment of hormone dependent advanced carcinoma of the prostate cancer (Stage D2).

Date of Issuance of First Patent(s) Pertaining to the Medicine: January 25, 1994

Notice of Compliance: July 06, 2005

Date of First Sale: August 15, 2006

ATC Class: L02AE04
Antineoplastic and Immunomodulating Agents; Endocrine Therapy; Hormones and Related Agents; Gonadotropin releasing hormone analogues.

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Trelstar 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 Trelstar was sold.

Scientific Review

Trelstar is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Trelstar 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 Lupron Depot PFS (*leuprolide acetate*), Suprefact (*buserelin acetate*), and Zoladex (*goserelin acetate*) as comparator drug products to Trelstar. All these medications share the same 4th level ATC class, are indicated for the treatment of endometriosis and prostate cancer and are considered clinically equivalent for these indications.

Eligard (*leuprolide acetate*) was not recommended as a comparator to Trelstar as it is only indicated for the treatment of advanced prostate cancer.

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 Trelstar 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 Trelstar was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicines.

Introductory Period (August to December 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost per Treatment (4-week)
Trelstar	3.75 mg	1 vial	$343.5800[(1)]	$343.5800
Lupron Depot PFS	3.75 mg	1 vial	$304.5000[(2)]	$304.5000
Lupron Depot PFS	7.5 mg	1 vial	$387.9700[(2)]	$387.9700
Suprefact	1 mg/mL	1 vial	$62.8000[(2)]	$62.8000
Zoladex	3.6 mg	1 vial	$381.7500[(2)]	$381.7500

Sources:
(1) Publicly available price as per the Regulations
(2) Ontario Drug Benefit Formulary, September 27, 2005.

In 2006, Trelstar was being sold in the seven countries listed in the Regulations. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries; the price in Canada was second highest, above the median international price.

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.

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