Report on New Patented Drug – Pradax

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

Brand Name: Pradax

Generic Name: (dabigatran etexilate)

DINs: 02312433 (75 mg capsule)
02312441 (110 mg capsule)

Patentee: Boehringer Ingelheim Canada Ltd.

Indication – as per product monograph: For the prevention of venous thromboembolic events (VTE) in patients who have undergone elective total hip replacement or total knee replacement surgery.

Date of Issuance of First Patent(s) Pertaining to the Medicine: October 3, 2006

Notice of Compliance: June 10, 2008

Date of First Sale: July 3, 2008

ATC Class: B01AE07
Blood and Blood Forming Organs; Antithrombotic Agents; Antithrombotic Agents; Direct thrombin inhibitors

Application of the Guidelines

Summary

The introductory prices of Pradax were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drug products in the therapeutic class comparison and did not exceed the range of prices of the same drug product in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Pradax was sold.

Scientific Review

Pradax is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Pradax be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products).

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 and 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 recommended products outside the 4th level ATC as they were no comparators in the same 4th level ATC. The HDAP recommended fondaparinux and the low molecular weight heparins (LMWH) (dalteparin, enoxaparin, nadroparin and tinzaparin) as appropriate comparators to Pradax. These agents have the same indication as Pradax. Acenocoumarol, warfarin, acetylsalicylic acid, warfarin and unfractionated heparin were excluded as comparable products because, based on published guidelines and randomized controlled trials, these agents are not as effective and are associated with increased side effects including more stringent laboratory and clinical monitoring.

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 Pradax and the comparable drug products were based on the respective product monographs and supported by clinical literature.

Price Review

Under the Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products based on the TCC test or if it exceeds the range of prices of the same drug product sold in the seven countries listed in the Regulations.

The introductory price of Pradax 110 mg tablet was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparable drug products as shown in the table below.

Introductory Period (January to June 2007)

Brand Name (Generic Name)	Strength	Dosage Regimen (30 days)	Unit Price	Cost per Treatment (30 days)
Pradax (dabigatran etexilate)	110 mg/cap	60 capsules	$3.9250[1]	$235.5000
Arixtra (fondaparinux)	2.5 mg/0.5mL	15 mL	$30.1522[2]	$452.2830
Fragmin (dalteparin)	10,000 antiXa IU/mL	15 mL	$15.6000[2]	$234.0000
Fragmin (dalteparin)	25,000 antiXa IU/mL	6 mL	$39.0000[2]	$234.0000
Fragmin (dalteparin)	5,000 antiXa IU/mL	6 mL	$49.1400[2]	$294.8400
Fraxiparine (nadroparin)	5,700 antiXa IU/0.6mL	18 mL	$15.1000[3]	$271.8000
Innohep (tinzaparin)	20,000 antiXa IU/mL	5.25 mL	$32.0000[2]	$168.0000
Lovenox (enoxaparin)	100 mg/mL	36 mL	$20.5000[2]	$738.0000
Lovenox (enoxaparin)	30 mg/0.3 mL	36 mL	$20.6333[2]	$742.7988

Sources:
1 Publicly available price as per the *Patented Medicines Regulations*
2 Ontario Drug Benefit Formulary, June 2008
3 *Association québécoise des pharmaciens propriétaires*, 2008

Due to the titration dosing, a Reasonable Relationship test was conducted for Pradax 75 mg. The introductory price of Pradax 75 mg capsule ($3.9250) was within the Guidelines.

In 2008, Pradax was being sold in two countries listed in the Regulations, namely, Sweden and the United Kingdom. In compliance with the Guidelines, the prices of Pradax in Canada did not exceed the range of prices of the same drug product in those countries.

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 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 indicating the public prices are considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than that 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.

This report, including the references, is available on the PMPRB Web site under Patented Medicines; Reports on New Patented Drugs for Human Use; Pradax. ■