Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device Requirements Version 4

under the Therapeutic Goods Act 1989

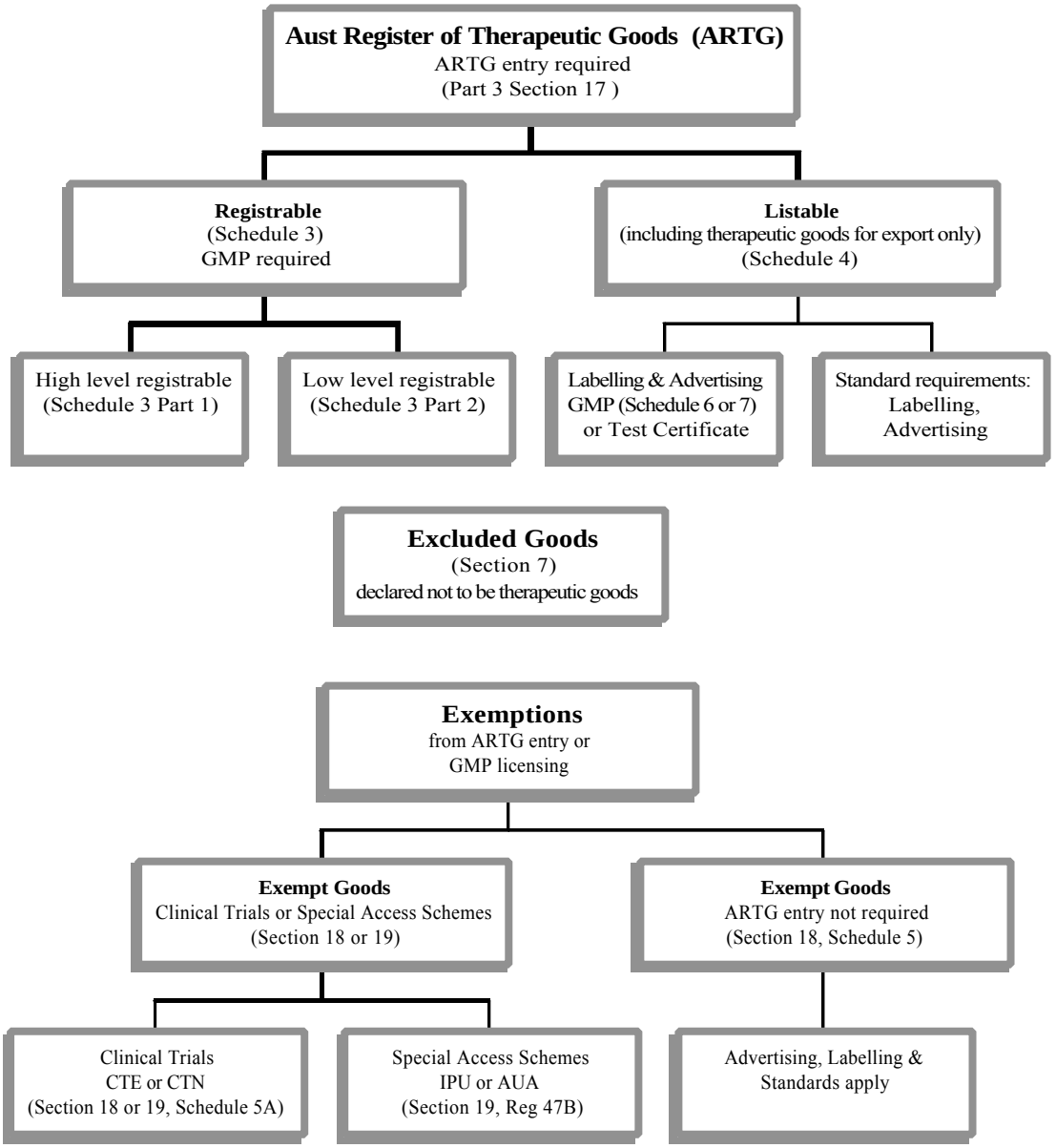
May 1998
Volume 1 of 2

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

Figure 1 Categorisation of Goods under the *Therapeutic Goods Act 1989*



Sections refer to *Therapeutic Goods Act 1989*
Schedules refer to *Therapeutic Goods Regulations*

The *Therapeutic Goods Act 1989*, and *Therapeutic Goods Regulations* and Therapeutic Goods Orders may be obtained from Government Info Shops
ph: 13 2447
web site http://www.agps.gov.au

1.1 INTRODUCTION

The *Therapeutic Goods Act 1989* (the Act) provides the legislative basis for uniform national controls over goods used in the prevention, diagnosis, curing, or alleviation of a disease, ailment, defect or injury. The Act applies to goods which are 'likely to be taken to be' for therapeutic use because of the way they are presented or advertised. Unless specifically excluded or exempt, therapeutic goods may not be supplied to the Australian market or exported unless included in the Australian Register of Therapeutic Goods (ARTG).

The Therapeutic Goods Administration (TGA) is the Division of the Department of Health and Family Services responsible for administering the Act

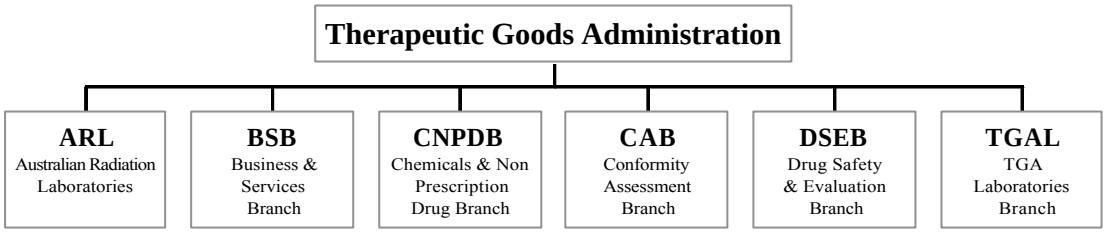


Figure 2 Branches of the Therapeutic Goods Administration

The Conformity Assessment Branch (CAB) is responsible for the regulation of therapeutic devices under the Act. The types of therapeutic devices which are required to be entered into the ARTG or are exempted from this requirement are defined in the Regulations to the Act and Orders made under the Act.

Interpretations of terms used in this document may be found in the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations*, the *Therapeutic Goods (Charges) Act 1989* and the glossary of this document.

What is a therapeutic device?

The term therapeutic device applies to devices or components of devices that are represented in any way to be, or are likely to be taken to be, for use in, or in connection with:

- preventing diagnosing, curing or alleviating a disease, ailment defect or injury in persons or animals; or
- influencing, inhibiting or modifying a physiological process in persons or animals; or
- testing the susceptibility of persons or animals to a disease or ailment; or
- influencing, controlling or preventing conception in persons; or
- testing for pregnancy in persons; or
- the replacement or modification of parts of the anatomies of persons or animals;

unless they achieve their principal intended action by pharmacological, chemical, immunological or metabolic means, though they may be assisted by such means.

Who is affected?

If therapeutic devices are imported, exported or manufactured, a sponsor must list or register the devices in the Australian Register of Therapeutic Goods (ARTG) before they can legally be supplied in Australia or exported from Australia. The TGA monitors products being supplied in a number of ways and those who intentionally contravene the Act are liable to prosecution.

Australian Register of Therapeutic Goods (ARTG)

The ARTG is a register of information about therapeutic goods for human use that may be imported, supplied in, or exported from, Australia (unless the goods are exempt from inclusion in the ARTG or are given specific approval for a special purpose under the legislation).

Therapeutic goods (both drugs and devices) are categorised, for the purposes of the Act, as one of the following:

- **Excluded**
- **Exempt**
- **Registrable** or
- **Listable**.

Sponsors should determine in the first instance if their product is an *Excluded* good, and therefore not regulated by the TGA. If this category is not applicable, sponsors should determine whether the product is a drug or a device and which branch of the TGA is responsible for assessment of the product. The control of prescription drug products is administered through the Drug Safety and Evaluation Branch (DSEB). Other types of drugs, vitamins, herbal preparations etc. are under the control of the Chemical and Non-Prescription Drug Branch (CNPDB) of the TGA. A summary of some therapeutic goods and their classifications according to the Act is given in Table 1.1.

All therapeutic devices must comply with the Therapeutic Goods Order for labelling (Appendix 16, *TGO 37 Labelling*), any other applicable TGOs and sections 4 & 7 of the *Therapeutic Goods Advertising Code* (see Appendix 1).

Products for export only

Therapeutic goods that are not supplied in Australia and are intended only for export are required to be listed in the ARTG before the goods can be exported. Export-only goods must comply with all relevant standards, except TGO 37 *Requirements for Labelling for Therapeutic Devices* (see Appendix 16). The listing application fee applies although annual charges are not levied for these products. Refer to Chapter 1.5 *Export of Therapeutic Devices.*

Devices declared to be drugs

Where the composition of a medical device includes a component which exacts its effect through pharmaceutical action, the devices are declared to be drugs under the Act and the evaluation of the product is performed by the Drug Safety and Evaluation Branch (DSEB) of the TGA. The full list may be found in the *Therapeutic Goods (Goods that are Not Therapeutic Devices) Order No 1 of 1992*.

Summary of the Categories of Therapeutic Goods under the Act

Excluded Devices

Some products which may have a therapeutic use are not regarded as therapeutic goods for the purposes of the Act. The *Therapeutic Goods (Excluded Goods) Order No 1 of 1992* provides a list of these types of products. Sponsors should contact the TGA for advice on the interpretation of this Order and the effect it would have on their products.

Exempt Goods

Therapeutic goods which are exempted from the requirements for registration or listing are specified in Schedule 5 & 5A of the *Therapeutic Goods Regulations*. These products are not required to be entered in the ARTG, but are still required to comply with labelling requirements, relevant standards and the advertising provisions of the Act.

Registrable Devices

Therapeutic devices which are required to be registered are specified in Schedule 3 of the *Therapeutic Goods Regulations. Sponsors* are required to submit data to establish the quality, safety and efficacy of their device for review by the TGA prior to the entry in the ARTG. Within the registrable category is a group of products incurring lower application and evaluation fees which reflect their different requirements for premarket assessment. Application and evaluation fees as well as annual charges apply to all registrable devices

Listable Devices

Therapeutic devices which are not required to be registered, or are not excluded or exempted, are required to be **listed** in the ARTG. Test certificates and/or acceptable evidence of Good Manufacturing Practice (GMP) are also required for some products. Application fees and annual charges apply to listable devices.

Clinical trials & *Special Access Schemes (SAS)*

Experimental or unapproved medical devices used in clinical trials are subject to either the Clinical Trial Exemption (CTE) or Clinical Trial Notification (CTN) requirements.The Individual Patient Use (IPU) and Authorised User Access (AUA) schemes allow access to unapproved medical devices, subject to approval, where there is a special patient need. Refer Chapter 1.24 *Access to Unapproved Devices.*

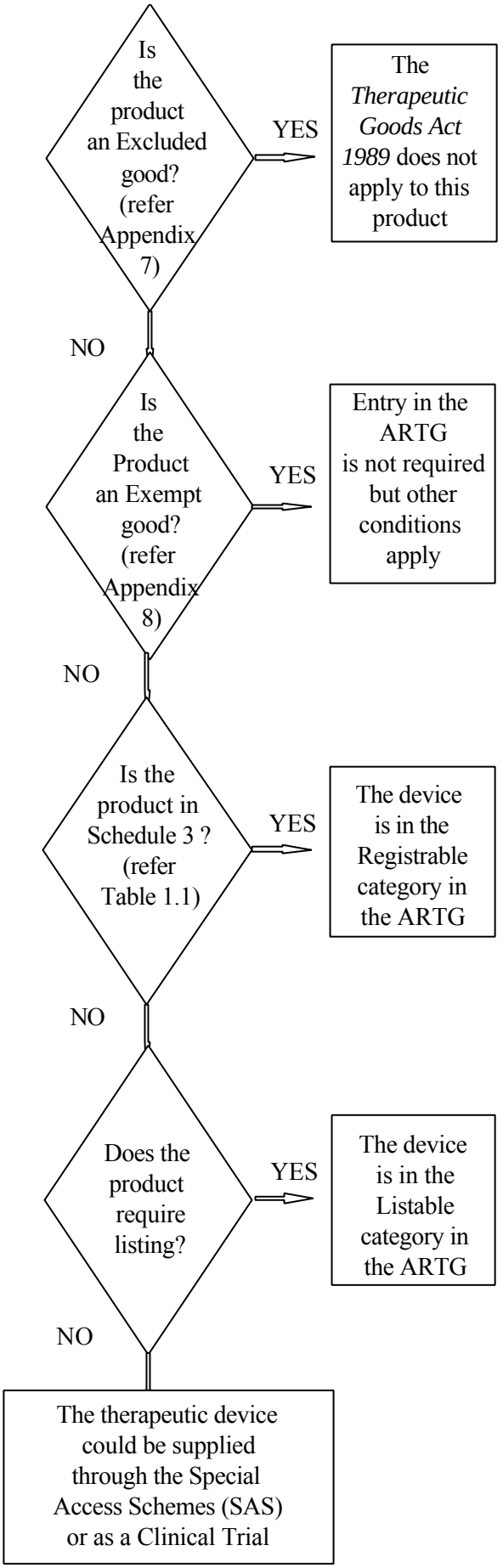


Table 1.1

EXAMPLES of therapeutic goods and their classifications according to the Act

If your product is not
Excluded,
Exempt,
or
Registrable
then it is
LISTABLE
in the
Aust Register of Therapeutic Goods (ARTG)

(the Listable category also includes all therapeutic devices intended for **Export only**)

* *Summary only, refer to schedules 3, 4, & 5 and the Excluded Goods Order for complete details, or the Appendixes of this document for extracts applicable to devices.*

EXCLUDED

Accupoint stimulators (non invasive)
Aids to physical comfort
Apparel non-sterile, health/protective/safety for home, recreation or occupation
Aromatherapy devices
Audio therapy devices
Breathalysers and blood alcohol equipment
Colour therapy devices
Cosmetics without therapeutic claims
Dental chewing gum (unmedicated)
Dental whiteners and bleaches
Denture adhesives and aids
Depilatory preparations (dermal)
Deodorants (dermal or with therapeutic devices)
Electric blankets
Fitness equipment excluding physiotherapy
Furniture, utensils or personal aids for the disabled
Hair dyes, colourants, perms, bleaches
Hair growth stimulators
Heat therapy devices
Household and personal aids for the disabled
Incontinence pads
Jewellery with reputed remedial powers but no therapeutic claims
Lipstick and facial make-up (not moisturisers), tinted with sunscreen as secondary component
Magnetic therapy devices
Massagers
Menstrual pads, but not tampons
Moisturisers, emollients, cleansers and barrier products, not for dispensing
Muscle stimulators (electric) for cosmetic purposes
Nail hardeners, nail biting deterrent products
Nitrogen as a power source
Oral hygiene products unscheduled with restricted claims
Ostomy aids (i.e. adhesive removers and non-medicated cleansers)
Sanitation, environmental control, detoxification equipment (not negative ion generator or humidifier)
Slimming devices
Solaria and sun lamps
Spa baths and saunas
Soaps and detergents, unmedicated
Spa and mineral waters, with no therapeutic claims
Sterilant gases
Sunglasses, non-prescription spectacles
Sunscreens (as a secondary purpose with no claimed SPF)
Tissues, human, for direct donor-to-host transplant
Vibrators
Water purification/treatment/fluoridation equipment
Wigs and other non-implantable aids

Table 1.1 cont.

EXEMPT

* Advertising and Labelling requirements apply to Exempt Goods

Clothing, non-sterile, except gloves, radiation shields and shielding apparel
Goods for approved or notified clinical trials
Goods given special access for individual patients
Communications equipment (not monitoring etc.)
Components (other than separate accessories or consumables, artificial limb components, programmers for electronic implants)
Containers (except syringes, solution bags and blood collection tubes)
Dental devices fabricated outside the mouth
Dental impression materials
Diagnostic tools and instruments X non-powered, non-sterile
Disinfectants X Household/Commercial grade (with no specific claims)
Exports X non-commercial (not for clinical trials)
Extemporaneous products (one-off or custom-made devices)
Hot and cold packs
Imported devices (prior to 15.2.91 and still used for treatment)
Imports pending approval for supply or remaining in customs control (e.g. Bond Store prior to re-export)
In vitro diagnostics (except Pharmaceutical Benefits; goods of human origin, intended for home use, HIV or HCV diagnosis)
Linen and bedding X non-sterile
Manufacturing, laboratory and dispensary equipment not for recycling human blood or tissue
Medicine dispensers, manual use
Furniture & equipment X non-powered for general patient care
Medical & dental instruments X non-powered, non-sterile (except cannulae, endoscopes etc.)
Orthoses and splints (simple)
Personal use imports X most (if in small quantities or for visiting sports teams)
Samples not for human use
Tissue, human, for transplantation (stored and not further altered)

REGISTRABLE

Active implantable medical devices e.g.
- Implantable cardiac pacing systems
- Implantable pacing leads etc.

Breast prostheses (implantable)
Contraceptive barrier devices X (where no standard is available)
Devices of human or animal origin
Disinfectants
- Hospital grade with specific claims
- Household/Commercial grade
- Instrument grade

Heart valves
HIV & HCV in vitro diagnostic kits
Intraocular fluids
Intraocular lenses (except approved posterior chamber PMMA)
Intra-uterine contraceptive devices
Drug infusion systems X powered (except some simple pumps)
Sterilants

DECLARED TO BE DRUGS

Antiseptics
Transdermal patches
Contraceptives, intra-uterine, containing hormones
Blood components, substitutes and expanders
Diagnostics, in vivo, including imaging agents
Demulcents and absorbents, ingested
Dialysis solutions
Enemas, douches, laxatives and irrigation fluids, unmedicated
Emollient/moisturising products for dispensing
Homoeopathic preparations
Medical gases and chemical oxygen generators
Saline, water for irrigation or injection (excluding that for contact lenses and for device inflation)
Spermicidal and viricidal sponges and membranes
Sunscreen preparations

Further Information
Chapter 1.8 *Application Procedures* contains details of the information required to be submitted for application for entry in the ARTG.

General information and TGA publications including the *Australian Therapeutic Devices Bulletin*, may be obtained from the TGA Publications Office.

TGA Publications Office
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 1 800 020 653
fax: 02 6232 8605.
web site: http://www.health.gov.au/tga
email: tga-information-officer@health.gov.au

The *Therapeutic Goods Act 1989*, and *Therapeutic Goods Regulations* and Therapeutic Goods Orders may be obtained from
Government Info Shops
ph: 13 2447
web site http://www.agps.gov.au

Australian and International Standards:
Standards Australia
National Sales Centre
ph: 1800 029 955 or
02 9746 4600
web site http://www.standards.com.au
email: sales@standards.com.au

Full addresses and a list of applicable TGOs can be found in Appendix 13, *Therapeutic Goods Orders and Standards*.

1.2 PARALLEL IMPORTING - 'UNAUTHORISED' DISTRIBUTORS

Parallel importing is the importation and/or supply of authentic products from the same manufacturer by a number of different suppliers. In the case of therapeutic goods there is no provision under the *Therapeutic Goods Act 1989* to prevent the supply of therapeutic goods by multiple sponsors provided the goods are entered in the ARTG by each sponsor. The TGA is not empowered to intervene in the relationship between commercial entities and enforce or support distribution or exclusive agency agreements and the practice of parallel importing is not considered by the TGA to be 'unauthorised distribution'.

An important function of the ARTG is the capacity to identify all suppliers of a particular product in the event of a problem. If a product recall is necessary all sponsors of that product appearing in the ARTG will be contacted by the TGA.

If, however, sponsors have reason to believe that therapeutic goods that are not listed or registered on the ARTG are being supplied they should contact the Surveillance Unit of the TGA. Refer to Chapter 1.23 *Penalties and Cancellations.*

1.3 PERSONAL IMPORTATION & DIRECT MARKETING

The Act prohibits the importation of therapeutic goods that are not entered in the ARTG unless these goods are intended for use by the individual or members of their immediate family. This applies equally to medical practitioners and health professionals.

While the Commonwealth of Australia has no jurisdiction under the Act to control the activities of overseas companies using direct marketing or mail order, their Australian customers will be in breach of the Act if they import and use unlisted or unregistered therapeutic goods on persons other than themselves or their immediate family.

Advertising
Publishers should be aware that under Regulation 6 (1) of the *Therapeutic Goods Regulations*, it is an offence for a person to publish an advertisement about goods for therapeutic use that are not registered or listed, unless the goods are exempt goods other than goods of a kind mentioned in Schedule 5. Companies operating outside Australia who advertise the availability of therapeutic goods through publications that are circulated in Australia are requested to include the following warning statement in the advertising:

THE SAFETY, EFFICACY OR QUALITY OF THESE PRODUCTS HAVE NOT BEEN ESTABLISHED BY THE THERAPEUTIC GOODS ADMINISTRATION.

SUPPLY OF THESE PRODUCTS BY THE IMPORTER TO PERSONS OUTSIDE THE IMPORTER'S IMMEDIATE FAMILY IS ILLEGAL.

USE OF THE PRODUCTS IS UNDERTAKEN AT YOUR OWN RISK.

The warning must appear in all material promoting unlisted or unregistered therapeutic goods available by mail order from Australia, including:

- all advertisements promoting the goods,
- all catalogue(s) and brochures depicting the goods,
- all of the actual goods or the packaging or labelling accompanying the goods.

Refer also to Chapter 1.14 *Advertising / Promotion* and Appendix 8, *Exempt Goods.*

1.4 QUARANTINE REQUIREMENTS - AQIS

Chapter 2.10 *Animal Origin Devices* and Chapter 2.15 *Human Origin Devices* alert sponsors to the infectivity potential of tissue-based products, and identify issues that are considered significant contributory factors in determining the clinical safety of the finished product. Schedule 3 Item 3(g) of the *Therapeutic Goods Regulations* stipulates that devices of human or animal origin for use in or on the body of a person are to be included in the ARTG as registered devices. There are, however, some exemptions from this clause of the Regulations including devices which

- are manufactured using animal-derived waxes; or
- incorporate heparin, unless heparin is being delivered as a drug; or
- are sutures conforming to a standard determined under Part 2 of the Act; or
- are made from sintered hydroxyapatite; or
- incorporate gelatin that conforms to generally accepted pharmacopoeial standards.

Devices consisting of, or containing, the above materials may be entered in the ARTG as **listed** goods. Sponsors of sutures, or products which incorporate heparin or gelatin, are required to include details of material source and production of these materials in the application for listing. Refer to Chapter 3.3 *Animal Derivatives Contained in Listed Devices*.

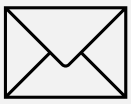
AQIS requirements

The approval of the Australian Quarantine and Inspection Service (AQIS) of the Department of Primary Industries and Energy (DPIE), is required before the importation of most therapeutic goods which contain human, animal or plant material.

AQIS defines biological material as any products of animal and or microbiological origin. These include

- products which contain material components sourced from micro-organisms,
- cell lines and hybridomas,
- serum,
- antiserum,
- enzymes,
- hormones,
- antibodies,
- toxins,
- toxoids,
- tissues or tissue extracts,
- secretions or exudates,
- blood and blood components,
- cell or microbiological culture media,
- microbial fermentation products,
- microbial extracts,
- microbial components.

The importation of these materials generally requires a 'Permit to Import Quarantine Material' issued by AQIS. However, for AQIS purposes, tissues (including organs) or fluids (including blood, serum, plasma, semen and urine) of solely human origin (excluding faeces and cell lines) which are clearly labelled or certified as such, do not require a Permit. The use of this human origin material is controlled by the TGA.



Australian Quarantine and Inspection Service (AQIS)
Department of Primary Industries and Energy (DPIE)
GPO Box 858
CANBERRA ACT 2601

ph: 02 6272 4578
fax:: 02 6273 2097
web site: http://www.webmaster@dpie.go v.au

1.5 EXPORT OF THERAPEUTIC DEVICES

Export-only products

Unless exempt, therapeutic goods which are intended for export and not for supply in Australia must be **listed** in the ARTG before being exported. An application fee is charged for listing export-only goods in the ARTG, but there is no annual charge for maintaining these listings.

Exported goods are required to comply with standards applicable to the goods in Australia but are not required to comply with statutory standards related to the labelling of goods supplied in Australia. Where the TGA has concerns about these goods, particularly in relation to safety prior to listing, evidence of informed consent by the regulatory authorities of the receiving country may be sought by the TGA as a condition of listing the goods in the ARTG.

Export certification scheme

The TGA may issue export certificates for goods for therapeutic use in humans, including certificates for the purposes of the World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. While there is no formal international agreement for therapeutic devices, some countries require certification from Australian exporters before allowing importation of the goods. The export certification will only be issued in relation to licensed manufacturers or manufacturers who have been subject to a GMP audit.

Before a certificate is issued by the TGA, the following information is required:

- sponsor,
- manufacturer, including any sub-manufacturers,
- country requesting the certification,
- identity of the product proposed for export, and
- AUST L or AUST R number, or a statement that the good is exempt.

Applications for export certificates should be made in writing using the prescribed form, *Application for Export Certification of a Therapeutic Device,* available from the TGA Publications Office. Please also refer to the current schedule of Fees & Charges (Appendices).

Under Section 58 of the *Therapeutic Goods Act 1989* the TGA may issue two types of Export Certificate, a 'Certificate of Free Sale' and an 'Export Certificate'.

Certificate of Free Sale

A Certificate of Free Sale applies to products that are NOT required to be manufactured on TGA licenced premises. A Certificate of Free Sale will be issued for products in one or more of the following categories:

- therapeutic devices manufactured in Australia which are not required to be manufactured on licensed premises (e.g. most non-sterile devices);
- therapeutic devices manufactured overseas.

Each original certificate
- applies only to the country of importation specified,
- is subject to an application fee (refer to Appendix 9, *Fees and Charges*).

There is no limit to the number of products which can appear on one certificate.

Exporters of products that are excluded goods or goods that are not considered to be therapeutic devices in Australia are advised to contact their state Chamber of Commerce which may be able to assist with a 'Certificate of Origin'. In such circumstances TGA may, if required, issue a statement that the goods are not regulated under the *Therapeutic Goods Act 1989*.

Export Certificate

An Export Certificate applies to products that are required to be manufactured on TGA licenced premises. A Certificate of Free Sale will NOT be issued for such products.

Each original certificate
- is made out to one specified country;
- is subject to an application fee (refer to Appendix 9, *Fees and Charges*);
- states that the product has been manufactured in accordance with *Good Manufacturing Practice (GMP)* and includes inspection details;
- can be issued for all goods which are manufactured at the same licensed site;
- is issued with one set of certified attachments.

Products that are not entered in the ARTG cannot be given Export Certificates or Certificates of Free Sale, except those goods exempt from registration/listing which can be issued with Certificates of Free Sale. The certificate issued by the TGA may also need to be endorsed by the Department of Foreign Affairs and Trade and authorised by the Embassy or Consulate of the importing country. The agent in the importing country should be able to provide advice if this is required.

Registration and International Liaison Section
Conformity Assessment Branch, TGA
Ph: 02 6232 8676
Fax: 02 6232 8687

Please also refer to Chapter 1.19 *Good Manufacturing Practice*

1.6 POSTMARKET COMPLIANCE PROGRAMS

The TGA operates a number of postmarket compliance programs to monitor device performance in use, and to ensure sponsors comply with the reporting and record keeping responsibilities imposed under the *Therapeutic Goods Act 1989.*

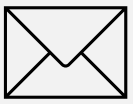
Incident Reporting Scheme

The Incident Reporting Scheme is the focal point of the postmarket compliance programs. The aim of the scheme is to monitor and investigate the causes and occurrences of incidents and possible adverse effects. The Scheme can also help prevent continued device problems.

The *Therapeutic Goods Act 1989* requires some events to be reported. It is a condition of registration or listing that a sponsor advise the TGA of all deaths, serious illness or serious injuries arising from or attributable in some way to the use or application of a device, as soon as possible after they become aware of the incident.

Under the Scheme, the TGA collates and examines reports of adverse incidents, deficiencies or matters of concern related to the use of therapeutic devices which may create a hazard, or place the patient or user at risk. Examples from such reports include compromised sterility, packaging or labelling defects, incomplete instructions, defective components, poor construction or design, and equipment malfunctions.

Reports for the Incident Reporting Scheme can be supplied to the Medical Devices Section of the TGA either on a pre-printed reporting form or on plain paper, and sent directly to:



Incident Reporting & Investigation Scheme
Medical Devices Section
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 1 800 809 361
fax: 02 6232 8785

Compliance Testing

If a therapeutic device is included in the ARTG because

- it complies with a Therapeutic Goods Order or other Standard, or
- the device sponsor has batch testing data or certification available to demonstrate that the devices supplied, either currently or in the past, are in compliance with the required Standard,

a number of the devices will be subject to random sampling and compliance testing by the Biomaterials and Engineering Section of the TGA Laboratories (TGAL).

Samples may be drawn from sponsors at any time for evaluation and testing for compliance with the appropriate standard.

Overseas Regulatory Action

Where therapeutic goods are distributed overseas as well as in Australia, it is a **mandatory** condition of listing or registration that a sponsor notify the TGA of any product recall or any regulatory action taken in relation to the goods outside Australia. This condition applies whether the goods are manufactured in Australia or imported.

Postmarket Audit Programs

A number of other postmarket audit programs are undertaken to check

- distribution records;
- the traceability of raw materials used in the manufacture of therapeutic goods;
- the tracking of component parts; and
- compliance with GMP for selected goods.

Further, listing a therapeutic device in the ARTG requires sponsors to make a number of declarations relating to the goods, based on the sponsor having documentary evidence on file to substantiate those declarations. That evidence is not examined by the TGA at the time of listing, but can be reviewed at a later date.

1.7 RECALLS

The failure of a therapeutic device to function as intended may result in misdiagnosis and subsequent incorrect or delayed treatment. Consequences to patients may be serious or life threatening. When deficiencies are identified in the quality, efficacy or safety of a therapeutic device, the appropriate action is to recall the product from the market place. The *Uniform Recall Procedure for Therapeutic Goods* has been agreed between the therapeutic goods industry, Commonwealth, state and territory health authorities, the Federal Bureau of Consumer Affairs, and consumer representatives appropriate to the specialised requirements for the recall of therapeutic goods. Both the Commonwealth *Trade Practices Act 1974* Sections 65R and 65F(7), and the *Therapeutic Goods Act 1989* Sections 30, 30A and 30B, contain powers in relation to recalls. When a recall action is proposed by a company, or advised from overseas, sponsors should immediately inform the TGA Recalls Coordinator prior to despatching recall letters to customers.

Recalls Coordinator
Secretariat & Recalls Section
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8636
fax: 02 6232 8659

Sponsors are directed to the current edition of the TGA publication *Uniform Recall Procedure for Therapeutic Goods* available from TGA Publications Office. This booklet gives detailed instructions on actions to be taken by sponsors when therapeutic goods are to be removed from supply for any reason.

Publications Office
Business and Services Branch, TGA
MDP 122
PO Box 100,
WODEN, ACT 2606

ph: 1 800 020 653
fax: 02 6232 8605

1.8 APPLICATION PROCEDURES

Therapeutic Devices Application Form

An application must be completed for each product to be entered in the ARTG. The attachment, Appendix 2, must be accurately completed for the application to be processed. It may be used to register or list a new therapeutic device, to add another listing or registration, or to vary information for an existing listing or registration.

Applications are acknowledged by the TGA Business Management Unit (BMU) and assigned a TGAIN (Therapeutic Goods Application Identification Number), which should be quoted in subsequent inquiries about the application.

Enquiries concerning the status of applications should be directed to:

Device Listing Enquiries
ph: 02 6232 8686

Device Registration Enquiries
ph: 02 6232 8777

The specific information required for specific devices is set out in the appropriate Chapter for the device. Reference should also be made to Chapter 1.9 *Reducing Annual Charges*, and Appendix 2, *Therapeutic Devices Application / Enterprise Details form*.

Enterprise Details Form

TGA maintains an ENTERPRISE database, in conjunction with the ARTG, which records current company details and identifies *Authorised Persons* able to make applications or request information from the TGA on the company's behalf. Sponsors must submit an *Enterprise Details* form

- when lodging an application for the first time, or
- if company details change, or
- if *Authorised Persons* have changed.

An Enterprise Identification number (ENTID) is allocated for all sponsors and manufacturers. Failure by sponsors to provide the TGA with current Enterprise details may result in applications being rejected.

If you are not aware of your Enterprise Identification number please contact the Operations Manager, ARTG for advice.

Operations Manager, ARTG
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph 02 6232 8590
fax: 02 6232 8581

Claims for exemption from registration for clinical trial purposes

Refer to Chapter 1.24 *Access To Unapproved Devices* for the requirements for exemption from registration/listing for clinical trial purposes.

Evaluation of *Grandfathered* Devices

Where a *grandfathered* device is subsequently subject to review to determine the continuation of its ARTG status, the evaluation fees (if applicable) are payable as for new therapeutic devices.

Registrable Device Applications

The devices which are required to be registered are specified in Schedule 3 of the *Regulations*. Depending on the history of the product in other markets and the relationships with similar marketed devices in Australia, there are three evaluation routes available to sponsors who wish to obtain registration for a device proposed for supply in Australia:

- full evaluation,
- partial evaluation based on claims of equivalence, or
- consideration by another regulatory authority.

Sponsors are advised to contact the Manager, Registrable Devices Unit, to arrange a pre-submission meeting in order to determine the information that should be provided.

The submission is assessed and additional information may be requested if required. The sponsor must:

- complete the *Therapeutic Devices Application* form
- complete the *Enterprise Details* form,
- attach the application fee.

Cheques are to be made payable to the Therapeutic Goods Administration, Application fees are non refundable.

- Forward the original *Therapeutic Devices Application* form,
  Enterprise Details form and
  application fee to:

Business Manager
Business Management Unit
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

- Forward a copy of the Application form together with 4 copies of the information to support the application, as outlined in this document, and including the applicable checklist to:

Manager, Registrable Devices Unit
Medical Devices Section
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

If the application is acceptable, TGA assesses the evaluation category and invoices the sponsor for the evaluation fee. The evaluation proceeds and the TGA advises a delegate of the Secretary of the Department of Health and Family Services whether or not the product is suitable for registration.

Following assessment of the application, if the product is deemed acceptable the device is entered in the ARTG database and a *Registration Certificate* together with a covering letter giving confirmation of device details is sent to the sponsor. The Business Management Unit (BMU) invoices the sponsor for the first annual charge.

If the application is rejected TGA notifies the sponsor, giving the reasons.

Listable Device Applications

Products that are not registrable, excluded or exempt are listable. To list a device the sponsor or agent must

- complete the *Therapeutic Devices Application* form,
- complete the *Enterprise Details* form (if one has not been lodged previously or if its details have changed), and

attach:

- application fee,
- labels (draft or sample),
- promotional material / instructions for use / product insert,
- additional information

  e.g. GMP evidence
  Test certificate,

and forward to:

Business Manager
Business Management Unit
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

- When the fee is cleared, the application is forwarded to the Medical Devices Listing Section. If the application is acceptable, the TGA advises a delegate of the Secretary of the Department of Health and Family Services that the product is suitable for listing.
- If the product is considered acceptable for listing, a *Certificate of Listing* is issued.
- BMU invoices the sponsor for the first annual charge if not paid already.
- Supply can commence when the sponsor receives the *Certificate of Listing*.

1.9 REDUCING ANNUAL CHARGES

Section 16 of the *Therapeutic Goods Act 1989* specifies the characteristics or criteria of *separate and distinct* goods – characteristics which distinguish one registrable or listable product from another for the purposes of the ARTG. These criteria are:

- a different formulation, composition or design specification; or
- a different strength or size (disregarding pack size); or
- a different dosage form or model; or
- a different name; or
- different indications; or
- different directions for use; or
- a different type of container (disregarding container size).

Grouping

The Act enables the TGA to determine that some separate and distinct goods, which share certain characteristics, may be *grouped* under a single ARTG entry. The *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991* (Appendix 19) specifies the circumstances in which separate and distinct therapeutic goods can be grouped. Grouped goods share the same AUST R or AUST L number and incur lower annual charges as a consequence. Grouping has no effect on ARTG applications or evaluations. Fees are charged for applications and evaluations for every separate and distinct product included in the grouped ARTG entry and for processing variations to information on the products in the ARTG. Orders and Amendments are available from Government Info Shops in each capital city. Contact details are available in Appendix 13, *Therapeutic Goods Orders and Standards.*

Grouping for registrable devices is limited to specific instances, while most listable devices are subject to grouping (refer Chapter 3.2 *Grouping of Listable Devices*). Several products may be grouped together as a single listing if the devices have the same sterility status, the same sponsor, the same manufacturer and fall within the same device classification (*Australian Device Group* or *ADG*) outlined in the Australian Devices Groups document. Refer to Chapter 2.2 *Grouping of Registrable Devices*.

The Medical Devices Section whenever possible, groups products according to the above criteria, on receipt of an application. A request for grouping from the Sponsor **is not necessary**

The *Australian Device Groups* document is available from the TGA Publications Office

ph:	1 800 020 653
fax:	02 6232 8605.
web site:	http://www.health.gov.au/tga
email:	tga-information-officer@health.gov.au

1.10 CHANGES OR VARIATIONS TO THERAPEUTIC DEVICES IN THE ARTG

Is notification or prior approval required?

Therapeutic goods are registered or listed subject to the condition that no changes are to be made to the data submitted in support of the application to register or list the products. If sponsors need to notify TGA of changes to registered and listed therapeutic devices or groups of devices, they should read *Changes or Variation to Therapeutic Devices in the ARTG* (see Appendix 3) which summarises the TGA's requirements. Changes are of two types:

(i) variations to product information for registered or listed therapeutic devices, which do not result in a new listing or registration;

(ii) additions of products to grouped registrations or listings.

Refer to the Appendix for further information.

If the TGA is sent a notification that isn't required, the TGA returns it to the sponsor or agent with the application fee minus a handling fee.

Change in Status of Devices in the ARTG or Previously Exempt

Where listable devices become registrable or registrable devices become listable, as a consequence of a change in regulatory policy, no **application** fees are payable in association with the transfer of the ARTG entry from one category to another. For transfers from the listable to registrable categories, evaluation fees may be required. Where exempt devices become listable or registrable, application fees and, where relevant, evaluation fees apply.

TGA Business Rules

Fees for processing relevant data when varying an entry in the ARTG are specified in Schedule 9, Item A of the *Therapeutic Goods Regulations*. These fees are payable for variations which must be notified to the TGA, or for which approval must be sought from the TGA, under Section 32 of the Act.

- The TGA has adopted the following business rules for calculating these fees:
- fees apply when the information that is to be changed relates to a therapeutic good rather than to the company, except when the change involves a transfer of sponsorship or a new sponsor name;
- the fee payable for processing a variation will not be more than the application fee for a new product of that type. Evaluation fees may be required.
- only one fee is payable for simultaneous applications for an identical variation as this is seen as one 'event'. To be considered an 'event', all applications must be lodged concurrently.

- where there are simultaneous applications for an identical variation for different categories of listed or registered medical devices, a separate fee is payable for each type of application and the applications must be submitted on the appropriate forms.
- if a change is forced on a sponsor by another agency the TGA may charge a processing fee. If a sponsor considers a change falls into this category and the imposition of a TGA processing fee is not appropriate, the sponsor should submit the application together with an explanation and a request that no fee be payable. The situation will be assessed and examined on its merits
- Changes to manufacturing licences, including change of company name, change of nominated person, and change of conditions, do not attract a processing fee because of the higher level of annual charges applying to manufacturing licences.

If the schedule of fees (see Appendices) does not refer to a proposed variation please contact:

Business Manager
Business Management Unit
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8264
fax: 02 6232 8222

1.11 FEES AND CHARGES

The Government has determined that the full cost of the Therapeutic Goods Program is to be recovered from the pharmaceutical and medical devices industry from the beginning of the 1997/98 financial year. Fees and charges are specified in the Act and *Regulations* together with the *Therapeutic Goods (Charges) Act 1989* and the *Therapeutic Goods (Charges) Regulations*. Refer to Appendix 9, *Fees and Charges*.

Application Fees

Application fees apply to the lodgement of applications for registration and listing of therapeutic devices in the ARTG and are non-refundable.

Evaluation Fees for Registrable Devices

A range of evaluation fees apply to the assessment of data submitted in support of an application for entry in the ARTG, depending on the nature and extent of data which must be submitted. The sponsor is advised of the evaluation fee by an invoice issued by the Business Management Unit and the application is deemed to have lapsed if this fee is not received within two months of the date of the invoice. Lapsed applications attract a new application fee if the sponsor wishes to have the data evaluated at a later date.

Annual Charges

An annual charge applies to the maintenance of entries in the ARTG for all therapeutic goods, except for goods manufactured solely for export. Sponsors are required to pay this charge within 28 days of the due date, or the registration or listing will be cancelled.

Waiving and Reduction of Fees and Charges

Regulation 45 in the *Therapeutic Goods Regulations* sets out the circumstances in which the TGA may waive or reduce application and evaluation fees. Regulation 4 of the *Therapeutic Goods (Charges) Regulations* sets out the circumstances under which annual charges are not payable.

ARTG Reinstatement Application Fee

An application fee applies for goods which can be reinstated in the ARTG within 30 days of their cancellation

1.12 CONFIDENTIALITY

The TGA respects the commercial-in-confidence nature of information submitted in support of applications for entry in the ARTG and will not make available to a third party, other than those directly involved in the assessment of the application, information which is regarded by the applicant as confidential in nature, except as required under the *Freedom of Information (FOI) Act 1982*, or as provided under Section 61 of the *Therapeutic Goods Act 1989*. The sponsor of the application will be consulted in relation to any proposed release of information under the FOI Act.

The applicant should clearly mark each page of such information (including letters discussing the application) **COMMERCIAL IN CONFIDENCE**. Information received from other regulatory agencies in relation to submissions received by the TGA is also treated as confidential and afforded the same protection outlined above.

1.13 RELEASE OF INFORMATION FROM THE ARTG

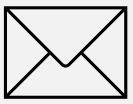
Section 61 of the *Therapeutic Goods Act 1989* identifies those classes of persons and or organisations to whom information may be released. TGA is able to provide information to the public about goods contained in the Australian Register of Therapeutic Goods (ARTG). The information held in the ARTG depends on whether the good is a device or drug. Outlined below is a list of information available for devices (refer to Regulation 46 of the *Therapeutic Goods Regulations*).

Information which may be released in relation to a device includes:

- whether the goods are included in the Register, and, if the goods are included, the
- registration or listing number of the goods, the date on which the goods were listed or registered and the class in which the goods are included;
- the name of the goods and the name and address of the sponsor of the goods;
- if any ingredient in, or component of, the goods is derived from an animal, the type of the animal; and
- the quantity of active substance in a pharmaceutical dosage form; and
- if the goods are supplied in a sterile state, the type of sterilisation used;
- a description of the devices, including the name and code (if any) by which the devices are classified.

Fees for the release of information from the ARTG are specified in the Commonwealth Freedom of Information fee schedule. In summary, a request carries a $35 application fee. This fee covers a simple single field enquiry with less than 10 pages of output. Ten pages or more of output are charged at 50 cents per page.

Requests for information, with the application fee, should be made to:



Attention BMU
Release of Information Officer
Australian Register of Therapeutic Goods (ARTG)
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
Woden ACT 2606

1.14 ADVERTISING / PROMOTION

The advertising of therapeutic goods is required to comply with provisions of Part 2 of the *Regulations*. Attention is drawn to Schedule 2 which defines those representations which are prohibited. Refer to Appendix 1, *Advertising Therapeutic Goods to the Public.*

Promotion of unapproved goods

Schedule 5 of the *Therapeutic Goods Regulations* exempts certain goods from registration or listing in the ARTG. (Refer to Appendix 8, *Exempt Goods*).

Item 3 specifically exempts

Asamples of therapeutic goods imported, exported, manufactured, or supplied for:

a) submission to a regulatory authority; or
b) subjection to developmental or quality control procedures; or
c) examination, demonstration or display; or
d) subjection to analysis or laboratory testing;

but not for supply for therapeutic use in humans≅.

Sponsors are able to import therapeutic goods not registered or listed in the ARTG (unauthorised goods) and display them at conferences, trade fairs and other events provided certain conditions are met.

Sponsors displaying unauthorised devices must ensure they are displayed in a manner that makes it clear that the

- devices are currently unauthorised, and are
- not available for supply, and have
- not been entered in the ARTG, and that
- their safety, quality and efficacy have not been established by the TGA.

Any promotional material about these products distributed at the meeting should also indicate these conditions.

These devices must be held under the direct control of the sponsor, until the goods are entered in the ARTG. The sponsor is able to hold such unapproved devices for up to twelve months but must maintain records relating to the source and supply of the devices and provide this information to the TGA if requested. The products must be destroyed or returned to the consignor of the devices within 1 month of the end of that period.

1.15 THERAPEUTIC GOODS ORDERS (TGO) & STANDARDS

Section 10 of the *Therapeutic Goods Act 1989* allows the Minister to determine the standards to be applied to therapeutic goods imported, supplied or exported from Australia. These determinations are referred to as Therapeutic Goods Orders and the Minister is required to seek the advice of the Therapeutic Goods Advisory Committee (TGC) before endorsing these Orders.

The Government has a commitment to adopt internationally accepted standards unless it can be demonstrated that there is a clear need to modify these standards in the interest of public health. The monographs of the *British Pharmacopoeia* (BP) are generally applicable to the goods supplied in Australia, and specific Australian standards, e.g. those standards developed by Standards Australia or the TGA, have been adopted where appropriate.

Contact details are contained in Appendix 13, *Therapeutic Goods Orders and Standards*.

1.16 PYROGEN / ENDOTOXIN FREE DEVICES

Products represented as being pyrogen-free must comply with TGO 50 *General Standard for Pyrogen and Endotoxin Content of Therapeutic Goods* (see Appendix 17). The scope of this Order applies to the following categories of therapeutic goods:

- parenteral products where the nature of the product makes testing practical and where:
  - the volume to be injected in a single dose is 15 mL or more, including those products requiring dilution, reconstitution or suspension before injection as appropriate; or
  - the label on the container indicates that the product is pyrogen-free;

- irrigation solutions, where the nature of the product makes testing practical;

- all sterile therapeutic devices which are intended for contact, directly or indirectly, with the cardiovascular system, the lymphatic system or the cerebrospinal fluid and nervous system, including:
  - containers used to store, administer or treat
    - blood or blood products;
    - any parenteral products in volumes greater than 15 mL;
    - irrigation solutions;
    - haemodialysis solutions;
    - peritoneal dialysis solutions; and
    - any injectables that contact cerebrospinal fluid;
  - transfusion and infusion assemblies;
  - extension sets, transfer sets, accessories or closures which connect to the fluid path of those containers or assemblies included in *containers* or *transfusion and assemblies* above;
  - intravenous catheters;
  - other drug delivery catheters;
  - implants, with the exception of orthopaedic and dental products which are exempt from the requirements of this Order;

- goods, where a test for pyrogen or endotoxin content is part of a statutory requirement.

Although test certificates demonstrating compliance are not required at the time of listing, these certificates must be retained by the sponsor and supplied upon request.

Laboratories undertaking testing to establish compliance with the requirements must have certification in the form of:
- NATA/NATA MRA partner or equivalent accreditation; or
- certification from a recognised authority to EN 45001 X *General Criteria for the Operation of Testing Laboratories*; or
- certification from a recognised authority to ISO Guide 25 X *General Requirements for the Competence and Calibration of Testing Laboratories*; or

- certification from a recognised authority of manufacturer's quality systems, including in-house test laboratories, to at least EN 46002 (where testing is conducted in-house).

Further details about NATA's mutual recognition agreements are available from:

The Coordinator
International Liaison
National Association of Testing Authorities, Australia (NATA)
7 Leeds Street
RHODES NSW 2138

ph: 02 9736 8222
fax: 02 9743 5311
web site: http://www.nata.asn.au
email: nata@nata.asn.au

1.17 ELECTRICAL SAFETY

Electrically powered therapeutic devices are required to meet a minimum level of electrical safety prior to entry in the ARTG.

Many State electricity supply authorities also require electronic equipment sold within their State to comply with applicable standards. The testing of devices against relevant standards is often a part of State tendering procedures. Sponsors should contact the relevant authorities to ensure that the device meets all the requirements in that State.

Electrically powered therapeutic devices can be divided into three categories on the basis of the risk of injury as a result of device failure or misuse.

Low Risk Devices where failure or misuse is unlikely to result in serious consequences.

Medium Risk Devices where failure or misuse would have significant impact on patient care but would not be likely to cause direct serious injury.

High Risk Life support devices, key resuscitation devices and other devices where failure or misuse is reasonably likely to result in serious injury to patients or others.

Table 1.2. Examples of devices and the various categories

NOTE: These lists are not definitive but are intended to indicate the types of devices in each category.

Low Risk	Medium Risk	High Risk
Aspirators	Blood warmers	Anaesthesia equipment
Cast cutters	Capnographs	Apnoea monitors
Light sources	Physiological monitors	Defibrillators
Paraffin baths	Radiant warmers	Ventilators
Electronic scales	Gas regulators	Haemodialysis equipment
Surgical tables	Ultrasound imaging	Radiotherapy equipment
Ultrasonic therapy	Endoscopes	Electrosurgery units
Examination lights	Lithotripters	Infant incubators
Surgical microscopes	Phototherapy units	Resuscitators

For the purposes of an application for entry in the ARTG, these categories will be divided into two groups

Group 1 **Low Risk**; and

Group 2 Equipment with an electrical patient circuit (applied part), where steps are deliberately taken to reduce the electrical impedance of a connection to the patient, for the purpose of measuring an electrophysiological parameter or delivering therapy

OR

Equipment without an electrical patient circuit, but classified as **high risk** or **medium risk**.

Group 1 Compliance Requirements

- A certificate of compliance with one of the overseas standards or *AS 3200.1:1990* as detailed for Group 2 devices.

  OR

- A Certificate of Approval or Certificate of Suitability issued by one of the state electrical approvals authorities.

  OR

- A certificate of compliance with Australia/New Zealand *AS 3551:1995* issued by a NATA/NATA MRA partner or equivalent accredited organisation, either a private organisation or a hospital based Biomedical Engineering department. AS 3551 is a subset of the AS 3200 test protocols which addresses only the fundamental safety aspects of the device, in much the same way as the previous option.

- A test report and Certificate of Compliance issued under the rules of the IECEE-CB Scheme.

Group 2 Compliance Requirements

- A certificate of compliance with one of the following overseas standards:

  International IEC601.1:1988 and amendments
  Europe EN 60601.1
  Great Britain BS 5724
  United States UL 2601
  Canada CSA C22.26:601

This certification is only acceptable if issued by a test house accredited to EN 45001 X *General Criteria for the Operation of Testing Laboratories*, or
ISO Guide 25-1990 X *General Requirements for the Competence of Calibration and Testing Laboratories*.

OR

- A certificate of compliance with Australia/New Zealand *AS 3200:1990* and amendments, issued by a NATA/NATA MRA partner or equivalent accredited test house.

Where part 2 standards exist for specific items of equipment, for example *AS 3200.2.4* for defibrillators, the certificate of compliance must include testing to both the *part 1* and *part 2* standard.

Sponsors of electrically powered therapeutic devices are required to make a declaration in the application form that the device complies with the necessary compliance requirements. However the TGA can request to see the certificates at any time.

Electromagnetic compatibility requirements

Electrically powered therapeutic devices are required to comply with the requirements of the Electromagnetic Compatibility (EMC) Framework currently being implemented by the Australian Communications Authority (ACA), in conjunction with the TGA for electromedical devices.

By agreement between the two agencies, the TGA regulates the EMC requirements for electromedical devices.

Full details of the EMC Framework and compliance requirements are available from ACA offices in the capital cities, or from:

The Manager
Radiocommunications Standards
Australian Communications Authority (ACA)
PO Box 78
BELCONNEN ACT 2616

Ph 02 6256 5555
fax: 02 6253 2424
web site http://www.aca.gov.au

Sponsors are required to ensure all electrically operated therapeutic devices are fully compliant with the following immunity requirements:

- *AS3200.1.2:1995 Approval and Test Specification Medical Electrical Equipment Part 1.2 General Requirements for Safety Collateral Standard Electromagnetic Compatibility Requirements and Tests*; or

- where a *part 2* standard to the AS3200 series of standards (for example *AS3200.2.24* for defibrillators) exists, the electromagnetic compatibility requirements specified in the *part 2* standard for that device. These are specified in *Section 36* of this series of standards.

- where a *part 2* standard is implemented by Standards Australia at some later date, after publication of DR4, the requirements of that *part 2* for the device category specified in that *part 2* standard take precedence over *AS3200.1.2:1995 — General Requirements for Safety Collateral Standard Electromagnetic Compatibility Requirements and Tests.*

The AS3200 series of standards are essentially identical to the IEC 601 series of standards, with amendments to accommodate local differences such as local supply voltages and spectrum allocation to broadcast services.

Compliance File

Sponsors are required to maintain a compliance file for a therapeutic device. The file should contain all relevant documentation to support the declaration, made in the application for entry in the ARTG, that the device is electrically safe and is in compliance with appropriate standards. Maintenance of a compliance file is also a requirement of the Electromagnetic Compatibility Framework administered by the Australian Communications Authority to demonstrate that a device is in compliance with the EMI/EMC requirements of the Framework.

The compliance file should include the following ;

- a description of the device, including photographic documentation (this may be in the form of promotional or application literature);
- technical description and specifications;
- a reference to standards used to demonstrate compliance, both with electrical safety requirements of the TGA, and with EMC requirements of the ACA;
- copies of test reports used to support declarations of compliance;

and also for EMC compliance only

- a signed declaration of conformity.

The compliance file is, however, subject to audit by the TGA for electrical safety compliance and the ACA for EMC compliance.

1.18 MUTUAL RECOGNITION AGREEMENT (MRA) WITH EUROPE

Australia has negotiated a mutual recognition agreement (MRA) on standards and conformity assessment with the European Union (EU), which is anticipated to come into effect in early 1998.

The EU-MRA applies to medical devices manufactured in the European Union and in Australia and New Zealand which are subject to third party conformity assessment. Devices incorporating animal-derived tissues, radioactive materials, in vitro diagnostics, and devices manufactured in other countries (even if those devices bear CE marking) are excluded.

The MRA recognises the competence of conformity assessment bodies in the EU that are approved by the Department of Health and Family Services to undertake conformity assessment of medical devices to Australian requirements for entry in the ARTG. Conversely the EU recognises the competence of conformity assessment bodies designated by the Department to undertake assessment of medical devices for compliance with the requirements for certification ('CE marking') for entry to the EU market. Initially it is proposed that the TGA will be the only designated conformity assessment body in Australia under the terms of the MRA.

The EU-MRA includes an eighteen month transition period to allow each party to gain confidence in the other's procedures and processes for the premarket assessment of high risk devices. During this period, the TGA will request sponsors to provide evaluation and audit reports from Notified Bodies with their ARTG applications for registration.

Products manufactured in the USA or other countries which bear the CE mark are not included in this agreement. The '*rules of origin*' arrangements in the agreement may be reviewed in the future as the EU negotiates more bilateral agreements with its other trading partners.

How The Agreement Will Work

The EU member states will recognise the competence of the TGA to undertake conformity assessment on products of Australian/New Zealand origin with the essential requirements of the European Directives — 90/385/EEC (Active Implantable Devices Directive) and 93/42/EEC (Medical Devices Directive). It is anticipated that the In Vitro Diagnostics Directive will be included following its implementation in Europe, which is anticipated to be mid 1998. The TGA will be using the procedures specified in EU Council decision 93/465/EEC. Conversely the TGA will recognise the competence of European notified bodies to undertake conformity assessment of medical devices manufactured in the EU with the Australian requirements for entry in the ARTG. Notified bodies offering conformity assessment for Australia will be asked to issue a certificate of conformity to the Australian requirements along with other relevant documentation of conformance to the EC medical device directives for CE marked devices.

Requirements for the ARTG

For all medical devices supplied in Australia:

- a sponsor must be a resident of or carrying on business in Australia;
- the Australian sponsor must complete and submit a *Therapeutic Devices Application* form and provide the certification of conformity issued by the European notified body;
- for registrable devices, the actual evaluation and audit reports of the European notified body should accompany the application for entry in the ARTG;
- the sponsor should attach to the application a copy of the certificate of conformity from the Notified Body that performed the assessment;
- the Australian sponsor must also complete and submit an *Enterprise Details* form if it is the first application for entry of a therapeutic device in the ARTG or if details of the enterprise have changed (see Appendix 2a);
- the current application fees must be paid (evaluation fees apply for the first 18 months that the agreement is in force).

Conformity Assessment of Medical Devices

Australian and New Zealand manufacturers of medical devices wishing to CE mark their products for the European market have the option of retaining the TGA to perform the conformity assessment according to the essential requirements of the European Directives — 90/385/EEC and 93/42/EEC. To qualify, products must undergo the final significant manufacturing step in Australia or New Zealand.

Copies of the European medical devices directives are available from:

Hunter Publications PO Box 404 ABBOTSFORD VIC 3067	Information Officer Delegation of the European Commission to Australia and New Zealand 18 Arkana Street YARRALUMLA ACT 2600
ph: 03 94175361 fax: 03 94197154 email: pdavies@ozemail.com.au	ph: 02 6271 2777 fax: 02 6273 4445 email: australia@ecdel.org.au

1.19 GOOD MANUFACTURING PRACTICE (GMP)

The *Therapeutic Goods Act 1989* requires that sponsors of goods manufactured overseas establish that the manufacture is equivalent to that required of Australian manufacturers.

Extract from *Therapeutic Goods Act 1989*

"Manufacture" *in relation to Therapeutic Goods means;*
(a) to produce the goods; or
(b) to engage in any part of the process of producing the goods or bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing and releasing for supply of the goods, or of any component or ingredient of the goods as part of that process."

Licensing and GMP certification

The Good Manufacturing Practice and Licensing Section (GMPALS) audits Australian and overseas manufacturers of therapeutic goods. It issues manufacturing licences to acceptable Australian manufacturers, based on compliance with the manufacturing principles as determined under Section 36 of the Act.

Sponsors of **Registrable Devices** are required to provide an acceptable evidence of Good Manufacturing Practice (GMP). Sponsors of **Listable devices** included under **Schedule 6** for overseas manufacturers, or not exempted under **Schedule 7** for Australian manufacturers are required to provide an acceptable form of evidence of GMP. Refer to Table 1.3 for a summary of devices requiring GMP.

Schedule 8 specifies the **persons** exempt from the requirement to hold a licence to manufacture therapeutic goods. Refer to Tables 1.4 and 1.5 for a summary of goods or persons exempt from GMP licencing.

Audits of Australian manufacturers assess the level of compliance with the quality systems guidance documents. During this inspection the manufacturers are expected to have their quality manual available for review.

For manufacturers of devices that are

- registrable if supplied in Australia, or active implantable medical devices (AIMD),**ISO 9001/EN 46001** or **ISO 13485** is required.
- For manufacturers of other devices**ISO 9002/EN 46002** or **ISO 13488** is required as a minimum as specified in Schedule 6 or 7 of the *Regulations* (manufacturers may elect to adopt ISO 9001/EN 46001 or ISO 13485 instead).

Full quality system audits are conducted at an appropriate interval, and shorter surveillance audits are conducted annually on intermediate years.

Overseas Manufacture

Where a product is imported or a step in the manufacture is conducted outside Australia, the sponsor is required to provide evidence that the standard of manufacture is equivalent to that which would be expected if the product was made in Australia. Acceptable forms of evidence are detailed in Appendix 10, *GMP — Standard of Overseas Manufacturers*.

The sponsor may either supply an acceptable form of evidence or arrange for the TGA to undertake an audit. A condition of registration or listing of both new and existing products is that, in the event of suitable evidence of GMP compliance not being supplied for the overseas manufacturer(s), the sponsor is liable for the cost of a GMP audit undertaken by TGA.

Evidence which requires assessment, such as audit reports or Plant Master files, is reviewed by the TGA and information on the standard of overseas manufacturers is maintained on the GMP database.

Evaluation of applications is facilitated if sponsors submit current acceptable evidence of GMP compliance with each application for registration or listing.

Australian sponsors must provide evidence of continuing compliance with GMP for overseas manufacturers of therapeutic goods before the current compliance expires. Failure to supply acceptable information will result in cancellation of the product's registration or listing.

It is an offence for the sponsor to change the site of manufacture without prior approval from the TGA.

GMP Audit & Licensing Section (GMPALS)
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8629
fax: 02 6232 8426

Plant Master Files

In countries where the manufacturing standard is less well known, initial evidence of GMP compliance could consist of a Plant Master File for the manufacturing site. It should be noted that TGA charges a fee for evaluating plant master files. Furthermore, a GMP audit of the factory must be arranged within 12 months of the plant master file being evaluated to confirm acceptable GMP compliance.

Site Information files

A Site Information file is a document prepared by a manufacturer, including recent photographs, to provide specific information about the production and control of manufacturing operations at a particular site. It is intended to be a relatively brief document which should provide a clear and complete review of the firm's operation.

A list of Australian manufacturers licensed to manufacture therapeutic goods, and updated editions of the *Standard of Overseas Manufacturers* (see Appendix 10) and guidelines for Plant Master files and Site Information files are available from the TGA Publications Office

ph: 1 800 020 653 or
02 6232 8610
fax: 02 6232 8605
web site: http://www.health.gov.au/tga
email: tga-information-officer@health.gov.au

Table 1.3. Examples of Devices requiring GMP — Summary only
refer to Schedule 6 & 7 of Regulations for complete details

blood bags
blood collection tubes
bandages, dressings, adhesive tapes etc
condoms
contact lenses (soft)
contraceptive devices
dental restorative materials
devices used for the prevention of transmission of disease
devices included as Pharmaceutical Benefits
diaphragms
disinfectants / sterilants (after 1/1/98)
drainage bags
gloves (examination & surgical)
implants
IVDs for home use
IVDs of human origin
lubricants for internal use
non-glass containers — for blood or injection
parenteral infusion bags
sterile devices

Table 1.4. Persons Exempt from Licensing to Manufacture
refer to Schedule 8 of the Regulations for complete details

Biomedical engineers, pharmacists, and radiochemists in public hospitals
Registered health care workers dispensing for patients under their care
Herbalists/homoeopaths/nutritionists for clients
Supplementary labelling (address/ARTG No. only)
Pharmacists in their place of practice for supply other than by wholesale from their premises

Table 1.5. Goods Exempt from Licensing to Manufacture
(unless supplied as Pharmaceutical Benefits)
refer to Schedule 7 of the Regulations for complete details

Goods for Phase 1 Clinical Trials

Therapeutic Devices:

Components
Containers except
blood bags
blood collection tubes
drainage bags
non-glass containers for blood or injection
parenteral infusion bags
Dentrifices, with no active ingredient or low fluoride
Non-sterile devices except
bandages, dressings, adhesive tapes etc.
contraceptive devices
condoms
contact lenses (soft)
dental restorative materials
devices used for the prevention of transmission of disease
diaphragms
disinfectants/sterilants (until 31/12/97)
gloves (examination & surgical)
implants
IVDs for home use, PBS listing, HIV or HCV diagnosis or of human origin
lubricants for internal use

1.20 REJECTION OF AN APPLICATION

Where an application for a therapeutic device does not include information necessary to have it registered or listed in the ARTG, the application is considered for rejection. The various stages at which an application could be considered for rejection are as follows.

1. If the application for a listable or registrable therapeutic device is unable to satisfy the criteria specified in Section 23 of the Act, the application can be rejected without any recourse to an appeal.

2. (a) If during the course of processing or evaluating a **registrable** therapeutic device application, the delegate determines that the criteria specified in Section 25 of the Act are not satisfied, then the application is considered for rejection.
   (b) If during the course of processing a **listable** therapeutic device application, the criteria specified in Section 26 of the Act are not satisfied, then the application is considered for rejection.

Where an application is considered for rejection, a letter is sent to the sponsor advising that the TGA intends to reject the application. Sponsors may be given the opportunity to show cause why the application should not be rejected.

Except for rejections made under Section 23, Section 25 and Section 26 rejections are considered as appealable under Section 60. Refer Chapter 1.21 *Appeals Against Decisions.*

Application fees are non-refundable. If a rejection or withdrawal relates to a registrable device application, any fees paid for evaluation categories connected with that application, which had not been started or concluded before the rejection process was initiated, are refunded.

If an application for registration or listing is withdrawn the Department may retain the application and any material submitted in connection with the application as stated in Section 53 of the Act.

1.21 APPEALS AGAINST DECISIONS

The procedures for appeals against decisions made by the TGA administering the *Therapeutic Goods Act 1989* are described in Section 60 the Act. The procedures provide for sponsors to request a review of the decision taken by the TGA. A request for such a review should be made in writing within 90 days of the written advice of the TGA decision, and should be sent to the following address:

The Minister for Family Services
Parliament House
CANBERRA ACT 2600

The letter should be headed;
'Appeal under Section 60 of the Therapeutic Goods Act 1989'.

In accordance with the Act, the Minister generally delegates the reconsideration review to an officer of the department. The result of the appeal, subject to the *Administrative Appeals Tribunal Act 1975*, may be further referred to the AAT for a review of the Minister's or Delegate's reconsideration.

1.22 ENFORCEMENT

The TGA has established the Surveillance Unit to monitor compliance with the Act, to investigate alleged breaches of the Act, and to initiate criminal prosecutions where appropriate. Information regarding the illegal supply of therapeutic goods, should be referred to the TGA Surveillance Unit.

Manager, Surveillance Unit
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8640
fax: 02 6232 8643

Options available to the TGA include criminal prosecutions for offences under the legislation, and heavy monetary fines. Illicit goods that have been seized during these investigations have been forfeited to the Commonwealth and destroyed.

1.23 PENALTIES AND CANCELLATIONS

Penalties

The Act provides for the imposition of penalties for:

- illegal importation, exportation, manufacture or supply of therapeutic goods,
- failure to comply with conditions of listing or registration of therapeutic goods in the ARTG,
- making false declarations at the time of listing or registration. Penalties for failure to comply with the provisions of the Act may include
- removal of the goods from the Register;
- recall of goods supplied, either to batch level or all goods;
- financial penalties imposed by the Court under the Act.

Offences that can be prosecuted under the *Therapeutic Goods Act 1989* are specified in Sections 20, 21, 22, and 22A. They relate to the illegal import, export, manufacture or supply in Australia of therapeutic goods that have not been not included in the ARTG. Goods which are exempt from the Act or goods that are the subject of an approval under Section 19 or 19A (Special Access Schemes and Clinical Trials) are exempt from these penalties. The maximum penalties that can be imposed upon conviction for an offence by a natural person are $24,000 and for an incorporated body $120,000 for each offence. (Refer to Chapter 1.24 *Access to Unapproved Devices*).

Cancellations

A registration or listing may be cancelled if:

- the conditions of the registration or listing have not been met, or
- the criteria established in Section 30 of the Act are met.

Sponsors should note that Section 30 also applies to listable devices. As the listing process, through Section 26, minimises the ARTG entry requirements, Section 30(2)(a), in particular, is applied to ensure that sponsors, on request from the TGA, can verify that their products meet their advertised claims and performance specifications. If sponsors cannot satisfactorily establish the quality, safety or efficacy of their products and if a decision to cancel the entries in the ARTG is confirmed, the sponsor is also required to recall any affected products.

Consistent with the principles of natural justice, any proposal to deregister or delist any product in the ARTG is submitted to a sponsor who is then allowed a certain period of time in which to show cause why the cancellation should not take effect. The sponsor may also be given the opportunity to submit any data to support their case. Once this time has elapsed and any submitted information has been assessed, a decision may be taken to cancel the registration or listing. If this decision is taken, sponsors have another opportunity, using Section 60 of the Act, to lodge an appeal. This process is explained in the cancellation letter.

Extract from Section 30 (2)(a) *Therapeutic Goods Act 1989*

"...the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if
(a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable...".

1.24 ACCESS TO UNAPPROVED THERAPEUTIC DEVICES: CLINICAL TRIALS & SPECIAL ACCESS SCHEMES (SAS)

Section 19 of the *Therapeutic Goods Act 1989* provides access to medical devices not registered or listed in the ARTG under the following special access and supply arrangements. Section 18 exempts these goods from entry in the ARTG.

The importation of biological material generally requires a *Permit to Import Quarantine Material* issued by the Australian Quarantine and Inspection Service (AQIS). Refer Chapter 1.4 *Quarantine Requirements.*

Individual Patient Use (IPU) & **Authorised User Access (AUA)**
These schemes allow access to unapproved medical devices, subject to the TGA's approval where there is a special patient need.

Clinical Trial Exemption (CTE) & **Clinical Trial Notification (CTN)**
Experimental or unapproved medical devices used in clinical trials are subject to either the CTN or CTE schemes. Both schemes require Institutional Ethics Committee (IEC) approval, and the IEC determines which scheme is selected.

Although the CTN scheme is the more commonly used clinical trial process, the CTE scheme may be more appropriate in the instance where the experimental device introduces new technology or materials which have not previously been evaluated. The CTE scheme requires extensive evaluation of the device by the TGA prior to the commencement of the trial.

Both the CTE & CTN schemes allow for experimental use in humans to obtain data on the clinical safety and effectiveness of a device. If these data already exist, exemption for the supply of unregistered devices under either clinical trial scheme is not appropriate and these data should be submitted as part of a submission for registration of the device in the ARTG.

Consistent with the intent of the TGA to harmonise requirements for clinical trials with those of the European Union, submission of data for the CTE scheme must comply with European standard EN540:1993, with reference to departmental documents, *Guidelines for Good Clinical Research Practice 1991* and *Statement on Human Experimentation and Supplementary Notes 1992*.

The CTN scheme is reviewed by the supervising IEC and is not subject to the TGA's approval. The TGA is notified of the basic criteria of the trial.

TGA approval is not required for clinical trials of devices which are currently entered in the ARTG, provided the intended use is within the use approved for the product's entry in the ARTG. Such events may however be subject to requirements by an Institutional Ethics Committee (IEC) and individual practitioners should consider the issues of informed consent and their own legal obligations.

It is a serious offence for a sponsor to knowingly supply a device in Australia for use in humans unless it is registered, listed or exempt under the *Therapeutic Goods Act 1989.* Refer Chapter 1.23 *Penalties and Cancellations.*

Specific clinical enquiries may be directed to:

The Medical Adviser
Clinical Section
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 62328615
fax:: 02 62328785

Incident Reporting Scheme enquiries, Report Forms and other TGA publications are available from:

TGA Publications Office
ph: 1 800 020 653
fax:: 02 6232 8605
email: tga-information-officer@health.gov.au
web site: http://www.health.gov.au/tga

NHMRC document *'Statement on Human Experimentation and Supplementary Notes 1992'* available from:

NHMRC Publications Office
ph: 02 6289 7646
fax:: 02 6289 8776
web site http://www.health.gov.au/nhmrc

Clinical Trial Exemption Scheme (CTE)

Prior discussion with the TGA allows areas of difficulty to be identified at an early stage. Relevant Therapeutic Goods Orders (TGOs) and Standards applicable to specific devices are contained in Appendix 13, *Therapeutic Goods Orders / Standards*.

Information to be Submitted for a CTE

- Sponsor's name and address (including telephone and facsimile numbers) and TGA Enterprise ID Number, or *Enterprise Details* form (see Appendix 2a);
- contact person;
- formal submission data (original and one copy required). Submissions must be in English, typed on A4 paper in type size no smaller than 10 point, and presented in labelled and numbered volumes. The submission should include a Table of Contents and follow the methodology prescribed in European Standard EN540 :1993.
- Clinical Investigation Plan, including
- Clinical Investigators Brochure,
- Case Report Form,
- Adverse Events due to device use, including known incidences of device explantation;
- CV of Clinical Investigators;
- details of institutions used in trial;
- Ethics Committee approval for each participating institution;
- copy of agreement between Clinical Investigator(s) and Sponsor;
- copy of agreement between Clinical Investigator(s), Sponsor and Monitor;
- documents relating to compensation for subjects in the event of injury;
- Informed Consent Form;
- final report (to be supplied at conclusion of clinical trial).

Additional Requirements

The sponsor must supply a signed statement agreeing to the following:

- compliance with NHMRC publication *Statement on Human*
- *Experimentation and Supplementary Notes 1992*;
- compliance with TGA publication *Guidelines for Good Clinical Research Practice 1991*;
- that the TGA must be notified in writing of severe adverse events and all adverse device effects occurring in multicentre clinical investigations within **fifteen days**; deaths or serious injury must be notified within **72 hours**;
- that if requested by the TGA the sponsor shall cease to supply the device for investigation;
- that the device must be clearly labelled '**investigational use only**' or with equivalent wording;
- documented procedures for long term follow up of trial subjects;
- that Annual Summary Reports are to be provided post approval, or upon request from the CAB;
- that a checklist summarising the above requirements must be completed and may be used by the CAB as an initial check for the completeness of the submission. A proforma of the checklist follows.

Clinical Trial Exemption Scheme
Application for Exemption under Section 19(1)(b)

A completed checklist must be attached to the original application.
An entry must be made on each line under Page No / Volume

ITEM	Page No. & Volume	Office Use Only Approved / Rejected	Office Use Only Action / Comment
Application letter			
Sponsor details			
(i) enterprise identification number, OR (ii) completed Enterprise Details Form			
Contact person			
Clinical Investigation Plan			
Clinical Investigator's Brochure			
Case Report Form			
Adverse Event Details			
CV of clinical investigators			
Details of institutions used in trial			
IEC approval for participating institution(s)			
Agreement between Clinical Investigator(s) and Sponsor			
Agreement between Clinical Investigator(s), Sponsor and Monitor			
Compensation Agreement			
Informed Consent Form			
Compliance with NHMRC document 'Statement on Human Experimentation and Supplementary Notes 1992'			
Signed statement agreeing to additional conditions			
Long term follow up procedures			

Clinical Trial Notification Scheme (CTN)

There is no requirement for provision of data to the TGA, but a copy of the Investigation Plan and some general device information are requested.

Role of the Ethics Committee

Each Clinical Investigation Plan and related Informed Consent Form should be reviewed in conjunction with data provided by the sponsor to support the proposal. Discussion with other IECs currently reviewing the trial should be encouraged. If however the IEC feels that it does not have sufficient expertise to review the technical data submitted then it should either ;

- enlist the help of an appropriate technical adviser (it may, however, not be appropriate for this person to be paid by either the sponsor or the investigator) OR
- decline to accept the proposed trial under the CTN scheme and inform the sponsor that the trial should be conducted under the provisions of the CTE.

It is the responsibility of the IEC to inform the investigator of the result of its review and, if approval to conduct the trial is granted, to certify this on the Clinical Trial Notification.

The CAB recommends that the IEC use the definitions and methodology prescribed in European Standard EN540 :1993, and consult departmental publications *Guidelines for Good Clinical Research Practice 1991* and *Statement on Human Experimentation and Supplementary Notes 1992.*

Format of Clinical Trial Notification

Notification is to consist of a letter from the sponsor giving the following information or undertakings.

- sponsor's name and address, business and after hours telephone numbers;
- name and description of device including trade name(s), if applicable;
- details of the design, composition, specification, mode of action and application of the device;
- method of use in the trial;
- title and aim of trial or study and whether single- or multi-centre;
- unique identifying number for the proposed trial;
- certification of the chair of the IEC approving the trial;
- notification fee;
- time schedule for trial or study with expected starting and completion dates;
- the notification must be signed and dated by the sponsor.

The sponsor must also supply a signed statement agreeing to the following:

- that the TGA is to be notified in writing of severe adverse events and all adverse device effects occurring in multicentre clinical investigations within **fifteen days**; deaths or serious injury are to be notified within **72 hours**;
- that if requested by the TGA the sponsor will cease to supply the device for investigation;
- that the device must be clearly labelled '**investigational use only**' or with equivalent wording;

and the sponsor must

- ensure the trial does not commence until approval has been obtained from the IEC, and the TGA has provided formal acknowledgment of the notification;
- provide the IEC and the Monitor with details of any other Australian IECs requested to review the trial, and details of other trials either currently running or completed that involve the same or similar devices;
- notify the Clinical Investigators, the IEC, the Monitor and the TGA of the cessation overseas of any relevant trial due to action taken by regulatory agencies overseas or any withdrawals from the market for safety reasons.

Role of the TGA

The TGA will acknowledge that the sponsor has complied with statutory requirements following receipt of the completed notification form and the notification fee. The TGA does not conduct any review of the safety of the device or of any aspect of the proposed trial.

The TGA may require a trial under the CTN scheme to cease if the trial is not being undertaken in accordance with regulations, or where the TGA considers that allowing the trial to proceed carries an unacceptable risk of death, serious illness or serious injury to the subjects.

Special Access Schemes

Individual Patient Use (IPU)

The IPU scheme provides individuals with access to, and the use of, unregistered or unlisted medical devices for their own use where:

- the patient has a demonstrated clinical need for the device;
- the patient is likely to benefit from the use of this 'experimental' device; and
- no other device currently marketed in Australia is suitable.

Other requirements are

- the provision of sufficient information to ensure informed consent from the patient;
- an undertaking to report any adverse effects to the TGA;
- compliance with the protocol of any ongoing clinical trials associated with the product; and
- certification by the requesting clinician and patient that they accept responsibility for any adverse consequences.

The TGA maintains a database of IPU approvals. Note that conduct of a clinical trial is preferred to the granting of IPUs where it is apparent that the number of persons being treated under the IPU Scheme is increasing. Sponsors should not promote unregistered devices to practitioners through the IPU scheme.

Penalties apply under Section 20 of the *Therapeutic Goods Act 1989* for the supply of unregistered medical devices without proper authorisation. Refer to Chapter 1.23 *Penalties and Cancellations.*

Obtaining an IPU

Approvals under Section 19(1) of the Act are arranged by direct contact between the treating practitioner and a medical officer in the Clinical Section of the CAB. On the first occasion, the treating doctor should contact a medical officer in the Clinical Section; when the procedure is familiar to the practitioner, application can be made by facsimile or letter. Applications should not be made by sponsors; however, discussion between a sponsor and the Clinical Section may be necessary on some occasions to arrange urgent supply. Applications should be made to the Medical Adviser at CAB.

IPU application forms are available from the TGA Publications Office. The following information is requested on the IPU application form and must be included in all written applications:

- device name and manufacturer;
- number of devices required for this patient name;
- phone, fax and address of supplier;
- concise justification for the use of this unregistered or unlisted device;
- name (or initials) of patient;
- date of birth of patient;
- proposed date of procedure;
- name, phone, fax, and address of the practitioner;
- signature of practitioner.

Approval Process

Applications are received by the medical officer. In some cases further information may be requested from the clinician or the sponsor. A decision is usually reached within 24 hours. If approved, both the applicant and the sponsor are sent copies of the approval permitting supply of the requested device for the identified patient. In urgent cases this approval is sent by facsimile. Decisions regarding IPU applications are subject to appeal under Section 60 of the Act. Refer Chapter 1.21 *Appeals Against Decisions.*

Reporting of Adverse Events

All adverse events observed with the use of an unregistered or unlisted device used under this scheme should be reported to the CAB's Device Incident Reporting scheme. Where IPU approval is sought to replace a failed device, a Device Incident Report should be completed describing the nature of the problem.

Medical Device Incident Report forms
ph: 1800 020 653
fax: 02 6232 8785

Importation of Unregistered Products for IPU use

To facilitate availability for urgent cases, a sponsor may be granted approval by the Medical Devices Section of CAB to import a limited supply of a product. Sponsors should write to CAB outlining the basis of their request for import approval, including details of the product and the manufacturer. A letter of approval is then returned to the sponsor.Letters should be addressed to:

Head, Medical Devices Section
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8793
fax: 02 6232 8785

Authorised User Access (AUA)

In certain situations there is a need to use an unregistered product over a period of time on a group of patients suffering from a serious illness. This situation may arise when the product has a limited market, is highly specialised or an urgent need exists while the product is under evaluation by the CAB. Use of the IPU scheme may in these circumstances be cumbersome.

The AUA scheme permitted under Section 19(5) of the Act enables authorised medical practitioners to use unregistered (or unlisted) medical devices on a specified patient group for specified indications.

Requirements

An authorised practitioner is

- a specialist medical practitioner in hospital practice; and
- endorsed by either the Ethics Committee of the hospital in which the practitioner practises for the particular use, or by the relevant specialist College or Society.

The authorisation must

- state the name of the authorised practitioner;
- identify the device concerned;
- state the particular therapeutic intervention(s) for which the device is to be used;
- describe the category of patient to which the approval applies;

- specify a reporting period; reports must be filed by the authorised doctor to the CAB using the supplied reporting form. If there has been no use of the device, a nil report should be filed; and
- specify an expiry date.

Obtaining an AUA

Applications for approvals under the AUA scheme must be made on the Application Form which can be obtained from the TGA Publications Office or from the Clinical Section, CAB. Decisions regarding AUA applications are subject to appeal under Section 60 of the Act. Refer Chapter 1.21 *Appeals Against Decisions.*

Reporting

Report forms are provided by the CAB with the approval letter. The completed report form should be sent directly to the Clinical Section, CAB and a copy forwarded to the appropriate College and Ethics Committee.

Supply of Goods

The applicant must inform the supplier of the goods that supply is being requested under the AUA scheme and provide the AUA approval number and expiry date for the approval.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au