Report on New Patented Drugs – Travatan

Brand Name:	Travatan
Generic Name:	travoprost
DIN:	02244896 0.4 mg/mL
Patentee:	Alcon Canada Inc.
Indications (as per product monograph):	For the reduction of intraocular pressure in patients with open angle glaucoma or ocular hypertension who are intolerant or insufficiently responsive to another intraocular pressure lowering medication.
Notice of Compliance:	November 9, 2001
Date of First Sale:	November 2001
	In most cases, patents are issued before the drugs come to market. In this case, the first patent pertaining to Travatan was issued in May 2002 and it came under the PMPRB's jurisdiction at that time.
ATC Class:	S01EE04 *Ophthalmologicals, Antiglaucoma preparations and miotics, Prostaglandin analogues*

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

PMPRB

Application of the Guidelines

Summary:

The introductory price of Travatan at the date of first sale was 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 by an amount sufficient to trigger the investigation criteria and the price did not exceed the range of prices in other comparator countries where Travatan was sold. This price continued to be within the Guidelines when Travatan came under the PMPRB's jurisdiction in 2002.

Scientific Review:

Travatan is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) reviewed it 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 Guidelines and the policies on TCCs.

Travatan 0.4 mg/mL is indicated for the lowering of intraocular pressure (IOP) in patients with ocular hypertension or open angle glaucoma. Considering the prevalence of open angle glaucoma, particularly in the elderly population, this application was considered by the HDAP as the primary indication.

The 4th level ATC comparators include Rescula (unoprostone), Lumigan (bimatoprost) and Xalatan (latanoprost). According to the respective product monographs, all of these agents share the same indication. Rescula and Lumigan were not available on the Canadian market at the time Travatan was first sold and when it came under the PMPRB's jurisdiction. Therefore, Xalatan is the only comparable medicine for purposes of the TCC.

The PMPRB's 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 Travatan and the comparator are based on their respective product monographs and supported by clinical literature. See the table below.

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 prices of all of the comparable drug products in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*.

The price of Travatan was considered to be within the Guidelines relative to the TCC test, as it did not exceed the prices of the other drugs in the therapeutic class by an amount that triggered the investigation criteria. The price continued to be within the Guidelines in 2002.

Name	Strength	Dosage Regimen[1]	Unit Price	Cost Per Day
Travatan	0.4 mg/2.5 ml	1 drop in each eye daily in the evening (0.1 ml)	1 bottle (2.5ml) = $26.50[2]	$1.06
Xalatan	0.5 mg/2.5 ml	1 drop in each eye daily in the evening (0.1 ml)	1 bottle (2.5ml) = $26.00[2]	$1.04

1 The HDAP recommended that the drop sizes be assumed to be the same for each product, 0.05 ml/drop, as is usual practice for eye drops.
2 Liste des médicaments, Régie de l'assurance maladie du Québec, juin 2003.

Travatan was also being sold in Germany, Sweden, the United Kingdom and the United States. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries. The price in Canada of ranked 2nd lowest, below the median international price.

Evidence/ References:

The references are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; Travatan.

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. ■