



Commonwealth Department of
Health and
Family Services

*Australian
Medical
Device
Requirements
Version 4*
*under the
Therapeutic Goods
Act 1989*

May 1998

DR4
Volume 1

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**Australian Medical
Device Requirements
version 4**

**under the
*Therapeutic Goods Act 1989***

DR4

Volume 1 of 2



Commonwealth Department of
**Health and
Family Services**

TGA **THERAPEUTIC
GOODS
ADMINISTRATION**

May 1998

Foreword

Australian Medical Device Requirements - version 4 under the *Therapeutic Goods Act 1989* DR4

This document describes the information to be supplied by a sponsor in support of an application for listing or registration of therapeutic goods which are therapeutic devices in the Australian Register of Therapeutic Goods (ARTG), for assessment by the Conformity Assessment Branch of the Therapeutic Goods Administration, in accordance with sections 25 & 26 of the *Therapeutic Goods Act 1989*.

Submission of this information will enable the determination of the application for registration or listing and, accordingly, this document is approved for the purposes of subsection 23(2b) of the *Therapeutic Goods Act 1989* with effect from 30 September 1997.

This document also outlines the information required to be submitted in support of applications to vary information about therapeutic goods included in the register, which are made under subsection 32(3), (4) or (5) of the *Therapeutic Goods Act 1989*.

Mr Terry Slater
National Manager
Therapeutic Goods Administration
(Delegate to the Secretary)

May 1998

Note

Some information in this document may be subject to change because of amendments to Australian legislation. The sponsor is responsible for ensuring that the current regulatory requirements are fully met.

How to Use DR4

DR4 has been organised into the following blocks:

Volume 1	
Introduction	1.0
Application Procedures for Registrable & Listable Devices	
Common Aspects to all Applications	
Unapproved Devices	
Information applicable to all Registrable Devices	2.0
Information applicable to all Listable Devices	3.0
Volume 2	
Appendices	4.0

Information covering the operation of the *Therapeutic Goods Act 1989* and the general requirements of the Therapeutic Goods Administration [TGA] is contained in Block 1.0

Specific requirements for Registrable or Listable devices are contained in Blocks 2.0 & 3.0

The structure of DR4 is shown on the following pages. Sponsors should refer to the general as well as the specific information blocks prior to making application to the TGA.

Sponsors are also advised to obtain copies of the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations* for use in conjunction with this document.

Glossary of terms used in this document are located at the end of DR4.

Symbols



Important information to note



Mailing Address



Telephone/facsimile/Internet contact details

Italics

Indicates a term for which a definition is provided or the title of another document or to a chapter of DR4

STRUCTURE OF DR4

Introduction

1.0

Therapeutic Goods Act 1989 flowchart

- 1 Introduction
 - What is a therapeutic device?
 - Who is affected?
 - Aust Register of Therapeutic Goods (ARTG)
 - Export only
 - Declared to be drugs
 - Excluded / Exempt / Registrable / Listable
 - Clinical trials and SAS
 - Examples of therapeutic devices (summary)
- 2 Parallel importation / Unauthorised distributors
- 3 Personal imports / Direct marketing
- 4 Quarantine requirements (AQIS)
- 5 Export of therapeutic devices
- 6 Postmarket Compliance Program
- 7 Recalls

Application Procedures for Registrable & Listable Devices

- 8 Application Procedures
 - Registered Devices
 - Listed Devices
- 9 Reducing Annual Charges
 - Grouping
- 10 Changes or variations to devices
 - TGA business rules
- 11 Fees & Charges
- 12 Confidentiality
- 13 Release of information from the ARTG

Common Aspects to all Applications

- 14 Advertising
 - Promotion of unapproved devices
- 15 Therapeutic Goods Orders (TGO's) & Standards
- 16 Pyrogen or Endotoxin free devices
- 17 Electrical Safety
- 18 Mutual Recognition Agreement (MRA) with Europe
- 19 Good Manufacturing Practice (GMP)
- 20 Rejection of an application
- 21 Appeals against decisions
- 22 Enforcement
- 23 Penalties & Cancellations

Unapproved Devices

- 24 Access to unapproved devices
 - Clinical Trials
 - Clinical Trial Exemption (CTE)
 - Clinical Trial Notification (CTN)
 - Special Access Schemes
 - Individual Patient Use (IPU)
 - Authorised User Access (AUA)

Information applicable to all Registrable Devices

2.0

- 1 Information applicable to all registrable devices
 - Evaluation Fee Structure
 - Format of submissions
- 2 Grouping of registrable devices
- 3 Equivalence / abridged submissions
- 4 Overseas evaluations
- 5 Risk analysis
- 6 Sterility
- 7 Biological Safety & Biocompatibility Testing
- 8 Human Clinical Data

Specific high level registrable device policies

- 9 Active Implantable Medical Devices (AIMD)
- 10 Animal origin devices
- 11 Breast prostheses
 - (not saline or water)
- 12 Drug infusion systems
 - (powered, non implantable)
- 13 Extracorporeal therapy systems
- 14 Heart valve prostheses
- 15 Human origin devices
- 16 Intraocular lenses (IOL)
- 17 Intraocular viscoelastic fluids (IOF)
- 18 Intrauterine contraceptive devices (IUCD)

Specific low level registrable device policies

- 19 Barrier contraceptive devices
- 20 Breast Prostheses (saline)
- 21 Disinfectants:
 - Instrument grade
 - Sterilants
 - Hospital grade with claims
- 22 HIV / HCV In vitro diagnostics (IVD)

STRUCTURE OF DR4 CONT.

Information Applicable to all Listable Devices 3.0

- 1 Information applicable to all listable devices
- 2 Grouping of listable devices

Specific Listable Device Policies

- 3 Animal derivatives contained in listed devices
- 4 Bandages, dressings & allied products etc.
- 5 Barium lime
- 6 Blood bags
- 7 Catheters (urethral)
- 8 Condoms
- 9 Contact lenses & contact lens care products
- 10 Contrast media injectors (powered)
- 11 Dental products
- 12 Dental restorative materials
- 13 Devices for people with disabilities
- 14 Diaphragms (contraceptive)
- 15 Disinfectants
 - without claims
 - hospital grade
- 16 Drug infusion injectors
- 17 Ducted and wired systems
- 18 Endoscopes and accessories
 - First aid kits (see Kits)
- 19 Gloves examination / surgical
- 20 Hearing and speech aids
- 21 In vitro diagnostics (IVD)
- 22 Insulin needleless injectors
- 23 Insulin syringes
- 24 Intraocular lenses (IOL)
- 25 Kits - therapeutic devices kits
- 26 Oral hygiene products
- 27 Penile implants (inflatable)
- 28 Podiatry
- 29 Soda Lime
- 30 Sutures and ligatures
- 31 Tampons - menstrual

Appendices 4.0

- 1 Advertising Therapeutic Goods to the Public
- 2 Application form
 - Enterprise Details form
- 3 Changes to Devices
- 4 Conditions - Standard and Specific
- 5 Drug / Device Distinction List
- 6 ECRI codes
- 7 Excluded Goods
 - (extract from Excluded Goods Order)
- 8 Exempt Goods
 - (extract from Schedule 5 & 5A)
- 9 Fees & Charges
 - (extract for Therapeutic Devices)
- 10 GMP Standard of OS Manufacturers
- 11 Human or Animal Origin Therapeutic Devices
- 12 Publication List (TGA)
- 13 Therapeutic Goods Orders and Standards
- 14 TGA Branch Structure
- 15 TGO 11 (Sterility)
- 16 TGO 37 (Labelling)
- 17 TGO 50 (Pyrogen / Endotoxin free)
- 18 TGO 54, 54A & guidelines (Disinfectants)
- 19 Therapeutic Goods (Single Therapeutic Goods) Order