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## Report on New Patented Drugs - Elidel

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:** Elidel  
**Generic Name:** (*pimecrolimus*)  
**DIN:** 02247238 10 mg/g topical cream  
**Patentee:** Novartis Pharmaceuticals Canada Inc.

### Indication - as per product monograph:

For short-term treatment and intermittent long-term therapy of mild to moderate atopic dermatitis in non-immunocompromised patients 2 years of age and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative, conventional therapies.

**Date of Issuance of First Patent(s) Pertaining to the Medicine:** May 8, 2001

**Notice of Compliance:** March 19, 2003

**Date of First Sale:** March 24, 2003

**ATC Class:** D11AX15  
*Other dermatological preparations, Antihidrotics, Other dermatologicals.*

## **APPLICATION OF THE GUIDELINES**

### **Summary**

The introductory price of Elidel 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 Elidel was sold.

### **Scientific Review**

Elidel is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Elidel 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 4<sup>th</sup> 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.

Of the compounds within the same 4<sup>th</sup> level ATC class as Elidel, only Protopic (*tacrolimus*) is both available in Canada and shares the same indication as Elidel. Consequently, the HDAP recommended Protopic as the sole comparator for the purpose of a TCC test for Elidel.

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 Elidel and Protopic are based on the respective product monographs and supported by clinical literature.

### **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 based on 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 table below, the price of Elidel was within the Guidelines relative to the TCC test as it did not exceed the cost per day of the comparable medicine.

Introductory Period (March to June 2003)				
Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Elidel (cream)	1%	1 gr	\$1.96 <sup>1</sup>	\$1.96
Protopic (cream)	0.03%	1 gr	\$2.15 <sup>2</sup>	\$2.15

<sup>1</sup> Quebec Formulary – October 2003

<sup>2</sup> Ontario Drug Benefit Formulary, January 2003

In 2003, Elidel was being sold in Germany, Sweden, Switzerland, 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 was second highest 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.*

## References – Elidel

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