

April 1, 2009

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

**1.0 Product Summary**

- 1.1 Concerta (methylphenidate hydrochloride) is a new formulation of an existing compound indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children.
- 1.2 Three Canadian patents have been issued that pertain to Concerta: Patent No. 1,222,950 was granted on June 16, 1987 and expired on June 16, 2004. Canadian Patents No. 2,265,668 and No. 2,264,852 were granted on August 23, 2005 and November 1, 2005 and will expire on November 12, 2017 and September 16, 2017, respectively. Janssen-Ortho Inc. is the patentee for purposes of the PMPRB".
- 1.3 On June 26, 2003, Health Canada issued a Notice of Compliance to Janssen-Ortho Inc. and sales of Concerta began in Canada on August 7, 2003 in three strengths: 18 mg, 36 mg and 54 mg tablets. On June 30, 2004, Health Canada issued a Notice of Compliance to Janssen-Ortho Inc. for Concerta 27 mg tablet and sales began in Canada on January 8, 2005.

**2.0 Application of the MNE from the Adderall XR matter**

- 2.1 An Order of the Board setting the MNE price for Adderall XR was issued on August 27, 2008. The Board's Decision on the merits in the Adderall XR matter held that the MNE price established by Board Staff in accordance with the Guidelines was inappropriate. The Board also indicated that Concerta is considered in the same therapeutic class as Adderall XR.
- 2.2 The calculations of Board Staff applying the principles set out in the Adderall XR Decision result in the following MNE prices for each strength of Concerta:

	18 mg	27 mg	36 mg	54 mg
2003	1.9652		2.4544	2.9296
2004	2.0006		2.4986	2.9823
2005	2.0084	2.2660	2.5535	3.0479
2006	2.0040	2.3113	2.6046	3.1089
2007	2.0064	2.3158	2.6248	3.1742
2008	2.0122	2.3224	2.6324	3.2504

2.3 The ATP of Concerta was below the MNE price for each strength in the latest reporting period.

### 3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Janssen-Ortho Inc. that the prices of Concerta are or were excessive for purposes of the *Patent Act*.

### 4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 This VCU is made for the purposes of resolving through an agreed settlement the issues raised in the proceedings commenced by the Notice of Hearing.

4.2 For the purposes of this negotiated settlement Janssen-Ortho Inc. undertakes as follows:

4.2.1 To agree to the MNE prices for Concerta 18 mg, 27 mg, 36mg and 54 mg tablets in accordance with 2.2 above

4.2.2 To make a payment to Her Majesty in right of Canada to offset the cumulative revenues that Board Staff, has calculated that Janssen-Ortho Inc. has received since August 7, 2003 in excess of the applicable MNE price less the amount by which the MNE price exceeded the ATP for each strength of Concerta in the second half of 2008.

4.2.3 To make a payment to Her Majesty in right of Canada, in the amount of \$1,464,441.58, within thirty (30) days of acceptance of this VCU by the Board, to offset the amount calculated in accordance with 4.2.2.

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

Date:

April 1, 2009.

Signature:



Company Officer: Chris Halyk

Position: President

Patentee: Janssen-Ortho Inc.