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 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 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 (including medicines), or
- are included on the ARTG under Part 3-2A of the Act (biologicals).*

  * Those wanting to import and/or supply or export a product that is exempt or otherwise approved under Part 3-2 or Part 3-2A of the Act that does not conform with a standard that applies to the product should contact the TGA.

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;
- 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/consent-import-supply-or-export-therapeutic-goods-do-not-comply-standards-information-industry>.

Processing fee

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

- the goods have the same active ingredient, unless the consent relates to a breach of paragraph 3(2)(l) of TGO 69 (name and address of sponsor or supplier);
- all the issues in relation to granting consent are the same for all the goods; and
- the non-compliance in relation to the goods relate to the same part or parts of a standard applicable to the goods.

There is a maximum of 20 ARTG entries in each application.

A processing fee is charged for an application for consent in relation to goods registered or listed under Part 3-2 of the Act i.e. complementary medicines, over-the-counter medicines, sunscreens, prescription medicines (both chemical and biological medicines) and therapeutic devices. **Currently, there is no fee for processing an application for consent in relation to biologicals i.e. those included in the ARTG under Part 3-2A of the Act.**

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

Section 1. Sponsor and product details

1.1 Sponsor details

Sponsor name	Australian Red Cross Lifeblood - An Operating Division of the Australian Red Cross Society
TBS Client ID	45769
Postal address	Attention s22 GPO Box 5103 Melbourne VIC 3001
Contact person	s22
Position (for example regulatory affairs officer, agent of sponsor)	s22
Telephone number	s22
Fax number	n/a
Email address	s22 @redcrossblood.org.au 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

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

Include a maximum of 20 products only. Add an attachment if there are additional products.

Product Name	ARTG No.	Batches affected (if relevant)	Specify the relevant consent required for each ARTG entry*
All blood components as per TMF	n/a	n/a	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, to supplying, or to exporting, non-compliant products without the Secretary's consent. If the product has been manufactured overseas, consent would generally be required for both 'import' and 'supply'. An Australian manufactured therapeutic good 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 product/s do not comply with the part or parts of the standard For example: Section 3(2)(l) of Therapeutics Goods Order No. 69 - General requirements for labels for medicines - the label does not include the name and address of the current sponsor or supplier of the goods.	Proposed changes to the Guidelines for the Selection of Blood Donors to reduce the deferral period for donors with a sexual activity risk factor from 12 months, to 3 months, since last contact, which does not comply with: Therapeutic Goods Order No. 88 - Standards for donor selection, Part 3 section 9(4), Table 1 (k) A donor whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues. Ineligible for 12 months from last contact. Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019 / Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components 19th edition: Standards for selection of donors, Chapter 2, section 4, table
2.2 Provide an explanation of the circumstances that led to the goods not complying with the relevant part or parts of the standard.	Not applicable. This is a request for a proposed change to blood donor selection criteria

Information and questions	Answers
2.3 Describe: • the real or potential risks associated with the non-compliance if the non-compliant product 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).	Refer to the attached documents for submission RR17-045.
2.4 If there is potential for supply shortage of compliant 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 compliant goods[1]	Not applicable
2.5 Proposed duration of the consent (should it be granted) e.g. the expected timeframe for depletion of the non-compliant 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.	Permanent
2.6 Describe: • the strategies implemented or proposed to be implemented to rectify the non-compliance, and • the expected timeframe for implementation.	Not applicable
2.7 Any other relevant matters • for instance, any time critical date for decision and reasons.	Not applicable

[1] Sponsors should consider whether the circumstances warrant providing information to the Medicines Shortages Information Initiative: see <https://www.tga.gov.au/medicine-shortages-information-initiative>

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 ☑

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	s22 [redacted]		
Signature	s22 [redacted]	**Date**	18 December 2019

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

** For instance, the sponsor's 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