



Therapeutic Goods Act 1989

# Application\* for a Licence to Manufacture Therapeutic Goods

- To ensure that a new manufacturer is audited in a timely manner, if possible the applicant is requested to submit an application for a new licence at least 4 months ahead of the expected audit time.
- This form should be completed by or for each Australian manufacturer, who is not exempted from the requirement to hold a licence, of:
  - medicines, or
  - other therapeutic goods, or
  - existing listed or registered therapeutic devices. Note: this is applicable only during the transition period (ending 4 October 2007) under the new medical device legislation.
- Note that:
  - a reference to **other therapeutic goods** in this application form is a reference to therapeutic goods that are not medicines or medical devices (e.g. in vitro diagnostic devices, devices manufactured from human tissues), and
  - a reference to **therapeutic devices** in this application form is a reference to therapeutic devices where the granting of a licence to manufacture is not in support of a new entry on the Australian Register of Therapeutic Goods (ARTG). This application form is not applicable to **medical devices** requiring conformity assessment under Chapter 4 of the *Therapeutic Goods Act 1989*.
- Where an item number is given, e.g. **A1** appears on the form, a corresponding note is given in the adjacent guide.
- Incomplete forms may be returned to the applicant. Please type or print in black pen. Any alterations must be initialled and dated. Application forms with white out will be returned.
- The licence application form must be accompanied by the prescribed application fee. For amount refer to the summary of fees and charges available from the TGA Internet website <http://www.tga.gov.au>.  
The completed form should be sent to:

Financial Services Group  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606

**Note:** Cheques should be made payable to Therapeutic Goods Administration

- **Manufacturing principles:** pursuant to the *Therapeutic Goods Act 1989*, the Minister may determine written principles to be observed by a manufacturer of therapeutic goods. These principles will primarily comprise the Codes of Good Manufacturing Practice (GMP) or reference to quality systems which are developed in collaboration with the therapeutic goods industry. Information on the Australian Codes of GMP and relevant Quality Management System standards is available on the TGA website at <http://www.tga.gov.au>.
- The licence is the property of the Therapeutic Goods Administration and must be returned upon demand. The licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.

\* Application form approved by the delegate for the purpose of paragraph s.37(1)(a) of the *Therapeutic Goods Act 1989*.

(Signed June 2004)

AR Gould  
Chief GMP Auditor

## Section A. Manufacturer Details

### **A1** The Manufacturer's Business Name

Full, legal name of licence applicant: (must be full, *legally identifiable name* eg 'ABC Pty Ltd', 'Newcorp Ltd trading as XYZ', 'Gillian Linda Smith trading as MNR', or 'Western Australia Health Board trading as the EFG Hospital'). Spaces are provided for the following options. Please insert as applicable.

- a) Name if sole trader  
The individual's full name if trading as an individual trader
- b) Name of Corporation  
If a corporation, the name of the registered company under the companies code and the ABN/ACN number
- c) Name if trading under other business name  
The business name, or name under which you propose to trade for purposes of the Act  
(if different from (a) or (b))

### **A2** Certification in relation to the applicant, and persons involved with the applicant, for a licence to manufacture therapeutic goods

The certification seeks assurances that the requirements of Section 38 of the *Therapeutic Goods Act 1989* (the Act) have been satisfied and that the information provided in this application is current and correct at the time it was signed by the manufacturer. The certification is intended to establish whether the applicant for a manufacturing licence is a fit and proper person to hold a licence. Further, the Therapeutic Goods Administration must consider whether all persons who participate in or are likely to participate in managing the affairs of an applicant for a licence, or otherwise have effective control, or likely to have effective control, over the applicant, are fit and proper persons.

The applicant should note that under Section 41 of the Act, a licence can be suspended or revoked if the holder of a licence, or any of the persons who participate in or are likely to participate in managing the affairs of, or otherwise has or is likely to have effective control over the holder of the licence, ceases to be a fit and proper person to hold a licence.

See Appendix A for extracts of Sections 38 and 41 of the Act.

**A1** Manufacturer's Business Name

Name if sole trader	<input type="text"/>
Registered company name if corporation	<input type="text" value="ABN/ACN"/>
Name if trading under other business name	<input type="text"/>

**A2** Certification in relation to the applicant, and persons involved with the applicant, for a licence to manufacture therapeutic goods

I, \_\_\_\_\_  
[NAME OF LICENCE APPLICANT AND, WHERE APPLICABLE, POSITION HELD]

\_\_\_\_\_  
[COMPANY NAME]

\_\_\_\_\_  
[COMPANY ADDRESS]

understand that the certification below is made for the purpose of assisting the Therapeutic Goods Administration to consider whether the applicant,

I/ \_\_\_\_\_, for a licence to manufacture therapeutic goods  
[NAME OF LICENCE APPLICANT]  
 (the Applicant), persons who participate in, or are likely to participate in, managing the Applicant's affairs (Applicant Managers) and persons who have, or are likely to have, effective control over the Applicant (Applicant Controllers) are fit and proper persons for the purposes of section 38 of the *Therapeutic Goods Act 1989*, an extract of which is attached as Appendix A to this application.

**Office use only**

Fee	<input type="text"/>
Client ID	<input type="text"/>
TGAIN	<input type="text"/>

I hereby certify that:

- (a) there has been no suspension or revocation of a manufacturing licence or conformity assessment certificate (however described) issued to:
  - (i) the Applicant, any Applicant Manager or Applicant Controller, or
  - (ii) any other person who controls the Applicant or any Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities), or
  - (iii) any other person controlled (either directly or indirectly through one or more interposed entities) by the Applicant or any Applicant Manager or Applicant Controller;
  
- (b) there has been no conviction for an offence against a law of the Commonwealth, a State or Territory against:
  - (i) the Applicant or any Applicant Manager or Applicant Controller, or
  - (ii) any other person who controls the Applicant or any Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities), or
  - (iii) any other person controlled (either directly or indirectly through one or more interposed entities) by the Applicant or any Applicant Manager or Applicant Controller;
  
- (c) there has been no failure to comply with a condition of a manufacturing licence or conformity assessment certificate (however described) by:
  - (i) the Applicant, any Applicant Manager or Applicant Controller, or
  - (ii) any other person who controls the Applicant or any Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities), or
  - (iii) any person controlled (either directly or indirectly through one or more interposed entities) by the Applicant or any Applicant Manager or Applicant Controller.

**A4** Persons signing the certification

Persons signing the certification should be the manufacturer, or the manufacturer's duly appointed agent. Where the manufacturer is a corporation, the declaration is to be signed by a Director of that company or the Company Secretary.

Name Your full name

Position Your role in the organisation, e.g. Owner, Director



## Section B. Location of Proposed Licensed Premises

- B1** **Street address** The actual street number and name, Suburb/Town, State/Territory and postcode to be used to identify the location of the manufacturing site.
- Postal address** This information is only required if the address the manufacturer wishes to use for quality system audit / licensing correspondence is different to the street address. The postal address may be either the street number and name or the Post Office Box.
- Telephone** The telephone number of the manufacturer, including the STD code.
- Fax number** The number of the transmission of facsimile correspondence including the STD code.

**B2** **Additional sites**

Manufacturing is defined as production of the goods or engaging in any part of the process of producing the goods or bringing the goods to their final state. This includes processing, assembling, packaging, labelling, storage, sterilising, testing or release for supply of the goods or of any component or ingredient.

A separate application is required in respect of each premise EXCEPT:

- (a) where parts or groups of buildings on one or more sites are engaged in making the same kind(s) of goods under the same direct production and quality control management;
- (b) where starting materials or work in progress is stored or where finished goods are temporarily stored before return to the warehouse area from which they are dispatched.

Premises means a structure, building, aircraft, vehicle or vessel or a place (whether enclosed or built upon or not) or a part of a thing referred to as a structure, building, aircraft, vehicle, vessel or place.





**C1** Product Details

<b>PRODUCT DETAILS</b> - Specify type of product to be manufactured, eg tablets, herbal tablets, capsules, cream, herbal extracts, condoms, gloves, etc	<b>Specify the steps</b> in manufacture that are conducted at this site, eg all steps in manufacture, packaging, release, manufacture of dosage form, etc	Sterile Yes/No
1. _____	_____ _____ _____	
2. _____	_____ _____ _____	
3. _____	_____ _____ _____	
4. _____	_____ _____ _____	
5. _____	_____ _____ _____	
6. _____	_____ _____ _____	
7. _____	_____ _____ _____	
8. _____	_____ _____ _____	



<b>PRODUCT DETAILS</b> - Specify type of product to be manufactured, eg tablets, herbal tablets, capsules, cream, herbal extracts, condoms, gloves, etc	<b>Specify the steps</b> in manufacture that are conducted at this site, eg all steps in manufacture, packaging, release, manufacture of dosage form, etc	Sterile Yes/No
9. _____	_____ _____ _____	
10. _____	_____ _____ _____	
11. _____	_____ _____ _____	
12. _____	_____ _____ _____	
13. _____	_____ _____ _____	
14. _____	_____ _____ _____	
15. _____	_____ _____ _____	
16. _____	_____ _____ _____	

**C2** Supplementary Information

Supplementary information may be provided for any relevant details that may influence the granting of a licence or any restrictions placed upon it.

**C3** Microdose Products

'Microdose Products' means solid dosage forms nominally containing less than 2mg or 2% w/w of an active ingredient per unit dose of the product except for multivitamin, trace mineral, homoeopathic and unscheduled herbal preparations.

Small volume parenterals - less than 100mL and

Large volume parenterals - 100mL or more.

'SUSDP' refers to the Standard for the Uniform Scheduling of Drugs and Poisons'

**C2** Supplementary Information

Please state any additional information relevant to the issuing of a licence:


**C3** Please state whether manufacture (whether for human, animal or any other purpose) includes:

- Penicillins
- Cephalosporins
- Other antibiotics
- Biological products
- Medicine/device combination (primary purpose-medicine)
- Large volume parenterals
- Small volume parenterals
- Other sterile dose forms
- Cytotoxic medicines
- Microdose Products
- Hormones or Steroids
- Medicines to which any schedule of the SUSDP applies

State which schedules

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Please state therapeutic and other goods (e.g. veterinary products, food products, cosmetics) to be manufactured at the same premises and which do not require a licence to manufacture under the *Therapeutic Goods Act 1989*.


## Section D. Sub-manufacturer Details

### **D3** Lists of manufacturers/sponsors

Lists of manufacturers/sponsors are not required where the manufacturer is engaged principally in work for others and has a variable clientele/products range.

**D1** Product or stages of manufacture (excluding testing) which are to be contracted to another manufacturer

Product/Stage	Manufacturer	Address

**D2** Testing which is to be contracted to another manufacturer

Nature of tests	Name of Testing laboratory/Service	Address

**D3** Products or stages of manufacture (including testing) which are to be made or performed for another manufacturer/sponsor

Product/Stage	Manufacturer/Sponsor	Address

## Section E. Nomination of Persons Having Control

### **E1** Person who will have control of production of the goods

The Act requires that the applicant must identify the persons who will have and maintain control of the production of the goods. The Regulations to the Act require that changes be notified promptly to the Therapeutic Goods Administration.

### **E2** Relevant Qualifications

Relevant qualifications are those relevant to the manufacture of therapeutic goods including those in related sciences and management.

### **E3** Relevant Experience

Relevant experience is that relevant to the manufacture (including quality management) of therapeutic goods or products involving comparable good manufacturing practice or experience which the applicant believes should be taken into consideration as relevant.

### **E4** Person who is in control of Quality Control/Assurance measures for the manufacture of the goods

The Act requires that the applicant must identify the persons who will have and maintain control of the production of the goods. The Regulations to the Act require that changes be notified promptly to the Therapeutic Goods Administration.

### **E5** Relevant Qualifications

Relevant qualifications are those relevant to the manufacture of therapeutic goods including those in related sciences and management.

### **E6** Relevant Experience

Relevant experience is that relevant to the manufacture (including quality management) of therapeutic goods or products involving comparable good manufacturing practice or experience which the applicant believes should be taken into consideration as relevant.

**E1** Person who will have control of production of the goods

Surname	Given names	Position in Company

**E2** Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

**E3** Relevant experience (last job first)

Number of years	Employer	Position held

**E4** Person who is in control of Quality Control/Assurance measures for the manufacture of the goods

Surname	Given names	Position in Company

**E5** Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

**E6** Relevant experience (last job first)

Number of years	Employer	Position held

## Section F. Additional Information

### **F1** Date of audit

Before a licence is issued, the Manufacturer Assessment Section (MAS) will conduct an audit of your company's manufacturing operations to assess conformity with the Manufacturing Principles determined under the Act. In order to schedule an audit the applicant should indicate an approximate date from which they will be ready for an audit. If this date changes after the application is submitted, the MAS should be notified as soon as possible.

### **F2** Site Master File/Technical Master File/Quality Manual

Part of the reporting aspects of the audit can be addressed by receiving information on related company details, e.g. details of the company's facilities, personnel structure and operating procedures including manufacturing activities, prior to audit. It is expected that this information be prepared by the auditee in the form of a Site Master File for a medicine manufacturer, a Technical Master File for a blood/blood components and haematopoietic progenitor cells manufacturer, or a Quality Manual for a therapeutic device or other therapeutic good manufacturer.

Explanatory notes and guidelines for the preparation of a Site Master File and a Technical Master File are available on the TGA website at <http://www.tga.gov.au>.

A Technical Master File and a copy of this licence application must be forwarded to the address below at the same time that the original of this form and payment are forwarded to the Financial Services Group as specified on the front cover.

For a Site Master File or a Quality Manual that is not submitted with this licence application, please forward it to the address below as soon as possible.

Application Entry and Coordination Section  
Office of Devices, Blood and Tissues  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
Australia

or delivered by courier to:

Application Entry and Coordination Section  
Office of Devices, Blood and Tissues  
Therapeutic Goods Administration  
136 Narrabundah Lane  
Symonston, Canberra, ACT 2609

For further information or queries regarding this application contact 02 6232 8629

## Section F. Additional Information

F1 Approximate date when ready for audit

 /  / 

F2 Site Master File/Technical Master File/Quality Manual

Site Master File      Enclosed       To be forwarded

Technical Master File      Enclosed

Quality Manual      Enclosed       To be forwarded

**Note:**

- Before a pre-licence audit is conducted, medicine manufacturers must submit a Site Master File for review.
- A manufacturer of blood, blood components and haematopoietic progenitor cells must lodge a Technical Master File with a licence application.

Please provide an estimate of the time taken to complete this form

***Include***

- The time actually spent reading the instructions, working on the question and obtaining the information
- The time spent by all employees in collecting and providing this information

hrs

mins

# Appendix A

*Extract from Therapeutic Goods Act 1989*

## Section 38 Grant of licence

(1) Where:

- (a) a person has made an application to carry out steps in the manufacture of therapeutic goods at particular manufacturing premises; and
- (b) the prescribed application fee has been paid; and
- (c) any applicable prescribed inspection fees have been paid; and
- (d) the applicant has complied with any requirements made by the Secretary under subsection 37(2) in relation to the application;

the Secretary must grant the applicant a licence to carry out those steps at those premises unless the Secretary is satisfied that:

- (e) the applicant will be unable to comply with the manufacturing principles; or
  - (f) the premises are not satisfactory for the manufacture of the goods; or
  - (g) the applicant is not a fit and proper person to hold a licence; or
  - (h) a person who is participating in, or is likely to participate in, managing the applicant's affairs is not a fit and proper person to participate in the management of the affairs of a holder of a licence; or
  - (i) a person who has, or is likely to have, effective control over the applicant is not a fit and proper person to have effective control over a holder of a licence.
- (1A) Without limiting the matters to which the Secretary may have regard in considering whether the applicant or person is not a fit and proper person for the purposes of paragraph (1)(g), (h) or (i), the Secretary must have regard to:
- (a) any suspension or revocation of a manufacturing licence granted to:
    - (i) the applicant or person; or
    - (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities); or
    - (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time of the suspension or revocation; or
  - (b) any conviction, for an offence against a law of the Commonwealth or a law of a State or Territory, against:
    - (i) the applicant or person; or
    - (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities); or
    - (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time the offence was committed or the time of the conviction; or
  - (c) any failure to comply with a condition of a manufacturing licence by:
    - (i) the applicant or person; or
    - (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities); or
    - (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time of the failure.

(1B) In subsection (1A):

*manufacturing licence* means:

- (a) a licence granted under this Part; or
- (b) a licence, granted under a law of a State or Territory relating to therapeutic goods, relating to manufacturing therapeutic goods.

## Section 41 Revocation and suspension of licences

- (1) Subject to subsection (2), the Secretary may, by notice in writing given to the holder of a licence, revoke the licence, or suspend the licence for a period specified in the notice, if:
- (a) the holder has been convicted of an offence against this Act; or
  - (aa) the holder controls another person (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
  - (ab) the holder controlled another person (whether directly, or indirectly through one or more interposed entities) when the other person committed an offence against this Act or a law of a State or Territory relating to therapeutic goods, and the other person has been convicted of that offence; or
  - (ac) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
  - (b) the holder has breached a condition of the licence; or
  - (c) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has breached a condition of a licence; or
  - (ca) the holder controls another person (whether directly, or indirectly through one or more interposed entities) and that other person has, while controlled by the holder, breached a condition of a licence; or
  - (cb) the holder is not a fit and proper person to hold a licence; or
  - (cc) a person who is participating in managing the holder's affairs is not a fit and proper person to participate in the management of the affairs of a holder of a licence; or
  - (cd) a person who has effective control over the holder is not a fit and proper person to have effective control over a holder of a licence; or
  - (d) the holder requests in writing that the licence be revoked or suspended, as the case may be; or
  - (e) the holder ceases to carry on the business of manufacturing the goods to which the licence relates; or
  - (f) the annual licensing charge, or any applicable prescribed inspection fees, have not been paid within 28 days after they become payable; or
  - (g) the goods are exempt under section 18A and the holder has breached a condition of the exemption in relation to those goods.
- (1A) Without limiting the matters to which the Secretary may have regard in considering whether the holder or another person is not a fit and proper person for the purposes of paragraph (1)(cb), (cc) or (cd), the Secretary must have regard to the matters set out in paragraphs 38(1A)(a), (b) and (c).
- (2) Where the Secretary proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Secretary must, unless the Secretary considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury:
- (a) by notice in writing given to the holder, inform the holder of the action that the Secretary proposes to take and of the reasons for that proposed action; and
  - (b) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable prescribed inspection fee—give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Secretary in relation to the proposed action.
- (3) Where the holder makes submissions in accordance with paragraph (2)(b), the Secretary is not to make a decision relating to the revocation or suspension of the licence before taking into account the submissions.
- (4) A licence may be revoked notwithstanding that the licence is suspended.
- (5) Where a licence is suspended, the Secretary may, by notice in writing given to the holder of the licence, revoke the suspension.
- (6) Where the Secretary revokes or suspends a licence, the Secretary must cause particulars of the decision to be published in the Gazette as soon as is practicable after the decision is made.