Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product:	Kuvan
Generic Name:	sapropterin dihydrochloride
Manufacturer:	BioMarin Pharmaceutical Canada Inc.
Submission Type:	Request for Advice
Date Submission Received:	2011-Jun-01
Date NOC Issued:	2010-Apr-30
Targeted CDEC Meeting:	2011-Oct-19
Priority Review Granted:	Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	CADTH Request for Advice Assessment complete	10	2011-Jun-15		- 2011-Jun-6: Manufacturer informed of request for advice - Information or comments due 2011-Jun-17 - 2011-Jun-16: Target Time changed from 5 to 10 days - 2011-Jun-17: Manufacturer information or comments received
2	CADTH Reviewers' reports or other document sent to Manufacturer	45	2011-Aug-31	2011-Aug-31	
3	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Sep-12	2011-Sep-12	
4	CDEC Meeting		2011-Oct-19	2011-Oct-19	
5	CDEC Recommendation or Response to Request for Advice sent to Drug Plans, FWG and Manufacturer	5	2011-Oct-26	2011-Oct-26	
	OR				
6 (a)	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10			- No Embargo period because Request for Advise did not result in a Revised Recommendation
	OR				
6 (b)	No Embargo Period if Request for Advice does not result in a Revised Recommendation		2011-Oct-26	2011-Oct-26	- Record of Advice issued
7 (a)	Final Recommendation sent to Drug Plans, FWG, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5			
	OR				
7 (b)	Clarification and Final Recommendation sent to Drug Plans, FWG, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
7 (c)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates			
8	Final Recommendation sent to Drug Plans, FWG, and Manufacturer	5			

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.
** The CDR review process is initiated AFTER a submission is deemed complete. The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.
*** The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the notice of Final Recommendation.
Reflects updates as of Thursday noon.