

**Decision: PMPRB-06-D5-ADDERALL XR
- Board Order**

**IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4,
as amended**

**AND IN THE MATTER OF Shire BioChem Inc.
(the “Respondent”) and the medicine “Adderall XR”**

ORDER

Pursuant to the provisions of section 83 of the *Patent Act*, R.S.C. 1985, c. P-4 (the “Act”), the Patented Medicine Prices Review Board (the “Board”) issued a Notice of Hearing on January 18, 2006 to determine whether Shire BioChem Inc. (“Shire”) is selling or has sold the medicine known as Adderall XR in any market in Canada at a price that is or was excessive and, if so, what order, if any should be made.

Upon conducting its hearing and for the Reasons of the Board provided in *PMPRB-06-D3-Adderall XR – Merits*, issued on April 10, 2008, and *PMPRB-06-D4-Adderall XR – Admissibility of Evidence*, issued on July 16, 2008, the Board orders as follows:

1. The maximum non-excessive (“MNE”) prices of Adderall XR in its 10, 20 and 30 mg strengths for the period from September 12, 2002 to December 31, 2002, inclusive, are:

Strength	MNE Price for September 12, 2002 to December 31, 2002
10 mg	\$1.9252
20 mg	\$2.3875
30 mg	\$2.8498

2. The MNE prices of each of the 10, 20, and 30 mg strengths of Adderall XR are deemed to have increased by the Consumer Price Index ("CPI") for the years 2003 to 2008, inclusive, as follows:

MNE Prices for the 10, 20 and 30 mg strengths Adderall XR				
Year	10 mg MNE Price	20 mg MNE Price	30 mg MNE Price	CPI Factor
2002	\$1.9252	\$2.3875	\$2.8498	
2003	\$1.9791	\$2.4544	\$2.9296	1.028
2004	\$2.0147	\$2.4985	\$2.9823	1.018
2005	\$2.0591	\$2.5535	\$3.0479	1.022
2006	\$2.1002	\$2.6046	\$3.1089	1.020
2007	\$2.1443	\$2.6593	\$3.1742	1.021
2008	\$2.1872	\$2.7124	\$3.2377	1.020

3. The MNE prices of Adderall XR in its 5, 15 and 25 mg strengths for the period from April 13, 2004 to December 31, 2004 are:

Strength	MNE Price for April 13, 2004 to December 31, 2004
5 mg	\$1.7728
15 mg	\$2.2566
25 mg	\$2.7404

4. The MNE prices of each of the 5, 15 and 25 mg strengths of Adderall XR are deemed to have increased by the CPI for the years 2005 to 2008, inclusive, as follows:

MNE Prices for the 5, 15 and 25 mg strengths Adderall XR				
Year	5 mg MNE Price	15 mg MNE Price	25 mg MNE Price	CPI Factor
2004	\$1.7728	\$2.2566	\$2.7404	
2005	\$1.8118	\$2.3062	\$2.8007	1.022
2006	\$1.8480	\$2.3524	\$2.8567	1.020
2007	\$1.8868	\$2.4018	\$2.9167	1.021
2008	\$1.9246	\$2.4498	\$2.9750	1.020

5. The MNE prices for each of the 5, 10, 15, 20, 25 and 30 mg strengths of Adderall XR for the year 2009, and any subsequent year, are to be calculated on an annual basis in accordance with the CPI adjustment methodology set out in Schedule 4 of the Patented Medicine Prices Review Board's Compendium of Guidelines, Policies and Procedures (the "Guidelines");
6. In accordance with subsection 83(1) of the Act, Shire shall cause the maximum prices at which it sells Adderall XR in Canada to be reduced to the MNE prices required by this Order within 30 days from the date of this Order;
7. In accordance with subsection 83(2) of the Act, Shire shall offset the amount of excess revenues estimated to have been derived by Shire from the sale of Adderall XR at excessive prices from September 12, 2002 until the date on which the price reductions referred to in paragraph (6) above come into effect as follows:
- With respect to the period from September 12, 2002 to December 31, 2007, Shire shall pay to Her Majesty in Right of Canada, within 30 days of the date of this Order, on or before September 29, 2008, \$5,622,863.63; and
 - With respect to the period from January 1, 2008 to the date on which the price reductions referred to in paragraph (6) come into effect, Shire shall pay to Her Majesty in Right of Canada a further amount equal to the amount of the excess revenues estimated by the Board to have been derived by Shire from the sale of Adderall XR in its 5, 10, 15, 20, 25 and 30 mg strengths at excessive prices and make the payment within 30 days of receipt of a notification from the Board of its estimate of excess revenues based on the information filed with the Board in response to paragraph (8) below;

8. Within 30 days of the date of this Order, on or before September 29, 2008, Shire shall:
- (a) Notify federal/provincial/territorial Ministers of Health or their representatives and all customers of the price decreases required by this Order (a copy of which shall be included in such notifications) and the effective date of such price decreases;
 - (b) Submit copies of the above-noted notifications to the Board; and
 - (c) Provide to the Board the following information, in the same form as required by paragraph 4(1)(f) of the *Patented Medicines Regulations*, for the period January 1, 2008 to the date on which the price reductions referred to in paragraph (6) come into effect:
 - (i) The quantity of Adderall XR sold in its 5, 10, 15, 20, 25, 30 mg strengths in Canada; and
 - (ii) Either the average price per package or the net revenue from sales of Adderall XR in its 5, 10, 15, 20, 25 and 30 mg strengths in Canada.

Board Members: Dr. Brien G. Benoit
Thomas (Tim) Armstrong

Board Counsel: Gordon Cameron

Sylvie Dupont
Secretary of the Board

August 27, 2008