Report on New Patented Drugs

MAbCampath

Brand Name:	MAbCampath (previously sold as Campath)
Generic Name:	alemtuzumab
DIN:	n/a
Patentee:	Berlex Canada Inc.
Indication (as per product monograph):	MAbCampath is indicated for the treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy.
Notice of Compliance:	Pending approval
Date of First Sale:	May 22, 2002 (under the Special Access Program)
ATC Class:	L01XC04 *Antineoplastic and Immunomodulating Agents, Antineoplastic Agents, Other antineoplastic agents, Monoclonal antibodies*

Application of the Guidelines

Summary:

The price of MAbCampath 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 in which it was sold.

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that MAbCampath be reviewed as a category 2 new drug (breakthrough or substantial improvement) as it provides a substantial improvement in therapeutic effects over available therapies used for the treatment of B-CLL in patients who have been treated with alkylating agents and have failed Fludara (fludarabine) therapy.

The HDAP did not recommend any comparator drugs for purposes of a therapeutic class comparison:

- 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 therapeutic class comparisons (TCCs).
- Although there are a number of drug products in the same 4th level ATC as MAbCampath, the HDAP recommended that, for purposes of the Price Guidelines, none of them are clinically equivalent in addressing the same indication.
- Although a number of chemotherapy protocols using drugs from other ATC classes are used in this indication, the HDAP did not recommend that they be considered as clinically equivalent to MAbCampath for purposes of a TCC.

Price Review:

For price review purposes, the PMPRB relies on price information filed by the patentee as required by the Regulations. Pursuant to section 87 of the Patent Act information filed by patentees is confidential. In the case of MAbCampath, 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. According to information derived from public sources, the 2002 ex-factory prices for MAbCampath ranged from about $502.27 to $2432.30 per vial.

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 *Patented Medicines Regulations* (IPC test). It was not possible to conduct a TCC test for MAbCampath as the HDAP did not identify any comparable medicines. The price of MAbCampath was within the Guidelines, as the Canadian price was below the median international price in those countries in which it was sold.

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

Country	Price per ampoule
Canada	$650.0000
Germany	—
France	$767.2408
Italy	$502.2741
Sweden	$663.7202
Switzerland	—
U.K.	$577.9698
U.S.	$1733.9446 to $2432.3096

Sources

Italy: L'informatore farmaceutico, December 2002*
France: Sempex August 2002
Sweden: Prislista, May 2002*
UK: Mims, Mims May 2002*
US: U.S. Department of Veterans Affairs website and Redbook, May 2002.

* Derived from publicly available formulary price using regulated wholesale mark-ups set out in PMPRB Study Series S-0215.

Evidence/ References:

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

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. ■