Report on New Patented Drugs – Sutent

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: Sutent

Generic Name: (*sunitinib malate*)

DIN: 02280795 (12.5 mg capsule)
02280809 (25 mg capsule)
02280817 (50 mg capsule)

Patentee: Pfizer Canada Inc.

Indication - as per product monograph:
For the treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance.

Date of Issuance of First Patent(s) Pertaining To the Medicine: March 21, 2006

Notice of Compliance: May 26, 2006

Date of First Sale: June 24, 2006

ATC Class: L01XE04

Antineoplastic and Immunomodulating Agents; Antineoplastic Agents; Other Antineoplastic Agents.

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Sutent 12.5 mg, 25 mg and 50 mg capsules were 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 prices did not exceed the range of prices in other comparator countries where Sutent was sold.

Scientific Review

Sutent is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that it be classified as a category 3 new medicine as it provides moderate, little or no therapeutic advantage in the treatment of GIST.

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. The Guidelines provide that it may, however, be appropriate to include products from other ATC classes if they are clinically equivalent for the appropriate indication to the drug product under review. 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 Gleevec (*imatinib*) as a comparator to Sutent 50 mg capsule as it is indicated and used for the treatment of GIST. Since the 12.5 mg and 25 mg capsules doses are used primarily for downward dose adjustments, a comparable dosage regimen cannot be defined. Therefore, the HDAP recommended that the 12.5 mg and 25 mg capsules be compared on a milligram to milligram basis with the 50 mg capsule.

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 Sutent and the comparator Gleevec are based on respective product monographs and comparative clinical trial data.

Price Review

Under the Guidelines, the introductory price for 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 it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations, 1994.*

The price of Sutent 50 mg capsule was within the Guidelines as the cost of treatment did not exceed the cost of treatment of the comparator medicine.

Introduction Period (July to December 2006)

Name	Strength	Dosage Regimen (6 weeks)	Unit Price	Cost per Treatment (6 weeks)
Sutent	50 mg capsule	28 capsules	$248.1425[1]	$6,947.9900
Gleevec	400 mg tablet	84 tablets	$102.3283[2]	$8,595.5772

Sources:
1) No publicly available price for 2006. PPS Pharma January 2007.
2) Ontario Drug Benefit Formulary, January 6, 2006

As no comparators were identified for Sutent 12.5 mg and 25 mg capsules, the prices were compared to the price of the 50 mg capsule in a Reasonable Relationship test. The prices of $62.0357[1] for the 12.5 mg capsule and $124.0711[1] for the 25 mg capsule were within the Guidelines at introduction.

In 2006, all three strengths of Sutent were being sold in France, Germany, 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 Sutent in Canada were the lowest of those countries.

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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