**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.]**