June 2019

VOLUNTARY COMPLIANCE UNDERTAKING
OF
PFIZER CANADA ULC
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Xalkori (200 mg/capsule and 250 mg/capsule) is indicated as monotherapy for use in patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastic non-small cell lung cancer (NSCLC).

1.2. Health Canada issued a Notice of Compliance (NOC) for Xalkori on April 25, 2012. Sales in Canada commenced on May 24, 2012.

1.3. The last reported patent pertaining to Xalkori will expire on November 23, 2026. Pfizer Canada ULC (Pfizer) 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 2018 National Average Transaction Price (N-ATP) of Xalkori 200 mg exceeded its National non-Excessive Average Price (N-NEAP) by 2.1%, generating excess revenues of $54,955.56.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Pfizer that the prices of Xalkori 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, Pfizer will undertake:

4.1.1 To agree that the 2018 N-NEAPs for Xalkori 200 mg and 250 mg are as follows:

Year	Xalkori 200 mg	Xalkori 250 mg
2018	$125.7285	$130.4485
2019	$128.7460	$132.1036

4.1.2 To offset the excess revenues accrued by Pfizer in respect of Xalkori 200 mg by making a payment of $54,955.56 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-ATP for Xalkori 200 mg does not exceed the 2019 NEAPs as outlined in paragraph 4.1.1;

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.

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 for Xalkori 200 mg as of December 31, 2019, as calculated based on the semi-annual price and sales data filed by Pfizer;

4.1.5 To calculate subsequent N-NEAPs for Xalkori in accordance with the PMPRB's Guidelines; and

4.1.6 To ensure that the prices of Xalkori remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Frederic Lavoie

Position: VP, Access & Government Relations

Patentee: Pfizer Canada ULC

Date: June 19, 2019