Report on New Patented Drugs - Lyrica

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 in Canada after January 1, 2002.

Brand Name: Lyrica

Generic Name: (pregabalin)

DIN: 02268418 25 mg capsule
     02268426 50 mg capsule
     02268434 75 mg capsule
     02268450 150 mg capsule
     02268485 300 mg capsule

Patentee: Pfizer Canada Inc.

Indication - as per product monograph:

For the treatment of peripheral neuropathy in adults.

As adjunctive therapy in the treatment of partial seizures with or without secondary generalization in patients 12 years of age and older.

Date of Issuance of First Patent(s) Pertaining to the Medicine: March 26, 2002

Notice of Compliance: June 3, 2005

Date of First Sale: August 4, 2005

ATC Class: N03AX16
           Nervous System, Antiepileptics,
           Antiepileptics, Other Antiepileptics

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Lyrica 50 mg, 75 mg, 150 mg, and 300 mg capsules were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing comparable medicines and the prices did
not exceed the prices of the same medicine in the comparator countries where Lyrica 50 mg, 75 mg, 150 mg, and 300 mg capsules were sold.

The introductory price of Lyrica 25 mg capsule was found to be within the Guidelines because its price bore a reasonable relationship to the prices of the other strengths of Lyrica and the price did not exceed the prices in the comparator countries where Lyrica 25 mg capsule was sold.

**Scientific Review**

The Guidelines provide that new DINs with multiple approved indications will be categorized based on the approved indication for which the medicine offers the greatest therapeutic advantage in relation to alternative therapies for the same indication in a significant population. Where there is no apparent single approved indication for which the medicine offers the greatest therapeutic advantage, the approved indication representing, potentially, the greatest proportion of sales will be the basis for categorization and selection of comparable medicines.

The PMPRB's Human Drug Advisory Panel (HDAP) could not establish for which indication the medicine offers the greatest therapeutic advantage in relation to alternative therapies. Epidemiologic data supports neuropathic pain as being more frequent in the Canadian population, with a greater disease burden than is reported for epilepsy. Therefore, the HDAP recommended the primary indication for Lyrica be neuropathic pain.

Lyrica is a new active substance and the HDAP recommended that Lyrica 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 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 selection of the Guidelines and the policies on TCCs.

The HDAP identified Lamictal (*lamotrigine*), Neurontin (*gabapentin*), and Topamax (*topiramate*) as comparable medicines for Lyrica. These medicines share the same 4th level ATC and are currently used for the treatment of neuropathic pain.

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 Lyrica and the comparable medicines are based on the respective product monographs and supported by clinical literature.

The HDAP could not derive a comparable dosage regimen for the Lyrica 25 mg strength and recommended that it be compared to the other strengths.

**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 in the TCC test, or if the price in Canada exceed the range of the prices of the same medicine sold in the countries listed in the *Patented Medicines Regulations* (Regulations).

The introductory prices of Lyrica 50 mg, 75 mg, 150 mg, and 300 mg capsules were within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparable medicines. The introductory price of Lyrica 25 mg capsule ($0.747 1$) was within the Guidelines based on the Reasonable Relationship test.

**Lyrica 50 mg capsule – Introductory Period (August to December 2005)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Strength</th>
<th>Dosage Regimen</th>
<th>Unit Price</th>
<th>Cost per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyrica</td>
<td>50 mg capsule</td>
<td>3 capsules</td>
<td>$1.173 1</td>
<td>$3.519 0</td>
</tr>
<tr>
<td>Lamictal</td>
<td>100 mg tablet</td>
<td>2 tablets</td>
<td>$1.326 2</td>
<td>$2.652 0</td>
</tr>
<tr>
<td>Neurontin</td>
<td>300 mg capsule</td>
<td>3 capsules</td>
<td>$1.990 2</td>
<td>$3.980 0</td>
</tr>
<tr>
<td>Topamax</td>
<td>100 mg tablet</td>
<td>2 tablets</td>
<td>$3.150 2</td>
<td>$3.150 0</td>
</tr>
</tbody>
</table>

**Lyrica 75 mg capsule – Introductory Period (August to December 2005)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Strength</th>
<th>Dosage Regimen</th>
<th>Unit Price</th>
<th>Cost per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyrica</td>
<td>75 mg capsule</td>
<td>2 capsules</td>
<td>$1.518 1</td>
<td>$3.036 5</td>
</tr>
<tr>
<td>Lamictal</td>
<td>100 mg tablet</td>
<td>2 tablets</td>
<td>$1.326 2</td>
<td>$2.652 0</td>
</tr>
<tr>
<td>Neurontin</td>
<td>300 mg capsule</td>
<td>3 capsules</td>
<td>$3.150 2</td>
<td>$3.150 0</td>
</tr>
<tr>
<td>Topamax</td>
<td>200 mg tablet</td>
<td>1 tablet</td>
<td>$3.150 2</td>
<td>$3.150 0</td>
</tr>
</tbody>
</table>
### Lyrica 150 mg capsule – Introductory Period (August to December 2005)

<table>
<thead>
<tr>
<th>Name</th>
<th>Strength</th>
<th>Dosage Regimen</th>
<th>Unit Price</th>
<th>Cost per Day</th>
</tr>
</thead>
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<tr>
<td>Lyrica</td>
<td>150 mg capsule</td>
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<td>$2.3218$</td>
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<tr>
<td>Lamictal</td>
<td>100 mg tablet</td>
<td>4 tablets</td>
<td>$1.3260$</td>
<td>$5.3040$</td>
</tr>
<tr>
<td>Neurontin</td>
<td>600 mg capsule</td>
<td>3 capsules</td>
<td>$3$</td>
<td>$3$</td>
</tr>
<tr>
<td>Topamax</td>
<td>200 mg tablet</td>
<td>2 tablets</td>
<td>$3.1500$</td>
<td>$6.3000$</td>
</tr>
</tbody>
</table>

### Lyrica 300 mg capsule – Introductory Period (August to December 2005)

<table>
<thead>
<tr>
<th>Name</th>
<th>Strength</th>
<th>Dosage Regimen</th>
<th>Unit Price</th>
<th>Cost per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyrica</td>
<td>300 mg capsule</td>
<td>2 capsules</td>
<td>$2.3218$</td>
<td>$4.6436$</td>
</tr>
<tr>
<td>Lamictal</td>
<td>100 mg tablet</td>
<td>4 tablets</td>
<td>$1.3260$</td>
<td>$5.3040$</td>
</tr>
<tr>
<td>Neurontin</td>
<td>600 mg capsule</td>
<td>6 capsules</td>
<td>$3$</td>
<td>$3$</td>
</tr>
<tr>
<td>Neurontin</td>
<td>800 mg capsule</td>
<td>3 capsules</td>
<td>$3$</td>
<td>$3$</td>
</tr>
<tr>
<td>Topamax</td>
<td>200 mg tablet</td>
<td>4 tablets</td>
<td>$3.1500$</td>
<td>$12.6000$</td>
</tr>
</tbody>
</table>

1 Publicly available price as per the Patented Medicines Regulations
2 Ontario Drug Benefit Formulary, September 22, 2005
3 At publication of this report, the price of Neurontin is under review

In 2005, Lyrica 25 mg, 50 mg and 300 mg capsules were being sold in six of the seven countries listed in the Regulations, namely Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries. The price of Lyrica 25 mg capsule was the 4th highest price, below the median international price; the price of Lyrica 50 mg capsule was the 5th highest price, below the median international price; and the price of Lyrica 300 mg capsule was the 6th highest price, below the median international price.

In 2005, Lyrica 75 mg and 150 mg capsules were being sold in the seven countries listed in the Regulations, namely France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries. The price of Lyrica 75 mg capsule was the 4th highest price, above the median international price and the price of Lyrica 150 mg capsule was the 2nd highest price, above 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.

References – Lyrica


