

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
DRAXIS HEALTH INC.  
TO  
THE PATENTED MEDICINE PRICES REVIEW BOARD**

**1 Product Summary**

Zanaflex (tizanidine) is a patented medicine sold in Canada by Draxis Health Inc. (Draxis Health).

- 1.1 Zanaflex is a short-acting drug indicated for the management of spasticity. Zanaflex is classified in the WHO ATC index 1999 as a member of the 4<sup>th</sup> level ATC class M03BX - Muscle relaxants, centrally acting agents - other centrally acting agent. It is supplied in tablets containing 4 mg of tizanidine hydrochloride (DIN 02239170).
- 1.2 Canadian Patent 1,299,576 pertaining to Zanaflex was granted to Novartis AG of Switzerland on April 28, 1992 and will expire on April 28, 2009. Elan Pharmaceuticals (the licensee of the Canadian patent) sold the Canadian marketing rights for Zanaflex to Draxis Health on June 18, 1999. Accordingly, Draxis Health is the patentee for purposes of the Patented Medicine Prices Review Board (the Board).
- 1.3 Health Canada issued a Notice of Compliance for Zanaflex on June 29, 1999. Draxis Health began selling Zanaflex on October 28, 1999. The price of Zanaflex has been approximately \$0.6808 per tablet since the date of first sale.

**2 Application of the Excessive Price Guidelines**

- 2.1 Board staff conducted its review of the price of Zanaflex in accordance with the Board's Excessive Price Guidelines. Zanaflex was a new active substance at the time of its introduction in Canada and was classified by Board staff as a category 3 new medicine for purposes of the Board's Guidelines. A Therapeutic Class Comparison test (TCC) was conducted by Board staff using Lioresal (baclofen) and Valium (diazepam) as comparators. For purposes of the Guidelines, 24 mg per day of Zanaflex was compared to 80 mg per day of Lioresal and 40 mg per day of Valium.
- 2.2 By applying the Board's Excessive Price Guidelines, Board staff concluded that the price of Zanaflex of \$0.6808 per tablet exceeded the 1999 maximum non-excessive (MNE) price of \$0.6161 per tablet by 10.5%. In 2000, the price of Zanaflex continued to exceed the CPI-adjusted MNE price of \$0.6327 per tablet by 7.6%.

As a result, Board staff have calculated that Draxis Health received excess revenues of \$62,559 during the period October 28, 1999 to December 31, 2000.

### 3 Terms of the Voluntary Compliance Undertaking

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Draxis Health that the price of Zanaflex is or was excessive for purposes of the *Patent Act*.
- 3.2 In order to comply with the Excessive Price Guidelines and policies of the Board, Draxis Health undertakes as follows:
  - 3.2.1 To reduce the average selling price within 30 days of acceptance of this VCU so that the average price for 2001 does not exceed the 2001 MNE price.
  - 3.2.2 To offset excess revenues received by Draxis Health during the period October 28, 1999 to December 31, 2000 by making a payment to Her Majesty the Queen in the right of Canada, within 30 days of the acceptance of this undertaking, in the amount of \$62,599.
  - 3.2.3 To ensure that the price of Zanaflex remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction.

Draxis Health Inc.

Signature: Dan Brazier  
(Original signed by)

Title: President, Draxis Pharmaceutica Division

Date: September 21, 2001