Report on New Patented Drugs — Olmetec Plus

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products conducted by Board Staff for purposes of applying the Board’s pre-2010 Guidelines for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Olmetec Plus

Generic Name: olmesartan medoxomil/hydrochlorothiazide

DIN: 02319616 (20 mg/12.5 mg per tablet)
     02319624 (40 mg/12.5 mg per tablet)
     02319632 (40 mg/25 mg per tablet)

Patentee: Schering-Plough Canada Inc.

Indication – as per product monograph: Indicated for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate.

Date of Issuance of First Patent Pertaining to the Medicine: January 19, 1999

Notice of Compliance: November 21, 2008

Date of First Sale: December 22, 2008

ATC Class: C09DA08
   Cardiovascular System; Agents Acting on the Renin-Angiotensin System; Angiotensin II Antagonist, Combinations; Angiotensin II antagonists and diuretics

Application of the Guidelines

Summary
The introductory prices of Olmetec Plus were found to be within the pre-2010 Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the range of prices in other comparator countries where Olmetec Plus is sold.

Scientific Review

Olmetec Plus is a new active substance and the PMPRB’s Human Drug Advisory Panel (HDAP) recommended that Olmetec be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products in the treatment of essential hypertension).

The Therapeutic Class Comparison (TCC) test of the pre-2010 Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drug products that are clinically
equivalent in treating 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. See the PMPRB's then *Compendium of Guidelines, Policies and Procedures “up to 2009”* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended losartan/hydrochlorothiazide (Hyzaar), valsartan/hydrochlorothiazide (Diovan-HCT), irbesartan/hydrochlorothiazide (Avalide), candesartan /hydrochlorothiazide (Atacand Plus) and telmisartan/hydrochlorothiazide (Micardis Plus) as the most appropriate comparators to Olmetec Plus. The HDAP had also recommended eprosartan/ hydrochlorothiazide (Teveten Plus) as a comparator. However, a dosage regimen could not be derived for this agent. All these agents share the same 4th level ATC classification, share the same indication and are clinically equivalent in addressing the approved indication of Olmetec Plus.

The pre-2010 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 regimen for Olmetec Plus and its comparable drug products have been selected based on their respective product monographs as well as the available clinical trials and reviews relevant to Olmetec Plus.

**Price Review**

Under the pre-2010 Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the Therapeutic Class Comparison (TCC) test or it exceeds the range of prices of the same drug product sold in the seven countries listed in the *Patented Medicines Regulations* (Regulations). At introduction, the costs of treatment of Olmetec Plus were within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

<table>
<thead>
<tr>
<th>Name</th>
<th>DIN</th>
<th>Strength</th>
<th>Dosage Regimen/Day</th>
<th>Cost per Day</th>
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<tbody>
<tr>
<td>Olmetec Plus (olmesartan medoxomil/hydrochlorothiazide)</td>
<td>02319616</td>
<td>20/12.5 mg tablet</td>
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<td>$0.9900</td>
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<td>Hyzaar (losartan potassium/hydrochlorothiazide)</td>
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<td>300/25 mg tablet</td>
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<td>$1.1279</td>
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**Sources:**

1. Publicly available price as per the *Patented Medicines Regulations*
2. La Régie de l’assurance maladie du Québec, June 2009.

At the time of introduction, Olmetec Plus 20 mg/12.5 mg tablet was sold in four of the seven countries (i.e., Germany, Switzerland, United Kingdom and United States) listed in the Regulations. Olmetec Plus 40 mg/12.5 mg and Olmetec Plus 40 mg/25 mg were sold in the United States only. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in these countries. The price of Olmetec 20 mg/12.5 mg was second highest of the four countries in which it was sold, above the median international price. Olmetec Plus 40 mg/12.5 mg and 40 mg/25 mg were lower than the United States price.

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 drug products sold in Canada to ensure that such prices are not excessive.

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

In Summary Reports under the pre-2010 Guidelines, the PMPRB refers to the publicly available prices of comparators, provided that such prices are not more than 10% above a non-excessive price, in which case no price will be made available. Publication of these prices is for information only and should not be construed as indicating that the public prices are considered to be within the pre-2010 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 product, nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

**References — Olmetec Plus**


Canadian Hypertension Education Program. 2008 CHEP recommendations for the management of hypertension.


Canadian Hypertension Education Program. 2009 CHEP recommendations for the management of hypertension.


