Common Drug Review [1]

Submission Status

Product: Picato
Generic Name: ingenol mebutate
Manufacturer: Leo Pharma Inc.
Indication: Actinic keratosis
Submission Type: Request for Advice
Date Submission Received: 2014-May-26 **Date NOC Issued:** 2013-Jan-30
Orginal Targeted CDEC Meeting: 2014-Oct-15

Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
CADTH request for advice approach detemined	10	2014-Jun-09	2014-Jun-12	- Manufacturer informed of request for advice: 2014-May-26 - Information or comments due 2014-Jun-09 - Manufacturer requested an extension that was granted until 2014-Jun-12 - Manufacturer information/comments received: 2014-Jun-12 - Review has been initiated 2014-Jun-18
CDR review reports or other document sent to manufacturer [3]	45	2014-Aug-25	2014-Sep-03	- New target date: 2014-Sep-03
Comments from manufacturer on CDR review reports received by CADTH	3	2014-Aug-28	2014-Sep-12	- New target date: 2014-Sep-08 - New target date: 2014-Sep-12
CDEC meeting		2014-Oct-15	2014-Oct-15	
If the request for advice does not result in a new or revised CDEC recommendation: record of advice document sent to drug plans and manufacturer	5 to 7	2014-Oct-22	2014-Oct-22	
Record of advice document posted	Variable		2014-Oct-30	
OR				
If the request for advice results in a new or revised CDEC recommendation: CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7			
Embargo period and validation of redacted CDR review reports [4] Manufacturers may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	10			
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)	5			
CDEC final recommendation posted [5]	Variable			
Final CDR review reports posted [6]	Variable			
OR				
Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made)[7]	Variable			
CDEC final recommendation posted [5]	Variable			
Final CDR review reports posted [6]	Variable			
OR				
Placed on CDEC agenda for reconsideration (At manufacturer's request)	25 Depends on Meeting Dates			
Final recommendation sent to drug plans and manufacturer	5			
CDEC final recommendation posted [5]	Variable			
Final CDR review reports posted [6]	Variable			

[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] 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).

[4] The recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of final recommendation. A manufacturer may request an extension of up to 20 extra business days solely for the purpose of preparing and filing a request for reconsideration (i.e., a total of 30 business days)

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

[6] 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.

[7] The time frame required to address a request for clarification at drug plans, request for reconsideration, or a resubmission based on reduced price, depends on the amount of work required needed to address the request and the dates for CDEC meetings.

This submission status report reflects status as of Thursday noon.