VOLUNTARY COMPLIANCE UNDERTAKING
OF
INSMED INCORPORATED
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Arikayce (amikacin liposome inhalation suspension) is not approved in Canada. In the United States, Arikayce is indicated for adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.

1.2. Arikayce 590 mg/vial ("Arikayce") is made available by Insmed Incorporated ("Insmed") to Health Care Professionals on a named patient basis for specific physician requests through Health Canada's Special Access Programme (SAP). Arikayce was first sold in Canada on August 20, 2021.

1.3. In the United States, Arikayce is available as a sterile, aqueous, liposome suspension for oral inhalation in a unit-dose glass vial containing amikacin 590 mg/8.4 mL. The product is dispensed as a 28-vial kit.

1.4. The first reported patent pertaining to Arikayce was granted on May 22, 2012. The last reported patent pertaining to Arikayce is set to expire on May 15, 2035. Insmed is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Guidelines

2.1 The Human Drug Advisory Panel (HDAP) recommended Arikayce be classified as a Slight or No Improvement.

2.2 Arikayce has been sold in Canada at the price of $565.3796 per vial. It was determined by PMPRB Staff that these prices exceeded the thresholds set out in the Guidelines by an amount which triggered the investigation criteria.

3.0 Position of the Rights Holder

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

4.1.1 To accept the Lowest International Price Comparison (LIPC) as the price test in the determination of the Maximum Average Potential Price (MAPP) for Arikayce;

4.1.2 To agree that the MAPP and 2022 Non-Excessive Average Price (NEAP) are as follows:

Year	MAPP/NEAP
2021	$476.8893
2022	$480.2275

4.1.3 To reduce the price of Arikayce from $565.3796 to the 2022 NEAP described in 4.1.2 within 60 days of the acceptance of the VCU;

4.1.4 To file evidence with the PMPRB Staff within 30 days of the price reduction that customers have received notification that the price has been reduced;

4.1.5 To make a payment to His Majesty in right of Canada within 30 days of receiving PMPRB Staff's notification of any remaining cumulative excess revenues as of December 31, 2022, as calculated based on the total 2022 price and sales data filed by Insmed; and

4.1.6 To ensure that the price of Arikayce remains within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: Original signed_____

Name: Drayton Wise_____

Position: Chief Commercial Officer_____

Rights Holder: Insmed Incorporated_____

Date: _____7-oct-2022_____

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a rights holder to comply with the terms of the VCU to close an investigation initiated by PMPRB Staff. Consideration of a VCU is an administrative procedure and does not constitute an admission or determination by the PMPRB that the price submitted by the rights holder, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.