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Report on New Patented Drug - Angiomax

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

Brand Name: Angiomax
Generic Name: *(bivalirudin)*
DIN: 02246533 250 mg/vial
Patentee: Oryx Pharmaceuticals

Indication - as per product monograph:

For use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA).

Date of Issuance of First Patent(s) Pertaining to the Medicine: December 14, 1999

Notice of Compliance: October 9, 2002

Date of First Sale: May 8, 2003

ATC Class: B01AE06
Blood and blood forming organs, Antithrombotic agents, Antithrombotic agents, Direct thrombin inhibitors

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Angiomax 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 Angiomax is sold.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Angiomax be reviewed as a category 3 new drug product (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.

The HDAP recommended Hepalean (*heparin sodium*) combined with Reopro (*abciximab*), and Integrilin (*eptifibatide*) as the most suitable comparators for the conduct of a TCC test. Although these agents are not in the same 4th level ATC class, they are clinically equivalent at addressing the approved indication.

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 Angiomax and the comparators are based on the respective product monographs and supported by clinical literature.

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 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*.

Introductory Period (May to June 2003)

Name	Strength	Dosage Regimen	Unit Price	Cost Per Treatment
Angiomax	250 mg/5 ml	2.60 ml	\$410.0000 ¹	\$214.2000
Hepalean	10000 units/ml	6.26 ml	\$0.9580 ²	\$5.9971
Reopro	2 mg/ml	11.9 ml	\$107.3300 ³	\$1,277.2270
			\$108.2880	\$1,283.2241
Integrilin	2 mg/ml	12.6 ml	\$3.8000 ³	\$47.8800
Integrilin	0.75 mg/ml	201.6 ml	\$1.1125 ³	\$224.2800
			\$4.9125	\$272.1600

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

² Ontario Drug Benefit Formulary, January 2003

³ PPS Pharma, January 2003

In 2003, Angiomax was also being sold in the United States. In compliance with the Guidelines, the price in Canada did not exceed the price in the United States.

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.

References - Angiomax

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