Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Zenhale

Generic Name: mometasone furoate/formoterol

Manufacturer: Merck Canada Inc.

Indication: Asthma maintenance (adults, children 12 or older)

Submission Type: Initial

Date Submission Received: 2011-Feb-16 **Date NOC Issued:** 2011-Jan-11

Targeted CDEC Meeting: 2011-Jul-20 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments
1	Submission deemed complete	5	2011-Feb-24	2011-Feb-24	- Submission deemed complete.
2	Patient group input submission received		2011-Mar-10	2011-Mar-10	Patient group submissions received.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2011-May-11	2011-May-11	
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-May-20	2011-May-20	
5	CDEC Meeting		2011-Jul-20	2011-Jul-20	
6	CDEC Recommendation *** Sent to Drug Plans, FWG and Manufacturer	5 to 7	2011-Jul-27	2011-Jul-27	
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Aug-11	2011-Aug-11	- Request for reconsideration received 2011-Aug-2 - Request for reconsideration granted 2011-Aug-9
8 (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				
8 (b)	Clarification and Final Recommendation sent to Drug Plans, FWG, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
8 (c)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2011-Sep-21	2011-Sep-21	
9	Final Recommendation sent to Drug Plans, FWG, and Manufacturer	5	2011-Sep-28	2011-Sep-28	- Notice of Final Recommendation issued.

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

** The Formulary 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 Procedure for Common Drug Review, section 8.3.3a, states "…the CDEC recommendation will be sent to the Manufacturer, FWG and to the drug plans within five (5) to seven (7) business days following the CDEC meeting…". The original target date is based on five (5) business days.

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

This submission status report reflects updates as of Thursday noon.