

Instructions for use

For guidance on how to make a minor variation submission please refer: [Variations to prescription medicines - excluding variations requiring evaluation of clinical or bioequivalence data: Process guidance](#)

Details of the conditions and data requirements for variation's codes can be found at the following links:

- [Variations to prescription medicines - excluding variations requiring evaluation of clinical or bioequivalence data, Appendix 1: Variation types - chemical entities](#)
- [Variations to prescription medicines - excluding variations requiring evaluation of clinical or bioequivalence data, Appendix 2: Variation types - biological medicines](#)

This template should be modified where necessary to meet your individual regulatory requirements. Please note that this is a generic template and may not suit all submission types.

All **highlighted text** should be amended by the sponsor or applicant where necessary.

[Date of submission]



Application Entry and Support Team
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Submission details

Sponsor (Applicant)	[Full Sponsor name and client ID] or [Applicant name and client ID and the name of sponsor you are acting on behalf of]
Regulatory affairs contact and details	[Title and name] [Individual email, generic email, and phone if available]
Drug substance name(s)	[Drug substance name(s) as appears on the ARTG]
Application number	[Preferably final number, not draft "MV"]
eSubmission identifier	[eCTD or NeeS number]
Sequence number	[XXXX]
Related sequence	[If required]

List of varied products

AUST R	Product name
[AUST R 1]	[Product name 1 as it appears on the ARTG]
[AUST R 2]	[Product name 2 as it appears on the ARTG]
[AUST R...]	[Product name...]

Notes to evaluator

Optional examples include:

[This submission PM-XXXX-XXXXX-X-X is related to pending submission PM-ZZZZ-ZZZZZ-Z-Z please evaluate these together.]

[This submission is to align with the variations made to the parent medicine in submission PM-XXXX-XXXXX-X-X approved on XX/XX/XXXX.]

[A letter of access is provided for submission or DMF number]

Administrative information

Optional examples include:

[Confirmation that payment of the relevant fee will be performed upon receipt of the invoice from the product billing section.]

[A description of the electronic dossier provided for the sequence, including type and number of electronic media, approximate submission size, and if appropriate, characteristics relating to the media]

[A statement that the electronic dossier is virus free with a description of the software used to check the files for viruses]

[An indication of which validation tool and version was used as well as a statement addressing any issues found in the accompanying validation report.]

[A statement regarding confidentiality of the information provided. Note: all information provided to the TGA is regarded as confidential and is not disclosed to other parties unless specifically permitted by the intellectual property rights holder]

Kind regards,

[Signature]

[First and last name of applicant]

[Position title]

[Sponsor (Applicant) name]

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.]

Appendix 1

The appendices should include any additional information that cannot be included elsewhere in the dossier. We suggest that this appendix not be used for superfluous information that is not pertinent to the evaluation of your submission.