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 self-assessable 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 does not require 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 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 can be found in *Minor variations to registered prescription medicines: chemical entities*[1] and *Minor variations to registered prescription medicines: biological medicines*[2].

Please note that this application form can only be used for minor changes in formulation relating to colouring agent, flavour or fragrance or the addition, deletion, or variation to, the formulation of an imprinting ink.

Please note that if additional quality-related changes are intended for the proposed medicine and the changes may be self-assessed, details should be provided under section 2.1 There is no need to complete a separate 9D(3) Self-Assessable request form for the proposed medicine.

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].

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.

A summary of fees and charges[6] is also available on the TGA website.

Section 2. Details of application

2.1 Details of variation (i.e. difference between the existing and proposed medicine)

Please list the formulation of the existing medicine and the formulation of the proposed medicine, including any imprinting ink used. 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 quantities as a percentage.

If relevant please also provide details of other quality-related changes intended for the proposed medicine, giving sufficient information to update the ARTG entry.

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.

[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>
[5] <https://www.tga.gov.au/resources/resource/forms/credit-card-payment-authorisation>
[6] <https://www.tga.gov.au/how-we-regulate/fees-and-payments/summary-fees-and-charges>

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:

2.3 Other information in relation to the 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:	

Is Module(s) 1.6.1, 1.6.2 and/or 1.6.3 attached? Yes ☐ No ☐

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

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

2.3.2 Good Manufacturing Practice (GMP)

If the request involves adding, ceasing or changing sites of manufacture, or steps of manufacture at existing sites from the existing medicine, 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 GMP section[10] of the TGA website.

Details of Changes to Overseas Manufacturers from existing medicine

Client ID (eg. 12345)	TGA GMP Clearance number (eg. MI-2012-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.

Details of Changes to Australian Manufacturers from existing medicine

Client ID (eg. 12345)	Licence number (eg. MI-2012-CL-12345-1)	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 are submitted with the application? (Please attach relevant documentation)

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

Revised labels ☐

Other ☐

[10] <https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medicine/good-manufacturing-practice-gmp>

If other, please describe:	

Note:

- If the application is approved, 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.

2.4 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 applications

Are you submitting any other applications with this application, such as a request for a correction?

Yes ☐ No ☐

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

2.5 Requirements for self-assessment

Details of Variations (i.e. how the proposed medicine is different to the existing medicine)

Please give a brief description of the differences between the proposed medicine and the existing medicine, providing adequate information for TGA file records and for updating the ARTG entry.

For each variation (difference) proposed, please state under which subsection in sections 4.2 or 5.2 of *Minor variations to registered prescription medicines: chemical entities*[11] or *Minor variations to registered prescription medicines: biological medicines*[12] is applicable for the request.

Relevant section of guidance	Description of variation

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

Compliance with specific conditions

For each specific variation requested please describe which conditions have been met citing the relevant section of the guidance documentation. Do not repeat the specific conditions contained in the guidance documentation.

Relevant section of guidance	Specific conditions met

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

[11] <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>
[12] <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>

Information provided

For each specific variation (difference), please list the information provided. The submitted information should only be those specified as 'Required information' in the relevant section of *Minor variations to registered prescription medicines: chemical entities*[13] or *Minor variations to registered prescription medicines: biological medicines*[14].

Relevant section of guidance	Required information provided

Please attach additional pages to the form if there is additional required information.

[13] <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>
[14] <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>

Section 3. Sponsor declaration

Sponsors should note that section 22A and section 22B of the *Therapeutic Goods Act 1989* provide criminal and civil 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[15]. ☐

I certify that this application is of a kind that can be made under section 23 as a self-assessable application[16]. ☐

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[17]. ☐

I certify that the variations applied for are supported by data which can be provided to the TGA upon request. ☐

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. ☐

[15] It is a condition of registration that information on the ARTG about a registered prescription medicine cannot be changed (apart from limited exceptions) without the approval of the Secretary.

[16] 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 >).

[17] 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)			