Report on New Patented Drugs

Xatral

Brand Name	Xatral
Generic Name:	alfuzosin hydrochloride
DIN:	02245565 10 mg tablet
Patentee:	Sanofi-Synthélabo Canada Inc.
Indication (as per product monograph):	For the treatment of the signs and symptoms of benign prostatic hyperplasia.
Notice of Compliance:	February 21, 2002
Date of First Sale:	February 21, 2002
ATC Class:	G04CA01 *Urologicals, Drugs Used in Benign Prostatic Hypertrophy, Alpha-adrenoreceptor antagonists*

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.

Application of the Guidelines

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. The Guidelines provide that it may, however, be appropriate to include products from other ATC classes if they are clinically equivalent for the appropriate indication to the drug product under review. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs on our website, under Legislation, Regulations, Guidelines.

Summary:

The introductory price of Xatral 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 and the price did not exceed the range of prices in other comparator countries where Xatral was sold.

Scientific Review:

Xatral 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.)

Benign prostatic hyperplasia (BPH) is a non malignant enlargement of the prostate. Two types of medicines are used in BPH: alpha adrenergic receptor antagonists (alfuzosin, tamsulosin, terazosin, doxazosin) which relax the prostatic smooth muscle via the blockade of sympathetic adrenergic receptors and 5α-reductase inhibitors (finastride) which reduce prostatic size via hormonal mechanisms.

Members of the same 4th level ATC class as Xatral include Flomax (tamsulosin) and Hytrin (terazosin). A fourth alpha antagonist, Cardura (doxazosin) has been classified in the cardiovascular class according to the 2002 ATC Index. Despite the different ATC classification, Cardura is indicated and used for BPH therapy.

Although Xatral and Flomax are uroselective alpha antagonists and are associated with fewer postural symptoms than the older agents, available scientific literature considers Xatral, Flomax, Hytrin and Cardura to provide similar improvements in lower urinary tract symptoms. Consequently, the HDAP recommended Flomax, Hytrin and Cardura as appropriate comparators for Xatral.

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 Xatral and the comparators are based on their respective product monographs and supported by clinical literature. See table in price test section below.

Price Review:

Under the Guidelines, the introductory price for a new category 3 drug product will be presumed to be excessive if it exceeds the price of all of the comparable drug products based on the TCC test, and if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations, 1994*.

As shown in the following table, the price of Xatral 10 mg tablet was within the Guidelines relative to the TCC test as it did not exceed the prices of the other drugs in the therapeutic class.

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Xatral	10 mg/tab	10 mg/day	$0.95[1]	$0.95
Flomax	0.4 mg/tab	0.4 mg/day	$0.95[2]	$0.95
Hytrin	5 mg/tab	5 mg/day	$0.96[3]	$0.96
Cardura	4 mg/tab	4 mg/day	$0.86[3]	$0.86

1 PPS, July 2002
2 Liste des médicaments, Régie de l'assurance maladie du Québec, 2001
3 Ontario Drug Benefit Formulary, 2001

At the time of introduction in Canada, Xatral was being sold in France, Germany, Italy, Sweden, Switzerland, and the United Kingdom and therefore was determined to be within the Guidelines relative to the highest price component of the International Price Comparison Test. The price in Canada was the lowest of these countries.

Evidence/ References:

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

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. ■