

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
OTSUKA CANADA PHARMACEUTICAL INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Samsca (tolvaptan) is indicated for the treatment of clinically important, non-hypovolemic-hyponatremia.
- 1.2 The first Canadian Patent No. 2,449,952 pertaining to Samsca was issued to Otsuka Pharmaceutical Co., Ltd. (Japan) on September 28, 2010, and the last issued Canadian Patent No. 2,662,967 will expire on June 14, 2022.
- 1.3 Health Canada issued a Notice of Compliance (NOC) for Samsca on July 25, 2011. Otsuka Canada Pharmaceutical Inc. (Otsuka) commenced sales in Canada on November 10, 2011, and September 29, 2011, for the 15 mg and 30 mg strengths of Samsca, respectively.
- 1.4 Otsuka voluntarily filed information on Samsca with the Patented Medicine Prices Review Board (PMPRB) in April 2015; Otsuka was in failure to report.
- 1.5 Otsuka is the patentee for purposes of the *Patent Act* and the PMPRB.

2.0 Application of the Excessive Price Guidelines

- 2.1 The Human Drug Advisory Panel (HDAP) recommended Samsca be reviewed as a Slight/No Level of Therapeutic Improvement and did not identify any comparator drug products.
- 2.2 In accordance with the Guidelines, a Median International Price Comparison (MIPC) test was conducted for both strengths of Samsca. The results of these tests indicated that the introductory prices of Samsca exceeded the Guidelines by an amount which triggered the investigation criteria.
- 2.3 As Samsca was sold in fewer than five countries, the MIPC was calculated on an interim basis. It was to be re-calculated when three years had elapsed since introduction, or when sales were reported in five or more comparator countries, whichever occurred first. The three years period elapsed in 2014. The MIPC was re-determined and its impact is reflected in the table set out in paragraph 4.1 below.

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

- 2.4 During the first period of sale in 2011, the National Average Transaction Price (N-ATP) and the Market-Specific Average Transaction Prices (MS-ATPs) of Samsca 15 mg exceeded the MIPC by 59.0%, generating \$1,855.83 in excess revenues; the N-ATP and the MS-ATPs of Samsca 30 mg exceeded the MIPC by 58.0%, generating \$1,835.57 in excess revenues. The N-ATPs and MS-ATPs of Samsca continued to exceed the Guidelines in the subsequent reporting periods.
- 2.5 The list price for both strengths of Samsca was reduced to \$90.4110 in April 2015.

3.0 Position of Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Otsuka Canada Pharmaceutical Inc. that the prices of Samsca are now, or were at any time since the date of first sale, excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

Otsuka Canada Pharmaceutical Inc. agrees to undertake the following:

- 4.1 To agree that the MAPPs and N-NEAPs for Samsca are as follows:

Year	15 mg/tablet	30 mg/tablet
2011	\$157.2084	\$158.2217
2012	\$159.5665	\$160.5950
2013	\$161.1386	\$162.1772
2014	\$124.8401	\$124.8401
2015	\$125.9637	\$125.9637
2016	\$126.0399	\$106.5368

- 4.2 To ensure the 2016 N-ATPs of both strengths of Samsca does not exceed the 2016 N-NEAP as stated in 4.1 above, and to ensure that the price in each market where Samsca is sold is within the Guidelines;
- 4.3 To offset cumulative excess revenues received by Otsuka Canada Pharmaceutical Inc. as at December 31, 2015, by making a payment to Her Majesty in right of Canada in the amount of \$200,000.00 within 30 days of the acceptance of this VCU;

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- 4.4 Remaining excess revenues will be offset by way of the price reduction set out in subparagraph 2.5 above. Any excess revenues that have not been repaid by the end of the first data filing period in 2016, will be offset by a further payment, within 30 days of the filing of the January to June 2016 semi-annual price and sales data as required by the Patented Medicines Regulations;
- 4.5 To ensure that the price of both strengths of Samsca remains within the Guidelines in all future periods in which Samsca is under the PMPRB's jurisdiction.

Name: Michael Laranjo
Position: Country Executive Director
Market Access, Commercial Operations, Finance & Administration
Patentee: Otsuka Canada Pharmaceutical Inc.
Date: April 22, 2016

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