

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
UPJOHN CANADA ULC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1. Zoloft (sertraline hydrochloride) is indicated for the symptomatic relief of depressive illness, for the symptomatic relief of panic disorder with or without agoraphobia, and for the symptomatic relief of obsessive-compulsive disorder (OCD).
- 1.2. Health Canada granted a Notice of Compliance for Zoloft 50 mg capsule (DIN 01962817) and 100 mg capsule (DIN 01962779) on January 30, 1992.
- 1.3. Zoloft 50 mg and 100 mg were first sold in Canada on February 1, 1992 and November 3, 1992 respectively.
- 1.4. The last reported patent pertaining to Zoloft will expire on February 9, 2020. Upjohn Canada ULC is the patentee for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board.

2.0 Application of the Excessive Price Guidelines

- 2.1 The National Average Transaction Prices (N-ATPs) of Zoloft 50 mg and 100 mg began to exceed their respective National Non-Excessive Average Prices (N-NEAPs) in 2017. As of December 31, 2018, cumulative excess revenues for both products were calculated to be \$754,647.71.

3.0 Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Upjohn Canada ULC that the prices of Zoloft are now, or were at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 Pursuant to this VCU, Upjohn Canada ULC will undertake:

- 4.1.1 To agree that the 2018 N-NEAPs for Zoloft 50 mg and 100 mg are as follows:

Year	Zoloft 50 mg	Zoloft 100 mg
2018	\$1.5371	\$1.6780
2019	\$1.5425	\$1.6839

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

June 2019

- 4.1.2 To offset the excess revenues accrued by Upjohn Canada ULC for Zoloft 50 mg and 100 mg by making a payment of \$754,647.71 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU;
- 4.1.3 To ensure that the 2019 N-ATPs for Zoloft 50 mg and 100 mg do not exceed the 2019 NEAPs as outlined in paragraph 4.1.1;
- 4.1.4 To make a further payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining cumulative excess revenues as of December 31, 2019, as calculated based on the semi-annual price and sales data filed by Upjohn Canada ULC; and
- 4.1.5 To ensure that the prices for Zoloft 50 mg and 100 mg remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Sylvain Rocheleau

Position: General Manager, Upjohn Canada

Patentee: Upjohn Canada ULC

Date: June 21, 2019

Signature: _____

Name: Steve Borrelli

Position: Corporate Controller

Patentee: Upjohn Canada ULC

Date: June 21, 2019

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