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

1.0 Product Summary

1.1. Health Canada granted a Notice of Compliance with conditions to AstraZeneca Canada Inc. (AstraZeneca) for LYNPARZA (olaparib) 50 mg per capsule (DIN 02454408) on April 29, 2016. LYNPARZA is an antineoplastic agent indicated for monotherapy use in the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA mutated high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response to platinum-based chemotherapy. The conditions were lifted on May 2, 2018.

1.2. On May 4, 2018, Health Canada approved two new strengths in a tablet form of LYNPARZA, 100 mg per tablet (DIN 02475200) and 150 mg per tablet (DIN 02475219), along with the inclusion of BRCA wild type patients to the above indication, for both tablet DINs.

1.3. On May 8, 2018, Health Canada approved both DINs of the tablet form of LYNPARZA for use in monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated human epidermal growth factor receptor 2 negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

1.4. The LYNPARZA 50 mg capsules were first sold on May 16, 2016. The LYNPARZA 100 mg and 150 mg tablets were first sold on May 23, 2018.

1.5. The last reported patent pertaining to LYNPARZA will expire on October 5, 2029. AstraZeneca 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 Human Drug Advisory Panel recommended that LYNPARZA be classified as a Moderate Improvement based on primary factors and identified AVASTIN (bevacizumab) as the most appropriate comparator for the purposes of conducting a Therapeutic Class Comparison (TCC) test.

2.2 The National Average Transaction Price (N-ATP) of LYNPARZA 50 mg capsule exceeded the Maximum Average Potential Price (MAPP) during the May to June 2016 introductory review period by an amount that triggered an investigation. By December 31, 2017, cumulative excess revenues totaled $119,808.55.

2.3 The N-ATPs of the 100 mg and 150 mg tablets were above their respective MAPPs during the May to June 2018 introductory review period, but not by an amount sufficient to trigger an investigation.

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.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by AstraZeneca that the prize of LYNPARZA is now, or was 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*.

3.2 Furthermore, AstraZeneca does not agree with the therapeutic class comparison carried out by the Patented Medicine Prices Review Board in the introductory price review of LYNPARZA.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, AstraZeneca will undertake:

4.1.1 To agree that the 2016 MAPP for LYNPARZA 50 mg capsule is $15.8028, and that the 2018 MAPPs for LYNPARZA 100 mg and 150 mg tablets are $64.8548.

4.1.2 To agree that the Non-Excessive Average Prices (NEAPs) for each DIN of LYNPARZA are as follows:

Year	50 mg/capsule (DIN 02454408)	100 mg/tablet (DIN 02475200)	150 mg/tablet (DIN 02475219)
2016	$15.8028	n/a	n/a
2017	$15.9766	n/a	n/a
2018	$16.2137	$64.8548	$64.8548
2019	$16.4665	$65.8925	$65.8925

4.1.3 To ensure that the 2018 N-ATP for each DIN does not exceed the 2018 NEAP outlined in section 4.1.2;

4.1.4 To reduce the 2018 N-ATP of LYNPARZA 50 mg capsule below the 2017 NEAP in order to offset cumulative excess revenues received by AstraZeneca up to December 31, 2017, as described in Schedule 13 of the Guidelines;

4.1.5 To make a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining cumulative excess revenues as of December 31, 2018, as calculated based on the semi-annual price and sales data filed by AstraZeneca;

4.1.6 To reduce the list prices of LYNPARZA effective January 1, 2019 to the 2019 NEAPs described in section 4.1.2, and to take no list price increase in 2019;

4.1.7 To ensure that the price of each DIN of LYNPARZA remains within the PMPRB's Guidelines in all future periods in which LYNPARZA is under the PMPRB's jurisdiction.

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.

Signature: _____

Name: _____

Position: _____

Patentee: AstraZeneca Canada Inc.

Date: _____

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.