Common Drug Review [1]

Submission Status

Product: Aloxi (IV)

Generic Name: palonosetron hydrochloride

Manufacturer: Eisai Limited

Indication: nausea and vomiting, moderate emetogenic chemotherapy

Submission Type: Initial

Date Submission Received: 2012-Oct-05 **Date NOC Issued:** 2012-Mar-14

Targeted CDEC Meeting: 2013-Feb-20 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
1	Submission deemed complete	5	2012-Oct-15	2012-Oct-15	
2	Patient group input submission received [3]		2012-Oct-26	2012-Oct-26	- Call for patient input posted on 2012-Oct-05 - Patient group input deadline: 2012-Oct-26 - No patient group input submission received
3	CADTH Reviewers' Reports sent to Manufacturer[4]	45	2013-Jan-04	2013-Jan-08	- New Target date: 2013-Jan-08
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2013-Jan-15	2013-Jan-17	- New Target date: 2013-Jan-17
5	CDEC Meeting		2013-Feb-20	2013-Feb-20	
6	CDEC Recommendation Sent to Drug Plans and Manufacturer	5 to 7	2013-Feb-27	2013-Feb-27	
7	Embargo Period [5] Manufacturers may make a Request for Reconsideration or Resubmission based on reduced price during embargo period received [6] and Drug Plans may make a Request for Clarification of the Recommendation	10	2013-Mar-13	2013-Mar-13	- Resubmission based on reduced price during the embargo period - Placed on the 2013-Apr-17 CDEC meeting agenda
8	Placed on CDEC Agenda For Resubmission (resubmission based on reduced price during embargo period) [6]	25 Depends on Meeting Dates	2013-Apr-17	2013-Apr-17	
9	CDEC Recommendation (resubmission based on reduced price during embargo period) [6] Sent to Drug Plans and Manufacturer	5 to 7	2013-Apr-24	2013-Apr-24	
10	Embargo Period [5] (resubmission based on reduced price during embargo period) [6] Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2013-May-08	2013-May-08	
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)	5	2013-May-15	2013-May-15	- Notice of Final Recommendation issued
	OR				
11 (a)	Clarification and **Final Recommendation** sent to Drug Plans and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
11 (b)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates			
12	**Final Recommendation** sent to Drug Plans and Manufacturer	5			

[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 binders (5 business days) and time allocated for distribution of binders 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] Resubmission based on reduced price during embargo period must meet requirements as described in section 8.6 of Procedure for CDR

This Submission Status Report reflects status as of Thursday noon.