

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

**1.0 Product Summary**

- 1.1 Xalkori (200 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 metastatic 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 Canadian Patents 2,577,937; 2,632,283; 2,578,066 and 2,517,256 pertain to Xalkori and Pfizer Products Inc. (US) is considered the owner of these patents. The first patent pertaining was patent no. 2,577,937, which was laid open on March 2, 2006. The last patent pertaining will expire on November 23, 2026.
- 1.4 Pfizer Canada Inc. is the patentee for purposes of the *Patent Act* and the Patented Medicines Prices Review Board (PMPRB).

**2.0 Terms of the Voluntary Compliance Undertaking**

In order to comply with the Voluntary Compliance Undertaking (VCU), Pfizer Canada Inc. agrees to undertake the following:

- 2.1 To agree to the terms of the Confidential Undertaking which are incorporated herein attached as Appendix A of this VCU:
- 2.2 To agree that the MAPPs and/or NEAPs for Xalkori 200 mg/capsule and Xalkori 250 mg/capsule are as below:

YEAR	MAPP and/or N-NEAP	
	Xalkori 200 mg/capsule	Xalkori 250 mg/capsule
2012	\$146.9601	\$146.9601
2013	\$147.9867	\$146.7840
2014	\$143.0483	\$144.0345
2015	\$129.1393	\$130.8196

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.

2016	\$133.0134	\$134.7441
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- 2.3 To reduce the N-ATP for Xalkori 200 mg/capsule and 250 mg/capsule in 2016 to a price that is below the 2016 N-NEAP as stated above and to ensure that the price in each market where Xalkori 200 mg/capsule and 250 mg/capsule is sold is within the Guidelines;
- 2.4 To ensure that the price of Xalkori remains within the Guidelines in all future periods in which Xalkori (200 mg/capsule and 250 mg/capsule) is under the PMPRB's jurisdiction.

Name: Frederic Lavoie

Position: Vice President, Access and Government Relations

Patentee: Pfizer Canada Inc.

Date: June 3, 2016

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