Australian Government
Department of Health
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>.

TGA SAFETY ISSUE REPORTING FORM

Date of TGA notification:

Safety Issue:

Please complete a separate report for each new issue

Type of safety notification

Significant safety issue (SSI)? Yes ☐ No ☐

*A SSI is one that requires the urgent attention of the TGA as it warrants prompt regulatory action and/or communication to patients and healthcare professionals due to the seriousness **AND** potential major impact on the benefit-risk balance of the medicine and/ **OR** because of a significant risk of harm to public health. SSIs must be reported within 72 hrs of awareness by the sponsor.*

Date of SSI awareness by the sponsor (Day 0):

Other safety issue (OSI)? Yes ☐ No ☐

OSIs require action by the TGA but have been assessed as being unlikely to alter the benefit-risk balance of the medicine. OSIs must be reported within 30 calendar days of assessment completion by the sponsor.

Date of OSI assessment completion by the sponsor (Day 0):

Initial notification? ☐ Follow-up notification? ☐

If follow-up notification, what was the date of the initial notification:

Product Details

Please complete the below table details for each product affected by this safety issue. Please add extra rows as required.

Ref	Product Name	ARTG Number	Active Ingredient(s)	Australian Sponsor	Supplied in Australia?
1					
2					
3					

Is your company the product innovator? Yes ☐ No ☐

If no, please identify the innovator:	

Safety Issue Source

Sponsor Pharmacovigilance ☐ Overseas Regulator ☐ Other (please specify) ☐

Comments:	

Safety Issue Details

Brief description of safety issue: *Should include a summary of:* *- how the safety issue came to your attention including key dates* *- available evidence that supports the safety issue* *- the risk and potential impact of the safety issue* *- whether or not this is a class safety issue.*	
Summary of sponsor assessment: *If an assessment of this safety issue has not been completed by your company, please explain why not here.*	
Outline of key actions taken by other regulators *You can include links to any relevant regulator safety assessments or published meeting outcomes here.*	

Outcome of safety issue assessment

Do you intend to update your Australian Product Information document? Yes ☐ No ☐

If yes, please provide an estimated date for submission of your SRR:

Are you considering any other actions (e.g. DHCPL, cancellation from the ARTG, further assessment)? Yes ☐ No ☐

If yes, please describe, including an estimated timeframe for completion:

Pre-submission checklist

Have you:

Attached your completed safety issue assessment? Yes ☐ No ☐ N/A ☐

Attached copies (or supplied web links for) all relevant safety issue assessments or published meeting outcomes of other regulators? Yes ☐ No ☐ N/A ☐

Attached (or supplied web links for) any other relevant documents you have referenced in this form? Yes ☐ No ☐ N/A ☐

Safety issue notification submitted by:

Name			
Position			
Email		Phone	

Please submit this completed form by email to the Pharmacovigilance Branch Signal Investigation Coordinator at si.coordinator@health.gov.au.

Should you require further guidance, please see Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements.