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 <http://www.tga.gov.au/about/tga-information-to.htm>.

Form for notifying exceptional release of a biological

Therapeutic Goods Act 1989

Read carefully before completing

This is the form approved by the Secretary of the Department of Health for a sponsor to notify the Secretary of use of a non-conforming biological for the purposes of paragraph 33B(2)(a) of the Therapeutic Goods Regulations 1990.

Responsibility for use of the product appropriately rests with the patient's medical practitioner. Non-conforming biologicals may only be released for use in patients with serious medical conditions in the circumstances prescribed in regulation 33A of the Therapeutic Goods Regulations 1990.

A copy of the form must be forwarded to TGA within 28 days of the date of release of the biological.

Privacy Information

- For general privacy information, go to Privacy on TGA website.
- The TGA collects personal information of sponsors, doctors and patients who supply or receive non-conforming biologicals.
- The purpose of this collection is to enable the tracing of the biological and the notification of patients who received it should adverse events emerge from the use of the biological; and to monitor the use of non-conforming biologicals in accordance with Part 5A of the Therapeutic Goods Regulations 1990.
- The collection of personal information in relation to non-conforming biologicals is authorised under Part 5A of the Therapeutic Goods Regulations 1990.

1. Patient and product details

Patient details (initials, DOB and sex)			
Diagnosis			
Name of biological		ARTG number	
Reason why the biological is non-conforming			
Australian sponsor of product			
Dosage form		Quantity to be supplied	
Route/Method of administration		Dosage	
Unique identifier(s) of biological			
Name and address for supply of product (Hospital Pharmacist or Doctor)			
Date of release (dd/mm/yyyy)			

2. Documentation from treating medical practitioner of circumstances under which biological is supplied

Copies of ALL of the following documents MUST be attached to this form

· written statements from the medical practitioner specifying:

☐ the details of the proposal to use the nonconforming biological (including sufficient background information to show that the circumstances provided for in regulation 33A have occurred).

☐ that the patient or guardian has been told about the likely risks and benefits from the use of the biological.

☐ the reason that the biological is nonconforming with standards applicable to the biological under section 10 of the Act or was not manufactured in accordance with relevant manufacturing principles under section 36 of the Act.

- written informed **consent from the patient/legal guardian**, or a statement from the treating medical practitioner explaining why the patient/guardian cannot give consent.

3. Approval from medical or scientific director of sponsor's facility

☐ A copy of the written approval for the release of the biological from the medical or scientific director of the sponsor's facility from which the supply of the biological is to occur **MUST** be attached to this form.

Name(s)		Position(s)	
Email			
Telephone		Date of Approval (dd/mm/yyyy)	

4. Sponsor contact person

Contact Person(s)		Occupation/ Position(s)	
Address			
Email			
Telephone		Fax	
Name of Person completing this form		Signature(s)	

Send the completed form to:

Medical Officer – Exceptional Release
Biological Science Section
Therapeutic Goods Administration
PO BOX 100
WODEN ACT 2606

or:

Fax: 02 6203 1731

Email: bloodandtissues@tga.gov.au