October 2006

Report on New Patented Drugs - TNKase

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: TNKase

Generic Name: *(tenecteplase recombinant)*

DIN: 02244826 50 mg/vial

Patentee: Hoffmann-La Roche Limited, Canada

Indication - as per product monograph:

For IV use in adults for the lysis of suspected occlusive coronary artery thrombi associated with evolving transmural myocardial infarction to reduce the mortality associated with acute myocardial infarction

Date of Issuance of First Patent(s) Pertaining to the Medicine: June 17, 2003

Notice of Compliance: October 17, 2001

Date of First Sale: October 2001

ATC Class: J01FA15
Antiinfectives for Systemic Use, Antibacterials for Sytemic Use, Macrolides, Lincosamides and Streptogramins, Macrolides

APPLICATION OF THE GUIDELINES

Summary

The introductory price of TNKase 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 prices in the other comparator countries where TNKase was sold.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that TNKase 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. 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 Streptase (*streptokinase*), Activase (*alteplase*) and Retavase (*reteplase*) as the most appropriate comparators for TNKase as the comparators are within the same 4th level ATC classification, share the same indication as TNKase and have comparable clinical efficacy rates.

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 TNKase and the comparators are based on their respective product monographs, clinical literature, current practice guidelines and clinical practice.

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 TNKase was within the Guidelines as the cost per treatment did not exceed the cost per treatment with the comparator medicines.

Introductory Period (July to December 2003)			
Name	**Strength**	**Dosage Regimen**	**Cost per Treatment**
TNKase (*tenecteplase recombinant*)	**50 mg/vial**	**0.8 vial**	**$2,196.8000[1]**
Streptase (*streptokinase*)	1.5 MU/vial	1 vial	$595.0000[2]
Activase (*alteplase*)	100 mg/vial	1 vial	$2,746.0000[1]
Retavase (*reteplase*)	10.4U/vial	2 vials	$1,900.0000[1]

1. PPS Pharma, January 2003
2. Association québécoise des pharmaciens propriétaires (AQPP), October 2003

At introduction, TNKase 50 mg/vial was sold in all seven countries listed in the Regulations. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries; the price of TNKase in Canada was third highest of the seven countries, above the median international price.

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.

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