Reports on New Patented Drugs – Xigris

Brand Name:	Xigris
Generic Name:	drotrecogin alfa
DIN:	02247129 5 mg/vial 02247130 20 mg/vial
Patentee:	Eli Lilly Canada Inc.
Indication – as per product monograph:	For the reduction of mortality in adult patients with severe sepsis (sepsis, may be associated with acute organ dysfunction) who have a high risk of death (e.g., as determined by APACHE II, or multiple acute organ dysfunctions), when added to current best practice.
Notice of Compliance:	January 31, 2003
Date of First Sale:	February 12, 2003 (5 mg vial) March 25, 2003 (20 mg vial)
ATC Class:	B01AD10 *Blood and Blood Forming Organs, Antithrombotic Agents*

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 Price Guidelines, for all new active substances introduced after January 1, 2002.

PMPRB

Application of the Guidelines

Summary:

The introductory prices of the Xigris drug products were found to be within the Guidelines because the prices in Canada did not exceed the median of the prices of the same drug products in those countries listed in the *Patented Medicines Regulations* (Regulations) in which they were sold or did not do so by an amount sufficient to trigger any of the investigation criteria under the *Compliance & Enforcement Policy*.

For information on the Criteria for Commencing an Investigation, please see Schedule 5 of the Compendium of Guidelines, Policies, and Procedures, as posted on our website under Legislation, Regulations and Guidelines.

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Xigris be reviewed as a category 2 new drug (breakthrough or substantial improvement) based on the following information:

- Sepsis, a severe infection, remains a major cause of death in hospitalized patients. Despite a massive research effort over the past two decades to identify innovative therapies for sepsis, current treatment strategies consist primarily of anti-infective agents and a variety of supportive measures.
- Although some forms of treatment (mainly supportive care) are available to this patient population, thus far no other drug product has received approval for the sole treatment of acute sepsis in adults and children.
- The HDAP concluded that Xigris represents a substantial improvement over all other currently available therapies. The HDAP acknowledged the potential adverse effects of Xigris, however came to the conclusion that the benefits (i.e. decreased mortality) would be expected to outweigh the potential adverse effects.
- There are a number of drug products in the same 4th level ATC class as Xigris; however none of them are clinically equivalent in addressing the treatment of sepsis. In addition, there appears to be no other medication available to this patient population and thus no alternative treatment modalities that address sepsis in the same manner and show the same efficacy as Xigris. As a result, the HDAP recommended no comparators for the conduct of a Therapeutic Class Comparison (TCC) Test.

Evidence/ References:

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

Price Review:

Under the Guidelines, the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a TCC Test, *and* the median of the international prices identified in an International Price Comparison (IPC) Test.

As no comparable drug products could be identified for purposes of conducting a TCC Test, the prices of the Xigris drug products were considered to be within the Guidelines as they did not exceed the median of the international prices identified in the IPC Test, or did not do so by an amount that triggered the investigation criteria.

Xigris[1]	Canada	France	Germany	Italy	Sweden	Switzerland	UK	US	Median
5 mg	$335.00	$334.96	$334.96	$334.96	$358.35	$302.31	$326.60	$318.21	$334.96
20 mg	$1340.00	$1338.96	$1338.96	$1338.96	$1422.75	$1433.33	Not Sold	$1275.16	$1338.96

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