Australian Government
Department of Health
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>.

Application for consent to import, supply or export therapeutic goods that do not conform with standards - section 14/14A

There are criminal offences under section 14 and civil penalties under section 14A of the *Therapeutic Goods Act 1989*, for persons who import, supply or export therapeutic goods (other than medical devices) that do not conform with standards applicable to the goods, unless consent has been given by the Secretary of the Department of Health in relation to the goods.

The TGA expects conformity with the standards applicable to therapeutic goods; however, there may be some exceptional circumstances preventing conformity with applicable standards in relation to particular goods.

This application is for therapeutic goods that are:

- listed or registered goods included in the ARTG under Part 3-2 of the Act (including medicines), or
- biologicals included in the ARTG under Part 3-2A of the Act.*

* If you are wanting to import, supply or export a good that is not included in the ARTG you should contact the TGA.

The person in relation to whom the goods are included in the ARTG or an authorised representative of that person needs to:

- complete and sign this application form;
- attach all relevant documentation; and
- submit the completed form and documentation to the TGA together with the applicable fee.

More information can be found on the TGA website at <https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-prescription-medicine/application-types/consent-import-supply-or-export-therapeutic-goods-do-not-comply-standards-information-industry>.

Processing fee

For an application relating to therapeutic goods (including biologicals) with a single entry in the ARTG, a fixed application fee for processing the application applies.

For an application relating to therapeutic goods (including biologicals) with separate entries in the ARTG, a variable application fee for processing the application applies, **provided** the way in which the goods do not conform with the applicable standard is the same for all the goods. The variable fee is comprised of a fee for the first entry plus an additional fee for each separate entry.

A list of current fees and charges, and a Credit Card Authorisation form, is available on the TGA website <https://www.tga.gov.au/how-we-regulate/fees-and-payments>.

Section 1. Applicant and therapeutic good details

1.1 Applicant details

Entity name	
TBS Client ID	
Postal address	
Contact person	
Position (for example regulatory affairs officer, agent)	
Telephone number	
Fax number	
Email address	

I consent to receive notification of a decision in relation to this application by email. Yes ☐ No ☐

1.2 Therapeutic good details

Specify the type of goods	☐ Prescription medicines
	☐ Over-the-counter medicines
	☐ Listed medicines
	☐ Assessed listed medicines
	☐ Registered complementary medicines
	☐ Other therapeutic goods listed
	☐ Other therapeutic goods registered
	☐ Blood, tissues or biologicals

Add an attachment if there are additional therapeutic goods.

Product name	ARTG No.	Batches affected (if relevant)	Specify the relevant consent required for each ARTG entry*
			Import ☐ Supply ☐ Export ☐
			Import ☐ Supply ☐ Export ☐
			Import ☐ Supply ☐ Export ☐
			Import ☐ Supply ☐ Export ☐

* These reflect the fact that the offences under s14 and civil penalties under s14A are in relation to importing, supplying, and exporting, non-conforming goods without the Secretary's consent. If the goods have been manufactured overseas, consent would generally be required for both 'import' and 'supply'. A therapeutic good manufactured in Australia may only require 'supply' and/or 'export'.

Section 2. Details of request (attach additional material where necessary)

Information and questions	Answers
2.1 Describe: • the part or parts of the standard for which the consent is required, and • how the therapeutic goods do not conform with the part or parts of the standard For example: Section 9(5) of the *Therapeutics Goods Order No. 91 – Standard for labels of prescription and related medicines* - the name of the active ingredient on the main label has a text height of less than 3.0 millimetres	
2.2 Provide an explanation of the circumstances that led to the therapeutic goods not conforming with the relevant part or parts of the standard.	

Information and questions	Answers
2.3 Describe: • the real or potential risks associated with the non-conformance if the non-conforming therapeutic goods were to be exported, imported or supplied; and • the strategies implemented or proposed to be implemented to minimise the risk (e.g. letters to healthcare professionals).	
2.4 If there is potential for supply shortage of conforming goods if consent is not granted, an indication of the impact on immediate and future supply, including where relevant: • information on the stock levels of conforming goods[1]	
2.5 Proposed duration of the consent (should it be granted) e.g. the expected timeframe for depletion of the non-conforming goods or batches, and reasons • if expected to be long-term (but not permanent) then consent may be limited to 2 years to allow for review; • if proposed to be permanent, provide justification.	
2.6 Describe: • the strategies implemented or proposed to be implemented to rectify the non-conformance; and • the expected timeframe for implementation.	
2.7 Any other relevant matters • for instance, any time critical date for decision and reasons.	

[1] Applicants should consider whether the circumstances warrant providing information to the Medicines Shortages Information Initiative: see <https://apps.tga.gov.au/prod/MSI/search> Application for consent to import, supply or export therapeutic goods that do not conform with standards - section 14/14A (May 2021)

Section 3. Declaration

I am the person in relation to whom the goods are included in the ARTG for the purposes of this application*	Yes ☐ No ☐
OR	
I am authorised to act on behalf of the person in relation to whom the goods are included in the ARTG for the purposes of this application**	Yes ☐ No ☐
I acknowledge that it is a serious offence under Commonwealth law to give information that is false or misleading in a material particular to the Secretary for the purposes of making this application for consent under sections 14 and 14A.	Yes ☐

I declare that the information provided in this form is to the best of my knowledge, current and correct.

Name			
Signature		**Date**	

* For instance, the regulatory affairs officer.

** For instance, the agent.

Please send the completed form and processing fees to Product Billing and Industry Assistance at the address below:

Product Billing and Industry Assistance
TGA
PO BOX 100
Woden ACT 2606

Or facsimile: 02 6232 8222

Or Email: accountsrec@tga.gov.au