# Common Drug Review Status Report

## Submission Status

**Product:** Sovaldi

**Generic Name:** Sofosbuvir

**Manufacturer:** Gilead Sciences Canada Inc.

**Indication:** Hepatitis C, chronic

### Submission Type: Pre-NOC - Initial

<table>
<thead>
<tr>
<th>Date Submission Received</th>
<th>Date NOC Issued</th>
<th>Original Targeted CDEC Meeting</th>
<th>Priority Review Granted</th>
</tr>
</thead>
</table>

### Submission Status

#### Phase

- **Submission deemed complete:** 5 days
  - Target Date: 2013-Oct-08
  - Actual CDR Date: 2013-Oct-08
  - Submission placed in queue in accordance with CDR procedures. Review to be initiated pending availability of resources and target dates will be updated.
  - Review has been initiated 2014-Feb-27
- **Patient group input submission received:** 2013-Oct-23
  - Target Date: 2013-Oct-23
  - Call for patient input posted on 2013-Oct-01
  - Patient group input deadline: 2013-Oct-23
  - Patient group input submission received
- **Patient group input summary comments received:** 2014-Mar-14
  - Target Date: 2014-Mar-14
  - Patient input summary sent for review on 2014-Mar-07
  - Patient input summary feedback deadline: 2014-Mar-14
  - Patient input summary feedback received
- **CDR review reports sent to manufacturer:** 2013-Dec-23
  - Target Date: 2014-May-27
  - New target date: 2014-May-13
  - New target date: 2014-May-23
  - New target date: 2014-May-27
- **Comments from manufacturer on CDR review reports received by CADTH:** 2014-Jan-09
  - Target Date: 2014-Jun-05
  - New target date: 2014-May-23
  - New target date: 2014-Jun-03
  - New target date: 2014-Jun-05
- **Redaction response from manufacturer on CDR review reports received by CADTH:** 2014-Jan-14
  - Target Date: 2014-Jun-10
  - New target date: 2014-May-28
  - New target date: 2014-Jun-06
  - New target date: 2014-Jun-10
- **CDEC meeting:** 2014-Feb-19
  - Target Date: 2014-Jul-16
  - New target date: 2014-Jul-16
- **CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer:** 2014-Feb-26
  - Target Date: 2014-Jul-25
  - New target date: 2014-Jul-23
  - New target date: 2014-Jul-25
- **Embargo period and validation of redacted CDR review reports:** 2014-March-12
  - Target Date: 2014-Aug-11
  - New target date: 2014-Aug-07
  - New target date: 2014-Aug-11
- **Final recommendation sent to drug plans and manufacturer (No requests for clarification are made AND no request for reconsideration is made or request for reconsideration is resolved):** 2014-March-19
  - Target Date: 2014-Aug-18
  - New target date: 2014-Aug-18
  - Notice of final recommendation issued
- **CDEC final recommendation posted:** variable
  - Target Date: 2014-Aug-20
- **Final CDR review reports posted:** variable
  - Target Date: 2014-Oct-29

**OR**

- **Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made):** 5 days
  - Target Date: 2014-Aug-18
  - Notice of final recommendation issued
- **CDEC final recommendation posted:** variable
- **Final CDR review reports posted:** variable

**OR**

- **Placed on CDEC agenda for reconsideration (At Manufacturer’s request):** variable
  - Target Date: 2014-Aug-20
- **Final recommendation sent to drug plans and manufacturer:** variable
- **CDEC final recommendation posted:** variable
- **Final CDR review reports posted:** variable

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1 Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.

2 The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

3 The deadline for Patient Group Input is 15 business days after CADTH receives the Submission or up to 25 business days if advance notice of a Submission is received from the Manufacturer.

4 Target time is calculated, based on the date the reviewers receive copies of the manufacturer’s submission. Target time does not include the time allocated for receipt of manufacturer’s additional electronic copies (5 business days) and time allocated for distribution of electronic copies to reviewers (3 business days).

5 The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of Final Recommendation.

6 The target date for posting the CDEC final recommendation depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

7 The timing of the posting of CDR review reports depends on several factors, including the need for consultation with the manufacturer in case of disagreement with regard to redactions made.

This Submission Status Report reflects status as of Thursday noon.

2014-Oct-31

SR0356-000