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.

3.0 LISTABLE DEVICES

3.1 INFORMATION APPLICABLE TO ALL LISTABLE DEVICES

Therapeutic devices are classified as *Listable*, *Registrable*, *Exempt* (as detailed in Schedules 3, 4 and 5, respectively, of the *Regulations*), or declared not to be Therapeutic Goods (*Excluded Goods*). The majority of therapeutic devices are Listable.

Therapeutic goods *listed* in the ARTG are not subject to formal evaluation. However, information is required that reasonably demonstrates the safety and quality of the goods for the intended use. Some listable goods are required to comply with standards or Therapeutic Goods Orders (TGOs), and with other requirements such as Labelling and compliance with the Code of Good Manufacturing Practice (GMP).

In general, therapeutic claims made to promote a product supplied directly to the public will be assessed for compliance with the *Therapeutic Goods Advertising Code* (see Appendix 1). Evidence to substantiate these claims need not be presented in the application for listing. However, it is a condition of listing of the goods that this evidence is to be produced on request.

For listable devices that are subject to compliance with standards, and for others for which standards are currently under development, the specific information required by the TGA is set out in this document.

The TGA assesses the information included in an application for listing a therapeutic device in the ARTG, and tells the sponsor its decision. A certificate of listing is issued and the sponsor may only then commence supply of the goods to consumers. The TGA uses regular sampling and audit procedures to monitor compliance with the conditions of listing and will pursue any detected or reported instances of non-compliance. Severe penalties apply to individuals or companies unlawfully supplying therapeutic goods.

Information to be Supplied for Listing

The information required by the TGA to enter a device in the ARTG depends on whether or not the sponsor has already provided information for previously-listed products.

In general, the sponsor should provide the following information:

- completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence (Refer to Schedule 6 and 7)
- Test Certificates for the following:
  - *condoms,*
  - *bandages, dressings & allied products (non sterile)**;
- *microbial count certificate for the first five batches*
- product information, promotional material, Instructions for Use;
- labels (draft or sample).

Enterprise Details Form

All 'first time' sponsors must submit an *Enterprise Details* form (see Appendix 2a) that provides the details to be included in the ENTERPRISE database. They will be allocated an Enterprise Identification number (ENTID). This database is used in conjunction with the Australian Register of Therapeutic Goods (ARTG) to record company details and identify *Authorised Persons* who are able to make applications for listing, to request information from the TGA on the Company's behalf, or to vary or cancel entries in the ARTG. Manufacturer(s)' details not already supplied to the ARTG will also be required.

Any changes of *Authorised Persons* should also be supplied on this form and forwarded to:

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

ph: 02 6232 8590
fax: 02 6232 8581

Refer to Chapter 1.8 *Application Procedures* for further information.

Application Form

The application form asks for specific information about:

- the ECRI code applicable for the product;
- whether the product is to be listed or grouped;
- the sponsor and manufacturer(s) details;
- the provision of GMP evidence;
- the supply of a current Test Certificate (where applicable);
- the export or import status;
- product details;
- the type of product information provided;
- the type of labelling evidence provided;
- AUST L number if product is to be grouped to an existing listing.

Product Details

The product name must be provided, together with a description of the medical application and function of device.

Promotional Material / Instructions for use / Product Information

Promotional material and package inserts must be submitted with every application, to help categorise products in the ARTG. Labelling, including promotional material of goods supplied directly to the public, must comply with advertising requirements of the *Therapeutic Goods Regulations*, specifically clauses 4 & 7 of the *Therapeutic Goods Advertising Code* contained in Appendix 1, *Advertising Therapeutic Goods to the Public*.

Labelling Evidence

Either a sample or draft label must be supplied unless one has been supplied previously. Refer to Appendix 16, *TGO 37 General Requirements for Labels for Therapeutic Devices.*

Labels required for sterile devices:

in brief, on the Unit pack,

- the name of the device;
- the name of the manufacturer or sponsor, or the registered trade mark;
- the batch or serial number;
- the word 'sterile';
- the model designation or size;
- the names & quantity of all goods within package; and
- optional
  - single use only, or use only once, or do not re-sterilize ('disposable' alone is not acceptable);
  - 'sterile fluid pathway' etc. to qualify area of sterility.

in brief, on the Outer pack,

- the name of the device;
- the name & address of the manufacturer or sponsor;
- the batch or serial number;
- the names & quantities of all goods within package;
- the country of origin.

Standard & Specific Device Conditions

All listed therapeutic goods must comply with Section 28 of the*Therapeutic Goods Act 1989*. Specific conditions also apply to some groups of therapeutic devices, as shown in Table 3.1.

Table 3.1. Devices with specific conditions
refer to Appendix 4, *Conditions —Standard and Specific*

barium lime
bandages, dressings and allied products
catheters (urethral, single use, sterile)
condoms
contrast media injectors (powered)
dental restorative materials
diaphragms
disinfectants & sterilants
drug delivery systems (implantable)
gloves (examination & surgical)
insulin syringes and needles
IVDs
tampons — menstrual
penile implants (inflatable)
pyrogen free products
sutures & ligatures

Variations or Changes to Existing Listings

Refer to Chapter 1.10 *Changes or Variations to Devices.*

Licensing / GMP Evidence

Unless exempted, Australian manufacturers of therapeutic devices must be licensed. Schedule 7 of the *Regulations* determines those **products which are exempt** from licensing. Schedule 8 indicates those **persons** exempt from being licensed to manufacture therapeutic goods.

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 with each application. Examples of these devices are included in Table 3.2.

Table 3.2. Examples of listable devices requiring GMP — Summary only
refer to Schedule 6 & 7 of *Regulations* for complete details

- all sterile devices
- blood bags
- blood collection tubes
- bandages, dressings, adhesive tapes etc.
- condoms
- contact lenses (soft)
- contraceptive devices
- dental restorative materials
- devices included as Pharmaceutical Benefits
- diaphragms
- 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

Test Certificates

Test certificates must be able to be provided for specific groups of therapeutic devices.

Table 3.3. Listable Devices requiring Test Certificates
refer to Appendix 4, *Conditions — Standard and Specific*

- barium lime
- bandages, dressings and allied products (non- sterile)*
- catheters (urethral, single use)
- condoms
- dental restorative materials
- diaphragms
- disinfectants
- gloves (examination & surgical)
- insulin syringes
- IVDs of human origin
- menstrual tampons
- pyrogen-free products
- sutures & ligatures

** microbial count certificate*

Test Certificates where applicable, must be supplied to the TGA on request, except for **condoms** provided for at the time of application, and except for the first five batches of **non-sterile bandages, dressings and allied products,** for which a microbial count certificate must be supplied.

Unless otherwise indicated in specific device policies, test certificates must be signed and dated by the analyst, be less than 2 years old and be from an acceptable test laboratory.

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 — General Criteria for the Operation of Testing Laboratories; or
- certification from a recognised authority to ISO Guide 25 — 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

Refer to individual device policies in DR4 for further information.

3.2 GROUPING OF LISTABLE DEVICES

Grouping applies to most types of listable devices other than in vitro diagnostics for home use or those supplied as Pharmaceutical Benefits. Reference should be made to the order *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991* (Appendix 19).

Orders and Amendments are available from Government Info Shops in each capital city. Refer to Appendix 13, *Therapeutic Goods Orders / Standards* for addresses of Government Info Shops.

Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991 (Appendix 19) provides for grouping of separate and distinct listable devices if they:

- have the same sponsor; and
- have the same manufacturer; and
- are grouped in the same Australian Device Group; and
- have the same sterility status— sterile or non-sterile; and
- are not subject to different standards (TGOs); and
- if medicated devices, contain the same active ingredients; or
- if formulated devices, contain the same principal substances upon which the action of the devices depend.

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

What is a separate and distinct listable device product?

Listable devices are separate and distinct for entry in the ARTG if they have:

- a different design (ADG and ECRI code classification); or
- a different formulation (formulated and medicated devices only); or
- a different name ('trade' or proprietary name that identifies the product in the marketplace).

For all devices that are not subject to a product specific standard, where a product has the same ADG and ECRI classification but several different'trade names', the sponsor may nominate to include a product range as a single product entry in the ARTG. One application fee will cover this situation. However, if the sponsor wishes products that have the same ECRI classification to appear as separate products under the same grouped listing, then separate applications must be made, each with the application fee attached.

If a TGO applies to a device type (e.g. condoms, gloves, sutures, dental restorative materials, tampons, etc.), a strict interpretation of name is used. In these instances, 'name' is interpreted as meaning the 'trade' or proprietary name of the goods which readily identifies the products in the marketplace. Consequently these products cannot be grouped

Enquiries concerning the status of lodged applications should be directed to the Medical Devices Section:

Medical Device Listing Enquiries
Ph: 02 6232 8741

A summary of ERCI codes crossreferenced to their Australian Device Groups (ADGs) can be found in Appendix 6, *ECRI Codes.*

The complete ECRI code and ADG information is contained in the *Australian Device Groups* document 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

SPECIFIC LISTABLE DEVICE POLICIES

The TGA has formulated policies for regulating the following specific listable devices.

Specific listable Device policies	chap
Animal derivatives in listable devices	3.3
Bandages, dressings & allied products, etc.	3.4
Barium lime	3.5
Blood bags	3.6
Catheters (urethral)	3.7
Condoms	3.8
Contact lenses & contact lens care products	3.9
Contrast media injectors (powered)	3.10
Dental products	3.11
Dental restorative materials	3.12
Devices for people with disabilities	3.13
Diaphragms (contraceptive)	3.14
Disinfectants	3.15
without claims	
hospital grade	
Drug infusion injectors	3.16
Ducted and wired systems	3.17
Endoscopes and accessories	3.18
First Aid kits (see Kits)	
Gloves examination / surgical	3.19
Hearing and speech aids	3.20
In vitro diagnostics (IVD)	3.21
Needleless injectors	3.22
Insulin syringes	3.23
Intraocular lenses (IOL)	3.24
Kits — therapeutic devices kits	3.25
Oral hygiene products	3.62
Penile implants (inflatable)	3.27
Podiatry	3.28
Soda lime	3.29
Sutures and ligatures	3.30
Tampons — menstrual	3.31

Reference should also be made to the following Appendices:

1. *Advertising Therapeutic Goods to the Public*
5. *Conditions — Standard and Specific*
7. *ECRI codes*
8. *Excluded Goods*
9. *Exempt Goods*
11. *GMP — Standard of Overseas Manufacturers*
14. *Therapeutic Goods Orders/ Standards*
16. *TGO 11 — Sterile Goods*
17. *TGO 37 — Labelling*

3.3 ANIMAL DERIVATIVES CONTAINED IN LISTABLE DEVICES: DEVICES CONTAINING HEPARIN, GELATIN AND CAT GUT SUTURES

Sponsors of devices containing materials or ingredients excluded from the operation of Schedule 3 Item 3(g) of the *Therapeutic Goods Regulations* but which include heparin, gelatin or cat gut sutures are requested to ensure that the raw material is obtained from healthy animals. An application for listing should include details of:

- the species of animal from which the material is derived;
- the country of origin of the animals from which the material is obtained;
- the part of the animal used to manufacture this product (e.g. lungs of oxen, intestinal mucosae of oxen, pigs or sheep); and
- the procedure used to isolate, process and purify the animal material, including the concentrations of reagents and conditions of treatment.

Gelatin-containing Devices

Gelatin, derived from animal tissue, which conforms to an accepted Pharmacopoeial standard (e.g. *British Pharmacopoeia*, *European Pharmacopoeia* or *United States Pharmacopoeia*) and when associated with a device eligible for:

- listing in the ARTG, will be assessed for listing as a formulation of the device; or
- registration in the ARTG, will be evaluated for registration as a formulation of the device.

Evidence that the gelatin conforms to an accepted Pharmacopoeial standard must be submitted at the time of application. Australian sponsors of devices which contain gelatin must ensure that **all** batches of the gelatin which they propose to supply in Australia conform to an accepted standard. GMP applies to devices which are implants such as gelatin-coated stents, and GRF glue.

If evidence of the gelatin's compliance with a standard is not provided, an application for registration of the gelatin and associated device must be submitted to the Conformity Assessment Branch. Refer to Chapter2.10 *Animal Origin Devices* for guidance on the information and data on gelatin that is to be included in the submission, in addition to the information to be submitted for the associated device.

What to submit for a device with Gelatin (BP, USP, etc.)

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- labels (draft or sample);
- GMP evidence;
- promotional material / Instructions for Use/ package insert, etc.;
- evidence that the gelatin conforms to a generally accepted standard;
- a statement informing the Conformity Assessment Branch of the animal species and the part of the animal from which the gelatin is derived, the country of origin of the animals and the method of production of the gelatin.

3.4 BANDAGES, DRESSINGS AND ALLIED PRODUCTS

The TGA's requirements apply to all types of wound dressings (except for semi-solid dressings), bandages, adhesive dressings, adhesive tapes, absorbents and similar products used in the treatment of wounds, burns, lesions and in surgical procedures. Such products are usually textiles or tapes or combinations of both and may consist of natural or synthetic fibres. The TGA classifies these products into four groups with specific requirements applying to each group. Goods contained in Groups 1–3 require listing whilst goods in Group 4 are exempt from listing. Products may not be supplied to the Australian market or exported unless they are listed in the ARTG, except those which are exempt from listing.

The lists below, giving examples of products included in each group, are not exhaustive.

Group 1: Goods To Be Supplied Sterile

What to Submit for Listing

The sponsor should provide the following:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- labels (for unit and outer pack, as either draft or sample).

Group 1 Examples

- Primary Dressings, i.e. products applied to wounds, burns and broken skin:
  - Plain Dressings
  - Impregnated Dressings
  - Adhesive Dressings, adhesive strips
  - 'Combine' Dressing pieces
  - Gauzes
  - Wound Closures
- Surgical Absorbents, used in surgical procedure or introduced into body cavities to absorb blood and secretions:
  - Gauzes
  - Sponges
  - Swabs
  - Goods from Groups 2 and 3 which are supplied sterile

Group 1 Specific Conditions

- Where supplied in consumer packs these goods must be sterile and labelled 'Sterile'.
- These goods must comply with TGO 11 *Standard for Sterile Therapeutic Goods* (see Appendix 15).
- Products from Group 1 are not permitted to be sold non-sterile in retail consumer packs, and listing certificates will be conditioned accordingly.

Group 2: Goods Required To Be 'Clean' (Supplied Non-Sterile)

What to Submit for Listing

The sponsor should provide the following:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- labels (draft or sample);
- Site Information File;
- microbial Test Certificates.

Site Information File and Test Certificates are not required if the manufacturer has acceptable GMP.

Group 2 Examples

- Adhesive dressing in bulk lengths
- Combine dressing in bulk lengths
- Gauze and other absorbent dressings not individually wrapped and in 'bulk' packs
- Bandages (Cotton & Synthetic)
- Tubular gauzes
- Undercast padding
- Tubular elastic bandage
- Goods from Group 1 supplied non-sterile
- Cotton and Similar Absorbents
  - Cotton Wool
  - Cotton or rayon tipped applicators/swabsticks
  - Dental Rolls
  - Absorbent Rolls

Test Certificates

- Acceptable levels of cleanliness must be demonstrated **before** the goods will be listed in the ARTG. The total microbial count must be less than 10,000 micro-organisms per gram.
- A Test Certificate, showing compliance with the required microbial levels for a batch to be supplied in Australia, is to be submitted with all new applications. The certificate must conform to the method specified below in *Test for Microbial Count* or other acceptable method and the method should be stated. Test certificates must be in English, signed and dated by the analyst, and be less than six months old.
- Subsequently, test certificates will be required to be submitted for the next five batches of the product to be supplied in Australia, immediately prior to those batches being supplied.

Goods from Group 1 supplied non-sterile to users who will sterilize before use are also required to meet this requirement prior to supply.

Group 2 Specific Conditions

- It is a condition of listing that sponsors ensure that all batches supplied must be clean; i.e. less than 10,000 organisms per gram(this includes primary dressings supplied in bulk for terminal sterilisation by the purchaser).
- Sponsors must hold data to validate compliance and these data must be available to the TGA on request
- Samples may be taken at any time to check compliance with the requirements.

Test for Microbial Count

The total aerobic bacterial count shall be carried out on a sample of not less than one gram of material from each of five items of the product type under test. Where the product contains more than one component (e.g. gauze and cotton wool), all components shall be represented in the sample. Where the item weighs less than a gram then the whole item will be tested.

The sample shall be added to not more than 100 mL of 1 percent peptone water containing 0.1 percent Tween 80 and shall be stirred or shaken for at least 10 minutes at room temperature. If a stomacher or homogeniser is used, this time can be reduced to 1 minute.

Volumes of the peptone water, or dilutions of the peptone water shall be plated on

- plates with Trypticase Soy Agar (TSA) or Soybean Casein Digest Agar (SCDA) and incubated for 48 hours at 35–37^{o} C; and on
- plates with Sabouraud Dextrose Agar (SDA) or Low pH Mycophil Agar (LMA) and incubated for five days at 22–24^{o} C.

Plates shall be examined and the colony forming units (c.f.u.) counted.

- Dilutions and volumes plated should be adjusted to ensure that overlap of colonies is not significant.
- Numbers of c.f.u. counted per plate and numbers of replicate plates should be sufficient to give a reliable estimate of the total count.
- Estimates of total counts should be based on counts of a total of not less than approximately 200 colonies.
- The total count is the sum of the counts obtained on the two media.

Other methods may be acceptable but must be submitted to the Conformity Assessment Branch for assessment.

Group 3: Other Products

What to Submit for Listing

The sponsor should provide the following:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- labels (draft or sample).

Group 3 Examples

- Adhesive Tapes
- Elastic Tapes and Elastic Adhesive Bandages
- Casting Materials
  - Plaster of Paris Bandages
  - Synthetic Casting Materials

Group 4: Related Products Not Required To Be Listed

There are a number of products that do not require listing for the following reasons:

- related products (often sporting) may fall outside the operation of the Act if they
  - do not make therapeutic claims,
  - would not be perceived as suitable for therapeutic use (e.g. the treatment of wounds and burns), and
  - are not supplied sterile.
- Schedule 5, Item 7 of the *Therapeutic Goods Regulations* exempts a number of devices from listing in the ARTG including non-powered orthoses or splints that do not exert traction and non-powered hot or cold packs.
- Item 2(l) of *Therapeutic Goods (Excluded Goods) Order No.1 of 1998* (see Appendix 7) specifically excludes, from the operation of the Act, equipment or apparel intended for use in improving physiological fitness or modifying anatomical physique and appearance, except for equipment used for physiotherapy treatment.

Group 4 Examples

- Support or padded bandages designed to stabilise joints, restrict movement or protect against blows, e.g. neoprene knee or ankle supports
- Thermal bandages, supports designed to promote warmth/circulation in particular joints or muscle groups, e.g. lycra ankle socks
- Temporary splints such as inflatable splints
- Kidney belts, supportive clothing girdles, etc.

Refer also to Chapter 1.19 *Good Manufacturing Practice*, and to Appendices titled *Excluded Goods* and *Exempt Goods.*

Site Information File (SIF)

The SIF should be dated, and include the name, designation and signature of the person approving it (usually the firm's Chief Executive or Quality Assurance Manager).

General information required

The sponsor must provide the following information:

- brief information on the firm (including name and address), relation to other sites and, particularly, any other information relevant to understanding the manufacturing operation, including a locality map;
  - in not more than one A4 page, an outline of the firm's activities and other sites in addition to the site which is the subject of this document;

- manufacturing activities as licensed by the TGA or, if a licence has not yet been issued, the activities included in the Application for a Manufacturing Licence. For overseas firms the sponsor must state any applicable licensing provision and licence numbers, quoting the licence document as issued by the TGA. Any conditions and/or restrictions should be stated, and the equivalent for overseas locations.

- the name and exact address of the site, including telephone, fax and 24 hour telephone numbers:
  - name of Company (and trading name if different);
  - postal address (including code) and street address if different;
  - telephone and fax number and 24 hour contact telephone number;

- the type of actual therapeutic products manufactured on the site;

- a short description, in not more than one A4 page, of the site including size, location and immediate environment (photographs can be provided):
  - the location and immediate environment;
  - the size of the site, types of buildings and their ages;

- the number of employees engaged in:
  - production
  - Quality Assurance/Quality Control
  - storage and distribution
  - technical and engineering support services
  - total of the above.

  Note: include employees working only part-time on a full-time equivalent basis.

- use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis:
  - name and address of the firms employed;
  - a brief outline of the activity being undertaken in not more than 100 words (indicate who does the microbial testing for each batch);

- the use of outside subcontractors for any step of manufacture, including sterilization and release for supply:
  - names and addresses and telephone and fax numbers;
  - steps of manufacture undertaken;
  - whether 'release for supply' is involved;

- a short description, in not more than three A4 pages, of the quality management system of the firm:
  - state the firm's Quality Policy;
  - define the responsibility of the Quality Assurance function;
  - describe the elements of the QA system, e.g.
    1) QA organisational structure, responsibilities, procedures, processes,
    2) how quality is assured (see also section 6);
  - record if standards such as ISO 9000 series or EN4600 series standards are used by the company to assess its suppliers;
  - when suppliers of critical starting and packing materials, especially raw cotton, are assessed, give details of how this is done;
  - describe the 'release for supply' procedure for finished products.

Specific Information

Personnel

Provide an organisation chart showing the reporting relationships for quality assurance, production and quality control, with:

- organogram for quality assurance, production and quality control reporting relationships. Record senior managers and supervisors only.
- brief detail of academic qualifications, experience and responsibilities of key personnel.

Outline the arrangements for basic and in-service training and how records are maintained:

- describe how training needs are identified and by whom;
- give details of Company's training program;
- give brief details of training records kept.

Describe health requirements for personnel engaged in production:

- who is responsible for checking health of employees?
- is there a system for reporting sickness or contact with sick people before working in a critical area?
- are those who work in clean areas (sterile manufacture) subject to additional monitoring?

Describe personnel hygiene requirements, including clothing:

- briefly describe washing, changing and rest areas;
- briefly describe the protective clothing used.

Premises and Equipment

Premises

Give a simple plan or description of manufacturing areas and nature of construction and finishes, layout, etc. In not more than two A4 pages, and in a narrative format for preference (which can be limited to critical areas):

- provide a site plan, highlighting production areas. These areas must include all processing and packaging and critical storage areas.
- briefly describe the air control system, indicating the quality of air filtration, the criteria for changing the filters, and the frequency of revalidation of the system.

Briefly describe the treatment of cotton and other material. Specifically, mention how the hygiene and cleanliness are addressed:

- the type of treatment the cotton is exposed to, to reduce the microbial count — mention the chemical(s) used e.g. hydrogen peroxide or hypochlorite solution, etc.
- the sampling points, tests carried out and frequency of testing;
- the procedure and frequency for sanitation.

Equipment

Give a brief general description of major production and control laboratory equipment (a list of equipment is not required):

- describe the equipment calibration policy and the records kept;
- give the frequency of regular revalidation of critical equipment;
- outline the process validation;
- describe the system for the release for supply of development batches and validation batches.

Sanitation and Pest Control

Describe the cleaning and sanitation procedures for manufacturing areas and equipment.

- Are there written specifications and procedures for cleaning, cleaning agents to be used and the frequency of cleaning?
- Are cleaning agents changed from time to time?
- Have the cleaning procedures been validated and what was the method of evaluating the effectiveness of cleaning?
- Are cleaning methods monitored routinely by chemical and/or microbiological methods?
- What are the cleaning methods (and how often are they used) for the water supply system, air handling system and dust extraction system?
- Are there procedures for pest control?

Documentation

Note: this section refers to all documentation used in manufacture. Manufacture involves <u>all</u> activities relating to the production and control of therapeutic goods.

Describe the arrangements for the preparation, revision and distribution of necessary documentation for manufacture, e.g. batch records, SOPs.

- Is the documentation system governed by a Standard Procedure?
- Who is responsible for the preparation, revision and distribution of documents?
- Where are the master documents stored?
- What is the QA product release procedure?
- How is the documentation controlled?
- For how long are documents kept after the release of the batch?
- Detail any arrangements for electronic or microfilmed records.

Batch numbering system.

State how a 'batch' is defined and how batch numbers are generated and applied to finished products.

Production

Give a brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters.This narrative should be kept to a minimum, using generalized schematic layouts where possible. It should:

- describe the operations capable of being carried out at the site with the existing facilities;
- if only packaging is undertaken, give only a brief description of operations, e.g. labelling, filling etc., and the nature of containers used, e.g. sachets, cardboard packages;
- describe the production operations using flow charts if possible. Technical details are not required. Flow charts showing all processes and materials used, recycled and produced, including wastes, are essential for active raw material manufacture.
- describe how products are identified during production and how in-process storage is organised. In the case of medical devices, describe the extent of traceability from consumer to distributor to manufacturer to components to starting materials, as applicable.
- describe the in-process testing program;
- describe the procedure for the handling of raw materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage;
- state how non-conforming or reject materials are segregated and stored and state what document or system authorises, ensures and documents reprocessing or rejection and disposal.

Quality Control

Describe the Quality Control system, particularly microbial testing of final product, including:

- the activities of sampling, analytical testing, packaging and component testing, biological and microbiological testing;
- in the case of medical devices, how the question of 'retain' samples of products is addressed.

Distribution, complaints and product recall

Describe the arrangements and recording system for distribution.

- Is the warehouse secure?
- Is it environmentally controlled?
- Is there refrigerated storage?
- How are the materials stored, e.g. pallet racking?
- How is the status of products controlled, e.g. by computer, by label?
- What are the methods of distribution to customers?
- Does the despatch order (a) ensure first in/first out and (b) identify the lot number?

Describe the arrangements for dealing with complaints, including who is responsible for logging, classifying and investigating the complaint, and for product recalls.

Self Inspection

Give a short description of the self inspection/audit system.

3.5 BARIUM LIME

What to Submit for Listing

The sponsor should provide the following:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information / Instructions for Use / promotional material;
- labels (draft or sample).

Specific Conditions

Test Certificates

Barium lime must comply with TGO 47 which adopts the relevant USP monograph. 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— General Criteria for the Operation of Testing Laboratories; or
- certification from a recognised authority to ISO Guide 25 — 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).

* see Chap 3.1 for details

3.6 BLOOD BAGS

All blood bags and blood collection tubes (whether or not they contain anticoagulants) must be listed in the ARTG. Blood bags must comply with the following Australian standards:

- AS3787.1-1997: *General Requirements for Single Use, Sterile, Plasticised Polyvinylchloride (PVC) Packs for Human Blood; Part 1, Single Blood Packs,* and
- AS3787.2-1997: *General Requirements for Single Use, Sterile, Plasticised Polyvinylchloride (PVC) Packs for Human Blood; Part 2, Multiple Blood Pack Systems.*

What to Submit for Listing

The sponsor should provide the following:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- unit and outer labels (draft or sample);
- product information;
- details of contents:
  - a list of the ingredients of those blood bags that contain anticoagulants or preservatives. These ingredients must be in the *Australian Approved Names* (AAN) list and identified in the application as BP, USP, etc.
  - strengths and proportions of additives are not required.

If the product contains new chemical components that do not have AANs and have not been evaluated previously, they must first be assessed by the Drug Safety and Evaluation Branch (DSEB) of the TGA before an application for listing may be submitted.

Differentiating Between Blood Bag Products

Blood bag products are differentiated on the basis of whether they contain solutions or not. If two blood bags are identical in all aspects except for the fact that one contains solution and the other does not then they are classified as separate products. Bags containing different *combinations* of chemicals (anticoagulants) are*not* identified as separate products because they both contain solutions.

Grouping Blood Bags

Grouping criteria for listable devices apply to blood bags. Blood bags with and without solutions are grouped if sourced from the same principal manufacturer, as they are not regarded as formulated or medicated devices.

Please refer to Chapter 3.2 *Grouping of Listable Devices* and Chapter 1.19 *Good Manufacturing Practice.*

3.7 CATHETERS (URETHRAL)

All single use, urethral catheters for general medical use supplied in Australia, whether imported, exported or manufactured in Australia, must comply with TGO 59 and must be listed in the ARTG.

TGO 59, which adopts the standard AS/NZS 2696-1996, relates specifically for catheters made of a plastic material, or of natural or synthetic rubber or elastomer, or of a combination of components made from any of these materials.

What to Submit for Listing

Sponsors of single use catheters are required, prior to importation, to provide the TGA with the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- labels (draft or sample)
  - for unit and outer pack

  (labels must be in compliance with the Standard);
- GMP evidence (if sterile).

The submission of a completed application will be taken as evidence that the sponsor has established compliance with TGO 59.

Specific Conditions

Batch Size

Details of the Batch size must be provided when requested by the TGA or the testing laboratory (the size of the sample taken for testing will depend on the batch size). Accurate batch records, including batch numbers and batch size and records of distribution, must be held by the sponsor.

Test Certificates

Although test certificates complying with TGO 59 are not required at the time of the application, the sponsor must be able to supply the certificates to the TGA, on 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 — General Criteria for the Operation of Testing Laboratories; or
- certification from a recognised authority to ISO Guide 25 — 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).

* see Chap 3.1 for details

While TGA's primary concern with urethral catheters is cytotoxicity, other factors will continue to be monitored. Testing will therefore be directed more at the safety of materials, particularly latex, rather than at size or configuration. Refer also to Chapter 1.19 *Good Manufacturing Practice*.

3.8 CONDOMS (CONTRACEPTIVE, RUBBER)

All rubber contraceptive condoms supplied in Australia, whether imported, exported or manufactured in Australia, **must** be listed in the ARTG.

TGO 61 *Contraceptive Devices — Rubber Condoms* adopts International Standard ISO 4074-1:1996(E) *Rubber Condoms*, with some extra requirements. Supply of condoms which do not conform to TGO 61 is an offence under Section 14 of the Act.

Australian sponsors of contraceptive rubber condoms must ensure that **ALL** batches of contraceptive condoms which they propose to supply in Australia comply fully with all aspects of the Standard, including labelling and packaging requirements.

What to Submit for Listing

The sponsor should provide the following:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- Test Certificate;
- consumer pack and foil labels (draft or sample);
- package insert.

For every subsequent batch, a test certificate must be produced for inspection whenever the TGA so requests.

Test Certificates

At the time of listing, sponsors are required to submit a batch test certificate in compliance with TGO 61 *Contraceptive Devices — Rubber Condoms* for the first batch of condoms intended for supply into Australia.

The initial test certificate must be provided by an independent testing laboratory approved by the TGA. The certificate is to be signed and dated by an authorised person from the laboratory and must provide comments and results against each of the requirements for the Standard.

Similar testing must be performed on every subsequent batch of condoms intended for supply in Australia or for export. It is not necessary for these later certificates to be from the laboratory conducting the initial test but sponsors should ensure that the subsequent batch testing is conducted by a laboratory certified to carry out all tests required by TGO 61.

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 — General Criteria for the Operation of Testing Laboratories; or
- certification from a recognised authority to ISO Guide 25 — 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). Testing must be performed for every batch of condoms intended for supply in Australia or for export, and test certificates must be available for inspection on request by an authorised officer of the TGA.

* see Chap 3.1 for details

It is important that manufacturers and importers appreciate the significance of batch size, batch records and batch labelling. This information must be consistent with the definition of 'batch' in the Standard. Batch numbers must be assigned by the manufacturer at the time of manufacture and marked on each individually wrapped condom at that time. Details of the batch size must be made available when requested by the TGA or testing laboratory (the size of the sample taken for testing depends on batch size). Accurate batch records, including batch numbers and batch size must be kept, including records of all distribution.

Condoms are expected to meet the Standard at the time of supply to the consumer. Since age of the rubber and conditions of storage may affect the quality of the product, sponsors are advised to ensure that testing is done at an appropriate time relative to the time of intended supply.

Refer also to Chapter 1.19 *Good Manufacturing Practice.*

Condoms Which Include a Spermicide or Similar Agent

Nonoxynol-9 is approved for use as a spermicidal agent in condoms supplied in Australia. Information, including certificates of analysis, may be sought at any time about the quality, manufacture, etc., of Nonoxynol-9 used with a condom. Sponsors should ensure that they have access to this information at all times. The TGA will consider requests to supply condoms containing spermicides or agents other than Nonoxynol-9, on a case by case basis. Detailed information about the quality, safety and efficacy of the spermicide, etc., may be required.

Condoms in Novelty Packaging

The Department receives many requests to distribute condoms out of their original packaging for 'promotional' or 'educational' purposes. Requests have been received for permission to allow distribution of condoms with clothing, greeting cards, CDs, magazines, etc. Under such circumstances the integrity and traceability of the condom may be severely compromised and pose unacceptable risks to persons who may use the condom.

The TGA supports efforts to promote the use of condoms and to encourage safe sexual

practices. However, no approval can be given for any use involving the supply of condoms in packaging that does not conform with TGO 61. Unless the following conditions are observed, condoms in novelty packaging will be regulated as 'standard' condoms and must comply with all of the Departmental requirements for condoms. Failure to comply may result in prosecution under the Act. Condoms in novelty or non-standard packaging must be clearly presented as a novelty item only, and be boldly marked with the words 'not to be used during sexual intercourse' or with words of similar meaning, to indicate that the condom is not suitable for the prevention of pregnancy or as protection from the transmission of disease.

Some non-standard distribution is not under Commonwealth control, e.g. if members of a student body, union branch or area health organisation remove condoms from bulk packaging prior to distribution for educational purposes. Such organisations should take care to ensure that the condoms they purchase for distribution are listed in the ARTG and are stored and handled properly.

Novelty Products

Condom-like products sold for novelty purposes, such as 'Glow in the Dark' condoms, party novelties, etc., should be easily distinguished in all ways from condoms sold as therapeutic devices (i.e. contraceptives or prophylactics). The Department is concerned that consumers may mistakenly purchase these novelty products intending to use them for contraceptive or prophylactic purposes.

The suppliers of these novelty products must do the following:

- package the novelty so that it does not resemble a condom with therapeutic indications;
- name the product without suggesting or using terms that are generally used to describe condoms, e.g. rubbers, prophylactics, french letters, condoms;
- include, in the labelling, packaging or display explicit statements clearly indicating that the product is not intended to prevent pregnancy or the transmission of sexually transmitted diseases;
- promote and label the product so that potential purchasers will know it is a novelty.

If the labelling of a condom-like product does not clearly indicate that it is a novelty, then the Department will regulate that product as a therapeutic device, and all the Department's requirements for condoms will apply. Under these requirements, the sponsor must apply to list the device in the ARTG, provide evidence that the manufacturer conforms to an acceptable code of GMP, and provide test certificates from an independent testing facility demonstrating the novelty products conform to TGO 61.

Monitoring for Compliance with the Standard by the TGA

Samples for testing may be taken by the Department to check compliance with TGO 61, in accordance with Section 48 of *Therapeutic Goods Act 1989.* Where products are determined not to comply, sponsors may be required to withdraw the product from the market and are also liable to prosecution. Batch testing records may be requested at any time.

TGO 61 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

3.9 CONTACT LENSES & CONTACT LENS CARE PRODUCTS

Contact lenses and contact lens care products must be listed in the ARTG before they can be legally supplied in Australia. The Act does not affect optical laboratories or practitioners dispensing contact lenses on prescription for individual patients unless lens materials are to be directly imported.

What to Submit for Listing

For all soft contact lenses and contact lens care products and sterile goods, the sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- label (draft or sample); and
- details of the composition / formulation of the lens or lens care product.

Goods to be sold as 'sterile' must demonstrate sterility when tested according to the methods specified in TGO 11 *Standard for Sterile Therapeutic Goods* (see Appendix 15).

Goods that are manufactured in accordance with Appendix C of the *Code of Good Manufacturing Practice for Sterile Therapeutic Devices* or an equivalent Code, should comply with TGO 11. Refer to Chapter 1.19 *Good Manufacturing Practice.*

How Products/Actions Are Categorised

These products must be listed:

- all contact lenses including those with hard, soft, gas permeable, disposable or extended wear materials, whether therapeutic, vision corrective, or for colour change only;
- contact lens 'blanks' or 'buttons';
- contact lens care products used for cleaning, storing, disinfection, cushioning, conditioning, etc.

These products are exempt from listing:

- contact lenses dispensed for a particular patient by optical laboratories, practitioners etc.
- contact lens containers, storage cases;
- contact lens removers and inserters; and
- disinfection units— thermal, sonic, electrophoretic etc.

These actions must be licensed:

- the 'manufacture' of soft contact lenses for 'supply' in Australia unless they are produced or dispensed for specific patients on the written order of a registered health care practitioner.

These actions do not have to be licensed:

- the manufacture of hard or gas permeable lenses;
- the dispensing of contact lenses by a registered optical practitioner specifically for a patient under his or her care;
- the dispensing or production of contact lenses by a laboratory solely for individual patients on the prescription of a registered optical practitioner.

Refer also to Chapter 1.19 *Good Manufacturing Practice* and the Appendices *Excluded Goods* and *Exempt Goods.*

Contact Lenses

Contact lenses and blanks may be grouped for the purposes of listing in the ARTG provided they have the same:

- sponsor,
- manufacturer,
- material composition, and
- sterility status.

Materials which are identical in composition except for their water content and tinting will be treated as being the same material.

Contact Lens Care Products

All products which may come into contact with the eye are required to comply with the appropriate requirements of the *British Pharmacopoeia* (BP), and the general requirements for eye drops, eye lotions, eye ointments should be observed. The BP is a legally enforceable standard under the Act. It specifies that these products must be:

- sterile,
- supplied in containers which do not cause deterioration of the product; and
- in addition to the labelling requirements of TGO 37, be labelled with:
  - an expiry date,
  - formulation details,
  - the period after opening after which contents should not be used (usually one month),
  - the conditions under which the goods should be stored, and
  - a statement that care should be taken to avoid contamination during use.

Contact Lens Care Products may be grouped provided they have the same:

- sponsor,
- manufacturer,
- sterility status, and
- therapeutically active component or principle substance on which the action of the product depends.

Multi-dose Normal Saline Solutions

Multi-dose normal saline products for use with contact lenses which contain a preservative or are packaged in a manner which minimises the risk of in-use microbial contamination, must supply data demonstrating the effectiveness of the products' preservatives and/or packaging and verify the expiry date and open shelf-life assigned to the product. This data is to be supplied at the time of application.

3.10 CONTRAST MEDIA INJECTORS (POWERED)

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information / instruction for use / promotional material;
- labels (draft or sample).

Specific Conditions

Problems relating to the condition, use or application of the device must be reported to the Director, Conformity Assessment Branch, between 1 July and 1 October each year for the first three years after the initial entry in the ARTG.

Director,
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

3.11 DENTAL PRODUCTS

Dental therapeutic goods include drugs and devices. Most dental drugs are registrable and any information regarding the entry of these goods in the ARTG should be referred to the Drug Safety and Evaluation Branch (DSEB) of the TGA ph: 02 6232 8100.

Goods imported for use in the treatment of the importer or the importer's immediate family are exempt from entry in the ARTG under the circumstances outlined in Item 1 of Schedule 5 of the *Therapeutic Goods Regulations*. Refer also to Chapter 1.19 *Good Manufacturing Practice*, and Appendices titled *Excluded Goods* and *Exempt Goods.*

Dentists importing therapeutic goods for use in their own practices are still required to register or list the goods before using them on a patient.

The supply of unlisted or unregistered therapeutic goods will expose such dentists to the risk of prosecution. It is possible that such breaches of the law may jeopardise the protection given by existing professional indemnity or public liability schemes.

Products Required to be Listed

The following are examples of listable dental devices (the list is not intended to be exhaustive):

- dental equipment e.g. pulp testers, ultrasonic dental scalers, x-ray equipment, sterile hand instruments, syringes, needles etc.;
- Grafts, Implants & Prostheses of non-animal origin, e.g. bone screws and plates;
- non-restorative dental materials, e.g. endodontic paper points, gingival retraction cords without adrenalin;
- Restorative Dental Materials, e.g. resin based, glass ionomer cements, filling material.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information;
- labels (draft or sample),
  - both inner and outer labels are required for sterile products,
- GMP evidence.

Dental Products Subject to Standards

Dental restorative materials are required to comply with TGO 57. Refer to Chapter 3.12 *Dental Restorative Materials.*

3.12 DENTAL RESTORATIVE MATERIALS

Dental restorative materials are used for the restoration or replacement of teeth. These products must be listed in the ARTG when they are to be supplied either as separate single items or as items within multi-component systems.

Individual components (raw materials) of systems which are separately available are exempt from listing (*Therapeutic Goods Regulations* Schedule 5 Item 7(a)). Refer to Appendix 8, *Exempt Goods.*

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample);
- GMP evidence.

Specific Conditions

Test Certificates

TGO 57 is a mandatory requirement for the following dental restoratives. When requested by the TGA, sponsors will be required to produce the Test Certificates for any batch of goods supplied in Australia, showing compliance to the relevant standards:

- ISO 3107-1988: Cements, dental, zinc oxide
  - Dental zinc oxide/eugenol cements
  - Dental zinc oxide non-eugenol cements
- ISO 4049-1988: Composite resin-based restorative materials, light-cured or self-cured excluding pit and fissure sealants
  - Resin-based filling materials
- ISO 1559-1995: Dental amalgam, capsules or powder or tablet
  - Alloys for dental amalgam
- ISO 6876-1986: Endodontic filling materials, sealers/pastes
  - Dental root canal sealing materials
- ISO 1560-1985: Mercury, dental
  - Dental mercury
- ISO 6874-1988: Pit and fissure sealants
  - Dental resin-based pit and fissure sealants
- ISO 9917-1991: Water-based dental cements

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 — General Criteria for the Operation of Testing Laboratories; or
- certification from a recognised authority to ISO Guide 25 — 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).

* see Chap 3.1 for details

Labelling

Labelling of dental restoratives supplied separately as a single item or as components within a system must comply with TGO 37 *General Requirements For Labels For Therapeutic Devices* (see Appendix 16). Any components subject to TGO 57 *Dental Materials* must also conform with the labelling requirements of this order. Other components exempt from listing and not supplied as separate items have no special labelling requirements.

GMP

Evidence of the manufacturer's compliance with an acceptable code of GMP must be provided with each application. Refer to Chapter 1.19 *Good Manufacturing Practice.*

Types and Presentations of Dental Restorative Materials

Multi Component Restorative Systems

These are systems that consist of various items used for dental restoration:

- Universal bonding system
  etchant (gel, porcelain etchant, semi-gel)
  primer a, b
  bonding resin
  opaquers (base, catalyst)
  spatulas
  dental brushes, brush tips, brush handles.

Dental restorative systems of this form can be grouped and listed in the ARTG if they have the same:

- sterility status
- sponsor
- ISO standard applicable to the products, if specified in TGO 57.

Refer also to Chapter 1.9 *Reducing Annual Charges.*

Single Type Dental Restorative Systems

These systems consist of the same type of dental restorative material but in different presentations:

- dental amalgam systems
- amalgam powder, tablets, capsules
- dental cementation systems
- opacifier cements
- translucent cements
- resin cements.

Dental restorative systems of this form can be grouped and listed in the ARTG if they have the same:

- manufacturer
- sponsor
- formulation details
- sterility status
- ISO standard applicable to the products, if specified in TGO 57.

Restorative materials which are separately supplied

These are not raw materials and can be used with any other dental restorative systems:

- cavity liners
- cavity varnish.

These forms of dental restorative materials have to be listed separately in the ARTG. Grouping will be allowed if they have the same:

- formulation
- sponsor
- manufacturer
- sterility status
- ISO standard applicable to the products, if specified in TGO 57.

3.13 DEVICES FOR PEOPLE WITH DISABILITIES

Schedule 5 of the *Therapeutic Goods Regulations* exempts therapeutic goods from the requirement of being listed in the ARTG. Item 1 exempts goods that are imported for use in the treatment of the importer or the importer's immediate family. In practice, any person or their immediate family residing in Australia may produce, modify or import therapeutic devices for their own use. This allows a person to import and use therapeutic devices including those normally requiring listing such as powered wheelchairs, lifting devices and prostheses, without having to 'list' those devices.

The definition of ***sponsor*** in the Act enables any person in Australia to manufacture, import or export a therapeutic device on behalf of a disabled person, without listing the device in the ARTG.

Exempt Goods

As well as goods for personal use, Item 7 of Schedule 5 of the *Therapeutic Goods Regulations* exempts a number of other devices from the requirement of being listed in the ARTG. Goods that are exempt and may be used by people with disabilities include:

- non-powered equipment used in general patient care, if it does not constitute or contribute to the specific diagnosis, monitoring or treatment of a medical condition;
- furniture other than powered appliances for use in diagnosis or treatment of a medical condition;
- non-powered orthoses or splints that do not exert traction.

Schedule 5 therapeutic devices exempted from the requirement to be listed in the ARTG still have to comply with other parts of the Act including those relating to labelling and advertising.

Excluded Goods

Therapeutic Goods (Excluded Goods) Order No.1 of 1998 specifically excludes:

- household and personal aids, or furniture and utensils, for the disabled;
- incontinence pads, mattress overlays or mattress protectors;
- equipment or apparel intended for use in improving physiological fitness or modifying anatomical physique and appearance other than equipment used for physiotherapy treatment;
- non-prescription spectacles labelled for use solely for magnification of image or sun protection.

Examples of Excluded Or Exempt Goods

These are some of the devices/goods that are excluded or exempt from listing in the ARTG:

- walking frames, crutches, canes;
- non-powered trolleys, and carts to aid mobility;
- handles, rails, manually operated devices to increase dexterity or leverage e.g. devices to assist in turning off taps;
- furniture such as chairs assisting rising, non-powered adjustable beds;
- orthoses and external braces for limbs, i.e. leg calipers, neck braces, knee supports, etc.;
- spectacles, magnifying glasses and enlarging lights and other aids for the visually impaired;
- exercise equipment used to improve physiological fitness, i.e. exercise bikes and gym equipment.

Any therapeutic device that is supplied for use by people with a disability must be listed in the ARTG prior to supply, unless its supply is covered by the paragraphs above.

Refer also to Appendices *Excluded Goods* and *Exempt Goods.*

3.14 DIAPHRAGMS — CONTRACEPTIVE

All contraceptive diaphragms are required to be listed in the ARTG, and must comply with TGO 28 *Standard for Contraceptive Devices — Diaphragms*. This Order came into force on 10 April 1986 and adopts the Australian Standard AS1808:1984 *Contraceptive Devices — Diaphragms*. Australian sponsors of contraceptive diaphragms must ensure that ALL batches which they propose to supply in Australia comply with all aspects of the Standard, including its labelling and packaging requirements.

Recently, people have become more aware of the potential sensitisation associated with some latex products. The material of a diaphragm is intended to be in direct contact with body tissues for extended periods of time, so the Conformity Assessment Branch has proposed that they will investigate the extent of possible cytotoxic reactions by including some aspects of ISO 10993 *Biological Evaluation of Medical Devices* within the TGA testing regime. Sponsors should therefore be aware that their product may be tested for possible cytotoxic reactions during the course of its routine compliance testing.

What to Submit For Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- labels (draft or sample);
- GMP evidence;
- promotional material, instructions for use and package inserts;
- Test Certificate.

Specific Conditions

Test Certificates

Test Certificates must demonstrate full compliance with TGO 28. The Test Certificate must show comments against each requirement of the standard for a batch of diaphragms representative of those to be supplied in Australia (but not necessarily a batch which will be supplied in Australia). Test Certificates demonstrating compliance are required at the time of listing. These certificates must be retained by the sponsor and supplied upon request, and sponsors must ensure that each batch supplied in Australia meets the requirements of TGO 28.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 — *General Criteria for the Operation of Testing Laboratories*; or
- certification from a recognised authority to ISO Guide 25 — *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).

* see Chap 3.1 for details

3.15 DISINFECTANTS

Information to be supplied with an application for listing of disinfectants in the ARTG is described in Appendix 18, *TGO 54, 54A and Guidelines — Standard for Composition, Packaging, Labelling and Performance of Disinfectants and Sterilants*.

Other documents contained in Appendix 18 include the *ARTG Standardised Data Requirements for Disinfectants and Sterilants*, and the draft documents, *Changes to Disinfectants and Sterilants Included in the ARTG as Therapeutic Devices — Is Notification or Prior Approval Required?* and *Advertising Guidelines for Disinfectants and Sterilants.* (The draft documents when approved will be updated in the Appendix.) This Appendix may also serve as a guide to the sponsors of other products that have to meet TGO 54, but which are exempt from registration or listing.

The disinfectants which require listing in the ARTG are those classified as 'Hospital Grade without Specific Claims'. Labelling requirements are specified in Appendix 18, *TGO 54, 54A and Guidelines.* Manufacturing licences are not required for listable disinfectants.

Sponsors should also refer to Chapter 1.19 *Good Manufacturing Practice*, and the Appendices titled *Excluded Goods* and *Exempt Goods.*

Application procedures are described in the guidelines document attached to TGO 54. Applications for registration will be subject to evaluation by the Conformity Assessment Branch (CAB) and the Therapeutic Goods Administration Laboratories (TGAL) Branch, in accordance with Section 25 of the *Therapeutic Goods Act 1989*. Applications for listing will be reviewed by CAB in accordance with Section 26 of the Act.

3.16 DRUG INJECTOR PENS

If prefilled cartridges are to be supplied with the injector, the quality, safety and efficacy of the drug must first be assessed by the Drug Safety & Evaluation Branch (DSEB) of the TGA, ph: 02 6232 8127.

The drug delivery system is subject to listing in the ARTG, but the combination may not be marketed until the prefilled cartridge and the delivery system have both been entered in the ARTG.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information;
- data on specifications, manufacture, mode of action, performance test results and copies of patient instructions and labelling;
- labels (draft or sample)
  - in addition to compliance with the requirements of TGO 37, the labels should clearly state which prefilled cartridges can be used;
  - cartridge labels should clearly state in which injectors they can be used;
- list of countries in which product has been sold;
- an estimate of the number of devices sold, to date, in each country;
- a copy of instructions for use including:
  - how to use the device;
  - how to correctly load the device;
  - how to expel the air prior to each injection;
  - how to disinfect the septum prior to attachment of new needle; and advice to use a new needle for each injection;
- results of tests showing that the dosages are accurate over the full range of dosage settings, within the stated accuracy limit of the device;
- durability testing protocols and results for reusable devices;
- a sample and diagram to establish that:
  - the device visually displays the dose size (volume) to be delivered and the plunger is visible over all of its travel;
  - the device has audible and tactile indicators for setting the dosage; and
  - the plunger does not reset to zero if the device is dismantled.

3.17 DUCTED AND WIRED SYSTEMS

The TGA receives many enquiries from sponsors about the regulatory status of ducted aspiration, medical gases, and dialysis systems. The same concerns also apply to many powered systems where the power source is in a plant room or remote from the clinical situation. The problem is to determine where the 'device' starts and finishes and what aspects of such systems are required to be registered or listed.

The nature of the installation is considered when determining what is a 'device' and what is not. Anything which is part of the fabric or structure of a building or is permanently installed in a plant room or storage facility will not be regarded as a therapeutic device.

Electrical Systems

Wiring, generators, electric motors, and such equipment 'permanently' installed by an electrician in plant rooms remote from the patient environment will be exempted from listing as therapeutic devices.

Powered appliances, instruments etc., which have a therapeutic use and are near the patient or in the clinical environment, may be listable unless exempt or excluded.

Medical Gases

Bulk storage tanks left 'permanently' in place, including valves and regulators attached to those tanks, together with gas lines built into the building, will be exempted from listing.

Valves, regulators and flexible hoses attached to cylinders, together with lines and connections between the wall and the patient, will be regarded as listable therapeutic devices.

Aspiration Systems

Aspiration lines built into the building, pumps or engines, remote from the clinical environment and left 'permanently' attached will be exempted from listing. Tubing, connections, etc., between the wall and the patient will be regarded as listable devices.

Dialysis Systems

Pipes and lines built into the building together with mains water supplies, filtration units, pumps, etc., which are 'permanently' installed or plumbed and wired will be exempted from listing. Lines, filters and 'portable' equipment in the clinical environment and between the wall and the patient will be listable.

3.18 ENDOSCOPES AND ENDOSCOPIC ACCESSORIES

Endoscope is a generic term that refers to many specific interventional instruments such as laparoscopes, arthroscopes, laryngoscopes, colonoscopes, cystoscopes, etc., which are used to perform diagnostic as well as surgical procedures. Endoscopes generally comprise a modular series of metal tubes that can provide access and illumination, and enable manipulation, or observation of hollow organs, canals or cavities of the body. Endoscopic kits, sterile and non-sterile, may contain powered components such as light sources, a camera, electrosurgical forceps etc., as well as non-powered components.

Endoscopic Accessories are devices used with endoscopes, and necessary for the performance of the endoscopic procedure**.**

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- labels (draft or sample);
- GMP evidence (for sterile products).

Endoscopes will need to be listed separately if they are supplied separately.

Kits

- Endoscopic kits may contain a mixture of accessories as well as endoscopes. This type of kit will need to meet the requirements of listing as set out in the Kits policy (below). A sponsor can have a list of goods from which a kit can be put together for a specific surgical procedure.

These kits will be listed using the following classification:

Australian Device Group (ADG)	Kits, Trays, Packs — Procedural, Without Drugs (KTPWOD)

Labels

- Labelling of endoscopes and individual accessories must be in accordance with TGO 37 *General Requirements for Labels for Therapeutic Devices* (see Appendix 16). This includes the batch number, device name, name and address of manufacturer or sponsor, and the word 'sterile' if applicable.
- Due to the physical size of such devices it is acceptable to provide a label with the device that contains all the required information. The label can be in the form of an invoice provided that there is enough information to trace the device.

GMP
Sponsors must provide evidence, with each application, to demonstrate that the overseas manufacturer complies with an acceptable code of Good Manufacturing Practice. Australian manufacturers must be licensed to manufacture sterile therapeutic goods. Refer to Chapter 1.19 *Good Manufacturing Practice.*

Grouping

Endoscopes and endoscopic accessories, according to the *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991* (Appendix 19), can be grouped if they have the same:

- principal manufacturer; and
- classification in the Australian Device Group (ADG); and
- sterility status; and
- standard; and
- sponsor; and
- formulation, if applicable.

Endoscopes intended for different procedures (e.g. laparoscopes, cystoscopes, colonoscopes), supplied by a sponsor from the same manufacturer and of the same sterility status, will be grouped as separate products with distinct ECRI codes, but under the same ADG code ENDOSC.

Endoscopic accessories supplied by a sponsor from the same manufacturer and of the same sterility status will be listed as a single product or line entry in the ARTG under the ADG code ENDOAC for 'Endoscopic Accessories'. The single product line entry will be given a general name and generic ECRI code. Individual product listings from the sponsor will not be required. Variations in the product range are not required to be notified to TGA.

(Refer to Chapter 3.2 *Grouping of Listable Devices*).

Endoscopes and accessories are required to be listed separately according to their sterility status, under one of the following Australian Device Group (ADG) classifications:

- endoscopes (ENDOSC)
- endoscopic accessories (ENDOAC).

Other requirements

- Sponsors must ensure that all sterile devices comply with TGO 11*Standard for Sterile Therapeutic Goods* (see Appendix 15).
- Accessories, such as pre-loaded suturing devices, that have an applicable standard, cannot be included in the endoscopic accessories listing and must be separately listed.
- Sponsors must maintain detailed records of the distribution of their products in accordance with Standard Conditions of listed goods. (Refer to Appendix 4, *Conditions — Standard and Specific Devices*.

3.19 GLOVES (EXAMINATION, SURGICAL)

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- labels (draft or sample).

The Therapeutic Goods Act 1989 and *Regulations* require that **all** medical examination gloves and surgical gloves supplied in Australia must be listed in the ARTG by the sponsor of the gloves. Gloves included are:

- medical examination gloves
- surgical gloves

Labelling Requirements

Among other things, this Order requires gloves supplied for medical purposes to be clearly marked with at least the words 'examination gloves' or 'medical gloves'. Gloves not complying with this Order may be supplied to various industries for other purposes, but may closely resemble gloves for medical use. However, suppliers of gloves for other purposes are reminded that the definition of therapeutic goods in the*Therapeutic Goods Act 1989* includes;

'goods that are represented in any way to be, or that are, whether because of the way in which they are presented or for any other reason, **likely to be taken to be for therapeutic use**...'.

All form-fitting, seamless gloves resembling medical gloves, supplied into areas such as hospitals, health care facilities, included in First Aid kits and doctors' surgeries, are deemed to fall under the definition of therapeutic goods, because they are likely to be thought to be for therapeutic use. Suppliers of gloves for non-medical purposes into these areas must advise the buyer that the product is not for medical use. They should ensure that their products are easily distinguishable from medical gloves by clearly labelling them 'not for medical use' or with words having a similar meaning.

Suppliers of non-medical gloves into these areas who do not clearly identify their products as 'not for medical use' may be liable for prosecution under the*Therapeutic Goods Act 1989* or other Commonwealth laws.

It is illegal to supply any gloves intended for medical or dental use within Australia or for export without prior listing in the ARTG. Supply can be by sale, gift and sample or advertisement, whether free of charge or otherwise.

General Requirements

Examination Gloves

All gloves for general medical and dental use must comply with TGO 52 and be manufactured to an acceptable standard of GMP before they can be listed in the ARTG. TGO 52 came into effect on 18 June 1997 and essentially adopts the joint Australian / New Zealand Standard AS/NZS 4011:1997 *Single-use examination gloves — Specification* as the standard for gloves under the *Therapeutic Goods Act 1989.*

Presumption of single use

It is presumed that gloves for general medical and dental use supplied in Australia are for single use only unless specifically labelled to be for multiple use. Sponsors who supply gloves intended for multiple use are advised that such multiple use gloves will be required to continue to meet all of the requirements of TGO 52 after they have been cleaned and resterilized using methods recommended by sponsor.

Surgeons Gloves

All single-use, sterile gloves made from natural or synthetic rubber, intended for use in surgical procedures, must comply with TGO 53 and be manufactured to an acceptable standard of GMP before they can be listed in the ARTG. TGO 53 came into effect on 18 June 1997 and essentially adopts the joint Australian / New Zealand Standard AS/NZS 4079:1997 *Single-use sterile surgical rubber gloves — Specification* as the standard for gloves under the *Therapeutic Goods Act 1989.*

Sterile Gloves

All latex or vinyl form-fitting, single use, seamless gloves supplied sterile must also comply with TGO 11. Refer to Appendix 15, *TGO 11 Standard for Sterile Therapeutic Goods*.

Specific Conditions

Test Certificate

Sponsors must ensure that each batch supplied in Australia meets the standard. A Test Certificate must be obtained for each batch of gloves before they are supplied in Australia, and must show full compliance with the relevant TGO. The test certificate must consist of a detailed certificate of compliance with the relevant Order, with comments against each requirement of the standard. The Test Certificate need only be submitted when the TGA so requests.

The test certificate must be produced when requested by the TGA

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 — General Criteria for the Operation of Testing Laboratories; or
- certification from a recognised authority to ISO Guide 25 — 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).

* see Chap 3.1 for details

3.20 HEARING AND SPEECH AIDS

Prescribing practitioners and laboratories dispensing or programming hearing and speech aids for particular persons are not regarded as sponsors under the Act unless they are importers or manufacturers of the device.

An audiologist who sends prescriptions to an overseas laboratory, and then imports the hearing aids and supplies them to specific patients, is a sponsor and therefore is required to list the products in the ARTG. If the patient obtains the device as a personal import the device is exempt from listing.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence (if the good is sterile or implantable);
- labels (draft or sample);
- product information, instructions for use and promotional material.

Not all hearing or speech aids are listable devices. Refer to Appendices titled *Exempt Goods* and *Excluded Goods.*

Hearing Aid Products Required to be Listed

- Electrically operated hearing aids
- Bone conduction hearing aids
- Non-acoustic inputs to hearing aids
- Tactile hearing aids
- Tinnitus Maskers

Hearing Aid Products Exempt from Listing

These include:

- hearing aids that are personal imports of the user.
- non-powered equipment used in general patient care, such as ear trumpets, that does not constitute or contribute to a specific treatment of a medical condition.

Therapeutic devices exempted from the need to be listed in the ARTG must still comply with other provisions of the Act such as labelling and advertising requirements, and are subject to recall.

Special Requirements of some hearing aids

'Off-the-shelf' hearing aids used with patient-specific, custom-made ear moulds are listable devices in the ARTG. The custom-made ear mould itself is exempt from listing in the ARTG.

Where the components of a hearing aid, i.e. electronics, microphone, transducer, etc., are assembled by the supplier within the custom-made ear mould, the whole assembly (hearing aid) is exempt from listing in the ARTG, because these are classified as custom-made devices.

Speech Therapy Aids

Devices listed as speech therapy aids are externally applied, inserted or implanted and are used as aids or substitutes for impaired vocal ability. They include:

- artificial larynx prostheses; these may be pneumatic (internal and external devices) or electronic (intraoral or transcervical devices) which enable affected persons to simulate an approximation to normal laryngeal voice;
- speech therapy units; these devices are used as aids for speech deficiency or impediments and are used to provide auditory feedback to the patient.

Speech Therapy Aid Products Exempt from Listing

Speech therapy aids and accessories dispensed for a particular patient by laboratories or practitioners are exempt from listing. This does not include speech therapy aids commercially manufactured and subsequently modified for an individual patient.

Electromagnetic Compatibility Requirements

Electromagnetic compatibility requirements for hearing aids will be phased in over a four to five year period. These requirements will be centred on the Australian Standard *AS 1088.9-1995 — Hearing Aids, Immunity requirements and methods of measurement for hearing aids exposed to radiofrequency fields in the frequency range 300 MHz to 3 Ghz*.

AS 1088.6-1995 specifies performance requirements and defines two categories of compliance — C1 and C2.

After 1 July 1999, C1 compliance, which enables the majority of aids to be operated satisfactorily within 1 metre of a 2 watt digital cellular mobile handset, will be required for all new products before they can be entered in the ARTG. Existing products listed in the ARTG at that time will be allowed to be supplied until 1 July 2001. After that, all devices offered for sale will be expected to comply with C1.

At a date, yet to be specified, C2 compliance will be introduced, in consultation with suppliers and industry.

3.21 IN VITRO DIAGNOSTICS (IVDS) — LISTABLE

The term 'diagnostic goods for in vitro use' includes:

- any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, that is intended by the manufacturer to be used in vitro for examining specimens including blood and tissue donations, taken from the body of a person. These devices are intended solely or principally for providing information about a person's physiological state, state of health or disease, or congenital abnormality, or to determine the safety and compatibility of donor and recipient.

The term 'IVDs' includes:

- any in vitro diagnostic device intended by the manufacturer to be used in the home environment for self testing, as well as those that are supplied under the Pharmaceutical Benefits Scheme (PBS) for in vitro diagnosis.

Diagnostic instruments and equipment

Generally, diagnostic equipment is exempt from ARTG entry unless it interacts directly with the patient. Diagnostic imaging equipment is considered to be used *in vivo*, and instruments such as sphygmomanometers, thermometers, stethoscopes, etc., are also considered to be used *in vivo*. The precise exemptions can be found in Appendix 8, *Exempt Goods* under Schedule 5, Items 7 (b), (c) & (e).

Diagnostic test kits

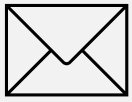
The following groups of IVDs must be registered or listed in the ARTG before being supplied in Australia:

- IVDs for home use or supplied as a Pharmaceutical Benefit (listable);
- IVDs for testing Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) infections (registrable). Refer to Chapter 2.22 *HIV / HCV In vitro Diagnostics*.
- IVDs containing material of human origin, including sera and controls (listable).

All other IVDs can be supplied in Australia without being registered or listed. However, Australian manufacturers of exempt diagnostics, who need export certification before their products can enter other countries, may apply to have those products listed as export-only products. These manufacturers should either have applied for a TGA licence or have a certified quality system in place. Refer to Chapter 1.19 *Good Manufacturing Practice.*

Antimicrobial test discs

in Antimicrobial Test Discs (Note: Disc includes wells and panels) do not have to be included in the ARTG; however, an Import Permit is required before they can be imported into Australia. Further information on this requirement can be obtained from:



Head, Chemistry Section
TGA Laboratories
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8542

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- product information, instruction for use and promotional material (provide only for IVDs for Home Use);
- labels (draft or sample).

Good Manufacturing Practice

Australian manufacturers of IVDs must be licensed, and overseas manufacturers must to provide acceptable evidence of Good Manufacturing Practice (GMP). Refer to Chapter 1.19 *Good Manufacturing Practice*.

Specific Conditions

Listable IVDs for **home use** or that are supplied as a Commonwealth Pharmaceutical Benefit under the *National Health Act 1953* or the *Veterans' Entitlement Act 1986* must:

- be accompanied by adequate instructions and information in Plain English and in Standard International Units, outlining clearly the nature, use and limitations of the test or equipment; and
- be labelled with:
  - the name of the device
  - the name and address of the sponsor or manufacturer
  - the Batch or Lot number
  - the names and quantity of all goods contained in the package.

Listable IVDs containing material of human origin (including sera and controls)

- These diagnostics will be grouped into a single ARTG listing application (regardless of sterility status) for each distinct manufacturing source.
- All such diagnostics supplied in Australia must be able to demonstrate compliance with TGO 34 *Standard for Diagnostic Goods of Human Origin* (available from Government Info Shops).

TGO 34 is a mandatory requirement. Supplying goods in Australia which do not comply with this order is an offence under the Act. TGO 34 specifies requirements for quality control of source material and testing for both Hepatitis B virus surface antigen and Human Immunodeficiency Virus. It also imposes additional labelling requirements.

Any goods found not complying with TGO 34 will be subject to recall and sponsors of such goods may be prosecuted.

With any initial application a declaration must be provided, stating that the goods comply with TGO 34, and that evidence is available to TGA on request.

- Sponsors are required to keep catalogues and records (to batch level) of the distribution of all goods supplied in Australia.

Although test certificates demonstrating compliance to TGO 34 are not required at the time of listing, they 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 — *General Criteria for the Operation of Testing Laboratories*; or
- certification from a recognised authority to ISO Guide 25 — *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).

* see Chap 3.1 for details

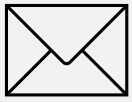
Refer also to Appendix 4, *Conditions — Standard and Specific.*

Quarantine — For Imported Devices Only

Compliance with the *Quarantine Act (1908)* is a function of the Australian Quarantine and Inspection Service (AQIS) of the Department of Primary Industries and Energy (DPIE). Sponsors are required to obtain an Import Permit for importation of biological (human, animal or plant) material. Further information on Quarantine requirements may be obtained by phoning AQIS on 02 6272 4578. Refer also to Chapter 1.4 *Quarantine Requirements (AQIS).*

Drugs of Dependence (DOD)

Sponsors of kits containing narcotics or other ingredients referred to under Schedules 4 or 8 of the *Customs (Prohibited Imports) Regulations* are required to obtain import permits in accordance with the *Customs Act 1901*. These permits are issued by the TGA.
Further information:



Aust. Customs Liaison Officer
Surveillance Unit
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

ph: 02 6232 8690
fax: 02 6232 8643

Grouping of Listable IVDs

IVDs containing material of human origin can be grouped by a sponsor into a single listing for each manufacturing source. There is no such provision for other groups of IVDs. Refer to Chapter 3.2 *Grouping of Listable Devices* and the *Therapeutic Goods (Single Therapeutic Goods) Order No. 1 of 1991* (see Appendix 19).

Grouping IVDs containing material of human origin

- All products from the same manufacturer are covered under the one listing.
- The Listing name will be a description of all products in the listing, regardless of sterility status, e.g. 'Adams Corp Diagnostic Goods,*In Vitro* — Human Origin manufactured by XYZ Inc, Australia'.
- The Product Name will be a general description of the grouped IVDs, e.g. 'XYZ Inc Human Origin IVDs' because one page of product detail covers all products in the application. The ARTG does not require individual product details for IVDs containing material of human origin.

Grouping IVDs for home use

- IVDs for home use cannot be grouped within listings, other than including different pack sizes for the same product.
- Separate applications must be made for each distinct product.
- For kits containing consumable items which are available separate from the kits, the consumables must be entered separately in the ARTG. For example, a Glucometer IVD with test strips available separately, requires two listing entries in the ARTG.

3.22 NEEDLELESS INJECTORS

A needleless injector can be listed when the following information has been supplied. If prefilled cartridges are to be supplied with the injector, however, the quality, safety and efficacy of the drug when delivered in this manner must first be assessed by the Drug Safety and Evaluation Branch (DSEB) of the TGA, ph: 02 6232 8127.

What to Submit for Listing

The sponsor should provide the following information

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample);
- data on specifications, manufacture, mode of action, performance test results and copies of patient instructions and labelling should be provided;
- a list of countries in which the product has been sold;
- the number of devices sold to date (estimate only);
- a list of brands of prefilled cartridges which may be used with the injector;
- results of tests showing that the dosages are accurate over the full range of pressure settings, with comments to say if this is within the stated accuracy limits of the device;
- durability testing results.

Labels

As well as complying with the requirements of TGO 37 *General Requirements for Labels for Therapeutic Devices* (see Appendix 16), injectors should clearly state which vials can be used. Labels on vials should clearly state in which injectors they can be used.

3.23 INSULIN SYRINGES

Insulin syringes are governed by TGO 41 which mandates compliance to Australian Standard AS1077:1992 *Single Use Syringes (sterile) for the Injection of 100 units per millilitre Insulin (U100)*.

What to Submit for Listing

The sponsor should provide the following information:

- A completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- product information, instruction for use and promotional material;
- labels (draft or sample).

Specific Conditions

Test Certificates

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 — *General Criteria for the Operation of Testing Laboratories*; or
- certification from a recognised authority to ISO Guide 25 — *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).

* see Chap 3.1 for details

3.24 INTRAOCULAR LENSES (IOL) — LISTABLE

Monofocal posterior chamber polymethylmethacrylate (PMMA) lenses, manufactured from a proven manufacturer, manufacturing process and design, are listable therapeutic devices.

The TGA requirements in this Chapter are based on similar requirements of the US Food and Drug Administration (FDA), and are outlined below.

Definitions

Modified lens A new intraocular lens for which an application for listing or registration is made, which is a modification of an existing approved lens. It is represented in this document by the subscript ($_m$).

Approved lens An intraocular lens that has been entered in the ARTG for supply in Australia, as either a listed or a registered device. This includes *grandfathered* lenses. It is represented in this document by the subscript ($_a$).

Approved lens range The range of characteristics defined by multiple approved lenses, that may be used collectively for comparison with a single modified lens.

Open-haptic lens An intraocular lens having two haptics, with each haptic having one end attached to the lens optic and the other end not attached to the lens optic.

Closed-haptic lens An intraocular lens having two haptics, with both ends of each haptic attached to the lens optic.

IOLs to Which Items 13 and 14 of Schedule 4 of the Regulations Apply

Listable IOLs are those referred to in item 13 , Part 1 of Schedule 4 of the *Regulations*, i.e. Monofocal intraocular lenses for placement in the posterior chamber of the eye where the optic material consists only of PMMA, and

- the intraocular lens is derived from a lens which has been registered in the ARTG for supply in Australia, or is listed in the ARTG for supply in Australia; and,
- the intraocular lens is manufactured by the same manufacturer using the same manufacturing processes and techniques as for the registered or listed lens; and the intraocular lens does not differ from the monofocal lens, by other than the following criteria:
    a. right or left handed version of a model;
    b. change in overall lens diameter within the range of 10.5 mm (capsular placement) or 11.0 mm (ciliary placement) to 14.5 mm;
    c. the addition or deletion of notches, loops or rounded ends to haptics;
    d. change in haptic angulation in the range of 0–10 degrees;
    e. change in the dioptric power range;
    f. change in the optic diameter within the range of 5.0 mm (capsular placement) or 5.5 mm (ciliary placement) to 7.5 mm;
    g. addition, deletion or moving of positioning holes on the optic which do not infringe on the central 4.25 mm of the optic;
    h. addition or deletion of a ridge on the posterior surface of the optic or modification of optic for weight reduction purposes, which does not

infringe on the central 4.25 mm of the optic;

i. change in the optic shape, where the change is not the first such change by the manufacturer;
j. change in haptic configuration, design or calibre which has no significant effect on the mechanical properties of the lens. The results of mechanical testing which confirm this do not have to be included with a listing application but must be made available on request by the TGA.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- product information, instruction for use and promotional material;
- labels (draft or sample);
- a statement that the product complies with requirements for listing of IOLs under Schedule 4, Items 13 and 14 of the *Regulations.*

Refer also to Chapter 1.19 *Good Manufacturing Practice* and Appendix 16, *TGO 37 General Requirements for Labels of Therapeutic Goods.*

Change in Haptic Configuration, Design or Calibre

Refer to part (j) above.

For a change in haptic configuration, design or calibre, the sponsor must demonstrate that the mechanical properties of the modified lens are not significantly different from those of either a single approved lens or an approved lens range. The only restriction is that the modified design must possess the same open-haptic or closed-haptic characteristics as the approved model(s).

Comparison to a Single Approved Lens

For sponsors who have only one approved model, a comparison between the modified model and approved model should include the following tests:

a. compression force
b. compression force as a function of contact angle per haptic
c. compression force after decay as a function of contact angle per haptic.

For each test the lens should be compressed to produce an overall diameter of 10.0 mm if the modified lens is only for capsular bag fixation, to 11.0 mm if the lens is only for ciliary sulcus fixation, or to both diameters if it is for either type of fixation.

The sponsor must determine the force necessary to compress the modified and approved models to produce the required overall diameter(s), i.e. 10 mm and/or 11 mm. The mean force value (χ) and the standard deviation (σ) must be calculated for both the approved and modified lenses. A minimum of 5 approved lenses and 5 modified lenses are required for testing.

The mean (χ) and standard deviation (σ) values are used to calculate upper force boundaries and lower force boundaries for both the approved and modified models.

Force Boundaries: For the approved lens, the upper force boundaries (UFB_a) and lower force boundaries (LFB_a) are to be calculated using the following equations:

$UFB_a = \chi_a + 3\sigma_a$
$LFB_a = \chi_a - 3\sigma_a$, (when $\chi_a \geq 0.1$ g)
$LFB_a = \chi_a - \sigma_a$, (when $\chi_a < 0.1$ g)

The upper force boundaries (UFB_m) and lower force boundaries (LFB_m) for the modified model are to be calculated using the following equations:

$UFB_m = \chi_m + \sigma_m$
$LFB_m = \chi_m - \sigma_m$,

For both the approved and modified models, the maximum standard deviation is restricted to 20%. This is explained in further detail in the table below titled 'Compression Results'.

For the modified lens to comply with listable parameter (j), the following are required:

a) the mean contact angle associated with the haptics on the modified model (CA_m) at the required compressed overall diameter(s) must be within ± 30% of the mean CA_a associated with the haptics on the approved model, at each of the compressed overall diameters;

b) all or any part of the range defined by the UFB_m and the LFB_m for the modified lens shall overlap the range defined by the UFB_a and the LFB_a for the approved model at each of the compressed overall diameters;

c) all or any part of the range defined by the UFB_m/CA and the LFB_m/CA for the modified lens must overlap the range defined by the UFB_a/CA and the LFB_a/CA for the approved model at each of the compressed overall diameters, both initially and then after decay;

Example of a Comparison with a Single Approved Lens

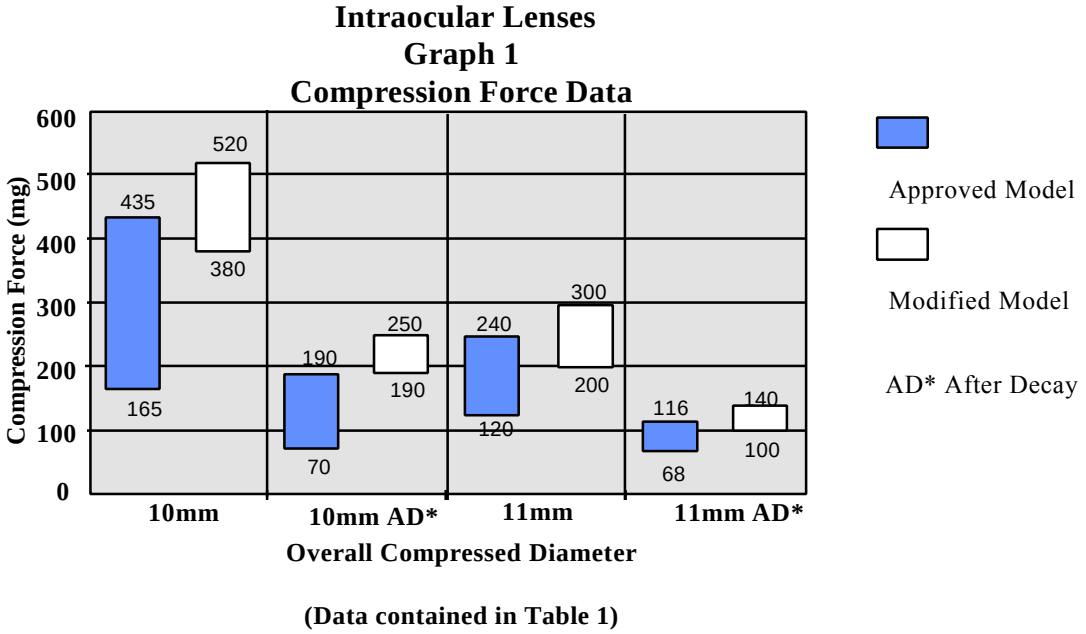
A sponsor has one approved monofocal posterior chamber lens. The haptic configuration of this model is modified from a J-shape to step-vaulted C-shape. The sponsor must show that the mechanical properties of the modified model are not significantly different from those of the approved model. Both lenses are tested for compression force, compression force as a function of contact angle and compression force, after decay, as a function of contact angle, and the results are compared.

TABLE 1: Compression Results

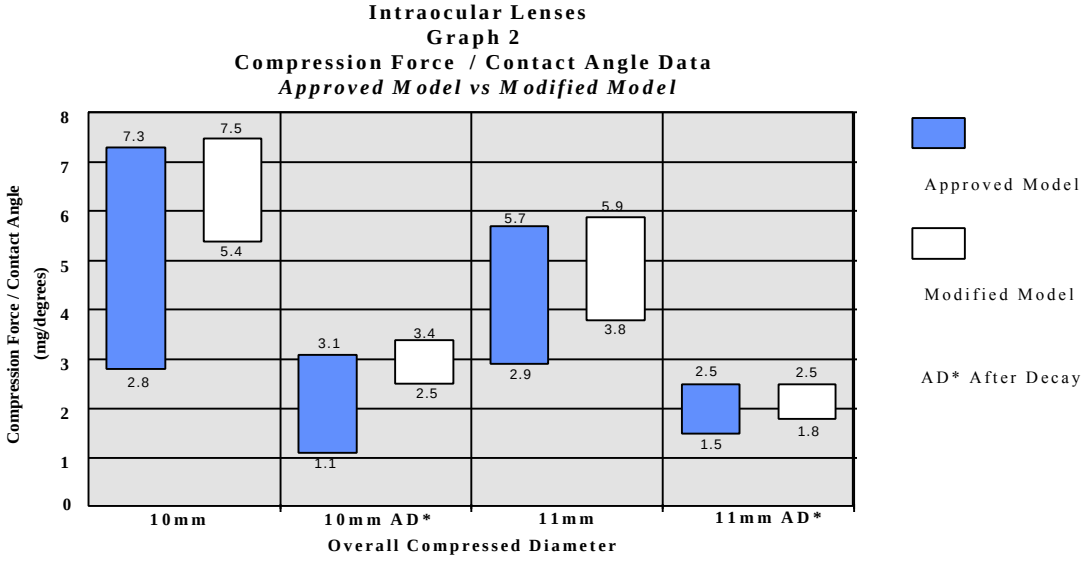
	Approved model				Modified model			
Compressed diameter (mm)	10 mm	11 mm	10 mm after decay	11 mm after decay	10 mm	11 mm	10 mm after decay	11 mm after decay
F_{mean} (mg)	300	180	130	80	450	250	220	120
σ (mg)	45	20	20	12	70	55	30	20
UFB (mg)	435	240	190	116	520	300[1]	250	140
LFB (mg)	165	120	70	68	380	200	190	100
CA (°)	60	42	52	44	70	52	74	55
UFB/CA (mg/°)	7.3	5.7	3.1	2.5	7.5	5.9	3.4	2.5
LFB/CA (mg/°)	2.8	2.9	1.1	1.5	5.4	3.8	2.5	1.8

NOTE: 1. $\sigma_m > 20\%$, therefore σ_m was restricted to 20% $\sigma_m = 50$ mg.

The following graphs display the calculated force ranges for both the approved and modified models:



(Data contained in Table 1)



(Data contained in Table 1)

Comparison of Results:

1. The mean CAs for the modified model, 70° (10 mm) and 52° (11 mm) are within 30% of the mean CAs for the approved model, i.e. 60° ± 30% (10 mm) and 42° ± 30% (11 mm).

2. The compression force ranges for the modified model, 380–520 mg (10 mm) and 200–300 mg (11 mm), are within the range defined by the approved model, 165–435 mg (10 mm) and 120–240 mm (11 mm). (See graph 1.)

3. The compression-force-after-decay ranges for the modified model, 190–250 mg (10 mm) and 100–140 mg (11 mm), are within the range defined by the approved model, 70–190 mg (10 mm) and 68–116 mm (11 mm).(See graph 1.)

4. The force/CA ranges for the modified model, 5.4–7.5 (10mm) and 3.8–5.9 (11mm) are within the range defined by the approved model, 2.8–7.3 (10mm) and 2.9–5.7 (11mm). (See graph 2.)

5. The force/CA-after-decay ranges for the modified model, 2.5–3.4 (10mm) and 1.8–2.5 (11mm) are within the range defined by the approved model, 1.1–3.1 (10mm) and 1.5–2.5 (11mm). (See graph 2.)

From the above results, it can be seen that the mechanical properties for the modified lens are not significantly different from those of the approved lens. Therefore, the modified lens complies with parameter (j) of the listable requirements.

Comparison with Multiple Approved Models

For sponsors who have several approved models, a comparison between the modified model and the approved lens range should include the following tests:

a. compression force as a function of contact angle per haptic
b. compression force after decay as a function of contact angle per haptic.

For each test the lens should be evaluated at an overall diameter of 10.0 mm if the modified lens is only for capsular bag fixation, at 11.0 mm if the lens is only for ciliary sulcus fixation, or at both diameters if it is for either type of fixation.

There is no restriction on the change in haptic contact angle for a modified model when it is compared to the approved range. The only restriction is that the modified design must possess the same open-haptic or closed-haptic characteristic as the approved models that define the range of acceptable characteristics. The sponsor may combine one-piece models and multi-piece models into the same range.

The testing calculations and data needed to construct the approved ranges are similar to those presented in the comparison with a singe model. The same restrictions apply in each case.

Example of a Comparison with Multiple Approved Models

A sponsor is claiming that model 6 is a listable lens based on a comparison with 4 approved lenses. The sponsor must construct the approved ranges defined by these 4 approved lenses, including:

- compression force range at 10 and 11 mm overall compressed diameter;
- compression force range after decay, at 10 and 11 mm overall compressed diameter;

TABLE 2: Compression Force

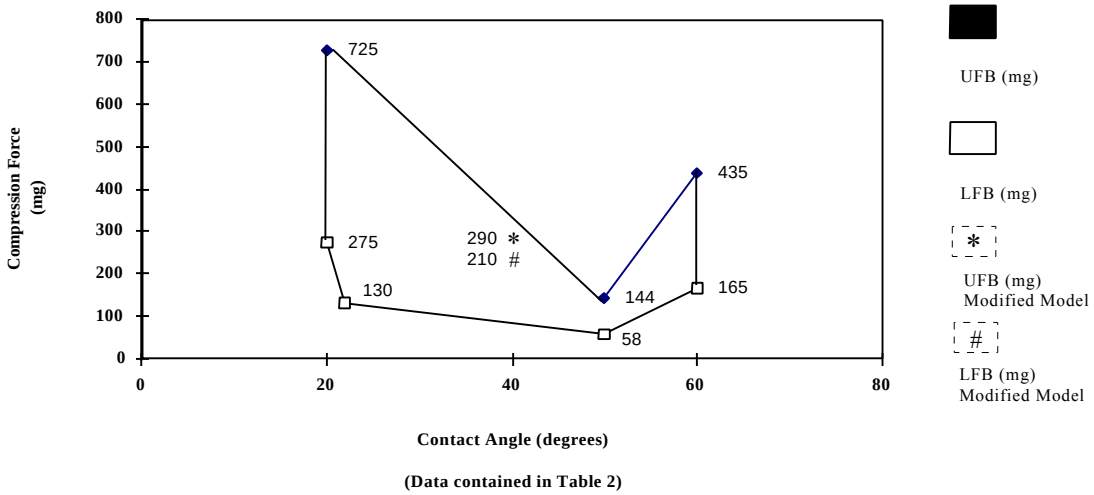
The compression force and contact angle results for the 4 approved lenses and the modified lens (at 10 mm compression) are as follows:

	Approved model 1	Approved model 2	Approved model 3	Approved model 4	Modified model
F_{mean} (mg)	90	300	500	250	250
σ (mg)	25	45	75	40	40
UFB (mg)	144	435	725	370	290
LFB (mg)	58	165	275	130	210
CA	50°	60°	20°	22°	40°

The approved range is constructed by connecting the UFB points together and the LFB points together. *In the case where 2 UFB or LFB points have contact angles within 5 degrees of each other, the larger or smaller value, respectively, must be used and the other value shall be disregarded.* However, if the UFB and LFB points for the models define the end of the contact angle range, they must not be disregarded.

The force range constructed from the 4 approved lenses is represented in Graph 5.
In this example, the force range calculated for lens 6 overlaps the force range defining the 4 approved lenses, thus fulfilling the listing requirement.

Intraocular Lenses
Graph 3
Force Boundaries For Approved Lenses
Compression Force per Contact Angle
Approved Models



(Data contained in Table 2)

Remaining Tests

If the lens is indicated for ciliary sulcus attachment in addition to capsular bag placement, the sponsor must also provide similar data for compression force at 11 mm, compression force after decay at 10 mm and compression force after decay at 11 mm.

The force, decentration and tilt ranges are to be calculated as for the second example and the compression force example given above.

If the data ranges for the modified lens overlap the corresponding ranges for the approved lenses, the modified lens will comply with listing requirement (j). Sponsors should update their approved boundary conditions each time they receive approval for a new model.

3.25 KITS — THERAPEUTIC DEVICES ASSEMBLED AS KITS

This Chapter outlines the requirements for combinations of therapeutic devices, or drugs and devices which are presented together. It does not cover drug delivery systems where the drug is provided in a device as a container or *composite packs* of drugs which are specifically covered by other TGA documentation for drug applications.

Generally, First Aid kits and procedural trays which may contain one or two drug products among a number of devices will be listed as devices, if the drug products are included separately in the ARTG.

Definitions
Kit: the word 'kit' applies to kits, trays, packs or sets containing different therapeutic goods.

First Aid Kit: a set of goods packed and supplied for the purpose of immediate medical assistance in an emergency.

Procedural Pack or Tray: a set of goods packed and supplied to facilitate a specific medical procedure.

Packs of Different Goods: packs made up of, for example, Orthopaedic replacement systems, Orthopaedic fixation packs, Contact lens starter packs, Packs of mixed diagnostics, Packs of different vitamin or herbal products, etc.

Rules

1. Sponsors of kits will be required to list the kit in the ARTG and supply a 'menu' list of all listable or registrable products supplied in their kits.

2. The following Australian Device Groups (ADGs) have been determined for kits:

Product	**ADG Code**
FIRST AID & EMERGENCY KITS	FAEMKT
KITS, TRAYS PACKS — PROCEDURAL, WITHOUT DRUGS	KTPWOD
KITS, TRAYS PACKS — PROCEDURAL, CONTAINING DRUGS	KTPCOD

   Where a sponsor supplies several kits in the same ADG (e.g. several First Aid kits) it is acceptable for that sponsor to make only one listing (e.g. Super First Aid Kits) under that ADG, if the 'menu' of components covers all the variations and combinations available within that range of kits.

3. Each drug component of the kit must be evaluated and registered by the Drug Safety & Evaluation Branch (DSEB) or listed by the Chemical and Non-Prescription Drug Branch (CNPDB) before it may be included in the kit or procedural tray. The AUST R or AUST L number(s) for the drug(s) must be included in the application to list the kit.

4. Each device component of the kit is generally required to be registered or listed in the ARTG. This may not be required for:
   a) listable device components if the sponsor is licensed as described under rule 7; or
   b) device components which are exempted from registration or listing under Schedule 5 of the *Therapeutic Goods Regulations*, even if the kit is supplied sterile, and which are not required to be included in the 'menu' of kit components;
   c) packs of different goods.

5. The processing of an application to list a kit will depend on the highest level of control required for any component. If a Schedule 4 or 8 (SUSDP)* drug or a new chemical entity drug is among the contents, that drug will be referred to DSEB for consideration of registration. Only after this is finalised can the listing of the kit proceed. If a drug from Schedule 3, 2 or unscheduled (SUSDP)* is among the contents, CNPDB will administer the process of registering the drug.
   (Standard for the Uniform Scheduling of Drugs and Poisons* —SUSDP, available from Government Info Shops in all capital cities.)

   If the kit contains only devices, the application will be forwarded directly to Conformity Assessment Branch. Kits **cannot** be supplied until all registrable or listable contents and the kit itself are entered in the ARTG.

6. Where a sponsor assembles a kit from a variety of products already entered in the ARTG the 'menu' of all registered or listed components should be cross-referenced with the relevant ARTG listing or registration numbers. The application for a kit listing should include the AUST R or AUST L number(s) of all component(s) together with the ECRI codes.

   If any kit component is also part of another listing, the product reference number of the component in that listing must be quoted in the application to list the kit.

In general, kit assembly is not licensable provided there is no alteration to the packaging of the items included in the kit.

As situations may vary, each sponsor should check whether their activity is licensable. e.g. taking examination gloves out of their primary pack and placing them loosely in a First Aid kit is a licensable manufacturing step.

7. Where the sponsor of the kit is also the manufacturer of the kit, and the sponsor is licensed and inspected under Part 4 of the *Therapeutic Goods Act 1989*, and the quality control of the components is a condition of the licence, the listable device components of the kit are exempt from separate listing in the ARTG, as they are considered to be raw materials. However, if such products are supplied separately in finished form, they must be listed. This exemption applies to listable devices only, not to registrable devices or drugs.

8. The *Regulations* require assessment of the standard of manufacture (GMP) of overseas manufacturers of devices specified in Schedule 6 of the Regulations. This requirement applies to the kit as a whole (e.g. sterile procedural tray) or to individual components of the kits (e.g. sterile bandages and dressings in a First Aid kit).

   If the kits are imported fully assembled, the GMP check of the manufacturer of the kit will suffice. If this GMP evidence is not available, separate GMP checks will be needed for each Schedule 6 device specified in the kit.

   If the sponsor or manufacturer assembles the kit as described in Rule 6, the GMP check of manufacturers of overseas components may be omitted.

9. Licensing of Kit Assemblers
   a) An assembler is not required to be licensed if the kit consists entirely of items that are excluded from the operation of the Act ('declared not to be therapeutic goods for the purposes of the Act') or entirely of items exempt from Part 4 of the Act (licensing) by Schedule 7.
   b) If all the (non-exempt) items are either:
      (i) fully imported (no local step of manufacture); or
      (ii) fully manufactured in Australia by licensed manufacturers; or
      (iii) a combination of (i) and (ii),

      and there is no un-licensed step of manufacture other than the assembling of the kit, no licence is required for the process of assembling or labelling the kit.
   c) A licence is required if the assembler does any of the following:
      (i) re-labels any item for which alicence to manufacture is required (however current TGA policy for device kits does not require a licence for adding a name and address or batch number or expiry date, which may be added by any 'wholesaler' (refer to Chapter 1.19 *Good Manufacturing Practice*); or
      (ii) re-packs any item for which a manufacturer's licence is required (involving loss of identification of the original manufacturer or removal from sealed primary packs); or
      (iii) releases any item for sale for which a manufacturer's licene is required (involving accepting responsibility that all steps of manufacture of the item have been successfully completed).

10. Labelling of Components and Kits
   a) All drug components, whether dedicated to a kit or available separately, must bear their unique AUST R or AUST L number on the label of the drug in addition to conforming to TGO 48.
   b) Kits containing a mix of registered or listed drugs must display the AUST L or AUST R number(s) of the drug(s) on the outer package label of the device kit.
   c) For device only kits, the provisions of TGO 37 will apply to the kit as an entity. AUST R numbers must be shown on registered device kits if the kit is the unit pack of the device.
   d) Device components of kits subject to other TGOs (e.g. sutures) must also comply with the labelling requirements of those Orders. Sponsors may seek exemption from the labelling requirements of the specific TGO where these requirements cause particular difficulties.
   e) The provisions of TGO 37 apply to the outer labels of First Aid kits and the

individual components, such as bandages, of the kit.

11. The conditions of registration or listing applied to specific groups of products will apply equally to products of that type which are components of kits. Therefore the sponsor of the registered/listed goods must keep such records, relating to the goods, as are necessary to:
    a) expedite recall if necessary of any batch of the registered or listed goods;
    b) identify the manufacturer(s) of each batch of the registeredor listed goods.

    Where any part of, or step in, the manufacture in Australia of the registered or listed goods is sub-contracted to a third party who is not the sponsor, copies must be kept of relevant Good Manufacturing Practice agreements relating to such manufacture.

12. Kits which contain components that are registrable products subject to evaluation, must at all times use the precise product (same brand or model and manufacturing plant) as is registered in the ARTG.

ARTG Procedures

The ARTG will link device and drug registrations or listings with the 'kits' listing so that all goods containing a registered or listed product can be identified in case of recalls, etc.

Any types of kits, trays, or packs for which applications cannot be processed using these rules will be referred to Branch Heads on a case by case basis for a decision, in the same way as drug/device distinctions are decided. Sponsors should submit a letter outlining their particular circumstances, with sufficient examples, catalogues, or other supporting evidence to allow their case to be considered.

3.26 ORAL HYGIENE PRODUCTS

Item 2 of Section 7 of the Act exempts certain oral hygiene goods from listing in the ARTG, as follows:

Item 2 Oral hygiene preparations and devices (including dentifrices, mouthwashes, breath fresheners, brushes and flosses) that are not included in a Schedule to the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP), if, on the label of the goods the benefits claimed to result from the use of the goods are restricted to those consequential on improvements to oral hygiene or the use of fluoride for the prevention of tooth decay.

According to separate but related Items, unmedicated dental chewing gums and goods for use with dentures are exempt:

Item 3 Unmedicated dental chewing gums.
Medicated chewing gums (including fluoride) are classified as registrable drugs.

Item 21 Goods for supply to the public for retention, cushioning or repairing of dentures.

Items Declared Not to be Therapeutic Goods (under Section 7)

To be declared 'not a therapeutic good' all goods in this group of oral hygiene products must be *not* subject to SUSDP poisons schedules, and claims made must be within the terms of the declaration.
Restriction of supply of preparations for the topical use of fluoride is mandated in Schedules 2 or 3 of the SUSDP.

Schedule 2 applies to preparations for topical use (including use on the teeth) **except** dentifrices containing 1000 mg/kg or less of fluoride ion or other preparations containing 15 mg/kg or less of fluoride ion.
Schedule 3 applies to dentifrices containing more than 1000 mg/kg of fluoride ion.

These are not therapeutic goods:

- dental floss, floss holders, floss-sticks, dental tape;
- dental chewing-gum which contains no medication;
- dental whiteners, polishes, stain removers;
- disclosing-rinse, drops, chewable tablets;
- electric toothbrushes, waterpiks;
- fresheners which are not ingested;
- sprays, mouthwashes or rinses;
- gum massagers;
- mouthwashes and rinses for cleansing, freshening, anti-plaque, anti-tartar;
- toothbrushes;
- toothpastes, gels, powders, polishes;
- toothpicks, inter-dental sticks.

Items Regarded as Therapeutic Goods

These items are therapeutic goods:

- breath Fresheners which are ingested;
- chewing-gums containing drugs (including fluoride);
- dentifrices or other preparations containing higher concentrations of fluoride ion than specified above or, if containing other agents, bearing therapeutic claims unrelated to oral hygiene (see NOTE below);
- desensitising toothpastes;
- mouthwashes and other preparations claimed to be 'antiseptic' or to prevent or treat sore throat, gingivitis, throat irritations, inflammation, mouth ulcers, tonsillitis, gum disease;
- toothache drops or applications, teething gels;
- preparations for treatment of mouth ulcers.

NOTE: Most oral hygiene products (including toothpastes) fall into the 'drug' category as they contain agents that act by chemical means.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample).

Refer also to Appendices titled *Excluded Goods*, *Exempt Goods* and *TGO 37 General Requirements for Labels for Therapeutic Devices.*

Advertising Claims

Claims and advertising statements which do not contravene the Section 7 exemption are permissable. The following list contains examples only and is not intended to be exhaustive. Claims such as the following may be used for excluded and therapeutic goods:

Gums	helps maintain healthy teeth and gums
Plaque (also Tartar, calculus)	removes, reduces, prevents, fights, loosens, helps neutralise plaque acids
Tooth decay	protects against, prevents, fights, complements tooth brushing, reduces cavities
Teeth and Tooth enamel (fluoridated products)	protects, toughens, hardens, strengthens; also cleans, shines, polishes, brightens, whitens, maintains healthy teeth, removes stains

Mouth	keeps your mouth and breath clean and fresh, fights bad breath, helps relieve dry mouth

Claims which would be regarded as therapeutic claims and which would render the goods liable to listing or registration as therapeutic goods include those which refer to treatment or to prevention of disease states of the mouth or gums.

Examples may refer to an abscess, antiseptic action, gumboil, gastritis, gingivitis, inflammation of gums, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, sensitivity, stomatitis, thrush; and claims of antiseptic action. Refer to Appendix 1, *Advertising Therapeutic Goods to the Public.*

3.27 PENILE IMPLANTS — INFLATABLE

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample).

Specific Conditions

Any problems relating to the condition, use or application of the device must be reported between 1 July and 1 October each year to:

Director
Conformity Assessment Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

3.28 PODIATRY

A large number of products are manufactured specifically for use in the field of podiatry. This Chapter outlines the way in which these products, such as adhesive tapes and padding, are regulated.

Refer also to Chapter 3.4 *Bandages, Dressings & Allied Products* as this also covers some podiatry products such as tapes, undercast padding and stockinet.

Excluded Goods Order No.1 of 1998 (see Appendix 7) excludes non-sterile protective or safety apparel or equipment, for use in the home or for occupational or recreational use, from regulation and entry in the ARTG. Non-sterile apparel (including fitted support or insulating garments) used as an aid to physical comfort or for relief of discomfort in persons with a disease, ailment, disability or injury are also excluded from regulation and entry in the ARTG.

Products likely to be used on wounds and trauma, such as undercast padding and stockinet, must be listed. Strapping and tapes used in podiatry are indistinguishable from those used in surgery generally and are also required to be listed.

Paddings that are felt or foam, with or without adhesive, and that are not likely to be used on broken skin, do not have to be listed in the ARTG, but remain therapeutic goods. This means that they are still subject to other provisions of the Act (e.g. labelling, sampling & testing and recalls).

Tapes and strapping used in podiatry are therefore listable. Non-sterile, non-medicated padding of various types, shapes, sizes, with or without adhesive backing, are exempt from the requirement for listing in the ARTG.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample).

Refer also to Appendices titled *Excluded Goods*, *Exempt Goods* and *TGO 37 General Requirements for Labels for Therapeutic Devices.*

3.29 SODA LIME

The *Therapeutic Goods Act 1989* and *Regulations* require that Soda lime supplied in Australia, whether imported, exported or manufactured in Australia, must be listed in the ARTG. Supply of Soda lime, within Australia or for export, without prior listing in the ARTG is illegal.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample).

Specific Conditions

Test Certificates

Soda lime must comply with the relevant monograph in the current edition of the *British Pharmacopoeia*.

Although Test Certificates are not required at the time of listing, the sponsor must be able to supply them to the TGA, on 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 — *General Criteria for the Operation of Testing Laboratories*; or
- certification from a recognised authority to ISO Guide 25 — *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).

* see Chap 3.1 for details

3.30 SUTURES AND LIGATURES (ABSORBABLE AND NON-ABSORBABLE)

All absorbable and non-absorbable monofilament and multifilament sutures, including those made from stainless steel, which are intended for therapeutic use in humans, are required to be listed in the ARTG. These sutures will fall into one of the following three Australian Device Groups:

PRODUCT	ADG CODE
Sutures & Ligatures, Absorbable	SUTABS
Sutures & Ligatures, Non-absorbable	SUTNAB
Sutures & Ligatures, Stainless Steel	SUTSSS

For more information refer to TGO 49 *General Standard for Sutures*.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- GMP evidence;
- product information, instruction for use and promotional material;
- unit and outer package labels (draft or sample).

Specific Conditions

Test Certificates

Sutures must comply with TGO 49 *General Standard for Sutures.* Although Test Certificates demonstrating compliance are not required at the time of listing, they must be retained by the sponsor and supplied upon request. The sponsor must ensure that every batch supplied in Australia complies with TGO 49.

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 — *General Criteria for the Operation of Testing Laboratories*; or
- certification from a recognised authority to ISO Guide 25 — *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).

* see Chap 3.1 for details

Related Products

Where a sponsor wishes to list a device that is preloaded with a suture that falls into one of the categories mentioned above, the sutures will require a separate listing. For example, if the device is an endoscopic suturing device, the device itself will require listing as an Endoscopic Accessory (Refer to Chapter 3.18*Endoscopes and Endoscopic Accessories*) and the sutures contained in this device will require a separate listing in the ARTG under one of the ADGs already mentioned.

3.31 TAMPONS — MENSTRUAL

Menstrual tampons must comply with TGO 51 *Standard for Tampons — Menstrual* which references AS/NZS 2869:1995 *Tampons — Menstrual.* They must also satisfy the normal conditions for entry in the ARTG as a listable device. The extra requirements are outlined in this Chapter, and the TGO and Australian Standard should be referenced for further information.

What to Submit for Listing

The sponsor should provide the following information:

- a completed Therapeutic Devices application form signed by an authorised person;
- appropriate fee;
- product information, instruction for use and promotional material;
- labels (draft or sample) supply and primary pack.

Packaging, Labelling and Product Information

Tampons are required to have at least two levels of packaging: a unit pack for each tampon; and a sturdy outer pack to enclose the separate unit packs. A further level of packaging is often used to enhance the packaging aesthetics. Each level of packaging is classified as either unit pack, primary pack or supply pack; the designation depends on the way the packaging is designed.

If the tampons are wrapped in their separate unit packs and then packed in a box without any further packaging, the cardboard box is designated both as the primary pack and as the supply pack (being the outermost packaging).

Tampons are sometimes supplied in 'purse packs' which contain approximately 10 tampons. These purse packs are often then enclosed in further packaging, e.g. cellophane wrapping or a cardboard sleeve. In this case, the cardboard purse packs are the primary packs, while the cellophane wrapper or cardboard sleeve is the supply pack.

When designating the words 'unit', 'primary', and 'supply' pack to the different levels of packaging the particular design of the packaging should be carefully considered.

Checklist for Labelling of Tampons

The following checklist is based on the requirements of TGO 51 and should be used to determine whether the packaging complies with the Order.

(a) Packaging

Tampons must comply with the modifications to AS/NZS 2869:1995 Section 9 as specified in Clause 2 of TGO 51:

- Each tampon shall be packed in a closed **unit pack** (the pack enclosing a single tampon and applicator, where provided) capable of maintaining product quality until opened by the consumer.
- The **unit pack** should be packed in a **primary pack** which is sufficiently robust to protect the tampons against damage during normal transport and storage. The **primary pack** should be designed, over-wrapped or sealed, so that tampering can be easily detected.
- The primary pack shall contain an information leaflet in accordance with Clause 11 of TGO 51.

(b) Marking

Tampons must comply with the modifications to AS/NZS 2869:1995 Section 10 as specified in Clause 3 of TGO 51.

Primary Packs

Primary packs (the pack containing one or more **unit packs**) must be permanently and legibly marked with the following information:

- the batch number of the tampons which may be immediately preceded by the words 'Batch No', 'Lot No' or by words or symbols having a similar meaning;
- an appropriate label as set out in the Table given below that corresponds to the relevant absorbency range, e.g. **'approximately 11 g absorbency. Suitable for medium flow'** where the absorbency range of the tampon is 9–13 g.

  For the following absorbency ranges (in grams), the label should state:

12–16	Approximately 14 g absorbency Suitable for heavy flow
9–13	Approximately 11 g absorbency Suitable for medium flow
6–10	Approximately 8 g absorbency Suitable for light flow
< 7	–

As tampons with an absorbency of < 7 g are not widely available in Australia and New Zealand, no absorbency range limits or range label is provided.

- a warning, in letters not less than 1.0 mm tall with the word 'IMPORTANT' in capital letters:

IMPORTANT: Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

Supply Packs

Supply packs (the pack that is supplied to the consumer — it may be the **primary pack**, or contain one or more **primary packs**) as received by the consumer, shall be permanently and legibly marked with the following information:

- description of the contents, including the number, and an appropriate label as set out in the Table above, that corresponds with the relevant absorbency range, e.g. **'10 tampons approximately 11 g absorbency. Suitable for medium flow'**;
- a list of the constituents of the body of the tampon, e.g. **deodorisers, cotton, viscose rayon, dyes, polypropylene, etc**.;

- the following warning, in letters not less than 1.00 mm tall with the word 'IMPORTANT' in capital letters:

IMPORTANT: Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

- If the information required above on the **primary pack** is clearly visible on that pack, then the information **need not be repeated** on the **supply pack**. If not, then the information **must be printed** on the **supply pack**.

Transport Pack

The **transport pack** (the pack intended for transportation of one or more **supply packs**), as received by the retailer, must be marked with a date code or the batch numbers of the enclosed primary packs.

Manufacturing Details

The following information must be permanently and legibly marked on the **supply pack**, or on the leaflet contained therein:

- registered name and address of the manufacturer, or
- for imported tampons, the registered name and address in Australia or New Zealand (as appropriate) of the distributor, or
- in the case of house brands or marketing brands, the registered name and address of the retailer or marketing organisation.

Information Leaflet

An information leaflet must comply with modifications to AS/NZS 2869:1995 Section 11 & Appendix G as specified in Clause 7 of TGO 51. It must be placed in **each primary pack** and contain information on TSS and tampon use, as set out in Appendix G of the Standard.

The following information is designed to help sponsors produce appropriate information about Toxic Shock Syndrome for inclusion in patient information leaflets.

Print

- Use lower case as much as possible. Upper case should be kept for main headings.
- Use a font style and size that is easily read.
- Avoid fonts that are similar to handwriting.
- Use a clear colour on a white background. Black on white is effective.
- Do not print over a photo or graphic which could obscure the font. Keep photos to margins.

Language

- Be clear about who the readers are, and what they want and need to know. Write with this in mind always. It may be worth providing the information in more than one language. There is a range of women's health organisations that would readily assist with translations.
- Use clear, well written English that avoids jargon.
- Do not use medical terms unless they are unavoidable. If they must be used then explain them.

Graphic Aids

- Because many of the people reading the information may have limited language and literacy skills, support your information where possible with the use of graphics, using simple line drawings or photos.
- Use graphics for the most important information rather than for everything.
- Make sure that graphics are next to the text they are describing.

Layout

- Whether using graphics or not, make sure that the reader knows where to start reading on the page.
- Avoid 'tricky' layouts.
- In English, readers generally work from left to right and top to bottom. As well, a bold arrow, large font, or highlighted text can help guide a reader to the most important information.
- Refer to the relevant health authority to ensure that the content of the leaflet is acceptable in the country of supply.

ABBREVIATIONS

AAN	Australian Approved Names
AAT	Administrative Appeals Tribunal
Act	*Therapeutic Goods Act 1989* (as amended)
ADEC	Australian Drug Evaluation Committee
ADG	Australian Device Group
ADI	Acceptable Daily Intake
ADRAC	Adverse Drug Reactions Advisory Committee
AIMD	Active Implantable Medical Devices
APMA	Australian Pharmaceutical Manufacturers Association
AQIS	Australian Quarantine and Inspection Service
ARTG	Australian Register of Therapeutic Goods
AUA	Authorised User Approval
AUST L	Australian Listing number
AUST R	Australian Registration number
BMU	Business Management Unit, Business and Services Branch TGA
BP	British Pharmacopoeia
BP Vet	British Pharmacopoeia Veterinary
CAB	Conformity Assessment Branch, Therapeutic Goods Administration
CE	Conformité European
CEN	European Committee for Standardisation
CNPDB	Chemicals & Non-prescription Drug Branch
CPE Regulations	Customs (Prohibited Exports) Regulations
CPI Regulations	Customs (Prohibited Imports) Regulations
CPMP	Committee for Proprietary Medicinal Products
CTE	Clinical Trial Exemption
CTN	Clinical Trial Notification
Department	Department of Health and Family Services
DFS	Department of Health and Family Services
DPIE	Department of Primary Industries & Energy
DR4	Australian Device Requirements —version 4
DSEB	Drug Safety & Evaluation Branch of the TGA
EC	European Community
ECRI	Emergency Care Research Institute
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
Enterprise ID	Number generated by the Enterprise database to identify sponsors
Enterprise database	Database of sponsors used in conjunction with the ARTG database
EPA	Environment Protection Agency of the United States of America
EU	European Union
FDA	Food and Drug Administration of the United States of America
FOI	Freedom of Information
Gazette	Commonwealth of Australia Gazette
GMP	Good Manufacturing Practice
GMPALS	Good Manufacturing Practice and Licensing Section CAB/TGA
HCV	Hepatitis C Virus
HEPA	High Efficiency Particle Absorption
HIV	Human Immunodeficiency Virus
IEC	International Electrotechnical Commission
in vitro	outside the body (of an animal or human)
in vivo	within, on in contact with, the body (of an animal or human)
IPU	Individual Patient Use

ISO	International Standardization Organisation
IUC	Intrauterine Contraceptive Device
IVD	In vitro diagnostic
MDD	Medical Devices Directive
MRA	Mutual Recognition Agreement
MSDS	Material Safety Data Sheet
NATA	National Association of Testing Laboratories
NB	Notified Body
NCCTG	National Coordinating Committee on Therapeutic Goods
NHMRC	National Health & Medical Research Council of the DFS
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOEL	No Observed Adverse Effect Level
NRL	National Reference Laboratory
PBS	Pharmaceutical Benefits Scheme
PCR	Polymerase Chain Reaction
PHV	Prosthetic Heart Valve
PMAA	Proprietary Medicines Association of Australia
PMMA	polymethylmethacrylate
PVC	Polyvinylchloride
Regulations	*Therapeutic Goods Regulations* (as amended)
RSI	Repetitive Strain Injury
SAC	Standing Arbitration Committee
SAS	Special Access Scheme
SCDA	Soybean Casein Digest Agar
SDA	Sabouraud Dextrose Agar
Secretary	Secretary to the Department of Health and Family Services
SIF	Site Information File
SOP	Standard Operating Procedure
SPF	Sun Protection Factor
STD	Sexually Transmissible Disease
SUSDP	Standard for Uniform Scheduling of Drugs and Poisons
TDEC	Therapeutic Devices Evaluation Committee
TENS	Transcutaneous Electric Nerve Stimulators
TGA	Therapeutic Goods Administration
TGAL	Therapeutic Goods Administration Laboratories Branch
TGC	Therapeutic Goods Committee
TGO	Therapeutic Goods Order
TSA	Trypticase Soy Agar
TSS	Toxic Shock Syndrome
UK	United Kingdom
USP	United States Pharmacopoeia
UV	Ultra Violet
WHO	World Health Organisation

GLOSSARY

ADG & ECRI Device Classification Systems

All registered or listed device products in the ARTG are classified using a combination of two classification systems. The first system is the Australian Device Group (ADG) developed by the TGA. This is used in conjunction with a classification system devised by the Emergency Care Research Institute (ECRI) in the USA. ECRI appropriates 'Device Terms' and 'International Medical Device Codes' (IMDC) using their Universal Medical Device Nomenclature System (UMDNS). All therapeutic device applications for registration / listing are assigned the appropriate ADG and ECRI codes by the TGA prior to entry in the ARTG to help classify the device products and enable easier search facilities within the ARTG database.

Australian Device Groups

The TGA classifies all therapeutic devices into Australian Device Groups (ADGs). The Emergency Care Research Institute (ECRI) Universal Medical Device Nomenclature System (UMNDS) code is also used to provide an additional level of classification for the purpose of entry in the ARTG. Different products sharing the same ADG and certain characteristics may be 'grouped' in the ARTG and annual charges are applied only on the one grouped listing. Refer to Chapter 1.8 *Application Procedures* and Chapter 1.9 *Reducing Annual Charges.*

Australian Register of Therapeutic Goods (ARTG)

The ARTG mainly comprises a computer database of information about therapeutic goods for human use that are imported, supplied in or exported from Australia (unless exempt from inclusion in the ARTG or given a specific approval for a special purpose under the legislation). The ARTG also holds information in hard copy, such as product labels and package inserts.

Biological Safety & Biocompatibility Testing

Evaluation of applications for registration includes appropriate biological/biocompatibility testing. Refer Chapter 2.7 *Biological Safety and Biocompatibility Testing.*

Clinical Trials/Use of Unapproved Devices

Devices intended for experimental purposes in humans are exempt goods under Section 19 of the Act or the *Regulations* to the Act. 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. However, supply of unapproved devices is provided for through the four special access schemes that TGA administers. These are the Clinical Trial Exemption (CTE), the Clinical Trial Notification (CTN), the Individual Patient Use (IPU) and Authorised User Approval (AUA). Refer Chapter 1.24 *Access to Unapproved Devices.*

Conditions of Registration/Listing

The Secretary may apply 'conditions' to the registration or listing of therapeutic devices. Conditions apply to all goods in relation to such matters as compliance with standards, notification of changes, licensing of manufacturers, keeping of records, sampling and problem reporting. Specific conditions may apply to a particular class of devices, and these are documented in Appendix 4. There are conditions applied to the registration or listing of goods accepted as currently supplied at the commencement of the *Therapeutic Goods Act 1989* commonly referred to as *grandfathered* goods. The date of commencement of the Act was 15 February 1991. An offence is committed if these conditions are knowingly or recklessly breached and significant penalties apply. Refer Chapter 1.23 *Penalties and Cancellations.*

Dental Restorative Materials

Materials used for the restoration or replacement of teeth.

Diagnostic goods for *in vitro* use

This term includes any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, that is intended by the manufacturer to be used *in vitro* for examining specimens including blood and tissue donations, taken from the body of a person. These devices are intended solely or principally for providing information about a person's physiological state, state of health or disease, or congenital abnormality, or to determine the safety and compatibility of donor and recipient.

Electrical Safety

Sponsors of electrically powered equipment or devices that are regulated as therapeutic goods are required to declare their compliance with AS 3200.1 *Approval and Test Specification — Medical Electrical Equipment* as part of the listing/registration. Independent test certificates confirming compliance with AS 3200.1 must be made available to the TGA on request. Electrically powered equipment or devices that are not regulated as therapeutic goods are still expected to satisfy electrical safety standards. Sponsors may need to comply with mandatory electrical safety requirements for different States and it is strongly recommended that they ensure their products also comply with appropriate recognised standards such as AS/NZS 3130:1995 *Approval and Test Specification — Beauty Therapy Equipment*. The *Trade Practices Act 1974* contains a number of provisions that relate to the safety of products for their intended purpose. Refer Chapter 1.17 *Electrical Safety*

Equivalence / Abridged Submissions

No general exemptions from evaluation will be given. For further details, sponsors should contact the Manager, Premarket, Medical Devices Section CAB. A device may however, be partially or fully exempted from evaluation if critical aspects of the device are equivalent to another device already evaluated and registered in the ARTG at the time the application is made. Refer Chapter 2.3 *Equivalence / Abridged Submissions.*

Excluded

Therapeutic Goods (Excluded Goods) Order No 1 1992 specifies those goods which are not regarded as therapeutic goods for the purposes of the Act.

Exempt

Therapeutic goods which are exempted from the requirements for registration or listing are specified in Schedule 5 of the *Therapeutic Goods Regulations*. These products are exempt from listing in the ARTG, but are still required to comply with labelling and other standards and the advertising provisions of the Act.

Export only

Therapeutic goods that are not supplied in Australia and are intended only for export are still required to be listed in the ARTG before they can be exported. Export-only goods must still comply with all relevant standards, except the standard for labelling. Goods that would normally be registrable are only required to be listed. The listing application fee applies; however annual charges do not apply to products for export only.

Good Manufacturing Practice (GMP)

GMP is a principal of operation that ensures the quality of manufactured products can be maintained and confirmed by controlling the procedures and processes used to produce them. The *Therapeutic Goods Act 1989* requires that the standard of manufacture of imported products be taken into consideration for registration and listing. Sponsors of certain therapeutic devices, including devices supplied sterile, are required to either supply an acceptable form of evidence of GMP with their registration/listing applications or agree to pay the costs of an audit by the TGA if it is considered necessary. Refer Chapter 1.19 *Good Manufacturing Practice*.

Grandfathered

Therapeutic goods accepted as currently supplied at the commencement of the *Therapeutic Goods Act 1989* are called 'grandfathered'. The date of commencement of the Act was 15 February 1991.

Grouping of Devices

The Act enables the Secretary to determine that some 'separate and distinct' goods, which share certain characteristics, may be 'grouped' under a single ARTG entry. Thse products share the same ARTG number (AUST L or AUST R number) and incur lower annual charges than if they were not 'grouped'. Refer Chapter 1.9 *Reducing Annual Charges.*

Heart Valve — Biological prosthetic heart valve

Posthetic heart valve composed wholly or partly of animal tissue.

Heart Valve — Mechanical prosthetic heart valve

Prosthetic heart valve composed wholly of synthetic materials.

Heart Valve — Predicate prosthetic heart valve

A prosthetic heart valve currently registered in the ARTG, which can be used as a reference during the testing and evaluation of a new type of prosthetic heart valve.

Heart Valve — Prosthetic

Device used to replace or supplement a natural valve of the heart, categorised according to the position in which it is intended for use (aortic or mitral).

IVD

The term IVD includes any in vitro diagnostic device intendedby the manufacturer to be used in the home environment for self testing, as well as those that are supplied under the Pharmaceutical Benefits Scheme (PBS) forin vitro diagnosis.

Kits

Therapeutic devices may be supplied in combination with other devicesand/or drugs. These combined presentations are referred to as kits and they include conventional first aid kits and procedural kits for surgery. Generally, first aid kits and surgical procedure kits which may contain one or two drug products among a number of devices will be listed as devices. Sponsors of kits are required to list the kit in the ARTG and supply a 'menu' list of all listable or registrable products supplied in their kits. Each device/drug component of the kit is generally also required to be listed or registered in the ARTG. Refer to Chapter 3.25 *Kits* as there are a number of important exceptions to this general statement. Drug delivery systems are subject to regulation by the TGA as drugs if the drug is provided in a device as a container, or if they consist of *composite packs* of drugs which are not considered kits.

Listable

All therapeutic devices which are not required to be registered (Schedule 3), or are not exempted (Schedule 5), are required to be 'listed' in the ARTG. The supplier has to provide the TGA with information about the product, but they do not have to undergo pre-market evaluation before supply. All products must also comply with the Therapeutic Goods Order for labelling (TGO 37), any other applicable TGOs and Sections 4 & 7 of the Therapeutic Goods Advertising Code. Test certificates or acceptable evidence of Good Manufacturing Practice (GMP) are also required for some products. Refer to Chapter 3.1 *Information Applicable to all Listable Devices.*

Manufacture in relation to Therapeutic Goods

To manufacture 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, sterilizing, testing and releasing for supply of the goods, or of any component or ingredient of the goods as part of that process'. *Therapeutic Goods Act l989*

Manufacturer — Principal/ Alternative/ Sub

Manufacturers who are responsible for the release for supply of therapeutic devices are deemed to be the Principal manufacturer. Alternate manufacturers undertake the same manufacturing procedures, but may or may not be principal manufacturers. Sub-manufacturers undertake part of the manufacturing process but are not responsible for final assembly or release for supply of the product.

Mutual Recognition Agreement (MRA) with the European Union

As part of a larger trade agreement, the TGA is pursuing a mutual recognition agreementwith the European Union (EU). The proposed agreement will cover most medical devices manufactured in the European Union and in Australia and New Zealand which are subject to third party conformity assessment. Initially the TGA will be a designated conformity assessment body (also referred to as 'notified body') for Australian manufacturers of medical devices seeking the CE mark in order to supply their products to EU countries. Reciprocally, for designated devices and annexes, European notified bodies will be able to approve devices to the TGA's requirements for supply in Australia. Refer Chapter 1.18*Mutual Recognition Agreement (MRA) with Europe*.

Overseas Evaluations

If a device has been evaluated by a recognised overseas regulatory authority the TGA may require less information in support of an application for entry on the ARTG. Applications for registration should include details of any regulatory action and the status of applications, either completed or forthcoming, made in any other country. The provision of information concerning registrable products approved by recognised overseas regulatory bodies such as the US Food and Drug Administration (FDA) is likely to expedite the approval process in Australia. Refer Chapter 2.4 *Overseas Evaluations.* For listable devices approved by a European notified body designated to approve devices for Australia, sponsors are still required to submit an application form and pay the application fee. Additional supporting information such as evidence of GMP, samples of labelling and test certificates will not, however, be required with these applications.

Plant Master Files

A detailed description of a manufacturer's facilities, operations and procedures, including photographs and copies of key documents such as the quality manual and important SOPs. As the Plant Master File may substitute for a GMP or quality system audit, the manufacturer must make a declaration that it is an accurate reflection of the operations and procedures currently in place. The TGA charges a fee to evaluate Plant Master Files. Refer Chapter 1.19 *Good Manufacturing Practice* and Appendix 10, *GMP — Standard of Overseas Manufacture.*

Postmarket Surveillance

While entry in the ARTG is a requisite to legally supplying therapeutic devices in Australia, the performance of therapeutic devices after they have been supplied is also monitored by the Medical Devices Section within the Conformity Assessment Branch. Sponsors of devices entered in the ARTG have ongoing obligations to the TGA such as the reporting of problems associated with the use of the device. Refer to Chapter 1.6 *Postmarket Compliance Programs* and the Appendix 4, *Conditions — Standard and Specific.*

Predicate Device

A device that has been previously evaluated and is currently listed or registered on the ARTG.

Problems with Medical Devices

The TGA is interested in learning about any safety issues or adverse incidents involving medical devices. Users and sponsors are encouraged to phone the Device Incident Reporting Scheme
ph: 1 800 020 653 fax: 02 6232 8687.

Registrable

Devices which require registration are subject to premarket evaluation of their quality, safety and efficacy. After that, the Secretary of the Department of Health and Family Services can approve their 'registration' in the ARTG. Therapeutic devices which are required to be registered are specified in Schedule 3 of the*Therapeutic Goods Regulations*. Within the registrable category is a group of products that are only partially evaluated for efficacy: these are referred to as **low level registrable** products. The degree of premarket evaluation is dependent on the potential risk of a product.

Separate and Distinct Goods

Section 16(1) of the Act describes the characteristics of 'separate and distinct' goods — characteristics which distinguish one registrable or listable device product from another for the purposes of entry in the ARTG. Refer Chapter 1.9 *Reducing Annual Charges.*

Site Information Files

A site information file contains a brief description of a manufacturer's facilities and operations. It is used primarily as background information by GMP auditors before they go on-site to undertake a GMP or quality system audit.

Sponsor

a person who
exports, or arranges the exportation of, the goods from Australia; or
a person who imports, or arranges the importation of, the goods into Australia; or
a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);
but not including a person who
exports, imports or manufactures the goods; or
arranges the exportation, importation or manufacture of the goods,
on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in Australia.
The TGA monitors products being supplied in a number of ways and those who knowingly contravene the Act are liable to prosecution. The following definitions from the Act are key in determining whether you are affected. Refer Chapter 1.23 *Penalties and Cancellations*

Sterility

Products that are supplied sterile are required to comply with TGO 11 and sponsors must provide satisfactory evidence of GMP at the time of their registration/listing application. Refer Chapter 2.6 *Sterility*, Chapter 1.19 *Good Manufacturing Practice* and Appendix 15, *TGO 11 Standard for Sterile Therapeutic Goods.*

Therapeutic Goods Orders (TGOs)

TGOs are the legislative basis for mandating Standards for particular therapeutic goods. Therapeutic devices subject to TGOs must comply with the requirements of the TGO and evidence of compliance may be required. TGA invokes Orders where there is no appropriate standard in the *British Pharmacopoeia* (which is the default Standard) and there are sufficient concerns about ensuring the safety of the particular therapeutic goods. TGA aims to avoid imposing uniquely Australian requirements. It harmonises, where possible, with best

international practice. A list of TGOs applying to therapeutic devices is provided in Appendix 13, *Therapeutic Goods Orders / Standards.*

Therapeutic device

Therapeutic goods consists of instruments, apparatus, appliances, materials or other articles (whether for use alone or in combination), together with any accessories or software required for their proper functioning, which do not achieve their principal intended action by pharmacological, chemical, immunological or metabolic means. However, they may be assisted in their function by pharmacological, chemical, immunological or metabolic means. This definition applies to goods or components of goods that are represented in any way to be for therapeutic use, or that are likely to be taken to be for therapeutic use, because of the way in which they are presented or for any other reason.

Therapeutic use

Therapeutic use means 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 anatomy in persons or animals.

Therapeutic Device Evaluation Committee (TDEC)

TDEC is an independent committee that advises and reports to the Minister on issues concerning the quality, safety and efficacy of medical devices. Membership of TDEC covers a wide range of relevant expertise including various medical specialities.

Traceability

Method used to identify the location of products along their path from the sponsor to the hospital or surgery

Tracking

Process used to establish the connection between a patient and an implantable device, post-operatively

Variations to Details of a Registration or Listing

Products are registered or listed in the ARTG on the basis of the information provided at the time of the original application. If changes are then made to the product or aspects of its manufacture, the sponsor must usually notify the TGA or obtain prior approval. Depending on the nature of the changes it may be necessary to lodge a new application on the Therapeutic Devices Application form and pay the applicable processing fee. A submission of data should accompany the form clearly identifying all changes. Appendix 3, *Changes to Devices* details the information that should be provided to show that the changes have not adversely affected the quality, safety or efficacy of the original device.