VOLUNTARY COMPLIANCE UNDERTAKING
OF
Gilead Sciences Canada Inc.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

TRUVADA

1.1. Truvada is a type of medicine called an HIV (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitor (NRTI). Truvada is a fixed-dose combination product containing two medicinal ingredients, Emtriva (emtricitabine 200 mg) and Viread (tenofovir disoproxil fumarate 300 mg).

1.2. Truvada is indicated:

1.2.1. In combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibits) for the treatment of HIV-1 Infection in adults; or

1.2.2. In combination with safer sex practices for Pre-Exposure Prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.

1.3. Health Canada issued a Notice of Compliance (NOC) for Truvada on January 6, 2006. Truvada was first sold in Canada on April 6, 2006 and is currently marketed in Canada by Gilead Sciences Canada Inc. (Gilead).

1.4. The last reported patent pertaining to Truvada expires on January 13, 2024. Gilead is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

GENVOYA

1.5. Genvoya (150 mg elvitegravir/150 mg cobicistat/200 mg emtricitabine/10 mg tenofovir alafenamide as 11.2 mg tenofovir alafenamide hemifumarate) tablets are indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 12 years of age and older (and weighing at least ≥35 kg) and with no known mutations associated with resistance to the individual components of Genvoya.

1.6. Health Canada issued an NOC for Genvoya on November 27, 2015. Genvoya was first sold in Canada on February 3, 2016 and is currently marketed in Canada by Gilead.

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.

1.7. The last reported patent pertaining to Genvoya expires on May 1, 2029. Gilead is the patentee for purposes of the *Patent Act* and the PMPRB.

2. Application of the Excessive Price Guidelines

2.1. The price of Truvada was within the thresholds set out in the Guidelines at introduction and in all subsequent periods up to and including 2015.

2.2. The 2016 National Average Transaction Price (N-ATP) price of Truvada exceeded the 2016 National Non-Excessive Average Price (N-NEAP) triggering the investigation criteria in the Guidelines. The 2017 N-ATP continues to exceed the 2017 N-NEAP.

2.3. The Human Drug Advisory Panel (HDAP) classified Genvoya as a Slight/No Improvement. Board Staff conducted a Therapeutic Class Comparison (TCC) test and a Highest International Price Comparison (HIPC) test.

2.4. The introductory N-ATP price for Genvoya exceeded the Maximum Average Potential Price (MAPP) and triggered the investigation criteria in the Guidelines. The N-ATP continued to exceed the N-NEAP in July to December 2016 and in January to June 2017.

2.5. As of December 31, 2016, cumulative excess revenues for Genvoya and Truvada totalled $479,733.49.

3. Position of the Patentee

3.1. This Voluntary Compliance Undertaking (VCU) constitutes no admission by Gilead that the prices of Truvada or Genvoya are now, or were 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.

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4. Terms of the Voluntary Compliance Undertaking

4.1. In order to comply with the Guidelines, Gilead undertakes:

4.1.1. To agree that the 2016 and 2017 N-NEAPs of Truvada are as follows:

YEAR	NEAP
2016 N-NEAP	$25.7181
2017 N-NEAP	$25.8369

4.1.2. To agree that the January to June 2016 MAPP, July to December 2016 N-NEAP, and the 2017 N-NEAPs of Genvoya are as follows:

YEAR	NEAP
2016 MAPP	$44.0000
2016 N-NEAP	$44.0000
2017 N-NEAP	$44.4840

4.1.3. To ensure that the 2017 N-ATPs of Truvada and Genvoya do not exceed the respective 2017 N-NEAPs as outlined in Sections 4.1.1 or 4.1.2, above, and that the prices of Genvoya are within the thresholds set out in the Guidelines in each market where it is sold;

4.1.4. To offset the excess revenues accrued by Gilead in respect of Truvada and Genvoya in 2016 by making a payment of $479,733.49 to Her Majesty in right of Canada within 30 days of acceptance of this VCU; and

4.1.5. To offset any remaining cumulative excess revenues for Genvoya and Truvada at the end of the period from January 1 to December 31, 2017, by making a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of remaining excess revenues calculated based on the semi-annual price and sales data filed by Gilead, as required by the Patented Medicines Regulations and the 2017 N-NEAPs set out in 4.1.1.1 and 4.1.2 above; and

4.1.6. To ensure that the prices of Truvada and Genvoya remain within the thresholds set out in the Guidelines in all future periods during which Truvada and Genvoya are under the PMPRB's jurisdiction.

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Date:	10/12/17

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