VOLUNTARY COMPLIANCE UNDERTAKING
OF
BOEHRINGER INGELHEIM (CANADA) LTD.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Spiriva Respimat is indicated as an add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (ICS ≥ 800 µg budesonide/day or equivalent) and long-acting β agonists (LABA) and who experienced one or more severe exacerbations in the previous year.

1.2. The first Canadian Patent No. 2,275,392 pertaining to Spiriva Respimat was issued to Boehringer lngelheim Pharma GMBH & Co. KG on June 29, 2004, and the last issued Canadian Patent No. 2,617,717 will expire on August 2, 2026.

1.3. Health Canada issued a Notice of Compliance (NOC) for Spiriva Respimat on December 17, 2014. Boehringer lngelheim (Canada) Ltd. commenced sales in Canada on December 19, 2014.

1.4. Boehringer lngelheim (Canada) Ltd. is the patentee for purposes of the *Patent Act* and the PMPRB.

2.0 Application of the Excessive Price Guidelines

2.1 As a new dosage form of an existing medicine, Board Staff reviewed Spiriva Respimat as a Slight/No Level of Therapeutic Improvement. Spiriva 18 mcg/cap was identified as the most appropriate comparator.

2.2 In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the introductory price of Spiriva Respimat exceeded the Guidelines based on the TCC test.

2.3 At introduction, the National Average Transaction Price (N-ATP) and the Market-Specific Average Transaction Prices (MS-ATPs) of Spiriva Respimat exceeded the Maximum Average Potential Price (MAPP), generating $15,776.20 in excess revenues. As of December 31, 2015, cumulative excess revenues were $61,147.70, triggering the investigation criteria.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Boehringer lngelheim (Canada) Ltd. that the price of Spiriva Respimat is now, or was at any time since the date of first sale, excessive for purposes of the *Patent Act.*

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines Boehringer lngelheim (Canada) Ltd. agrees to undertake the following:

4.1 To agree that the MAPP and 2016 N-NEAP for Spiriva Respimat are $1.0500 and $1.0710 respectively.

4.2 To ensure the 2016 N-ATP of Spiriva Respimat does not exceed the 2016 N-NEAP as stated in 4.1 above, and to ensure that the price in each market where Spiriva Respimat is sold is within the Guidelines;

4.3 To offset cumulative excess revenues received by Boehringer lngelheim (Canada) Ltd. as of December 31, 2015, the price of Spiriva was reduced in 2016 to a level below the 2015 MAPP at a national level and in each market where it is sold. Based on the PMPRB Guidelines for calculation of offset, this reduction is expected to offset the cumulative excess revenues of $61,147.70 by June 30, 2016;

4.4 To agree that any remaining excess revenues received by Boehringer lngelheim (Canada) Ltd. from the date of first sale to the date of the price reduction in paragraph 4.3 that have not been offset by June 30, 2016, are to be offset by making a payment to Her Majesty in right of Canada, within 30 days of the filing of the semi-annual price and sales data as required by the *Patented Medicines Regulations*, as calculated by Board Staff;

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

Signature: (Original signed by)

Name: Ernie Hampel

Position: Exec. Director, Market Access & Healthcare Affairs

Patentee: Boehringer lngelheim (Canada) Ltd.

Date: May 26, 2016

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.