

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
3M CANADA COMPANY
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Airomir (salbutamol sulphate) is a patented medicine which was sold in Canada by 3M Canada Company (3M Canada) prior to December 29, 2006.
- 1.2 Airomir (salbutamol sulphate) is indicated for the symptomatic management of asthma. Airomir is classified in the 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification index as R03AC, known as Anti-Asthmatics. Airomir is available in a CFC-Free 200 Metered Dose Inhaler.
- 1.3 Canadian Patent No. 2,161,632 pertains to Airomir. This patent was granted to 3M Company USA, on August 10, 1999 and expires on April 15, 2014. 3M Canada was the Canadian patentee until December 29, 2006 for all purposes relating to the *Patent Act* ("Act") and the *Patented Medicines Regulations* ("Regulations") in respect of the jurisdiction of the PMPRB.
- 1.4 Health Canada issued a Notice of Compliance ("NOC") for Airomir on August 20, 1997. It was introduced to the Canadian market in June 1999.
- 1.5 The marketing rights for Airomir were acquired by Graceway Canada Company effective December 29, 2006 and since that date, for purposes of the PMPRB's application of its Guidelines, Graceway Canada Company is the Canadian patentee and 3M Canada is a former patentee.

2.0 Application of the Excessive Price Guidelines by Board Staff

- 2.1 The price of Airomir was reviewed in accordance with the PMPRB's *Excessive Price Guidelines* ("Guidelines") and was found by Board Staff to be within the Guidelines from the time it was introduced to the Canadian market through December 31, 2003.
- 2.2 For the periods January 1, 2004 through December 29, 2006, the CPI adjusted MNE prices were found by Board Staff to be \$0.0230 for 2004, \$0.0238 for 2005 and \$0.0240 for 2006. The price of Airomir was found by Board Staff to have exceeded the CPI adjusted MNE prices with resulting excess revenues of \$485,498.58

3.0 Position of the Former Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by 3M Canada concerning the appropriate MNE prices or that the price of Airomir was, at any time since the date of first sale of the medicine, excessive for purposes of the *Patent Act*. Indeed, it is the position of the former patentee that the price of Airomir has at all times been non-excessive.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 In order resolve this matter as it pertains to the former patentee, 3M Canada agrees to undertake as follows:

4.1.1 To offset the cumulative excess revenues as alleged by Board Staff and received by 3M Canada during the period of January 1, 2004 to December 29, 2006 by making a payment to Her Majesty in Right of Canada, within 30 days of acceptance of this VCU, in the amount of \$485,498.58;

4.1.2 To notify the PMPRB in the event Airomir is marketed by 3M Canada in any future period in which Airomir remains under the PMPRB's jurisdiction.

3M Canada Company

Signature: Original signature by Nicholas Gangestad redacted

Company Officer: Nicholas Gangestad

Position: VP Finance & I.T.

Date: April 12, 2007