

## Report on New Patented Drugs - Alvesco

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

**Brand Name:** Alvesco

**Generic Name:** (*ciclesonide*)

**DINs:** 02285606 (100ug/actuation)  
02285614 (200ug/actuation)

**Patentee:** Altana Pharma Inc.

### Indication – as per product monograph:

For the prophylactic management of steroid-responsive bronchial asthma in patients 18 years of age and older.

### Date of Issuance of First Patent(s)

**Pertaining to the Medicine:** October 10, 2006

**Notice of Compliance:** September 11, 2006

**Date of First Sale:** September 27, 2006

**ATC Class:** R03BA  
Respiratory System; Drugs for Obstructive Airway Diseases; Other Drugs for Obstructive Airway Diseases, Inhalants; Glucocorticoids.

## APPLICATION OF THE GUIDELINES

### Summary

The introductory prices of Alvesco 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 and did not exceed the range of prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Alvesco was sold.

## **Scientific Review**

Alvesco is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Alvesco be classified as a category 3 new medicine (provides moderate, little or no therapeutic 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 World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) Classification System that are clinically equivalent in addressing the approved indication. See the Board's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended Flovent (*fluticasone*), Pulmicort Turbuhaler (*budesonide*), and QVAR (*beclomethasone*) as comparators to Alvesco. These active ingredients share the same 4<sup>th</sup> level ATC class, are indicated and used for the prophylactic management of corticosteroid-responsive asthma.

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 Alvesco and the comparable drug products were 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 prices 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 Regulations.

The introductory prices of Alvesco 100ug and 200ug/actuation were within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicines.

**Introductory Period (September to December 2006)**

<b>Name</b>	<b>Strength</b>	<b>Dosage Regimen</b>	<b>Unit Price</b>	<b>Cost per Treatment (Daily)</b>
Alvesco ( <i>ciclesonide</i> )	100ug	200ug/day	\$0.3450 <sup>(1)</sup>	\$0.6900
Flovent Diskus ( <i>fluticasone</i> )	50ug	300ug/day	\$0.2200 <sup>(3)</sup>	\$1.3200
Flovent Diskus ( <i>fluticasone</i> )	250ug	250ug/day	\$0.6000 <sup>(3)</sup>	\$0.6000
Flovent HFA ( <i>fluticasone</i> )	125ug	250ug/day	\$0.3000 <sup>(3)</sup>	\$0.6000
Pulmicort Turbuhaler ( <i>budesonide</i> )	200ug	400ug/day	\$0.2955 <sup>(3)</sup>	\$0.5910
QVAR ( <i>beclomethasone</i> )	100ug	200ug/day	\$0.2835 <sup>(2)</sup>	\$0.5670

**Introductory Period (September to December 2006)**

<b>Name</b>	<b>Strength</b>	<b>Dosage Regimen</b>	<b>Unit Price</b>	<b>Cost per Treatment (Daily)</b>
Alvesco ( <i>ciclesonide</i> )	200ug	400ug/day	\$0.5700 <sup>(1)</sup>	\$1.1400
Flovent Diskus ( <i>fluticasone</i> )	500ug	500ug/day	\$1.2000 <sup>(3)</sup>	\$1.2000
Flovent HFA ( <i>fluticasone</i> )	250ug	500ug/day	\$0.6000 <sup>(3)</sup>	\$1.2000
Pulmicort Turbuhaler ( <i>budesonide</i> )	400ug	800ug/day	\$0.5318 <sup>(3)</sup>	\$1.0635
QVAR ( <i>beclomethasone</i> )	100ug	500ug/day	\$0.2835 <sup>(2)</sup>	\$1.4175

**Sources:**

(1) Publicly available price as per the Regulations

(2) Régie de l'assurance maladie du Québec, Décembre 2006

(3) Association québécoise des pharmaciens propriétaires 2006

In 2006, Alvesco was being sold in three countries listed in the Regulations, namely Germany, Switzerland and the UK. In compliance with the Guidelines, the prices of Alvesco in Canada did not exceed the range of prices in those countries. They were the lowest of the international prices.

*The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.*

*Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by 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.*

*In its Summary Reports, the PMPRB will also refer to the publicly available prices of comparators provided such prices are not more than 10% above a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information purposes only and should not be relied upon as being considered within the Guidelines.*

*The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than stated 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 - Alvesco**

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