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 >.

Section 23 Category 3 application that creates a separate and distinct good

Application form

Note: Use this application form to apply for a variation to a registered prescription medicine (the existing medicine) that results in the creation of a separate and distinct good (the proposed medicine) and requires evaluation of data by the Therapeutic Goods Administration (TGA). The decision for this application will be made under section 25 of the *Therapeutic Goods Act* 1989 (the Act).

Please note that if additional quality-related changes are intended for the proposed medicine, details should be provided under **section 2.1** There is no need to complete a separate '9D(3) Category 3 form to vary an ARTG entry' for the proposed medicine.

Please refer to the *Australian Regulatory Guidelines for Prescription Medicines (ARGPM)* to determine the type of request or application relevant to the variation you would like to make. Further guidance on what constitutes a variation under section 23 of the Act can be found in *Minor variations to registered prescription medicines: chemical entities*[1] and *Minor variations to registered prescription medicines: biological medicines*[2].

Section 1. Sponsor and product details

1.1 Sponsor details

Sponsor name	
eBS Client ID	
Postal address	

[1] <https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-1-variation-types-chemical-entities>
[2] <https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-2-variation-types-biological-medicines>

Contact person	
Position (for example: regulatory affairs officer, agent of the sponsor)	
Telephone number	
Fax number	
Email address	

1.2 Product details of existing medicine

Medicinal product details

Single active ingredient ☐ Multi-active ingredient ☐ Multi-component ☐

Is the product: a biological medicine? ☐ OR a chemical medicine? ☐

AUST R	Product name	Active ingredient(s)	Strength	Dosage form	Pack/Container

Please attach additional pages to the form if there are more than six products.

1.3 Payment details

Relevant requests/applications in submission (for calculation of fees payable):	

A single fee may be payable for multiple applications in some cases, if the combination of applications meets the definition of "submission" in Part 1 of Schedule 9 to the Therapeutic Goods Regulations 1990. Further guidance is available in *Minor variations to registered prescription medicines: chemical entities*[3] and *Minor variations to registered prescription medicines: biological medicines*[4].

[3] <https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-1-variation-types-chemical-entities>

[4] <https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-2-variation-types-biological-medicines>

Please make cheques payable to the Therapeutic Goods Administration.

For credit card payments, please use the credit card authorisation form[5] which is available on the TGA website.

Section 2. Details of application

2.1 Details of variation

Please provide specific details of the variation resulting in a new ARTG entry that is being applied for in the box below[6]. If the request is in relation to a change in formulation please provide a list of the formulation of the existing medicine and the formulation of the proposed medicine. Please indicate which excipients or quantities are different from the existing medicine, and state the unit of measurements as they are expressed on the ARTG record. Do not express quantity as a percentage.

Please also provide details such as container type, pack sizes, proposed trade names, visual ID changes, shelf life and storage conditions etc, if such information is to be changed.

If the application is approved the proposed medicine will be approved for registration. This will require the approval of a new Product Information (PI) under subsection 25AA(1) of the Act. For that purpose, it is a requirement that a proposed PI be provided with all section 23 applications. Therefore, you must attach a clean copy and a marked-up copy of the draft PI to be approved for the new product with this application.

Please refer to the ARGPM for details on requirements for PI documents.

2.2 Information provided

Information on data requirements is available in the General dossier requirements for prescription medicines[7] and in and in Guidance 8, 12 and 13 of the ARGPM[8].

Have you provided all the required information? Yes ☐ No ☐

If '**no**', please provide a justification:

[5] < https://www.tga.gov.au/resources/resource/forms/credit-card-payment-authorisation>
[6] The TGA will only review variations that are described in the application form at the time of submission.
[7] https://www.tga.gov.au/resources/resource/guidance/general-dossier-requirements>
[8] https://www.tga.gov.au/resources/publication/publications/australian-regulatory-guidelines-prescription-medicines-argpm

2.2.1 Size of Submission

Note: All Category 3 applications should be formatted according to the Common Technical Document (CTD) format (see Section 1.6 of the ARGPM), however, only a single copy of any supporting data is required. In addition to the hard copy, **an electronic copy is required.**

Module	Number of Volumes	Double Sided?	Electronic copy attached?
		Yes ☐ No ☐	☐
		Yes ☐ No ☐	☐
		Yes ☐ No ☐	☐

2.2.2 Submission details

Please provide an overview of the data submitted in support of the proposed variation, including an overview of the proposed variation with cross-references to the relevant Module 3 sections, if relevant. Please also include information regarding proposed dates of implementation (pending TGA approval).

2.3 Other information in relation to the existing medicine and proposed medicine

2.3.1 Drug Master File (DMF), Plasma Master File (PMF) and Certificate of Suitability of Monographs of the European Pharmacopoeia (CEP)

Will your application make reference to any of the following:

Drug Master File Yes ☐ No ☐

TGA file number:

Plasma Master File Yes ☐ No ☐

Name of PMF:	
TGA file number:	

Certificate of Suitability of Monographs of the European Pharmacopoeia

Yes ☐ No ☐

Version of the DMF/PMF/CEP being referenced:	
Name of the company responsible for the DMF/PMF/CEP:	

Are Module(s) 1.6.1, 1.6.2 and 1.6.3 attached? Yes ☐ No ☐

Note: refer to Guidance 11 of the ARGPM and guidance on Module 1 of the Common Technical Document[9] for further information about DMFs, PMFs and CEPs.

2.3.2 Manufacturing Sites

If the request involves adding, ceasing or changing sites of manufacture, or steps of manufacture at existing sites, please provide details of those manufacturing sites or steps that are proposed to change.

Information is only required for new sites or those sites that are proposed to change. The relevant steps of manufacture are those that are acceptable for entry in the ARTG database.

Note: Requirements for GMP clearances, certifications and manufacturing licence applications are available from the TGA website. Clearance must be valid at the date of this request.

Details of Changes to Overseas Manufacturers from existing medicine

Client ID (eg. 12345)	TGA GMP Clearance number (eg. MI-01232006-CL-12345-1)	Manufacturer Name and full site address	Steps of manufacture	Expiry Date	Addition or cessation?

***Note:** GMP clearances must be valid for at least 6 months.

Please attach additional pages to the form if there are more than three manufacturers.

[9] <https://www.tga.gov.au/resources/resource/forms/ctd-module-1-additional-forms-and-proformas>

Details of Changes to Australian manufacturers from existing medicine

Client ID (eg. 12345)	Licence number (eg. MI-01232006-LI-123456-1)	Manufacturer Name and full site address	Steps of manufacture	Addition or cessation?

Please attach additional pages to the form if there are more than three manufacturers.

2.3.3 Additional documents provided

Which additional documents will be submitted with the application? (Please attach relevant documentation)

Certification/notification under section 25AB(3)(c)? ☐

Revised labels ☐

Other ☐

If other, please describe: ☐

Note:

- If the application is approved for certain changes in formulation and replacement of a trade name, the Groups Order will apply so that the proposed medicine will have the same ARTG entry as the existing medicine.
- Certification, or a notification that the patent certificate is not required, under section 25AB(3)(c) is a mandatory requirement and can be provided at any time prior to registration. However for timely inclusion on the ARTG should your application be approved, TGA recommends the certification or notification is provided as early as possible, preferably with the application.

2.3.4 Source of materials in proposed medicine

Is material of human or other animal origin used at any stage in the manufacture or formulation of this product? Yes ☐ No ☐

If '**no**', go to 2.4

Are you proposing to change any aspects of the material of human or animal origin?

Yes ☐ No ☐

If '**no**', go to 2.4

If '**yes**', please provide details for those aspects of the ingredients that are proposed to be changed:

Name of ingredient	Animal species (eg bovine)	Animal part (eg hide)	Country of origin

Please attach additional pages to the form if there are more than three ingredients.

For category IV ruminant ingredients, does the ingredient comply with the TGA's Supplementary requirements for therapeutic goods for minimising risk of transmitting transmissible spongiform encephalopathies (TSEs)?

Please refer to Transmissible Spongiform Encephalopathies (TSEs): TGA approach to minimising the risk of exposure[10]

Name of ingredient	Comply with requirements?
	Yes ☐ No ☐
	Yes ☐ No ☐
	Yes ☐ No ☐

Please attach additional pages to the form if there are more than three manufacturers.

If of animal origin, is the animal an endangered or native species? Yes ☐ No ☐

[10] <https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/guidelines-sterility-testing-therapeutic-goods/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure>

2.4 Related submissions

2.4.1 Submissions currently under evaluation

If your submission is related to any other submissions currently under evaluation with the TGA, please provide applicable submission numbers:

Submission ID	Details of submission

Please attach additional pages to the form if there are more than two submissions.

2.4.2 Concurrent submissions

Are you submitting this request simultaneously with any other requests under section 9D (such as s9D(1), Minor Editorial Change, Safety Related request)? Yes ☐ No ☐

If '**yes**', please provide details:

Section 3. Sponsor declaration

Sponsors should note that the *Therapeutic Goods Act 1989* provides penalties for making statements that are false or misleading in a material particular in or in connection with an application for registration of therapeutic goods.

I am the sponsor for the purposes of this request OR Yes ☐ No ☐

I am authorised to act on behalf of the sponsor for the purposes of this request. Yes ☐ No ☐

Tick boxes below, if applicable)

I declare that the information provided for the purposes of this application, is to the best of my knowledge, current and correct[11]. ☐

I certify that no aspects of the quality information have been changed, including manufacturing procedures and equipment, raw material and drug product specifications, other than the changes nominated in this application[12]. ☐

I certify that this application is an application for registration of a medicine of a kind that can be made under section 23 as a Category 3 application[13]. ☐

I certify that the hard copy dossier and electronic copy of the dossier provided to the TGA are identical. ☐

Where differences do exist, they are described below:

I certify that the PI provided with this application is based on the most recently-approved version of the PI for the existing medicine, that all of the proposed amendments relate to the application, and no other unidentified changes are being proposed or are being made to the PI. ☐

[11] It is a condition of registration that information on the ARTG about a registered prescription medicine cannot be changes (apart from limited exceptions) without the approval of the Secretary.
[12] As set out in *Minor variations to registered prescription medicines: chemical entities* (<https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-1-variation-types-chemical-entities>) or *Minor variations to registered prescription medicines: biological medicines* (<https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-2-variation-types-biological-medicines >).
[13] As set out in *Minor variations to registered prescription medicines: chemical entities* (<https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-1-variation-types-chemical-entities>) or *Minor variations to registered prescription medicines: biological medicines* (<https://www.tga.gov.au/resources/resource/guidance/variations-prescription-medicines-excluding-variations-requiring-evaluation-clinical-or-bioequivalence-data-appendix-2-variation-types-biological-medicines>).

Signature of authorised officer	Insert image or print out to sign:	Date	
Name			
Email			
Telephone number			
Fax number			
Position/Relationship to sponsor (if different to front page)			