Approved by the Vice-Chairperson – October 27, 2010

VOLUNTARY COMPLIANCE UNDERTAKING OF ASTRAZENECA CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 FASLODEX ® (fulvestrant) is indicated for the hormonal treatment of locally advanced or metastatic breast cancer in post menopausal women, regardless of age, who have disease progression following prior endocrine therapy. It is supplied as a pre-filled syringe with a strength of 50 mg/mL and is administered at monthly intervals as a single 5mL intramuscular injection.

1.2 Health Canada issued a Notice of Compliance (NOC) to AstraZeneca Canada Inc. (AstraZeneca) for FASLODEX on February 17, 2004 (DIN 02248624). FASLODEX was first sold in Canada on February 1, 2006.

1.3 Canadian Patent No. 2,351,004 pertaining to FASLODEX was granted to AstraZeneca AB, Sweden on February 18, 2003 and will expire on January 8, 2021. AstraZeneca is the patentee for the purposes of the Patented Medicines Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that FASLODEX be classified as a category 3 new drug product and identified oral hormonal treatments, namely, Tamofen (tamoxifen), ARIMIDEX® (anastrozole), Femara (letrozole), Aromasin (exemestane), and Megace (megestrol), as the most appropriate comparator drug products.

2.2 In accordance with the Board's *Excessive Price Guidelines* (Guidelines), a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The result of the TCC test indicated that the introductory price of $600.00 appeared to exceed the Guidelines as it was above the maximum non-excessive (MNE) price of $161.1990. The result of the IPC test indicated that the Canadian price was lower than the corresponding prices of FASLODEX in all seven of the PMPRB reference countries outlined in the Regulations.

2.3 The price of FASLODEX in Canada has remained constant at $600.0000 since it was first sold in 2006.

2.4 The Board's Notice and Comment dated June 11, 2010 provides the details for the rationale and background information surrounding the application of the ratio approach International Therapeutic Class Comparison (ITCC) test for FASLODEX.

2.5 ARIMIDEX® (anastrozole) has the largest share of market sales, is sold by AstraZeneca in Canada and is sold in all seven of the PMPRB reference countries. Applying the median international ratio of FASLODEX to ARIMIDEX® under the ITCC test to the price of ARIMIDEX® in Canada would yield an introductory MNE price of $521.2350. Cumulative excess revenues calculated by Board Staff as having been received by AstraZeneca as a result of selling FASLODEX at a price above the MNE price were $405,030.29 as of December 31, 2009.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by AstraZeneca that the price in Canada of FASLODEX is now, or was at any time since the date of the first sale of the medicine, excessive for purposes of the Patent Act.

3.2 AstraZeneca will not be bound by the undertaking herein unless this VCU is accepted by the Board.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, AstraZeneca agrees to undertake the following:

4.1.1 To agree that the MNE prices of FASLODEX are as follows:

2006	$521.2350
2007	$532.1809
2008	$544.6906
2009	$546.7755
2010	$558.7899

4.1.2 To reduce the price of FASLODEX within 30 days of the acceptance of this VCU so that it does not exceed the 2010 MNE price of $558.7899;

4.1.3 To offset the cumulative excess revenues received from February 2006 to December 31, 2009 by making a payment to Her Majesty in right of Canada in the amount of $405,030.29 within 30 days of the acceptance of the VCU;

4.1.4 To offset any excess revenues received during the period January 1, 2010 to the date of reduction of the price of FASLODEX as per 4.1.1 of this VCU by making a payment within 30 days of the filing of semi-annual price and sales data as required by the *Patented Medicines Regulations* in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling FASLODEX at a price in excess of the 2010 MNE price set out in sub-paragraph 4.1.1 above;

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reductions for FASLODEX and that this price reduction is the result of an undertaking to the PMPRB, to provide a reference to the PMPRB Web site for the complete text of the VCU, and to provide copies of such notifications to Board Staff;

4.1.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of FASLODEX has been reduced in a manner consistent with the terms of this VCU; and

4.1.7 To ensure that the price of FASLODEX remains within the Guidelines in all future periods in which FASLODEX is under the PMPRB's jurisdiction.

AstraZeneca Canada Inc.

Signature: Original signed by

Company Officer: Marion E. McCourt

Position: President and CEO

Date: June 11, 2010