

## **Common Drug Review**

**Project Status Report** 

Brand Name: 0	Odefsey

Non-proprietary Name: emtricitabine (F)/rilpivirine (R)/tenofovir alafenamide (TAF)

Applicant: Gilead Sciences Canada Inc.

Indication(s): HIV-1 infection

Project Type: Submission Date NOC Issued¹:

Date Received: 2016-Nov-24 Application Fee Schedule<sup>2</sup>: Schedule C

2017-Feb-10

Key Milestone <sup>3</sup>	Target Date	Actual Date	Comments
Application accepted for review	2016-Dec-08	2016-Dec-08	- Review has been initiated 2016-Dec-09
Patient group input received <sup>4</sup>	2016-Dec-15	2016-Dec-15	- Call for patient input posted on 2016-Oct-27 - Patient group input deadline: 2016-Dec-15 - Patient input submission received
Patient group comments on input summary received	2017-Jan-09	2017-Jan-09	Patient input summary sent for review on 2016-Dec-22     Patient input summary feedback deadline: 2017-Jan-09     Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2017-Mar-02	2017-Mar-02	
Comments from applicant on draft CDR review report(s) received by CADTH	2017-Mar-13	2017-Mar-13	
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2017-Mar-20	2017-Mar-20	
CDR review team's comments on draft CDR review report(s) sent to applicant	2017-Apr-06	2017-Apr-07	
Canadian Drug Expert Committee (CDEC) meeting	2017-Apr-19	2017-Apr-19	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2017-May-01 to 2017-May-03	2017-May-01	
Embargo period <sup>5</sup> and validation of redacted CDR review report(s)	2017-May-15	2017-May-15	
CDEC Final Recommendation issued to drug plans and applicant if: - no request for clarification is made AND - no request for reconsideration is made AND - no request for resubmission based on a reduced price during embargo period is made	2017-May-23	2017-May-23	
CDEC Final Recommendation posted <sup>6</sup>		2017-May-25	
Final CDR review report(s) <sup>6</sup> and patient input posted		2017-Jun-07	

<sup>&</sup>lt;sup>1</sup>CDR applications for submissions can be filed on a pre-NOC basis. When such a submission is received, this field will indicate 'pending' until the NOC (or NOC/c) is issued by Health Canada.

This CDR Project Status Report is posted every other week, reflecting status as of the end of day Wednesday (4:00 pm ET) of that week.

2017-Jun-09 SR0507-000

<sup>&</sup>lt;sup>2</sup> Refer to Appendix 1 of the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR\_Procedure.pdf) for details regarding CDR application fee schedules.

<sup>3</sup> Places refer to the Procedure for the CADTH Common Drug Review (https://www.cadth.ca/media/cdr/process/CDR\_Procedure.pdf) for complete details regarding the CDR process and to rested

<sup>&</sup>lt;sup>3</sup> Please refer to the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR\_Procedure.pdf) for complete details regarding the CDR process and targeted time frames for key milestones.

<sup>&</sup>lt;sup>4</sup> The call for patient group input is posted 20 business days inadvance of the applicant's anticipated date of filing the CDR application. Patient groups have a total of 35 business days for preparing and submitting patient input.

<sup>&</sup>lt;sup>5</sup> The embargoed CDEC recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of *CDEC Final Recommendation*. The applicant may make a request for reconsideration or resubmission based on reduced price during the embargo period, and the drug plans may make a request for clarification, as applicable (see section 8 of the *Procedure for the CADTH Common Drug Review*).

<sup>&</sup>lt;sup>6</sup> The timing for posting the CDEC Final Recommendation and CDR review report(s) depends on several factors including the need for consultation with the applicant regarding redaction issues.