Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

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>.

Additional trade names

Application form for prescription medicine sponsors

Please note: This form must be used for an application under section 23 of the *Therapeutic Goods Act 1989* for an additional trade name for a registered prescription medicine. For guidance, please see Additional trade names guidance - prescription medicines.

You need to provide all the information requested that is relevant to your application, answer all the questions and make all of the declarations. If you do not do this, there is a risk that your application will not comply with the requirements of section 23 and cannot be processed.

Section 1. Sponsor details

Sponsor details table

Sponsor name:	
TBS Client ID:	
Postal address:	
Contact person:	
Position: (e.g. regulatory affairs officer; agent)	
Telephone number:	
Fax number:	
Email address:	

Section 2. Medicine details

2.1 General details

Single active ingredient ☐ multi-active ingredient ☐ multi-component ☐

Is this medicine: a biological medicine? ☐ a chemical medicine? ☐

Active ingredients (and components, if multi-component):	

This form can be used to apply for additional trade names for more than one registered prescription medicine. However, all such medicines must contain the same active ingredient (see clause 1(3) in Part 1 of Schedule 9 to the Therapeutic Goods Regulations 1990).

2.2 Existing ARTG entries [parent medicine(s)]

AUST R	Trade name	Strength	Dosage form	Container type

Please attach additional pages if more than twelve ARTG entries.

2.3 New medicines

Trade name of new medicine	Strength	Dosage form	Container type	related to parent medicine AUST R

Please attach additional pages if more than twenty ARTG entries

Section 3. Good manufacturing practice

Provide all relevant manufacturing licence numbers (for Australian manufacturers) and GMP clearance numbers (for overseas manufacturers) along with the expiry dates in Module 1.7.

3.1 Manufacturing sites

☐ Yes ☐ No Are all manufacturing sites used for the parent medicines being used for the new medicines?

If 'No' provide information in the tables below.

Overseas manufacturing sites not to be included

GMP clearance number	Manufacturer name	Site address

Please attach additional pages if you need more than six entries in this table.

Australian manufacturing sites not to be included

Licence number	Manufacturer name	Site address

Please attach additional pages if you need more than six entries in this table.

3.2 Manufacturing steps

☐ Yes ☐ No Are all manufacturing steps used for the parent medicines being used for the new medicines?

If 'No' provide information in the tables below.

Overseas manufacturing steps not to be included

GMP clearance number	Manufacturer name	Site address	Step(s) to be removed

Please attach additional pages if you need more than six entries in this table.

Australian manufacturing steps not to be included

Licence number	Manufacturer name	Site address	Step(s) to be removed

Please attach additional pages if you need more than six entries in this table.

3.3 Pack sizes and/or container material types not to be included

☐ Yes ☐ No Are all the pack sizes and container material types used for the parent medicines being used for the new medicines?

If 'No' provide information in the tables below.

Pack sizes and/or container material types not to be included

Trade name of new medicine	Pack size	Container material type

Please attach additional pages if you need more than eight entries in this table.

Section 4. Related submissions

Provide details of submissions currently under evaluation for the parent medicine(s) (e.g. 9D(1) variations that are related to this submission).

Submission ID	Details of submission

Please attach additional pages if there are more than four related submissions.

Section 5. Check list

Answer the following questions.

☐ Yes ☐ No A name or livery that belongs to another company is proposed to be used on labels.

☐ Yes If yes, a letter of authorisation for the use of the other company's name or livery has been attached to the cover letter.

☐ Yes ☐ No Tablet markings are the same as for the parent medicine.

☐ Yes If no, justification for changing tablet markings from the parent medicine and dissolution data have been included in Module 3.

☐ Yes ☐ No A patent certification or notification as described in section 26B of the Act has been included in this submission.

Section 6. Sponsor declaration

Make the following declarations.

☐ Yes ☐ No 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.

I certify that to the best of my knowledge:

☐ Yes the ARTG records of the parent medicines are complete and accurate in all data fields.

OR

☐ Yes the ARTG records are incomplete and/or incorrect, 9D(1) request(s) to correct ARTG entries have been submitted (details entered in section 4 of this form) and all other aspects of the ARTG records of the parent medicines are correct.

In relation to this submission, I certify that to the best of my knowledge:

☐ Yes ☐ No The goods that are the subject of this submission are manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell.

☐ Yes If 'Yes', the draft Product Information and CMI include a statement that human embryos or human embryonic stem cells or any other material sourced from a human embryo or human embryonic stem cell were used in the manufacture of the therapeutic good.

I declare that if hard copies and electronic copies of the dossier have been submitted, they are identical.

I acknowledge that sections 22A and 22B of the *Therapeutic Goods Act 1989* provide for offences and civil penalties for making statements that are false or misleading in a material particular, or in connection with, an application under section 23 of the Act in relation to therapeutic goods.

I certify that to the best of my knowledge, the new medicines are identical to the parent medicines, with the exception of the differences identified in this submission.

I certify that:

- the Product Information provided with this submission is based on the most recent version of the parent medicine Product Information to have been approved by the TGA
- all proposed changes have been clearly identified
- all information in the Product Information is current and correct
- all of the differences from the approved Product Information for the parent medicines that are marked up in the annotated Product Information provided in Module 1.3.1 relate to the applications in this additional trade name submission.

I declare that the information provided for the purposes of this submission, is to the best of my knowledge, current and correct and that the certifications made by me in this form are correct.

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