JANSSEN-ORTHO

PROTECTED

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

1.0 Product Summary

1.1 Risperdal Consta is a patented medicine sold in Canada by Janssen-Ortho Inc. It is supplied as a powder for injectable prolonged-release suspension in single use vials for injection in strengths of 25 mg (DIN 02255707), 37.5 mg (DIN 02255723) and 50 mg (DIN 02255758).

1.2 Risperdal Consta (risperidone) is an anti-psychotic agent indicated for the management of manifestations of schizophrenia and related psychotic disorders. It is listed as N05AX08 in the WHO Anatomical Therapeutic Chemical (ATC) Classification System.

1.3 Canadian Patent No. 1,256,867 pertaining to Risperdal Consta was granted to Janssen Pharmaceutica Naamloze Vennootschap (Belgium) on July 4, 1989 and Canadian Patent No. 2,251,987 also pertaining to Risperdal Consta was granted to Alkermes Controlled Therapeutics Inc. (United States) and Janssen Pharmaceutica Naamloze Vennootschap (Belgium) on May 10, 2005. The last of these patents will expire on May 6, 2017. Janssen-Ortho is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 Health Canada issued a Notice of Compliance to Janssen-Ortho for Risperdal Consta on July 16, 2004 and sales of Risperdal Consta began in Canada on September 21, 2004 in three strengths – 25 mg, 37.5 mg and 50 mg vials.

2.0 Board Staff Position

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Risperdal Consta be classified as a category 3 new medicine as in HDAP's view it provides moderate, little or no therapeutic advantage over comparable medicines available in Canada. The HDAP identified Clopixol depot injection (zuclopenthixol decanoate), Fluanxol depot injection (flupenthixol decanoate), Haloperidol depot injection (haloperidol decanoate), Modecate depot injection (fluphenazine decanoate), Piportil L4 depot injection (pipotiazane palmitate), Risperdal oral (risperidone), Seroquel (quetiapine fumarate), and Zyprexa (olanzapine) as the most appropriate comparators. HDAP also recommended particular dosages to compare Risperdal Consta and the comparator medicines.

2.2 Using the comparators and dosages proposed by HDAP to apply the PMPRB's *Excessive Price Guidelines* ("Guidelines"), Board Staff conducted Therapeutic Class Comparison (TCC) tests and International Price Comparison (IPC) tests on the introductory prices of the 25 mg and 50 mg vials and a Reasonable Relationship (RR) Test and an IPC test on the introductory price of the 37.5 mg vial.

2.3 The results of the TCC and RR tests, as applied by Board Staff in paragraph 2.2 above, indicated that the introductory prices of the 25 mg ($243.2794), 37.5 mg ($362.5807), and 50 mg ($483.5036) vials appeared to exceed their respective maximum non-excessive (MNE) prices by 157.4%, 155.8% and 155.8%, respectively. A review of the subsequent reporting periods using this analysis, indicated to Board Staff that the prices of Risperdal Consta continued to exceed the Guidelines MNE.

3.0 Position of Janssen-Ortho Inc.

3.1 Janssen-Ortho does not accept the conclusions of HDAP in considering Risperdal Consta. Janssen-Ortho does not agree that Risperdal Consta is a category 3 medicine as in its view the clinical evidence clearly demonstrates that it offers substantial improvement over existing therapies. Furthermore, if a TCC Test were appropriate, Janssen-Ortho suggests that the comparative dosages proposed by HDAP are not consistent with medical practice.

3.2 Janssen-Ortho also notes that Risperdal Consta is priced at a higher level than the medicines identified by HDAP as comparators in all of the reference countries relied upon by Board Staff in applying the Guidelines. Indeed the original MNE proposed by Board Staff as a result of its analysis is significantly lower than the lowest price in any of the reference countries.

3.2 This Voluntary Compliance Undertaking (VCU) is made solely for the purpose of resolving this matter through negotiation and constitutes no admission by Janssen-Ortho whatsoever that the prices of Risperdal Consta are or were excessive for purposes of the Act.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 In order to resolve this matter, Janssen-Ortho agrees to undertake as follows:

4.1.1 To agree that the 2004 MNE prices of Risperdal Consta 25 mg, 37.5 mg, and 50 mg were $141.7500, $212.6250, and $283.5000, respectively.

4.1.2 To agree that the 2005 MNE prices of Risperdal Consta 25 mg, 37.5 mg, and 50 mg were $144.8685, $217.3028, and $289.7370, respectively.

4.1.3 To agree that the 2006 MNE prices of Risperdal Consta 25 mg, 37.5 mg, and 50 mg were $147.8453, $221.7679, and $295.6905, respectively.

4.1.4 To agree that the 2007 MNE prices of Risperdal Consta 25 mg, 37.5 mg, 50 mg are $151.1055, $226.6583, and $302.2110, respectively.

4.1.5 To reduce the prices of Risperdal Consta 25 mg, 37.5 mg and 50 mg vials to the 2007 MNE prices within 30 days of the acceptance of this VCU.

4.1.6 To offset the amount by which the cumulative revenues received from September 21, 2004 to December 31, 2006 exceeded the MNE's agreed to in paragraphs 4.1.1 to 4.1.3 by making a payment to Her Majesty in right of Canada in the amount of $4,386,172.99 within 30 days of the acceptance of this VCU.

4.1.7 To offset any amount by which revenues received during the period January 1, 2007 to the date of acceptance of this VCU exceed the MNE agreed to in paragraph 4.1.4, Janssen-Ortho undertakes to further reduce the prices of Risperdal Consta 25 mg, 37.5 mg and 50 mg vials below the 2007 MNE prices.

4.1.8 In the event that any revenues that exceeded the agreed MNE have not been offset by the end of December 2007, Janssen-Ortho shall make a payment to Her Majesty in right of Canada, within 30 days of the filing of the July to December 2007 price and sales data as required by the *Patented Medicines Regulations*, 1994 for such amount as is calculated from that data.

4.1.9 To provide notice to customers within 15 days of acceptance of this VCU of the price reductions for Risperdal Consta and that these price reductions are the result of an undertaking pursuant to an agreement with the PMPRB, to provide a reference to the PMPRB Web site for the complete text of the VCU, and to further provide copies of such notifications to Board Staff forthwith.

4.2.0 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the prices of Risperdal Consta have been reduced in a manner consistent with the terms of this VCU.

4.2.1 To ensure that the prices of Risperdal Consta remain within the Guidelines in all future periods in which Risperdal Consta remains under the PMPRB's jurisdiction.

Date: June 1, 2007

Signature: Original signature redacted

Company Officer: Chris Halyk

Position: President

Patentee: Janssen-Ortho Inc.