

# Report on New Patented Drug – Tarceva

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.

<b>Brand Name:</b>	Tarceva	
<b>Generic Name:</b>	<i>erlotinib</i>	
<b>DIN:</b>	02269023	150 mg/tablet
	02269015	100 mg/tablet
<b>Patentee:</b>	Hoffmann-La Roche Limited, Canada	
<b>Indication - as per product monograph:</b>	For the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen, and whose EGFR expression status is positive or unknown.	
<b>Date of Issuance of First Patent(s) Pertaining to the Medicine:</b>	February 17, 2004	
<b>Notice of Compliance:</b>	July 7, 2005	
<b>Date of First Sale:</b>	July 19, 2005 (150 mg/tablet) July 20, 2005 (100 mg/tablet)	
<b>ATC Class:</b>	L01XX341 <i>Antineoplastic and Immunomodulating Agents, Antineoplastic Agents, Other Antineoplastic Agents</i>	

## Application of the Guidelines

### Summary

The introductory price of Tarceva 150 mg/tablet was 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 price did not exceed the prices in the other comparator countries where Tarceva 150 mg was sold.

The introductory price of Tarceva 100 mg/tablet was found to be within the Guidelines because its price bore a reasonable relationship to the price of Tarceva 150 mg/tablet and the price did not exceed the prices in the other comparator countries where Tarceva 100 mg was sold.

### Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Tarceva be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

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 4<sup>th</sup> level of the Anatomical Therapeutic Chemical (ATC) System that are clinically equivalent in addressing the approved indication. 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 Taxotere (docetaxel), Alimta (pemetrexed) and Taxol (paclitaxel) as the most appropriate comparators for Tarceva. Based on clinical studies and available guidelines, these agents have proven efficacy rates in the second line treatment of advanced lung cancer after the failure of first line platinum-based therapy.

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 Tarceva and the comparators are based on their respective product monographs, available comparative clinical trial information as well as guidelines relevant to the subject matter.

Because Tarceva 100 mg/tablet represents titration strength for dose adjustment, a clinically equivalent therapeutic class comparison could not be established. The HDAP recommended that this strength should be compared to the 150 mg/tablet on an mg to mg basis.

## 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 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* (Regulations). The price of Tarceva 150 mg/tablet was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicines. The price of Tarceva 100 mg/tablet was within the Guidelines as the price of \$53.3333<sup>1</sup> per tablet did not exceed the price of Tarceva 150 mg when compared on a mg to mg basis, as recommended by the HDAP.

## Introductory Period (July to December 2005)

Name	Strength	Dosage Regimen	Cost per Treatment
Tarceva (erlotinib)	150 mg/tab	150 mg daily PO	\$1,680.0000 <sup>1</sup>
Taxotere (docetaxel)	80 mg/vial + 20 mg/vial	100 mg/m <sup>2</sup> every 3 weeks	\$1804.2525 <sup>2</sup>
Alimta (pemetrexed)	500 mg/vial	500 mg/m <sup>2</sup> every 3 weeks	\$3617.0000 <sup>2</sup>
Taxol (paclitaxel)	6 mg/ml	175 mg/m <sup>2</sup> every 3 weeks	\$ 904.3415 <sup>2</sup>

1. *Association québécoise des pharmaciens propriétaires* (AQPP), October 2005

2. IMS, December 2005

In 2005, Tarceva 150 mg/tablet and 100 mg/tablet were being sold in two of the seven countries listed in the Regulations, namely Switzerland 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 Tarceva in Canada were the lowest of those countries, below the median international price.

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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