Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for medical devices

(ARGMD) Part 4–Navigation and Reference

Version 1.1, May 2011

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, 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.

Version history

Version	Description of change	Effective date
V1.0	Initial publication	28/04/10
V1.1	· Updated references and contact details to reflect TGA's new organisational structure post TGA21 · Made multiple amendments and additions in Section 3. Essenti Principles, Principle 14—Clinical Evidence. · Made multiple amendments in Section 22. Post-market vigi ce and monitoring requirements. · Added a fourth part titled 'Navigation and Refer ce' t t includes: – a bibliography – consolidated contact details – an index – a glossary of terms · Made various punctuatio d grammar amendments · Reformatted for comp e w new TGA style manual	04/0 /1

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Section 24. Bibliography

Legislation

Therapeutic Goods Act 1989

Act Compilation: C2010C00430

Amendments up to Act No. 54 of 2010

Prepared by the Office of Legislative Drafting and Publishing

<http://www.comlaw.gov.au/>

Therapeutic Goods (Medical Devices) Regulations 2002

Legislative Instrument Compilation: F2010C00749

Incorporating amendments up to SLI 2010 No. 267

Prepared by the Office of Legislative Drafting and Publishing

<http://www.comlaw.gov.au/>

Therapeutic Goods Regulations 1990

Legislative Instrument Compilation: F2010C00737

Incorporating amendments up to SLI 2010 N[illegible]2

Prepared by the Office of Legislative Drafting [illegible]ublishing

<http://www.comlaw.gov.au/>

Section 25. Contact Details

Medical Devices Information Line

Phone

Free call (within Australia): 1800 141 144

Email

<devices@tga.gov.au>

Postal Address

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or

Courier Deliver

Office of Devices A[illegible]tion
Therapeutic Goo[illegible] Ad[illegible]nistration
136 Na[illegible]bu[illegible]h Lane
SY[illegible]NSTO[illegible] ACT 2609

Adverse Events

Reports should be submitted to <iris@tga.gov.au> where [illegible]. Otherwise, they may be sent to:

The Coordi[illegible]r
Medical Device Incident [illegible]ort Investigation Scheme (IRIS)
Thera[illegible]e[illegible] Goods Administration
PO Box 100
WODEN ACT 2606

Email: <iris@tga.gov.au>
Facsimile: 02 6203 1713
Telephone: 1800 809 361

Recall

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636

Device Inclusions and Application Audits

Postal Address		Courier Delivery
Devices Application Section	or	Devices Application Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609

Conformity Assessment Certifications

Postal Address		Courier Deli[illegible]
Devices Conformity Assessment Section	or	Devices Conformity [illegible]ssessment Section
Office of Devices Authorisation		Office of D[illegible]es [illegible]thorisation
Therapeutic Goods Administration		Therape[illegible]c Goods Administration
PO Box 100		1[illegible] N[illegible]rabundah Lane
WODEN ACT 2606		[illegible]MONSTON ACT 2609

Advertising

Complaints about advertisements appearing in [illegible] media

Complaints about advertisements appearing in [illegible] media are considered by the Complaints Resolution Panel; they should be submitted on forms available at <http://www.tgacrp.com.au>. The forms can be submitted electronically on line or sent to

The Executive Officer
Complaints Resolution Panel
PO Box 764
NORTH SYDNEY NSW 2059

Complaints about other forms of medical device advertisements (such as, labels, leaflets, flyers)

These complaints should be sent to:

Recalls & Advertising Section
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Clinical Trial Notification (CTN) Scheme

Postal Address		Courier Delivery
The Business Management Unit	or	The Business Management Unit
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609
Australia		Australia

Clinical Trial Adverse Event Reports

For reports to the TGA, the report should be clearly marked 'Clinical Trial Incident' and ser

Postal Address		Courier Delivery
Clinical Section	or	Clinical Section
Office of Devices Authorisation		Office of Devices Authorisation
Therapeutic Goods Administration		Therapeutic Goods Administration
PO Box 100		136 Narrabundah Lane
WODEN ACT 2606		SYMONSTON ACT 2609
Australia		Australia

Comments Regarding the ARGMD

The TGA welcomes comments and suggestions about the ARGMD; these should be directed to:

Email:

<ODAConsult@tga.gov.au>

Post:

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Section 26. Glossary

Declaration of Conformity (DoC)

The DoC is a document that the manufacturer signs to say that it is compliant with all the essential components of legislation and requirements applicable to the device. Australia requires manufacturers to hold a DoC for every device they manufacture.

An Australian Declaration of Conformity is distinct, though similar, to an EU Declaration of Conformity.

EC Certificate

The *EC Certificate* is a European (EU) equivalent to Australia's Conformity Assessment certificate. EC certificates, in general, define what type of devices the manufacturer may manufacture. As with Australia, high-risk devices additionally require the manufacturer to obtain an *EC Design-Examination* or *EC Type-Examination* certificate.

Manufacturers' Evidence

Manufacturers' Evidence (ME) is the substantive evidence of the manufacturer's Quality System that supports the scope of manufacture. It is usually in the form of an EC or TGA Certificate (or certificates) and is submitted to the TGA in order to support a later device inclusion application.

For systems and procedure packs (e.g. hip replacement systems, first-aid kits, and surgical procedure packs), a specially formed Declaration of Conformity (with supporting evidence) can also be considered to be the manufacturer's evidence. This occurs under the Special Conformity Assessment Procedure (Clause 5 of Schedule 3 of the Regulations).

Time Frames

Application time frames are given in working days and start from the date the e-Business application fee is paid. See also *Working day* in this Glossary.

Vital Physiological Process/Parameter

of a patient, means a process that is necessary to sustain life and the indicators of which may include any one or more of the following:

a. respiration
b. heart rate
c. cerebral function
d. blood gases
e. blood pressure
f. body temperature

Working day

A working day is any day other than a weekend, a public holiday in the Australian Capital Territory, or when the TGA is waiting on information requested of the applicant or waiting for payment of fees. Refer to subsection 3(1) of the Act for the definition of working day. See also *Time Frames* in this Glossary.

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Therapeutic Goods Administration

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www.tga.gov.au

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