**July 2006**

# Report on New Patented Drugs – Erbitux

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:** Erbitux

**Generic Name:** (*cetuximab*)

**DIN:** 100 mg/50 mL solution for IV infusion

**Patentee:** Bristol-Myers Squibb Canada Inc.

**Indication - as per product monograph:**

Used in combination with irinotecan, for the treatment of EGFR-expressing, metastatic colorectal carcinoma in patients who are refractory to irinotecan-based chemotherapy

**Date of issuance of First Patent(s) Pertaining to the Medicine:**

March 2, 1999

**Notice of Compliance:** September 9, 2005

**Date of First Sale:** June 24, 2005 (under Special Access Program)

**ATC Class:** L01XC06

*Antineoplastic and immunodulating agents, antineoplastic agents, other antineoplastic agents, monoclonal antibodies*

## APPLICATION OF THE GUIDELINES

### Summary

The introductory price of Erbitux under the Special Access Program 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* (Regulations) in which Erbitux was sold.

## Scientific Review

Erbitux is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Erbitux be reviewed as a category 3 new medicine as it provides moderate, little or no improvement over comparable medicines). Although Erbitux is the first agent that treats EGFR-expressing tumours, it did not meet the criteria for a category 2 new medicine (breakthrough or substantial improvement).

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) Test since Erbitux is the first agent that treats EGFR-expressing tumours.

## 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 prices of all comparable drug products, based on a TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the Regulations. The HDAP did not identify any comparators for the conduct of a TCC test. The Guidelines further state that when it is inappropriate or impossible to conduct a TCC test, Board Staff will give primary weight to the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines. The price of Erbitux under the Special Access Program was within the Guidelines as the price in Canada did not exceed the median of the international prices identified in an IPC test. The table below does not include a price for Erbitux in Canada as there is no publicly available source for its price.

**Introductory Period (July to December 2005)**

| Country | Price per 2 mg/mL |
|---|---|
| Canada | no public price available |
| France | |
| Germany | $321.0439* |
| Italy | $327.2386* |
| Sweden | $351.9374* |
| Switzerland | $294.5317* |
| UK | $302.1213* |
| US | $673.4977 |
| Median | $324.1413 |

* Derived based on methodology set out in Verification of Foreign Patented Drug Prices (2000), PMPRB Study Series S-0215.

## Sources:

**Germany:** Rote Liste, July 2005
**France:** Published in formulary, no price listed, Sempex, August 2005
**Italy:** L'informatore farmaceutico, December 2005
**Sweden:** Prislista, November 2005
**Switzerland:** Medwin Web site, July-December 2005
**U.K.:** Mims Web site, December 2005
**U.S.:** Average of Thomson Micromedex Wholesale Acquisition Cost (WAC), October 2005 and Federal Supply Schedule (FSS), July-December 2005.

*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.*

### References – Erbitux


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