Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

# Conditions – standard and specific

## Applying to registered or listed therapeutic goods under Section 28 of the Therapeutic Goods Act 1989

Standard – July 1995
Specific – March 1998

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.

# STANDARD CONDITIONS

**Applying to registered or listed therapeutic goods under Section 28 of the *Therapeutic Goods Act 1989*** (*Effective 1 July 1995*)

For the purposes of these conditions, words used in any of the paragraphs set out below shall have the same meaning as their counterparts in the *Therapeutic Goods Act 1989*. Unless otherwise specified, references to the 'Act' shall be a reference to the *Therapeutic Goods Act 1989*, as amended from time to time, and references to the 'Regulations' shall be to the Therapeutic Goods Regulations as amended from time to time. A reference to 'registered goods' or 'listed goods' shall be a reference to the goods included in the Certificate of Registration or the Certificate of Listing, as the case may be.

## APPLYING TO ALL REGISTERED OR LISTED THERAPEUTIC GOODS

### 1 Standards

The registered/listed goods must comply with standards applicable to those goods under part 2 of the Act;

### 2 Changes to Goods

Changes or variations in respect of any information concerning the registered or listed therapeutic goods, being information that would have been relevant* to a decision to register/list the goods in the Register, including information on the formulation of the registered/listed goods or other aspects of their manufacture, and the labelling of the goods, shall forthwith be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 28 of the Act, and where necessary*, the change or variation shall not be implemented until approved by the Secretary. (*Reference should also be made to Appendix *Changes to Therapeutic Goods)*

### 3 Australian Manufacturers

The Australian manufacturer or manufacturers of the registered/listed goods, and any subcontractor or testing facilities in Australia contracted to, or otherwise engaged to, manufacture the registered/listed goods, must be appropriately licensed to carry out the manufacture, or a step in the manufacture, of the goods or the class of therapeutic goods within which the registered/listed goods are included, unless otherwise exempted under the Act from the need to comply with such a requirement.

### 4 Records Held

The sponsor of the registered/listed goods shall keep such records relating to the goods as are necessary:

(a) to expedite recall if necessary of any batch of the registered/listed goods;
(b) to identify the manufacturer(s) of each batch of the registered/listed goods.

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

### 5

Each sponsor shall retain records of the distribution of all of the sponsor's registered/listed goods for a period of five years and upon the request of the National Manager, Therapeutic Goods Administration, shall provide the records or copies of the records to the National Manager.

## 6 Sampling

The sponsor of the registered/listed goods shall permit officers who have been authorised under the Regulations to do so to take samples of therapeutic goods and carry out related duties in accordance with the Regulations.

## 7 Overseas Regulatory Actions

Where the registered/listed goods are distributed regularly overseas as well as in Australia, product recall or any actions other similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia must be notified to the National Manager, Therapeutic Goods Administration immediately the action or information is known to the sponsor.

## 8 Date of Supply

The sponsor of the registered/listed goods shall advise the National Manager, Therapeutic Goods Administration (through the Operations Manager, Australian Register of Therapeutic Goods) of the date of initial supply of those goods.

## LISTED THERAPEUTIC GOODS

## 9 Indications

In relation to listed goods, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Director, Chemicals & Non Prescription Drug Branch, or Director, Conformity Assessment Branch, Therapeutic Goods Administration, shall produce such evidence to the Director.

## CONDITIONS APPLYING TO ALL REGISTERED OR LISTED DRUGS

## 10 Labels (see also condition 2)

A copy[1] of the label or, if more than one label, labels to be used in respect of the registered/listed drugs shall be provided to the National Manager, Therapeutic Goods Administration (through the Operations Manager, Australian Register of Therapeutic Goods), upon:

(a) the commencement of the supply of the registered/listed drugs; and
(b) request by the National Manager.

1 Where practicable actual labels should be provided attached to a sheet of paper which identifies the product by its Registration/Listing Name and Number. Photocopies (actual size) are acceptable where the label information is printed or embossed directly onto the container.

## 11 Registration/Listing Number

The registration or listing number shall be placed on the label of the registered/listed drugs in accordance with the requirements of the Therapeutic Goods Act 1989 and in the manner prescribed in the Regulations.

## 12 Expiry dates

The sponsor shall not supply the registered/listed drugs after the expiry date of the goods.

### 13 Colouring

Colouring agents used in registered/listed drugs for ingestion, other agents than those listed for export only, shall be only those included in the list of "Colourings for Use in Pharmaceuticals for Ingestion" issued by the National Health and Medical Research Council in November 1988 as amended from time to time.

### 14 Adverse reactions

All reports of adverse reactions or similar experiences associated with the use or administration of the registered/listed drugs shall be notified to the National Manager, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of drugs must retain records of such reports for a period of not less than 18 months from the day the National Manager is notified of the report or reports. It is a condition of registration that your company must comply with Appendix 20 of Volume 1 of the Australian Guidelines for the Registration of Drugs. That appendix deals with the reporting of adverse drug reactions.

## CONDITIONS APPLYING TO ALL REGISTERED DRUGS

### 15 Authorised Officer

It is a condition of registration that as the sponsor of this product you will comply with Regulation 24 of the Therapeutic Goods Regulations.

### 16 OverseasRegulatory Action

It is a condition of registration that your company must inform the TGA if an application is rejected in the USA or Canada at any time during or after registration in Australia and must submit detailed reasons for the rejection.

## REGISTERED OR LISTED THERAPEUTIC DEVICES

### 17 Problems with Therapeutic Devices

The sponsor of registered/listed therapeutic devices shall:

(a) keep a log of problems relating to the condition, use or application of the registered/listed therapeutic devices,

(b) as soon as possible after the sponsor becomes aware of it, report to the Director, Conformity Assessment Branch, TGA, all deaths, serious illness and serious injuries arising from or attributable in some way to, the use or application of the registered/listed therapeutic devices.

## REGISTERED THERAPEUTIC DEVICES

### 18 Registration Number

The registration number shall be placed on the label of the registered therapeutic devices in accordance with the requirements of the *Therapeutic Goods Act 1989* and in the manner prescribed in the Regulations.

### 19 Reports of Problems

The sponsor shall provide to the Director, Conformity Assessment Branch, Therapeutic Goods Administration:

(a) a summarised report in respect of problems relating to the condition, use or application of the registered therapeutic devices between 1 July and 1 October following the date of the registration of the registered therapeutic devices,

(b) and then submit annual summarised reports between 1 July and 1 October for the following three years.

## REGISTERED AND LISTED THERAPEUTIC DEVICES SPECIFIED UNDER REGULATION 16 (SCHEDULE 6)

### 20 Labels (see also condition 2)

A copy[1] of the label or, if more than one label, labels to be used in respect of the registered/listed goods shall be provided to the National Manager, Therapeutic Goods Administration (through the Operations Manager, Australian Register of Therapeutic Goods), upon:

(a) the commencement of the supply of the registered/listed goods; and

(b) request by the National Manager.

[1] Where practicable actual labels should be provided attached to a sheet of paper which identifies the product by its Registration/Listing Name and Number. Photocopies (actual size) are acceptable where the label information is printed or embossed directly onto the container.

## CONDITIONS APPLYING TO SPECIFIC CLASSES OF THERAPEUTIC GOODS

### 21 Conditions Applying to Drugs Which Include Bioflavonoids

Bioflavonoids shall comply with the monograph developed by the Nutritional Foods Association and the Therapeutic Goods Administration.

### 22 Conditions Applying to Drugs Which Contain Substances Which Are "Drugs of Dependence"

Where the registered or listed goods contain a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the goods, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

### 23 Goods Manufactured Overseas

Where the registered/listed goods are imported goods which if manufactured in Australia would be required under the provisions of the Act to be manufactured in licensed premises, the sponsor of the goods shall, upon request at any time by the Secretary or the Secretary's delegate appointed for the purposes of section 31 of the Act, provide to the National Manager, Therapeutic Goods Administration, an acceptable form of evidence which establishes the standard of manufacture of the goods. If this is not available, the sponsor shall pay the costs of an inspection of the principal manufacturer of the goods by Australian inspectors where this is considered necessary by the Secretary or the Secretary's delegate referred to in this paragraph.

# Specific Conditions

**on Registration or Listing applying to specific groups of therapeutic devices under Section 28 of the *Therapeutic Goods Act 1989***

**EFFECTIVE 1 MARCH 1998**

| | **Product Type** | **Applicable Therapeutic Goods Orders** | **Additional Conditions** |
|---|---|---|---|
| 1 | Bandages, dressings and allied products supplied non-sterile | | For non GMP approved manufacturers, total microbial count certificates, must be provided [3] for the subsequent five batches of product supplied following listing of the product. |
| 1.1 | Primary dressings, surgical absorbents or goods specified in Schedule 11 of the Regulations | TGO 11 - 'Standard for Sterile Therapeutic Goods' | Must be sterile and labelled "sterile" |
| 2. | Barium hydroxide lime | TGO 47 - 'Barium Lime' | Test certificate on request[1] |
| 3 | Catheters (Urethral) | TGO 59 - 'Polymer Urethral Catheters for General Medical Use' | Test certificate on request[1] |
| 4 | Condoms | TGO 61 - 'Contraceptive Devices - Rubber Condoms' | Test certificate must be obtained for every batch prior to supply |
| 5 | Contrast media injectors (powered) | | Annual problem reports to be lodged with CAB[2] |
| 6 | Dental restorative materials | TGO 57 - 'Standard for Dental Materials' | Test certificate on request[1] |
| 7 | Diaphragms (Contraceptive) | TGO 28 - 'Standard for Contraceptive Devices - Diaphragms' | Test certificate must be obtained for every batch prior to supply |
| 8. | Disinfectants & Sterilants | TGO 54 - 'Standard for Composition, Packaging, Labelling and Performance of Disinfectants and Sterilants'<br><br>TGO 54A -Amendment to TGO54 | Test certificate on request[1] |
| 9 | Gloves - examination | TGO 52 - 'Gloves for general medical and dental use' | Test certificate on request[1] |
| 9.1 | Gloves - surgical | TGO 53 - 'Single Use , Sterile (Surgical) Rubber Gloves' | Test certificate on request[1] |
| 10 | Implantable patient activated drug delivery systems | | Annual problem reports to be lodged with CAB[2] |
| 11 | In Vitro Diagnostics [IVDs] containing material of human origin | TGO 34 - 'Standard for Diagnostic Goods of Human Origin' | Test certificate on request[1]<br><br>Current catalogues and detailed records of importation and distribution of the goods must be kept by the sponsor. |

| | Product Type | Applicable Therapeutic Goods Orders | Additional Conditions |
|---|---|---|---|
| 11.1 | In Vitro Diagnostics [IVDs] approved for use as screening or as supplemental tests for the diagnosis of infection with Human Immunodeficiency Virus [HIV] (viral load assays excepted). | | May be supplied to authorised laboratories only |
| 11.2 | In Vitro Diagnostics [IVDs] approved as supplemental tests for the diagnosis of infection with Hepatitis C Virus [HCV] | | May be supplied to authorised laboratories only |
| 11.3 | In Vitro Diagnostics [IVDs] for home use or 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 which outlines clearly the nature, use and limitations of the test and expresses measurements in Standard International units |
| 12 | Insulin syringes | TGO 41 - 'Single-use syringes (sterile) for the injection of 100 units per millilitre of insulin (U-100)' | Test certificate on request[1] |
| 13 | Menstrual tampons | TGO 51 - 'Standard for Tampons - Menstrual' | Test certificate on request[1] |
| 14 | Penile implants - inflatable | | Annual problem reports to be lodged with CAB[2] |
| 15 | Pyrogen free - products presented as being such, and all devices specified in the Order | TGO 50 - 'General Standard for Pyrogen and Endotoxin Content of Therapeutic Goods' | Test certificate on request[1] |
| 16 | Silicone gel - devices containing (breast implants excepted) | | Annual problem reports to be lodged with CAB[2] |
| 17 | Sutures or ligatures | TGO 49 - 'General Standard for Sutures' | Test certificate on request[1] |

[1] **Test certificate on request** - the sponsor of the goods must obtain a test certificate, consisting of a detailed certificate of compliance containing comments against each requirement of the Order, for each batch of goods prior to supply in Australia . These certificates must be held by the sponsor and must be available whenever the Secretary or a delegate of the Secretary appointed for the purposes of Section 28 of the Act, should request it to be produced for inspection.
[2] **Annual problem reports** - a report of problems relating to the condition, use or application of the devices must be submitted to the Director, Conformity Assessment Branch between 1 July and 1 October each year.
[3] **Microbial count certificates** relating to non-sterile bandages, dressings and allied products must be submitted to the Senior Technical Reviewer, Conformity Assessment Branch.

**Therapeutic Goods Administration**

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