

VCU accepted by the Vice-Chairperson on December 15, 2005

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
JANSSEN-ORTHO INC.  
TO  
THE PATENTED MEDICINE PRICES REVIEW BOARD**

**1. Product Summary**

1.1 Risperdal is a patented medicine sold in Canada by Janssen-Ortho Inc. (Janssen) in the following tablet strengths:

DIN 02025280 - 1 mg	DIN 02025299 - 2 mg
DIN 02025302 - 3 mg	DIN 02025310 - 4 mg
DIN 02240551 - 0.25 mg	DIN 02240552 - 0.5 mg

1.2 Risperdal (*risperidone*) is an anti-psychotic drug indicated for the management of schizophrenia and related psychotic disorders. It is listed as N05AX08 in the WHO's ATC Index.

1.3 Canadian Patent 1,256,867 pertaining to Risperdal was granted to Janssen Pharmaceutica Naamloze Vennootschap (Belgium) on July 4, 1989 and will expire on July 4, 2006. Janssen is the patentee for all purposes relating to the *Patent Act* ("the Act") and the *Patented Medicines Regulations* ("Regulations") in respect of the jurisdiction of the Patented Medicine Prices Review Board (PMPRB).

1.4 Health Canada issued Notices of Compliance for Risperdal 1 mg, 2 mg, 3 mg and 4 mg tablets on April 23, 1993 and for Risperdal 0.25 mg and 0.5 mg tablets on July 29, 1999.

**2. Application of the Excessive Price Guidelines**

2.1 The prices of the six strengths of Risperdal tablets were reviewed in accordance with the PMPRB's *Excessive Price Guidelines* (the Guidelines) and were found to be within the Guidelines from the time they were introduced to the Canadian market through December 31, 2003.

2.2 For the period from January 2004 through December 31, 2004, the prices of the six strengths of Risperdal tablets exceeded their respective CPI-adjusted maximum non-excessive (MNE) prices by 0.55% to 0.88%. As a result, Janssen received revenues in excess of the Guidelines totalling \$669,426.81.

2.3 For the period from January to June 2005, the prices of the six strengths of Risperdal tablets continued to exceed their respective CPI-adjusted MNE prices calculated based on forecast CPI for 2005 by 0.9% to 1.3%. As a result, Janssen received revenues in excess of the Guidelines totalling \$587,807.57 in this period.

## Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Janssen that the prices of the six strengths of Risperdal tablets are or were excessive for purposes of the *Patent Act*.

## 3. Terms of the Voluntary Compliance Undertaking

- 4.1 In order to comply with the Guidelines and policies of the PMPRB Janssen undertakes as follows:
- 4.1.1 To agree that the 2004 MNE prices of Risperdal 1 mg, 2 mg, 3 mg, 4 mg, 0.25 mg, 0.5 mg tablets were respectively, \$1.0223, \$2.0410, \$3.0507, \$4.0643, \$0.4426, \$0.7410,
  - 4.1.2 To ensure that the average transaction prices of Risperdal 1 mg, 2 mg, 3 mg, 4 mg, 0.25 mg, 0.5 mg tablets do not exceed their respective 2005 MNE prices of \$1.0421, \$2.0806, \$3.1144, \$4.1481, \$0.4527, \$0.7568 based on forecast CPI for 2005. In the event that the actual CPI differs from the forecast CPI for 2005, an adjustment may need to be made to the 2005 MNE prices or the amount of excess revenues received for 2005.
  - 4.1.3 To offset excess revenues of \$669,426.81, Janssen undertakes to further reduce the average transaction prices of Risperdal tablets such that all excess revenues are offset no later than December 31, 2005.
  - 4.1.4 In the event the measures set out in 4.1.2 and 4.1.3 do not result in an offset of all cumulative excess revenues, to make a payment for any excess remaining at December 31, 2005 to Her Majesty the Queen in Right of Canada no later than January 31, 2006.
  - 4.1.5 To ensure that the prices of Risperdal 1 mg, 2 mg, 3 mg, 4 mg, 0.25 mg, 0.5 mg tablets remain within the Guidelines in all future periods in which they remain under the PMPRB's jurisdiction.

## Janssen-Ortho Inc.

Signature: Original signed by

Company Officer: Gary Pruden

Position: President & Chief Executive Officer

Date: December 12, 2005