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>.

COVID-19-related application for consent to supply goods that do not conform with Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines - 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 compliance with the standards applicable to the goods, however there may be some exceptional circumstances preventing compliance with applicable standards in relation to particular goods.

This application is for therapeutic goods that are listed or registered on the ARTG under Part 3-2 of the Act that are subject to Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.

Consent to **export** or **import** goods that do not conform to a standard that relates to labelling or packaging is **not required**. This application is only to request consent to **supply** goods that do not conform with Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.

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

- complete and sign this application form
- submit the form to the TGA together with the applicable fee

More information can be found on the TGA website at COVID-19 and eligibility to request consent to supply therapeutic goods that do not comply with the new labelling requirements of TGO 92.

Processing fee

An application can include goods in multiple ARTG entries **provided**:

- the request for consent relates only to non-compliance with TGO 92 in its entirety and is the same for all goods; and
- the goods are fully compliant with TGO 69.

A processing fee is charged for an application for consent in relation to goods registered or listed under Part 3-2 of the Act that are complementary medicines, over-the-counter medicines and sunscreens.

A list of current fees and charges is available on the TGA website: Fees and payments.

Section 1. Sponsor and product details

1.1 Sponsor details

Sponsor name	
TBS Client ID	
Postal address	
Contact person	
Position (for example regulatory affairs officer, agent of sponsor)	
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 Product details

Specify the type of goods	☐ Over-the-counter medicines (OTC)
	☐ Listed medicines (LM)
	☐ Registered complementary medicines (RCM)

Please attach extra page(s) if required.

Product name	ARTG No.	Batches affected (if relevant)	Type of goods
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐
			OTC ☐ LM ☐ RCM ☐

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

Information and questions	Answers
2.1 Has COVID-19 adversely impacted your ability to comply with TGO 92?	Yes ☐ No ☐
2.2 Are the labels on your product(s) fully compliant with TGO 69?	Yes ☐ No ☐
2.3 Proposed duration of consent Note: The maximum duration of consent is until 6 March 2021. For OTC and Registered Complementary Medicines, longer durations will only be given in extenuating and exceptional circumstances.	

Section 3. Declaration

I am the sponsor for the purposes of this application† Yes ☐ No ☐

OR

I am authorised to act on behalf of the sponsor for the purposes of this application‡ Yes ☐ No ☐

† For instance, the regulatory affairs officer of the sponsor.

‡ For instance, the sponsor's agent.

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**	

Please send the completed form and processing fees to Product Billing and Industry Assistance via email to accountsrec@health.gov.au, facsimile 02 6232 8222 or the address below:

Product Billing and Industry Assistance
Therapeutic Goods Administration TGA
PO Box 100
WODEN ACT 2606