

Summary of changes:

Variation 1: [Insert variation code and description here. For example: DMCM: Drug product manufacture – changes to the method of manufacture]

[Brief explanation of the changes including any justification necessary. Where a lengthier explanation is required (>1 page), please include this in the appendices of this document]

Affected AUST Rs	Approved information	Proposed information	Justification for change and supporting documents
[List AUST R no.]*	[Current information registered in the dossier]	[The revised information to be registered in the dossier, with changes highlighted in different font colour where possible]	[Links to the relevant eCTD Modules containing further information]

*AUST R should match the TGA issued application form

[Repeat above format for additional variations.]