

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.

# Report on New Patented Drugs – Aranesp

<b>Brand Name:</b>	Aranesp	
<b>Generic Name:</b>	darbepoetin alfa	
<b>DIN:</b>	02246354	10 mcg/syr
	02246355	20 mcg/syr
	02246357	30, 40, 50 mcg/syr
	02246358	60, 80, 100 mcg/syr
	02246360	150 mcg/syr
<b>Patentee:</b>	Amgen Canada Inc.	
<b>Indication (as per product monograph):</b>	For the treatment of anaemia associated with chronic renal failure (CRF), including patients on dialysis and patients not on dialysis.	
<b>Notice of Compliance:</b>	August 2, 2002	
<b>Date of First Sale:</b>	August 2002	
	In most cases, patents are issued before the drugs come to market. In this case, the first patent pertaining to Aranesp was issued November 5, 2002 and it came under the PMPRB's jurisdiction at that time.	
<b>ATC Class:</b>	B03XA02 <i>Antianemic Preparations, Other Antianemic Preparations</i>	

## Application of the Guidelines

### Summary:

The introductory prices of Aranesp at date of first sale were 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 or did not do so by an amount sufficient to trigger the investigation criteria and the prices did not exceed the range of prices in other comparator countries where Aranesp was sold. These prices continued to be within the Guidelines when Aranesp came under the PMPRB's jurisdiction in November 2002.

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:

Aranesp 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).

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 4<sup>th</sup> level of the Anatomical, Therapeutic, Chemical (ATC) System that are clinically equivalent in addressing the approved indication.

The only other agent that falls within the same 4<sup>th</sup> level ATC class as Aranesp is Eprex (epoetin alfa). Eprex also shares the same indication as Aranesp and is used in Canada for treating anaemia in patients with chronic renal failure. Consequently, the HDAP recommended that Eprex be the sole comparator for purposes of a TCC for Aranesp.

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 Aranesp and the comparator are based on the respective product monographs and supported by clinical literature. See the following table.

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## 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 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*.

As shown in the table below, the prices of Aranesp were considered within the Guidelines relative to the TCC test as they did not exceed the prices of the other drugs in the therapeutic class or did not do so by an amount that triggered the investigation criteria.

Name	Strength	Dosage Regimen	Unit Price/Syringe <sup>1</sup>	Cost Per Day
Aranesp	10 mcg/0.4 ml	1 syringe	\$26.80	\$26.80
Epex	1000 IU/0.5 ml	2 syringes	\$14.25	\$28.50
Epex	2000 IU/0.5 ml	1 syringe	\$28.50	\$28.50
Aranesp	20 mcg/0.5 ml	1 syringe	\$53.60	\$53.60
Epex	2000 IU/0.5 ml	2 syringes	\$28.50	\$57.00
Epex	4000 IU/0.4 ml	1 syringe	\$57.00	\$57.00
Aranesp	30 mcg/0.3 ml	1 syringe	\$80.40	\$80.40
Epex	2000 IU/0.5 ml	3 syringes	\$28.50	\$85.50
Epex	6000 IU/0.6 ml	1 syringe	\$85.50	\$85.50
Aranesp	40 mcg/0.4 ml	1 syringe	\$107.20	\$107.20
Epex	4000 IU/0.4 ml	2 syringes	\$57.00	\$114.00
Epex	8000 IU/0.8 ml	1 syringe	\$114.00	\$114.00
Aranesp	50 mcg/0.5 ml	1 syringe	\$134.00	\$134.00
Epex	3000 IU/0.3 ml	3 syringes	\$42.75	\$128.25
Epex	10000 IU/1.0 ml	1 syringe	\$133.95	\$133.95
Aranesp	60 mcg/0.3 ml	1 syringe	\$160.80	\$160.80
Epex	4000 IU/0.4 ml	3 syringes	\$57.00	\$171.00
Epex	6000 IU/0.6 ml	2 syringes	\$85.50	\$171.00
Aranesp	80 mcg/0.4 ml	1 syringe	\$214.40	\$214.40
Epex	8000 IU/0.8 ml	2 syringes	\$114.00	\$228.00
Aranesp	100 mcg/0.5 ml	1 syringe	\$268.00	\$268.00
Epex	10000 IU/1.0 ml	2 syringes	\$133.95	\$267.90
Aranesp	150 mcg/0.3 ml	1 syringe	\$402.00	\$402.00
Epex	10000 IU/1.0 ml	3 syringes	\$133.95	\$401.85

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

Aranesp was also sold in France, Germany, Italy, Sweden, Switzerland, and the United Kingdom in 2002. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries; the prices in Canada were lower than the prices in those countries.

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. ■

## Evidence/ References:

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