



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic goods orders & standards

applicable to therapeutic devices

May 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.

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THERAPEUTIC GOODS ORDERS & STANDARDS

Standards are made mandatory by the Delegate determining them **Therapeutic Goods Orders** (TGOs) under Section 10 of the *Therapeutic Goods Act 1989*. TGO's are adopted only after a clear need has been demonstrated, consultation with industry and other interested groups has occurred and the Therapeutic Goods Committee (TGC) has approved.

TGO's must pass through both houses of parliament and notification of the making of an Order is required to be published in the Commonwealth of Australia Gazette. Once a TGO is in force all appropriate products, regardless of their age or origin, must conform to the TGO.

The British Pharmacopoeia [BP] is the default standard for therapeutic goods in the absence of a specific TGO.

Further information:



Copies of Standards

Copies of Australian and overseas standards can **only** be obtained from Standards Australia. A handbook '*Register of Australian Standards Referenced in State and Commonwealth Legislation*' which deals with formal references to Standards in Acts and Regulations is also available.

Standards Australia
National Sales Centre
ph: 1800 029 955 or 02 9746 4600
website: <http://www.standards.com.au>
email: sales@standards.com.au

Copies of Legislation

The *Therapeutic Goods Act 1989*, and *Therapeutic Goods Regulations* and Therapeutic Goods Orders (TGO's) may be obtained from;

Government Info Shops
ph: 13 2447 in capital cities
website: <http://www.ausinfo.gov.au>

TGA Publications Office

TGO's are also available from the TGA Publications Office
ph: 1800 020 653
fax: 02 6232 8605
website: <http://www.health.gov.au/tga>
email: tga-information-officer@health.gov.au

The following Therapeutic Goods Orders are currently applicable to devices:

TGO NO.	TITLE	REFERENCED STANDARD
TGO 11	Standard for Sterile Therapeutic Goods	Stand alone
TGO 28	Standard for Contraceptive Devices Diaphragms	AS 1808:1984
TGO 34	Standard for Diagnostics of Human Origin	Stand alone
TGO 37	General Requirements for Labels for Therapeutic Devices	Stand alone
TGO 41	Single Use Syringes (Sterile) for the Injection of 100 Units per Millilitre (U100 Insulin)	AS 1077:1992
TGO 47	Barium Lime	US Pharmacopoeia
TGO 49	General Standard for Sutures	Stand alone
TGO 50	General Standard for Pyrogen and Endotoxin Content of Therapeutic Goods	Stand alone, cites tests in USP and BP
TGO 51	Standard for Tampons - Menstrual	AS/NZS 2869:1995
TGO 52	Gloves for General Medical and Dental Use	AS/NZS 4011:1997
TGO 53	Single-Use (Sterile Rubber Surgical Gloves)	AS/NZS 4179:1997
TGO 54, 54A, & guidelines	Standard for composition, Packaging, Labelling and Performance, of Disinfectants and Sterilants	Stand alone
TGO 57	Dental Materials	ISO Nos. 1559:1995, 1560:1985, 6876:1986, 3107:1988, 6874:1988, 4049:1988
TGO 59	Polymer Catheters for General Medical Use	AS/NZS 2696:1996
TGO 61	Contraceptive Devices Rubber Condoms	ISO 4074-1:1996(E)

Standards Australia

Copies of Australian, International and Foreign Standards are available from Standards Australia

Standards Australia

National Sales Centre
1 The Crescent
HOMEBUSH NSW 2140

PO Box 1055
STRATHFIELD NSW 2135

Information Line: ph: 1800 672 321
Aust. Standards: ph: 02 9746 4600
O'seas Standards: ph: 02 9746 4666
fax: 02 9746 3333
website: <http://www.standards.com.au>
email: sales@standards.com.au

NSW 51 King St
NEWCASTLE NSW 2300
ph: 049 270 499
fax: 049 293 540

ACT: Shop 5, Gallery Level
The Boulevard, City Walk
CANBERRA ACT 2601
ph: 02 6249 8990
fax: 02 6249 8989

VIC: 25 Raglan St
Locked Bag 802
SOUTH MELBOURNE VIC 3205
ph: 03 9693 3500
fax: 03 9696 1319

QLD: 67 St Paul Tce
P O Box 290
SPRING HILL QLD 4004
ph: 07 831 8605
fax: 07 832 2140

WA: 1274 Hay St
WEST PERTH WA 6005
ph: 09 321 8797
fax: 09 321 2929

TAS: 97 Murray St
HOBART TAS 7000
ph: 03 6231 5885
fax: 03 6231 5886

S A: 63 Greenhill Rd
WAYVILLE SA 5034
ph: 08 8373 4140
fax: 08 8373 4124

N T: c/- Territory Construction
Association
191 Stuart Highway
DARWIN NT 5790
ph: 08 8981 9666
fax: 08 8941 0275

Government Info Shops

Copies of the Therapeutic Goods Act & Regulations and all Orders can be obtained from the Government Info Shops in each capital city. **ph: 13 2447**, website **<http://www.ausinfo.gov.au>**.

New South Wales

32 York Street
SYDNEY NSW 2000
ph: 02 9299 6737
fax: 02 9262 1219

Shop 24, Horwood Pl
(off Macquarie St)
PARRAMATTA NSW
ph: 02 9893 8466
fax: 02 9893 8213

Tasmania

31 Criterion St
HOBART TAS 7000
ph: 03 6234 1403
fax: 03 6234 1364

ACT

10 Mort St
CANBERRA CITY 2601
ph: 02 6247 7211
fax: 02 6257 1797

Western Australia

1st Floor
Albert Facey House
469 Wellington Street
PERTH WA 6000
ph: 08 9322 4737
fax: 08 94814412

Victoria

190 Queen Street
MELBOURNE VIC 3000
ph: 03 9670 4224
fax: 03 9670 4115

Northern Territory Agent

NT Government Publications
13 Smith St
DARWIN NT 0801
ph: 08 8999 7152
fax: 08 8999 7972

Queensland

City Plaza
cnr Adelaide & George Sts
BRISBANE QLD 4000
ph: 07 3229 6822
fax: 07 32291387

South Australia

60 Waymouth Street
ADELAIDE SA 5000
ph: 08 8231 0266
fax: 08 8231 0135

North America Agent

Aubrey Books International Ltd
721 Ellsworth Drive
Suite 203-A
SILVER SPRING MD 20910-4436
ph: 301 587 3950
fax: 1 301 587 4088
email: aubrey@access.digex.com

** The Australian Government Publishing Service [AGPS] is now known as **AusInfo***

** Australian Government Bookshops are now known as **Government Info Shops***

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

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www.tga.gov.au