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 <http://www.tga.gov.au/about/tga-information-to.htm>.

Module 1.2.1: Application form to register or vary the registration of prescription medicines

Category 1 and Comparable Overseas Regulator (COR) report-based applications in the CTD format

This form must be used for the following Category 1 and COR report-based prescription medicines applications or variations where the dossier includes nonclinical, clinical or bioequivalence data[1]:

- extension of indications [C]
- major variation (new dosage form, change/increase in patient group, change in dosage (e.g. dosage amount, frequency of use or dose regimen), new strength, new route of administration) [F]
- change in formulation [G]
- change in container type (disregarding container size) [G]
- other variation (requiring evaluation of clinical, nonclinical, or bioequivalence data) [H]
- variation to Register entry resulting in a change of product information requiring evaluation of clinical, nonclinical, or bioequivalence data [J]

For all other Category 1 and COR report-based applications please use TGA Business Services (TBS).

[1] See Minor variations to prescription medicines if the variation does not include such data

Notice to Applicants

Complete the form as per the instructions, noting that the form is divided into three parts:

Part	
A - Applicant details	Complete one part A for each submission
B - Submission details	Complete one part B for each submission
C - Product details	Complete a separate copy of part C for each product in the submission. For part C composite packs, complete the information on pages 7-11, the manufacturing, shelf life and storage conditions etc. for the composite pack on pages 13-15, and then complete pages 16 to 19 for each component.

If you are submitting a COR report-based application, you must also submit the COR application checklist for each submission.

Please note:

- The information recorded should reflect the new ARTG record, not what is currently recorded in the Australian Register of Therapeutic Goods (ARTG) for the medicine
- Where a manufacturing site is being ceased, it should be included in part C with the annotation ‘to be ceased’
- Where the information requested within part C is not changing the relevant sections may be crossed through with the comment ‘not applicable’
- Details on the form after the label name field in part C do not need to be completed if there are no changes to the ARTG database record (for example, change in patient group, change to active ingredient manufacturing process)

If there is insufficient room in any field/section on this application form:

- enter ‘see attached’ in the field
- attach a separate page with the full details

Include the completed application form (Parts A, B and C and COR checklist, if relevant) in Module 1.2.1 of the CTD.

Part A Applicant details

Product (trade) name	
Applicant (sponsor) name	
TBS client ID	
Postal address	
Address for correspondence	

	Primary contact	Secondary contact
Contact person		
Position *(e.g. regulatory affairs officer, agent)*		
Telephone number		
Mobile number (optional)		
Fax number		
Email address		

Provide the following information if you are submitting this application on behalf of the applicant

Agent name	
TBS client ID	
Postal address	

I have attached a completed Agent Authorisation form ☐

Part B Submission details

Description of submission	
Is this a Category 1 application?	Y ☐ N ☐
Is this a COR report-based application? *If yes, provide the completed COR report-based checklist in Module 1.2.1.* *Submit all relevant COR documentation in Module 1.11.4.*	Y ☐ N ☐
Does this submission depend on the outcome of, or relate to, any other submission currently under evaluation by the TGA? *If yes, provide related submission ID/s (in the format PM-20xx-xxxxx-x-x)*	Y ☐ N ☐ PM-20
Is there one or more overseas manufacturer of the goods for which GMP clearance from the TGA have NOT yet been obtained, or requested, to establish that the overseas manufacturers of the goods are of an acceptable standard?	Y ☐ N ☐
Is this a literature based (bibliographic) submission? *If yes, provide details in Module 1.5.1.*	Y ☐ N ☐
Has this medicinal product been designated an orphan drug for the proposed indication? *If yes, provide a copy of the TGA letter approving the designation in Module 1.5.2.*	Y ☐ N ☐
Is a priority review determination in force for this medicinal product? *If yes, provide a copy of the TGA letter approving the determination in Module 1.5.2.*	Y ☐ N ☐
Are all ingredients within the formulation included in the TBS Ingredients database?	Y ☐ N ☐
Does this product contain or consist of genetically modified organisms? *If yes, provide a copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR in Module 1.5.3.*	Y☐ N ☐
Has the product been manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell? (see Regulation 9B of the Therapeutic Goods Regulations 1990).	Y☐ N ☐
Does the submission make reference to a Drug Master File (DMF) or a Plasma Master File (PMF) or to a European Directorate for the Quality of Medicines (EDQM) Certificate of Suitability (CEP)? *If yes, provide applicable documentation in Module 1.6.*	Y☐ N ☐

Description of submission	
Have pre-submission meetings or other pre-submission discussions with the TGA been held concerning this application? *If yes, provide details in Module 1.7.1.*	Y ☐ N ☐
Does the submission include a Risk Management Plan? *If yes, provide an appropriate RMP and Australian specific Annex in Module 1.8.2.*	Y☐ N ☐
Does the submission include individual patient data?	Y☐ N ☐
If not already included in the submission, does the applicant undertake to provide to TGA Individual Patient Data in the format that would be acceptable for submission in the EU or the USA within 15 working days of a request? Identify any clinical studies for which individual patient data are not available in the cover letter (Module 1.0.1).	Y☐ N ☐
Does the submission include bioavailability/bioequivalence information? *If yes, provide a summary of bioavailability/bioequivalence study/studies or justification for not providing biopharmaceutic studies, including references, in Module 1.9.*	Y☐ N ☐
Are there paediatric formulations for this product or have paediatric data been submitted?	Y☐ N ☐
If there are no paediatric formulations for this product or paediatric data have not been submitted, is there a formal justification as to why the product is not appropriate for use in children (Module 2)?	Y☐ N ☐
Has the existing or new PI been provided in the new PI format?	Y☐ N ☐

Sponsor Declaration

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

I acknowledge that the *Therapeutic Goods Act 1989* provides for offences and penalties for making statements that are false or misleading in connection with an application for registration or variation of therapeutic goods.

I apply to register, or vary the entry in the ARTG for the goods described in this submission and declare that the information provided in this form, including the COR-A and COR-B application checklist, and in the submission is, to the best of my knowledge, current and correct.

To the best of my knowledge, I certify that this submission is accompanied by such information and in the required format to allow the determination of the application (that is, complies with the current *Australian Regulatory Guidelines for Prescription Medicines* (ARGPM) for preparing applications to register medicinal products and any associated or supplementary guidelines).

Signature of Authorised Officer:		Date:	dd/mm/yyyy

Name	
Telephone number	
Fax number	
Email address	
Position/Relationship to Sponsor:	

Part C Product details

Product type					
Single active ingredient	☐	Multiple active ingredients	☐	Multiple components	☐
Biological	☐	Non-biological	☐		

Application type	
New chemical/biological entity, new salt/ester/isomer/complex/derivative of an existing active ingredient, a similar biological medicinal product [A]	☐
New fixed combination medicine [B]	☐
Extension of indications [C]	☐
Generic medicine [D]	☐
Major variation (new dosage form, change/increase in patient group, change in dosage (eg., dosage amount, frequency of use or dose regimen), new strength, new route of administration) [F]	☐
*Change in formulation [G]	☐
*Change in container type (disregarding container size) [G]	☐
*Other variation (requiring evaluation of clinical, nonclinical, or bioequivalence data) [H]	☐
Variation to Register entry resulting in a change of product information requiring evaluation of clinical, nonclinical, or bioequivalence data [J]	☐
Undefined regulatory activity *Do not use this regulatory activity without prior approval from the TGA*	☐

**Other than variations covered by Minor variations to prescription medicines*

Label name
Format: PRODUCT NAME Generic name Strength Dosage form Container type (150 characters maximum)

Proposed indications	
Is this an application for a new chemical/biological entity, new fixed combination, similar biological medicine or new generic medicine? If yes, provide the proposed indication(s) below.	Y☐ N☐
If no, is there a change to indication(s) included in the application? If there is a change to indication(s), provide the proposed indication(s) below.	Y☐ N☐

Currently approved indications
Provide currently approved indication(s) below. For a new generic medicine or a similar biological medicine, provide the approved indication(s) of the reference product in Australia.

Dose form	
Container type	
Container material	
Route(s) of administration	
Visual identification of dosage form	
ATC code	*Please indicate if application for the ATC code is still pending*

Sterility			
Is this product supplied sterile? ☐ Yes ☐ No If yes, by what method/s:			
Steam	☐	Part of product	
Dry heat	☐	Part of product	
Filtration	☐	Part of product	
Gamma irradiation	☐	Part of product	
Ethylene oxide	☐	Part of product	
Other (please specify)		Part of product	

Product formulation details *For single medicine products only. For multiple component medicine products refer to component formulation details*			
Active ingredient(s)	Quantity/Range From	Quantity/Range To	Units

Nominal fill volume (if appropriate)			

Excipient ingredient(s)	Quantity/Range From	Quantity/Range To	Units

Proprietary ingredient			
Proprietary ingredient name			
Quantity		Units	
Name of supplier			
Supplier's Client ID (if known)		Proprietary ingredient ARTG number (if known)	

Proprietary ingredient	
Has the supplier been requested to provide details to the TGA	Y☐ N ☐

Proprietary ingredient			
Proprietary ingredient name			
Quantity		Units	
Name of supplier			
Supplier's Client ID (if known)		Proprietary ingredient ARTG number (if known)	
Has the supplier been requested to provide details to the TGA			Y☐ N ☐

Source of material in product			
Was any material of human or other animal origin used at any stage in the development, manufacture or formulation of this component? If Yes, identify the species:			Y☐ N ☐
Name of ingredient	Animal species (e.g. bovine)	Animal part (e.g., hide)	Country of origin
For Category IV ruminant ingredients, does the ingredient comply with the TGA's Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongiform encephalopathies (TSEs)?			
Name of ingredient			Complies with TGA requirements
			Y☐ N ☐
			Y☐ N ☐

Source of material in product	
	Y☐ N☐
	Y☐ N☐

If of animal origin, is the animal an endangered or native species	Y☐ N☐

Pack sizes and Medicines Schedule	
Pack size	Medicines Schedule (S4, S8 or other as appropriate)

Shelf life / Storage conditions (Product)			
Proposed shelf life			
In use shelf life (if applicable)			
Additional shelf life information			
Proposed storage temperature:			
Store below -18°C (Deep freeze)	☐	Store below -5°C (Freeze)	☐
Store below 8°C (Refrigerate)	☐	Store at 2°C to 8°C (Refrigerate. Do not freeze.)	☐
Store below 25°C	☐	Store below 30°C	☐
Other (please specify)			

Shelf life / Storage conditions (Product)	
Proposed storage conditions	

Details of overseas manufacturers

Current GMP Clearance	GMP Clearance/Certification application submitted	GMP clearance or certification tracking number[#]	Manufacturer name	Country	Expiry date (if current)
☐	☐	(e.g. MI-YYYY-CL-NNNNN-N) (OR CE)-NNNNN-N)			
☐	☐				
☐	☐				
☐	☐				
☐	☐				

[#] Applications must have been submitted (draft status is not acceptable).

Note: All overseas manufacturers involved in the manufacture of the products should be entered

Details of Australian manufacturers

Current Licence	GMP Licence application submitted	Licence or Application tracking number[#]	Manufacturer name
☐	☐	(MI-YYYY-LI-NNNNN-N)	
☐	☐		
☐	☐		
☐	☐		

Details of Australian manufacturers			
Current Licence	GMP Licence application submitted	Licence or Application tracking number[#]	Manufacturer name
☐	☐		
☐	☐		

[#] Applications must have been submitted (draft status is not acceptable).

Note: All Australian manufacturers involved in the manufacture of the product should be entered.

For priority review and COR report-based applications:

- Provide the approved Good Manufacturing Practice (GMP) clearance or licence tracking number for all manufacturing sites relevant to the application; or
- Demonstrate that you have applied to obtain GMP approval for all manufacturing sites and provided the required supporting evidence with the GMP clearance, certification or licence application. We will 'verify' that your GMP application is effective (i.e. confirm that you have paid the required GMP application fees and all of the required evidence to support the GMP application for all relevant manufacturing sites has been lodged in support of the application) as part of the dossier acceptance process.

Product manufacturer details	
Manufacturer 1	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
Steps in manufacture	
Manufacturer 2	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
Steps in manufacture	
Manufacturer 3	

Product manufacturer details	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
Steps in manufacture	
Manufacturer 4	
Manufacturer's business name	
Manufacturer's site address	
Manufacturer's Client ID (if known)	
Steps in manufacture	

Note: Insert additional rows if there is insufficient room in the above tables.

Components *Please use a separate page for each component. Attach additional pages as required.*	
Component details	
Component name/description	
Dosage form	
Route(s) of administration	
Container type	
Container material	
Container condition	
Container closure	
Visual identification of dosage form	
Component sterility	

Components *Please use a separate page for each component. Attach additional pages as required.*			
Is this component supplied sterile? If yes, by what method/s:			☐ Yes ☐ No
Steam	☐	Part of product	
Dry heat	☐	Part of product	
Filtration	☐	Part of product	
Gamma irradiation	☐	Part of product	
Ethylene oxide	☐	Part of product	
Other (please specify)		Part of product	

Component Shelf life / Storage conditions *Complete the information below if the component has a shelf life different from that of the whole product*			
Proposed shelf life			
In use shelf life (if applicable)			
Additional shelf life information			
Proposed storage temperature:			
Store below -18°C (Deep freeze)	☐	Store below -5°C (Freeze)	☐
Store below 8°C (Refrigerate)	☐	Store at 2°C to 8°C (Refrigerate. Do not freeze.)	☐
Store below 25°C	☐	Store below 30°C	☐
Other (please specify)			
Proposed storage conditions			

Component formulation details *For multiple components only. For single medicine products refer to product formulation details*			
Active ingredient(s)	Quantity/Range From	Quantity/Range To	Units

Nominal fill volume (if appropriate)			

Excipient ingredient(s)	**Quantity/Range From**	**Quantity/Range To**	**Units**

Proprietary ingredient			
Proprietary ingredient name			
Quantity		Units	
Name of supplier			

Proprietary ingredient			
Supplier's Client ID (if known)		Proprietary ingredient ARTG number (if known)	
Has the supplier been requested to provide details to the TGA			Y☐ N☐

Proprietary ingredient			
Proprietary ingredient name			
Quantity		Units	
Name of supplier			
Supplier's Client ID (if known)		Proprietary ingredient ARTG number (if known)	
Has the supplier been requested to provide details to the TGA?			Y☐ N☐

Source of material in component			
Was any material of human or other animal origin used at any stage in the manufacture or formulation of this component? If Yes, identify the species:			Y☐ N☐
Name of ingredient	Animal species (e.g. bovine)	Animal part (e.g., hide)	Country of origin

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

Source of material in component	
	Y☐ N☐
	Y☐ N☐
	Y☐ N☐
	Y☐ N☐

If of animal origin, is the animal an endangered or native species	Y☐ N☐