**Report on New Patented Drugs – Celsentri**

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

**Brand Name:** Celsentri

**Generic Name:** (*maraviroc*)

**DIN:** 02299844 (150 mg tablet)
02299852 (300 mg tablet)

**Patentee:** Pfizer Canada Inc.

**Indication – as per product monograph:**
In combination with other antiretroviral agents, is indicated for treatment-experienced adult patients infected with CCR5-tropic HIV-1 who have evidence of resistance to multiple antiretroviral agents.

**Date of Issuance of First Patent(s) Pertaining to the Medicine:** June 27, 2006

**Notice of Compliance:** September 21, 2007

**Date of First Sale:** October 16, 2007

**ATC Class:** J05AX
Antiinfectives For Systemic Use; Antivirals For Systemic Use; Direct Acting Antivirals; Other antivirals

## APPLICATION OF THE GUIDELINES

### Summary

The introductory prices of Celsentri were 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 did not exceed the range of prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) where Celsentri was sold.

## Scientific Review

Celsentri is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Celsentri be classified 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 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification 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 HDAP recommended Aptivus (*tipranavir*), Fuzeon (*enfuvirtide*), and Prezista (*darunavir*) as the most appropriate comparators to Celsentri. Fuzeon shares the same 4th level ATC class as Celsentri and is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Aptivus and Prezista, two protease inhibitors, which do not share the same 4th level ATC class as Celsentri, are both indicated for treatment-experienced patients infected with HIV. They are included in treatment guidelines and review documents as treatment options for treatment-experienced adult patients.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The comparative dosage regimens for Celsentri and the comparators are based on products monographs, guidelines and published clinical trials.

## 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 price of all of the comparable drug products based on the TCC test, or if it exceeds the range of the prices of the same medicine in the seven comparator countries listed in the Regulations.

The introductory prices of Celsentri 150 mg and 300 mg tablets were within the Guidelines as the cost of treatment did not exceed the cost of treatment of the comparator medicines.

**Introductory Period (October to December 2007)**

| Brand Name (generic) | Strength | Dosage Regimen (daily) | Unit Price | Cost per Treatment (daily) |
|---|---|---|---|---|
| Celsentri (*maraviroc*) | 150 mg / tablet | 2 tablets | $16.5000[1] | $33.0000[1] |
| Celsentri (*maraviroc*) | 300 mg / tablet | 2 tablets | $16.5000[1] | $33.0000[1] |
| Fuzeon (*enfuvirtide*) | 108 mg / vial | 2 vials | $39.7600[2] | $79.5200[2] |
| Aptivus (*tipranavir*) + Norvir Sec (*ritonavir*) | 250 mg / capsule + 100 mg / capsule | 4 capsules + 4 capsules | $8.2500[2] + $1.3625[2] | $33.0000[2] + $5.4500[2] = $38.4500 |
| Aptivus (*tipranavir*) + Norvir Liquid (*ritonavir*) | 250 mg / capsule + 80 mg / mL | 4 capsules + 5 mL | $8.2500[2] + $1.0898[2] | $33.0000[2] + $5.4490[2] = $38.4490 |
| Prezista (*darunavir ethanolate*) + Novir Sec (*ritonavir*) | 300 mg / tablet + 100 mg / capsule | 4 tablets + 2 capsules | $6.9600[2] + $1.3625[2] | $27.8400[2] + $2.7250[2] = $30.5650 |
| Prezista (*darunavir ethanolate*) + Novir Liquid (*ritonavir*) | 300 mg / tablet + 80 mg / mL | 4 tablets + 2.5 mL | $6.9600[2] + $1.0898[2] | $27.8400[2] + $2.7245[2] = $30.5645 |

**Sources:**
(1) Publicly available prices as per Regulations
(2) Liste de médicaments du Québec, Régie de l'assurance de médicaments du Québec, Octobre, 2007

In 2007, Celsentri was being sold in four countries listed in the Regulations, namely France, Germany, Sweden and the United States. In compliance with the Guidelines, the prices of Celsentri in Canada did not exceed the range of prices in those countries. They were the lowest international prices.

*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 medicines sold in Canada to ensure that such prices are not excessive.*

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

*In its Summary Reports, the PMPRB will also refer 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 purposes only and should not be relied upon as being 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 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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