Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as **'For official use only'**.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Submission of an updated RMP

- Complete and provide this form when submitting an updated RMP after regulatory approval. See 'Risk management plans for medicines and biologicals: Australian requirements and recommendations' for information about when to submit updated RMPs.
- Submit your updated RMP/ASA (clean and annotated version) as a NeeS/eCTD sequence. This form should be submitted in module 1.0.1 and the updated RMP in module 1.8.2.
- Annotated and clean versions of the ASA and any other related documents that have been updated should be submitted.
- Changes to clinical study plan for provisionally registered products must be submitted as an ASA update to the relevant clinical section at TGA via the case management team for approval via streamlined.submission@health.gov.au. This is a separate process from other types of RMP updates.

Product details:

Product name [Trade name (generic name)]	
Sponsor	
Is this a provisionally registered product? If yes, provide a copy of the approval letter	☐Yes ☐No
Related submission number(s) (if any) [provide submission number of any application currently under evaluation by the TGA involving this product]	
EU-RMP and ASA versions last submitted [provide version number, DLP and date of the most recently submitted EU-RMP and ASA to the TGA]	
EU-RMP and ASA being submitted [provide version number, DLP and date for the EU-RMP and ASA being submitted with this form]	

Is this EU-RMP approved by the EMA	☐Yes ☐No ☐Under evaluation

Reason(s) for Update:

Change in summary of safety concerns	☐ RMP	☐ ASA
Change in pharmacovigilance plan	☐ RMP	☐ ASA
Change in risk minimisation plan	☐ RMP	☐ ASA
As requested by the TGA as a condition of registration	☐ RMP	☐ ASA
As requested by the TGA other reason (provide comments)	☐ RMP	☐ ASA
Other (describe the reason in the box below)	☐ RMP	☐ ASA

Describe the reasons for the update:

If the summary of safety concerns has changed, select all that apply:

Addition of new safety concern	☐ Yes	☐ No	
Removal of safety concern	☐ Yes	☐ No	
Reclassification of safety concern (Potential → Identified Risk)	☐ Yes	☐ No	
Are there changes to any Australian specific safety concern(s)	☐ Yes	☐ No	☐ N/A

Describe the changes and provide links to the section of the RMP and/or ASA where the changes are detailed:

If the pharmacovigilance plan has changed, select all that apply:

☐New activity proposed

☐Change to or early cessation of activity

☐Complying with TGA request

☐Completion of study requested by TGA

Describe the changes and refer to the sections in the RMP and/or ASA where the changes are detailed (provide links to annotated and clean versions of any updated documents, e.g. Targeted follow-up forms):

If the risk minimisation plan has changed, select all that apply:

- ☐ Change to routine risk minimisation activities
- ☐ Change to additional risk minimisation activities
- ☐ Cessation of activity
- ☐ New activity proposed
- ☐ Reporting on evaluation of effectiveness measures
- ☐ Complying with TGA request
- ☐ Other (describe the reason in the box below)

Describe the changes and provide links to the section of the RMP and/or ASA where the changes are detailed (provide links to annotated and clean versions of any updated documents, e.g. Patient Alert Cards):

Name of authorised officer on behalf of the sponsor			
Contact details	Phone: Email:		
Signature		Date	