Report on New Patented Drugs

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products by Board Staff, for purposes of applying the Board's Excessive Price Guidelines (Guidelines) for all new active substances introduced in Canada after January 1, 2002.

Sprycel

Brand Name: Sprycel

Generic Name: dasatinib

DINs: 02293129 (20 mg/tablet) 02293137 (50 mg/tablet) 02293145 (70 mg/tablet)

Patentee: Bristol-Myers Squibb Canada Co.

Indication – as per product monograph (as of date of first sale – 2007): For the treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate. Sprycel is also indicated for the treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy.

Date of Issuance of First Patent(s) Pertaining to the Medicine: August 25, 2009

Notice of Compliance: March 26, 2007

Date of First Sale: April 13, 2007

ATC Class: L01XE06
Antineoplastic and Immunomodulating Agents; Antineoplastic Agents; Other Antineoplastic Agents; Protein Kinase Inhibitors.

Application of the Guidelines

Summary

The introductory prices of Sprycel were found to be within the Guidelines because the prices in Canada did not exceed the median of the prices of the same drug product sold in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Sprycel was sold.

Scientific Review

Sprycel is a new active substance.

The Guidelines provide that new DINs with multiple approved indications will be categorized based on the approved indication for which the medicine offers the greatest therapeutic advantage in relation to alternative therapies for the same indication in a significant population.

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that the primary indication for Sprycel would be for the treatment of the chronic phase of CML in patients who are resistant or intolerant to prior therapy including imatinib mesylate, as it is during that phase that Sprycel is more likely to be initiated and this would offer the greatest therapeutic advantage.

The HDAP recommended that Sprycel be classified as a Category 2 new drug product (breakthrough or substantial improvement). The HDAP did not recommend any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

Price Review

Under the Guidelines, the introductory price of a Category 2 new drug product will be presumed to be excessive if it exceeds the highest of the prices of all comparable drug products based on the TCC test and/or the median of the international prices identified in an International Price Comparison (IPC) test.

No comparators were identified for purposes of conducting a TCC test. The introductory prices of Sprycel were below the median of the international prices identified in an IPC test. Sprycel was sold in four of the seven countries listed in the Regulations.

Introductory Period (April to June 2007)

Country and Median	Sprycel 20 mg Price per tablet (in Canadian dollars)	Sprycel 50 mg Price per tablet (in Canadian dollars)	Sprycel 70 mg Price per tablet (in Canadian dollars)
Canada	$34.2162	$68.4322	$75.4672
France	Not sold	Not sold	Not sold
Germany	$55.7060	$111.3968	$111.3968
Italy	Not sold	Not sold	Not sold
Sweden	$55.7355	$111.4710	$111.4710
Switzerland	Not sold	Not sold	Not sold
United Kingdom	$48.3781	$96.7562	$96.7562
United States	$37.4023	$74.7984	$82.4828
Median	$52.0421	$104.0765	$104.0765

Source: Publicly available prices as per the Regulations.

When the IPC test is conducted to determine the median price, an interim median international price is used in cases when the medicine is sold in fewer than five countries at the time of introduction. Unless it is excessive, the introductory price will be treated as an interim benchmark price. The interim benchmark price may be reviewed at the end of the three years or when the medicine is sold in at least five countries, whichever comes first.

In 2008, all three strengths of Sprycel were sold in six of the seven countries listed in the Regulations and the Canadian prices continued to be below the median of the international prices identified in an IPC test.

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.

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 drug products sold in Canada to ensure that such prices are not excessive.

The PMPRB reserves the right to exclude from the therapeutic class comparison test any drug product it has reason to believe is being sold at an excessive price.

In its Summary Reports, the PMPRB also refers to the publicly available prices of comparators, provided such prices are not more than 10% above a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information only and should not be construed as indicating the public prices are considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than stated and is not to be interpreted as an endorsement, recommendation or approval of any drug product, nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

This report, including the references, is available on the PMPRB Web site under Patented Medicines; Reports on New Patented Drugs for Human Use; Sprycel. ■