Report on New Patented Drugs – Tracleer

Brand Name:	Tracleer
Generic Name:	bosentan monohydrate
DIN:	02244981 62.5 mg/tablet 02244982 125 mg/tablet
Patentee:	Actelion Pharmaceuticals Canada Inc.
Indications (as per product monograph):	The treatment of pulmonary arterial hypertension in patients with WHO functional class III and IV primary pulmonary hypertension, or pulmonary hypertension secondary to scleroderma.
Notice of Compliance:	November 30, 2001
Date of First Sale:	January 4, 2002
ATC Class:	C02KX01 *Antihypertensives, Other Antihypertensives*

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 Tracleer 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 Tracleer was sold.

Scientific Review:

Tracleer is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Tracleer be reviewed 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. 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.

There are no other products at the same 4th level ATC class; Tracleer is the first entry in this class. Like Tracleer, Flolan (epoprostenol) may be used in combination with vasodilators (i.e., calcium channel blockers) and anticoagulants for the management of primary pulmonary hypertension. Flolan represents the only clinically equivalent agent used in the same place in therapy as Tracleer. Although Flolan is only available in a different dosage form, the HDAP recommended that Flolan is an appropriate comparator for the conduct of the TCC for Tracleer.

Flolan is administered intravenously directly into the bloodstream through a surgically implanted catheter by a portable, battery-operated pump. The pump is worn attached to a belt around the waist or carried in a small shoulder pack. Since the drug lasts only 3-5 minutes it must constantly be infused: it is slowly and continuously pumped into the body through the permanent catheter placed in a vein in the neck or chest. The Product Monograph states that Flolan must be reconstituted only as directed using a specific sterile diluent.

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 dosage regimen recommended by the HDAP was supported by the respective product monographs, clinical literature and clinical use. 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 price 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*.

As shown in the following table, the cost of treatment of Tracleer was slightly above the cost of treatment of Flolan. However, the Product Monograph for Flolan specifically states that it must be reconstituted only as directed using specific sterile diluent for Flolan. The cost of the diluent is $20.00 per day. As a result, the cost per day of treatment with Tracleer is lower than the cost of treatment with Flolan and therefore the price of Tracleer was considered to be within the Guidelines.

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Tracleer	125 mg/tab	250 mg	$59.90/tab[1]	$119.80
Flolan	1.5 mg/vial	4.75 mg	$35.00/vial[1]	$110.83

1 Liste de médicaments, Régie de l'assurance maladie du Québec, juin 2003.

A Reasonable Relationship Test was conducted for Tracleer 62.5 mg because the dose of Tracleer during the first four weeks of therapy varies greatly. The price of Tracleer 62.5 mg was considered to be within the Guidelines because it bore a reasonable relationship to the price of Tracleer 125 mg.

In 2002, Tracleer was also being sold in France, Germany, Switzerland, 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 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;Tracleer

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. ■