Report on New Patented Drugs – Nevanac

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 Excessive Price Guidelines (Guidelines) for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Nevanac

Generic Name: (*nepafenac*)

DIN: 02308983 (1 mg/ml)

Patentee: Alcon Canada Inc.

Indication – as per product monograph: Management of pain and inflammation associated with cataract surgery.

Date of Issuance of First Patent Pertaining to the Medicine: August 13, 2002

Notice of Compliance: April 17, 2008

Date of First Sale: August 21, 2008

ATC Class: S01BC10
Sensory organs; Ophthalmologicals; Anti-inflammatory agents; Anti-inflammatory agents, non-steroids.

Application of the Guidelines

Summary

The introductory price of Nevanac was 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 the price in Canada 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 Nevanac was sold.

Scientific Review

Nevanac is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended under the pre-2010 Guidelines that Nevanac 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 pre-2010 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. See the PMPRB's pre-2010 *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended diclofenac (Voltaren Ophtha) and ketorolac tromethamine (Acular and Acular LS) as appropriate comparators to Nevanac as they are clinically equivalent to Nevanac. These agents share the same 4th level ATC and the same indication as Nevanac, and are also recommended in clinical guidelines for the management of pain and inflammation associated with cataract surgery. There were no data or comparative trials to support the inclusion of drug products outside the 4th level ATC.

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

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 prices of all the comparable drug products based on the TCC test or it exceeds the range of prices of the same drug product sold in the seven countries listed in the Regulations.

The introductory price of Nevanac was within the pre-2010 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 (August to December 2008)

Brand Name (Generic Name)	Strength	Dosage Regimen*	Unit Price	Cost per Treatment*
Nevanac (nepafenac)	1 mg/ml	2.88 ml	$3.6960[1]	$10.6445
Voltaren Ophtha (diclofenac, 0.1%)	1 mg/ml	7.2 ml	$2.3693[2]	$17.0590
Acular Liquid (ketorolac tromethamine, 0.5%)	5 mg/ml	5.4 ml	$3.2000[2]	$17.2800
Acular LS (ketorolac tromethamine, 0.4%)	4 mg/ml	7.2 ml	$3.2000[2]	$23.0400

* Comparable dosage regimens are 16 days for Nevanac and 30 days for the comparable drug products.

Sources:

1 Publicly available price as per the *Patented Medicines Regulations*

2 *Association québécoise des pharmaciens propriétaires, 2008*

In 2008, Nevanac was sold in two countries listed in the Regulations, namely Sweden and the United States. The price of Nevanac 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 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 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 only and should not be construed as indicating the public prices are considered 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.

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