Report on New Patented Drugs

Gleevec

Brand Name:	Gleevec
Generic Name:	Imatinib mesylate
DIN:	02244725 100 mg capsule
Patentee:	Novartis Pharmaceutical Canada Inc.
Indication (as per product monograph):	Gleevec (imatinib mesylate) is indicated for the treatment of patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. Gleevec is also indicated for the treatment of patients with unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
Notice of Compliance:	NOC with conditions September 20, 2001 for CML and August 7, 2002 for GIST
Date of First Sale:	September 25, 2001 The first patent pertaining to Gleevec was issued November 26, 2002 and it came under the PMPRB's jurisdiction at that time.
ATC Class:	L01XX28 *Antineoplastic and Immunomodulating Agents, Antineoplastic Agents, Other antineoplastic agents*

Application of the Guidelines

Summary:

The price of Gleevec was found to be within the Guidelines because the price in Canada did not exceed the median of the prices of the same drug in those countries listed in the *Patented Medicines Regulations, 1994* (Regulations) in which it was sold.

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Gleevec be reviewed as a category 2 new drug (breakthrough or substantial improvement) based on the following information:

- Gleevec is recognized as the only agent indicated for use in all three stages of CML, i.e., blast crisis, accelerated phase and chronic phase after failure of interferon-alpha therapy and also for use in GIST.
- Under the Guidelines, new DINs with multiple approved indications are 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. This approved indication is considered the primary indication for purposes of selecting comparable medicines.
- Based on the scientific evidence, Gleevec provides the greatest therapeutic advantage in relation to its use in the chronic phase of CML after failure of interferon therapy. This stage of CML is therefore considered to be the primary indication.
- 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 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.

- There are a number of drug products in the same 4th level ATC as Gleevec, however none of them are clinically equivalent in addressing the same indication (i.e. in the chronic phase of CML after failure of interferon therapy).
- Although two drug products from other ATC classes, Hydrea (hydroxyurea) and Busulflex (busulfan) may be used in the chronic phase of CML, their uses are recognized as being palliative in nature and therefore are not considered to be clinically equivalent to Gleevec. As a result, the HDAP recommended no comparators for the conduct of a therapeutic class comparison for Gleevec.

Price Review:

Under the Guidelines, the price of a new drug in category 2 should not exceed the higher of the prices of other drugs that treat the same disease (TCC test) and the median of the prices of the same drug in the seven countries listed in the Regulations (IPC test). It was not possible to conduct a TCC test for Gleevec as the HDAP did not identify any comparable medicines. The price of Gleevec was within the Guidelines both at the time it was first introduced in September 2001 and when it became patented in November 2002, as the Canadian price was below the median international price in those countries in which it was sold.

The Regulations require that patentees file publicly available prices in the seven countries listed therein (see ss. 4(1)(g)). Schedule 3 of the Compendium of Guidelines, Policies and Procedures sets out the methodology to conduct an IPC test.

According to information derived from public sources, the ex-factory prices for Gleevec ranged from about $20.06 to $29.61 per capsule in other countries in late 2002. For price review purposes, the PMPRB relies on price information filed by the patentee as required by the Regulations. In the case of Gleevec, the patentee has provided price information for all seven countries for the relevant time periods and the price in Canada did not exceed the median of the foreign prices.

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. ■

Country	$CDN price per 100 mg capsule
Canada	$24.3500
Germany	—
France	—
Italy	$20.0620
Sweden	$29.6054
Switzerland	$22.6828
UK	$26.1962
US	$27.1313
Median	$26.1962

Sources

Italy: L'Informatore Farmaceutico, November 2002*
Sweden: Prislista, November 2002*
Switzerland: Medwin, November 2002
UK: MIMS, November 2002*
US: Average prices of US Red Book, November 2002 and prices available on the US Department of Veterans Affairs website.

* Derived from publicly available formulary price using regulated wholesale mark-ups set out in the PMPRB Study S-0215, *Verification of Foreign Patented Drug Prices 2000*.

The *Patented Medicines Regulations, 1994* and the Compendium of Guidelines, Policies and Procedures, are both available on our website under Legislation, Regulations, Guidelines.

Evidence/ References:

The references are available on the PMPRB website, under Other Publications; Patented Medicines; Reports on New Patented Drugs; Gleevec.