



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>>.

Notification of an authorisation to use a protected ingredient



- This form is to be completed by an ingredient owner authorising a sponsor to use a protected ingredient for the purpose of listing a medicine in the Register.
- The protected ingredient is the subject of an exclusivity period pursuant to the Therapeutic Goods (Permissible Ingredients) Determination.
- The ingredient owner is the person named in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) as having exclusive use of the protected ingredient in a listed medicine.
- There is **no fee** required for this notification.
- Please ensure you read [Applications for new substances in listed medicines - Australian regulatory guidelines](#) prior to completing and submitting this form

Send completed forms to the Complementary and OTC Medicines Branch at:

Email: complementary.medicines@health.gov.au **Fax:** 02 6203 1657

Post: Complementary & OTC Medicines Branch, TGA, PO Box 100, Woden ACT 2606, Australia

Section 1 - Details of notification

Ingredient owner

Name:	
Client ID:	
Postal address:	
Email address:	

Ingredient information

Ingredient Name:	
TGA Ingredient ID:	
Ingredient Type (active or excipient):	
Application ID:	
Date of inclusion in Therapeutic Goods (Permissible Ingredients) Determination	

Sponsors authorised to use the protected ingredient during the exclusivity period

If there are additional sponsors you authorise to use the ingredient, please add them as an attachment to the form.

Client ID	Client Name	Relationship to applicant



- **Please note:** The TGA will **not** intervene in or arbitrate disagreements between sponsors, manufacturers or suppliers in relation to authorisation agreements.

Section 2 - Declarations



- **Please note:** Under section 137.1 of the *Criminal Code Act 1995*, it is an offence to knowingly provide information to a Commonwealth entity that is false or misleading in a material particular, or to omit any information without which the information is misleading in a material particular.
- Penalty: 12 months imprisonment

I declare I am:

the ingredient owner named in the Therapeutic Goods (Permissible Ingredients) Determination as having exclusive use of the protected ingredient in a listed medicine

OR

authorised to make this declaration on behalf of the ingredient owner named in the Therapeutic Goods (Permissible Ingredients) Determination as having exclusive use of the protected ingredient in a listed medicine *

I declare that the information I have provided above is true and correct.

Full name:			
Position:*		Email:	
Telephone:		Facsimile:	
Signature:		Date:	

*e.g. managing director or regulatory affairs officer; agent of the applicant

Please note: We may request more information before accepting your market exclusivity notification. We will also need to confirm that you are an authorised person in the TGA Business Portal.