



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>>.

# CTD Module 1.5 - Assessed listed medicines – Restricted information certification

Section 26AF of the *Therapeutic Goods Act 1989* (the Act) sets out when the Secretary must not use restricted information in evaluating assessed listed [L(A)] medicines. The purpose of this form is for you to:

1. Confirm that:
  - a. you are **not** seeking to rely on restricted information [relating to another L(A) medicine] to support your application; **OR**
  - b. the person (i.e. sponsor) who is the owner of the restricted information [relating to another L(A) medicine] **has given the Secretary of the TGA permission to rely on that information to support your application (Part A)**

## AND

2. Advise whether any information you provide in your application **would** be restricted information that the Secretary must not consider when evaluating another L(A) medicine in the future (**Part B**).

Please refer to the [Data Protection Scheme for Assessed Listed Medicines Guidance](#) document on the TGA website for more information on restricted information.

Complete this form as per the instructions in Appendix 1 of the Data Protection Scheme for Assessed Listed Medicines guidance on the TGA website.

Please include this form in CTD Module 1.5 of your application dossier.

This form is divided into two parts:

Part	Instructions
<a href="#">A – Reliance on restricted information declaration</a>	<p>Complete one Part A for each application</p> <p>The information you provide in Part A relates to a certification that:</p> <ol style="list-style-type: none"><li>1. you are not seeking to rely on restricted information to support your application; <b>OR</b></li><li>2. the person (i.e. sponsor) who is the owner of the restricted information [relating to another L(A) medicine] has given the Secretary of the TGA permission to rely on that information to support your application along with details of this information.</li></ol> <p>Part A also requires you to include a list of all information provided to support this application.</p>
<a href="#">B – Eligibility for information to be restricted</a>	<p>Complete one Part B for each application</p> <p>The information you provide in Part B relates to whether any of the information provided in your application would be eligible to be considered restricted information.</p>

**Please note:**

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 information form (Parts A and B) and any attachments in CTD Module 1.

## Part A – Reliance on restricted information declaration

Medicine name in application	
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*Please complete the relevant certification.*

### 1. Confirmation that you are **not** seeking to rely on restricted information

- I certify that restricted information is **not** relied on to support this application.

*If you have selected this option, please also complete Section 4 (if relevant) and sign/date the certification at the end of Part A.*

**OR**

### 2. Confirmation that the person (i.e. sponsor) who is the owner of the restricted information [relating to another L(A) medicine] **has given the Secretary of the TGA permission to rely on that information**

The information relied on to support this application is:

- a. information that relates to another medicine that is listed in the Register under section 26AE of the Act; and
- b. the information would be restricted information in relation to that medicine, under section 26AF of the Act; **but**
- c. the person (i.e. the sponsor) in relation to whom that medicine is listed in the Register has given the Secretary permission to use the information in connection with this application.

- I enclose the permission for the Secretary of the TGA to use this information to evaluate my medicine as:

- i.  I am the sponsor/authorised to act on behalf of the sponsor of the L(A) medicine to which the information relates and give the Secretary permission to use the information.

*If you have selected this option, please complete Section 3, Section 4 (if relevant) and sign/date the certification at the end of Part A.*

- ii.  The sponsor of the L(A) medicine to which the information relates, has given the Secretary permission to use the information for this application. I have enclosed the Letter of Permission from that sponsor with this application.

*If you have selected this option, please complete Section 3, Section 4 (if relevant), sign/date the certification at the end of Part A and attach the Letter of Permission in Module 1.5.*

**3. Details of the medicine to which the information relates:**

Details of the medicine to which the information relates		
i.	Name of other medicine and AUST L(A) number	
ii.	Name of sponsor of other medicine	
iii.	Letter of Permission attached in Module 1.5	Yes <input type="checkbox"/> No (I am the sponsor of the other medicine) <input type="checkbox"/>
iv.	Clinical trial registry number(s) (CTN)	
v.	Universal trial number (if available) (UTN)	
vi.	Data protection expiry date	
vii.	Intermediate indication-active ingredient(s) combination	

**4. List of all supporting information provided with this application.**

This list is to be provided with all applications that include published or unpublished supporting information in the submission dossier. Enter the details of all human clinical trials provided (whether restricted or not). If there is insufficient space, please enter '**see attached**' and attach a separate page(s) with the full details in CTD Module 1.5.

Clinical trial registry number	Universal trial number (if available)	Document title and author details	File name in dossier
ACTRN12345678901234	U1234-5678-9012	Clinical study report ABC012021: Evaluation of the efficacy of X (containing 20mg standardised extract of Z) for alleviation of Y. A. Author.	Study-ABC012021
ACTRN11234567890123	Not applicable	Efficacy and safety of Z for Y: A randomised controlled trial. A. So and B. So	So-2015

Authorised officer's<sup>1</sup> name

Authorised officer's position

Sponsor's name

Signature

	Date	

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<sup>1</sup> The authorised officer is the person authorised by the sponsor to sign this certification. This could be an employee or other officer of the sponsor, or an agent acting on behalf of the sponsor (e.g. a regulatory affairs consultant).

## Part B – Eligibility for information to be restricted

Medicine name in application	
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Do you believe that any information that you have provided with this application would be restricted information under section 26AF of the Act if the application passes preliminary assessment and the medicine is listed in the Register following evaluation, and if the requirements of paragraphs 26AF(2)(da), (ea) and (eb) of the Act are met in relation to the information?

Yes

No

*If yes, please complete the information and certifications below.*

Note1: Paragraph 26AF(2)(da) provides that one of the criteria for information to be restricted information in relation to a medicine is that no other medicine with the indication in relation to which the information relates, and with the same active ingredients as the medicine, has been included in the Register under section 26AE at any time before the time the application to include the medicine in the Register was made.

Note 2: Paragraph 26AF(2)(ea) provides that one of the criteria for information to be restricted information in relation to a medicine is that the Secretary relied on the information in deciding to list the medicine;

Note 3: Paragraph 26AF(2)(eb) provides that one of the criteria for information to be restricted information in relation to a medicine is that at all times during the period:

- i. beginning on the day the application for the listing of the medicine was made; and
- ii. ending at the end of the day before the day that the medicine was included in the Register;

the information (except information set out in a prescribed clinical trial registry) was not available to the public.

### Details of information to be considered as restricted information

#### 1. New intermediate indication/active ingredient combination(s).

Please enter each new intermediate indication and the corresponding active ingredient for which you are requesting to have information considered as restricted.

New intermediate indication-active ingredient combinations(s)	
Active ingredient(s)	
New intermediate indication(s)	

2. List of information provided in your submission dossier that you are requesting be considered as restricted information that relates to the above active ingredient and intermediate indication combination for the medicine.

*If there is insufficient space, please enter 'see attached' and attach a separate page(s) with the full details in Module 1.5.*

Clinical trial registry number	Universal trial number (if available)	Document title and author details	File name in dossier
ACTRN12345678901234	U1234-5678-9012	Clinical study report ABC012021: Evaluation of the efficacy of X (containing 20 mg standardised extract of Z) for alleviation of Y. A. Author	Study-ABC012021

**Certifications**

I certify that:

Certifications		Acknowledgment
i.	This information is derived from a clinical trial in relation to an indication of the medicine.	<input type="checkbox"/>
ii.	The trial number of the trial is specified in section 2 of this certification.	<input type="checkbox"/>
iii.	The trial number of the trial is set out in a clinical trial registry prescribed by regulation 15AA of the Regulations for the purposes of subparagraph 26AF(2)(b)(ii).	<input type="checkbox"/>
iv.	This information is not available in the public domain and will not be made available to the public during the period of evaluation of this application except what is set out in the prescribed clinical trial registry.	<input type="checkbox"/>
v.	This information relates to an intermediate indication i.e.: i. a use of the medicine in preventing, curing or alleviating a disease, ailment, defect or injury in persons, other than a form	<input type="checkbox"/>

	<p>of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; or</p> <p>ii. a use of the medicine in connection with alleviating a disease, ailment, defect or injury in persons, being a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form.</p>	
vi.	The indication to which this information relates is not covered by a determination relating to permissible indications made by the Minister under paragraph 26BF(1)(a) of the Act that is in place at the time of this application.	<input type="checkbox"/>
vii.	No other assessed listed medicine with that indication, and with the same active ingredients, is listed in the Register under section 26AE of the Act	<input type="checkbox"/>
viii.	I own the clinical trial efficacy information (i.e. I have conducted or sponsored the study and have the legal right to use the study).	<input type="checkbox"/>

Authorised officer's<sup>2</sup> name

Authorised officer's position

Sponsor's name

Signature

	Date	

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<sup>2</sup> The authorised officer is the person authorised by the sponsor to sign this certification. This could be an employee or other officer of the sponsor, or an agent acting on behalf of the sponsor (e.g. a regulatory affairs consultant).