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

1.0 Product Summary

1.1 Vectibix 20 mg/mL (panitumumab) (Vectibix) is a recombinant, fully human IgG2 monoclonal antibody that binds specifically to the human epidermal growth factor receptor (EGFR). Vectibix is indicated for the treatment of previously untreated patients with non-mutated (wild-type) RAS metastatic colorectal carcinoma in combination with FOLFOX (infusional 5-fluorouracil, leucovorin, and oxaliplatin). Vectibix is also indicated as monotherapy for the treatment of patients with non-mutated (wild-type) RAS mCRC after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

1.2 Vectibix is available in Canada as a single-use vial under two DINs, DIN 02308487 (5 mL) and DIN 02308509 (20 mL). Health Canada issued a Notice of Compliance (NOC) applicable to both DINs on April 3, 2008. DIN 02308487 was first sold in Canada on May 27, 2008 and DIN 02308509 was first sold in Canada on January 3, 2017.

1.3 Canadian Patent No. 2,288,962 is the only patent filed with the PMPRB that pertains to Vectibix and was issued on August 30, 2011 and will expire on May 5, 2018. Amgen Canada Inc. (Amgen) is the patentee for purposes of the *Patent Act* and the *Patented Medicine Regulations* (the Regulations).

2.0 Application of the Excessive Price Guidelines

2.1 For the introductory period of January to June 2017 (the Introductory Period), Amgen filed Form 2, Block 4 filings as per the Regulations for Vectibix DIN 02308509. The Maximum Average Potential Price (MAPP) was established in accordance with the Reasonable Relationship Test in Schedule 4 of the PMPRB's Compendium of Policies, Guidelines and Procedures (the Guidelines). The National Average Transaction Price (N-ATP) of Vectibix DIN 02308509 exceeded the MAPP by 11.16%, triggering the investigation criteria set out in the Guidelines.

2.2 During the Introductory Period, Amgen sold Vectibix DIN 02308509 at a unit price consistent with the price of Vectibix DIN 02308495.

3.0 Positions of the Patentee and Board Staff

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Amgen that the price of Vectibix DIN 02308509 is now, or was at any time since the date of first sale, excessive for purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

3.2 It is the intention of this VCU to ensure that, until May 5, 2018, Vectibix DIN 02308509 is not sold to any customer class in any province at a price greater than that of the respective Introductory Period Average Transaction Price (ATP) in each customer class in each province.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Amgen will undertake:

4.1.1 To ensure that the January to June 2018 ATP of Vectibix DIN 02308509 for each province and each customer class within a province does not exceed the respective Introductory Period ATP in each province and in each customer class within a province where Vectibix DIN 02308509 is sold;

4.1.2 To repay any excess revenues, calculated by Board Staff, that are generated during the January to June 2018 reporting period in which any of the ATPs specified in 4.1.1 exceeds its respective introductory period ATP by making a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of excess revenues calculated for that particular customer class in that particular province based on the semi-annual price and sales data filed by Amgen; and

4.1.3 To ensure that the price of Vectibix DIN 02308509 remains within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Name: GEOFF SPRAGG

Position: EXEC. DIR. VALUE & ACCESS

Patentee: Amgen Canada Inc.

Date: Feb 13, 2018

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.