	Common Drug Review 1					
Submission Status						
Canadian Agency for Product:	Rituxan					
In Health Generic Name: rituximab						
Manufacturer:	Hoffman La-Ro	che Limited				
Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA), Indication: remission induction (adults)						
Submission Type:	New Indication					
Date Submission Received:	2012-Feb-24	D12-Feb-24 Date NOC Issued:		2011-Dec-12		
Targeted CDEC Meeting:	2012-Jul-18	B Priority Review Granted:		Not Requested		
Phase	Target Time (Business Days)	Target Date ²	Actual CDR Date	Comments		
Submission deemed complete	5	2012-Mar-02	2012-Mar-02			
Patient group input submission received ³		2012-Mar-16	2012-Mar-16	 Call for patient input posted on 2012-F Patient group input deadline: 2012-Ma Patient group input submission received 	r-16	
CADTH Reviewers' Reports sent to Manufacturer ⁴	45	2012-May-17				
Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2012-May-29				
CDEC Meeting		2012-Jul-18				
CDEC Recommendation Sent to Drug Plans and Manufacturer	5 to 7	2012-Jul-25				
Embargo Period ⁵ Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2012-Aug-09				
inal Recommendation sent to Drug Plans and /lanufacturer No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5					
OR						
Clarification and Final Recommendation sent to Drug Plans and Manufacturer Clarification Requested, no Request for Reconsideration made)	5					
OR						
Placed on CDEC Agenda For Reconsideration At Manufacturer's request)	25 Depends on Meeting Dates					
inal Recommendation sent to Drug Plans and lanufacturer	5					
	Generic Name: Manufacturer: Indication: Submission Type: Date Submission Received: Targeted CDEC Meeting: Phase ubmission deemed complete atient group input submission received ³ ADTH Reviewers' Reports sent to Manufacturer ⁴ omments from Manufacturer on Reviewers' Reports eceived by CADTH DEC Meeting DEC Recommendation ent to Drug Plans and Manufacturer mbargo Period ⁵ anufacturers may make a Request for econsideration and Drug Plans may make a equest for Clarification of the Recommendation anufacturer to Requests for Clarification is made or Request for econsideration is Resolved) OR laced on CDEC Agenda For Reconsideration and Recommendation sent to Drug Plans and anufacturer laced on CDEC Agenda For Reconsideration and facturer's request) nal Recommendation sent to Drug Plans and anufacturer laced on CDEC Agenda For Reconsideration and facturer's request) nal Recommendation sent to Drug Plans and anufacturer's request)	Consider Agency for Program and Technologies Product: Rituxan Generic Name: rituximab Manufacturer: Hoffman La-Ro Granulomatosis Indication: remission indux Submission Type: New Indication: Granulomatosis Indication: Zeremission indux Submission Type: New Indication: Date Submission Received: 2012-Feb-24 Targeted CDEC Meeting: 2012-Jul-18 Targeted CDEC Meeting: 2012-Jul-3 Indication: Reseived State ubmission deemed complete 5 Indication: Reseived State atient group input submission received ³ Indication: Indication: ADTH Reviewers' Reports sent to Manufacturer ⁴ 45 Indication: DEC Meeting Indicaturer 7 Indicaturer DEC Recommendation 5 to 7 Indicaturer Indicaturer mbargo Period ⁵ anufacturer 10 Indicaturer inal Recommendation sent to Drug Plans and anufacturer 5 Indicaturer io Requests for Clarification are made AND no equest for Reconsideration is made or Request for econsideration is made or Request for econsideration is made or Request for econsideration is m	Product: Rituxan Generic Name: rituximab Manufacturer: Hoffman La-Roche Limited Granulomatosis with Polyangitit Indication: Submission Type: New Indication Date Submission Received: 2012-Feb-24 Date Indication: Target Target Targeted CDEC Meeting: 2012-Jul-18 Priority Re Date Submission Received: 2012-Mar-02 ate 12 atient group input submission received ³ 2012-Mar-02 ate 2 atient group input submission received ³ 2012-Mar-02 ate 12 ADTH Reviewers' Reports sent to Manufacturer ⁴ 45 2012-Mar-16 DEC Meeting 2012-Jul-18 DEC Recommendation and Drug Plans and Manufacturer 5 to 7 2012-Jul-25 mbargo Period ⁵ anufacturers may make a Request for consideration and Drug Plans and anufacturer 5 5 5 OR acconsideration and Drug Plans and anufacturer 5 5 5 Margo Period ⁵ anufacturer 5 5 5 No Request for Clarification are made AND no equest for Clarification are made AND no equest for Clarification are made AND no equest for Clarification a	Product: Rituxan Generic Name: Intuximab Generic Name: Intuximab Manufacture: Hoffman La-Roche Limited Stamission Type: New Indication: Date Submission Type: New Indication: ubmission deemed complete 5 2012-Mar-02 2012-Mar-02 atient group input submission received ³ 2012-Mar-16 2012-Mar-02 ADTH Reviewers' Reports sent to Manufacturer ⁴ 45 2012-Mar-16 DEC Meeting 2012-Jul-18 Indication: DEC Recommendation ent to Drug Plans and Manufacturer 5 to 7 2012-Jul-25 Image String Strin	Product: Rituxan Generic Name: (Ituxinab Manufacture: Hoffman La-Roche Limited Manufacture: Hoffman La-Roche Limited Submission Type: New Indication: Date Submission Received: 2012-Mar.02 Date Submission Received: 2012-Mar.02 Phase Targeted CDEC Meeting: Target: Actual CDR Date Comments Ubmission doemed complete 5 2012-Mar.02 2012-Mar.02 Coll for patient input posted on 2012-Field ADTH Reviewers' Reports sent to Manufacturer ⁴ 45 2012-Mar.16 2012-Mar.02 Coll for patient input posted on 2012-Field DEC Meeting 2012-Mar.16 2012-Mar.16 Coll for patient input posted on 2012-Field Coll for patient input posted on 2012-Field ADTH Reviewers' Reports sent to Manufacturer ⁴ 45 2012-Mar.16 Coll for patient input posted on 2012-Field DEC Recommendation 5 to 7 2012-Mar.29 Coll for patient input posted on 2012-Field DEC Recommendation and Manufacturer 5 to 7 2012-Mar.29 Coll for patient input posted on 2012-Field DEC Recommendation 5 to 7	

¹ Refer to the Procedure for Common Drug Review on the Common Drug Review section of <u>www.cadth.ca</u> 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.

This Submission Status Report reflects status as of Thursday noon.