VOLUNTARY COMPLIANCE UNDERTAKING
OF
TEVA CANADA INNOVATION G.P.-S.E.N.C.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 Copaxone 20 mg/1.0 mL syringe is a formulation of an existing compound (glatiramer acetate) indicated for use in ambulatory patients with Relapsing-Remitting Multiple Sclerosis to reduce the frequency of relapses.

1.2 Health Canada issued a Notice of Compliance for Copaxone 20 mg/1.0 mL syringe on March 20, 2002. Teva Canada Innovation G.P.-S.E.N.C. ("Teva") began selling Copaxone 20 mg/1.0 mL syringe in Canada on May 15, 2002.

1.3 Canadian Patent No. 2,191,088 pertains to Copaxone 20 mg/1.0 mL syringe. This patent was granted to Yeda Research and Development Co., Ltd., Israel, on September 28, 2004 and will expire on May 23, 2015. Teva is, for the purposes of the Patented Medicine Prices Review Board ("PMPRB"), considered the Canadian patentee.

2.0 *Patent Act* Considerations

2.1 At the time Copaxone 20 mg/1.0 mL syringe was first sold in Canada in 2002, Teva also sold Copaxone in a 20 mg/1.0 mL vial. Upon entry, the price of the syringe was the same price as the vial. Teva discontinued selling Copaxone 20 mg/1.0 mL vial in July 2004. After 2004, Copaxone 20 mg/1.0 mL syringe was and is the lowest priced medicine in the therapeutic class, which includes Avonex, Rebif and Betaseron.

2.2 In 2002, Copaxone 20 mg/1.0 mL syringe was sold only in the United States. By 2005, it was sold in all seven comparator countries (France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States). From 2004 to present, the price in Canada has always been low compared to its price in the international comparator countries.

2.3 In 2004, the price increase of Copaxone 20 mg/1.0 mL syringe exceeded the PMPRB CPI Guideline. The publicly available (Block 5) price of Copaxone remained unchanged from 2004 through December 2012.

3.0 Terms of the Voluntary Compliance Undertaking (VCU)

This VCU constitutes no admission by Teva Canada Innovation that the price of Copaxone in Canada is now, or was at any time since the date of first sale, excessive for the purposes of the Patent Act.

3.1 Teva Canada Innovation agrees to undertake the following:

3.1.1 That the National Non- Excessive Average Prices (N-NEAPs) of Copaxone 20 mg syringe from 2003 to present are as follows:

2003	$36.0000
2004	$37.8000
2005	$39.6000
2006	$41.4000
2007	$43.2000
2008	$43.2000
2009	$43.2000
2010	$43.2000
2011	$44.4528
2012	$44.1937
2013	$44.4972
2014	$45.2368

3.1.2 To make a payment to Her Majesty in right of Canada in the amount of $248,222.32 within 30 days of the acceptance of this VCU.

3.1.3 To ensure that the national average transaction price of Copaxone 20 mg/1.0 mL syringe remains within the Guidelines in all future periods during which Copaxone 20 mg/1.0 mL syringe is under the PMPRB's jurisdiction.

Teva Canada Innovation G.P.-S.E.N.C.

Original signature redacted

Signature

Company Officer: Paul Rittman
Title: General Manager
Date: January 31, 2014