CADTH

Common Drug Review [1]

Submission Status

Product: Dymista

Generic Name: azelastine HCl and fluticasone propionate

Manufacturer/Applicant: Meda Pharmaceuticals Ltd.

Indication(s): Seasonal allergic rhinitis and rhino-conjunctivitis

Submission Type: New Combination

Date NOC Issued: 2014-Oct-23

Date Submission Received: 2014-Dec-09

Application Fee Schedule[1]: Schedule A

Orginal Targeted CDEC Meeting: 2015-May-20

Priority Review Status: Not Requested

Phase	Target Time (Business Days)	Target Date [2]	Actual Date	Comments
Submission/resubmission accepted for review	10	2014-Dec-23	2014-Dec-23	- Submission placed in queue in accordance with CDR procedures. Review to be initiated pending availability of resources and target dates will be updated. - Submission has been initiated 2015-Jan-16
Patient group input submission received [3]		2015-Jan-05	2015-Jan-05	- Call for patient input posted on 2014-Nov-07 - Patient group input deadline: 2015-Jan-05 - Patient input submission received
Patient group input summary comments received	5	2015-Jan-28	2015-Jan-28	- Patient input summary sent for review on 2015-Jan-21 - Patient input summary feedback deadline: 2015-Jan-28 - Patient input summary feedback received
CDR review reports sent to manufacturer[4]	45	2015-Mar-17	2015-Apr-01	- New target date: 2015-Apr-01
Comments from manufacturer on CDR review reports received by CADTH	7	2015-Mar-26	2015-Apr-13	- New target date: 2015-Apr-13
Redaction response from manufacturer on CDR review reports received by CADTH	5	2015-Apr-02	2015-Apr-20	- New target date: 2015-Apr-20
CDEC meeting		2015-May-20	2015-May-20	
CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7	2015-May-27	2015-May-27	
Embargo period and validation of redacted CDR review reports [5] Manufacturers may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	10	2015-Jun-10	2015-Jun-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	2015-Jun-17	2015-Jun-17	- Notice of final recommendation issued
CDEC final recommendation posted [6]	Variable	2015-Jun-19	2015-Jun-19	
Final CDR review reports and patient input posted [7]	Variable	2016-May-19	2016-May-19	
OR				
Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made)	5			
CDEC final recommendation posted [6]	Variable			
Final CDR review reports and patient input posted [7]	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 [6]	Variable			
Final CDR review reports and patient input posted [7]	Variable			

[1] Refer to appendix 1, section 2.2.1 of the *Procedure for the CADTH Common Drug Review* (August 2014), in the Common Drug Review section of www.cadth.ca for more details.

[2] The target dates for this report are based on the targeted 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 35 business days if advance notice (20 business days maximum) 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 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.

[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 the CDR review report(s) depends on several factors, including the need for consultation with the manufacturer in case of disagreement with regard to redactions made.

Refer to the *Procedure for the CADTH Common Drug Review* in the Common Drug Review section of www.cadth.ca for more details about the CDR process.

This submission status report reflects status as of Wednesday 4:00 pm EasternTime.