Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian medical devices guidance document number 35

Device – medicine boundary products

November 2005

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.

DISCLAIMER

This document is provided for guidance only. It should not be relied upon to address every aspect of relevant legislation. Please refer to the *Therapeutic Goods Act, 1989* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill, 2002* and the *Therapeutic Goods (Medical Devices) Regulations, 2002* for legislative requirements.

FURTHER INFORMATION

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

Telephone: 1800 141 144
Facsimile: (02) 6232 8299
Email: CAB.medical.device.information@health.gov.au
Website: www.tga.gov.au/industry/devices.htm
Mail: PO Box 100
Woden
ACT 2606

AMENDMENT SCHEDULE

Version Number	Date of Amendment	Summary of Amendments
1	June 2004	Original guideline
2	November 2005	Updated to reflect alcohol swabs with no claims regulated as medical devices, alcohol swabs with antiseptic claims regulated as medicines (item 24). Inserted page numbers.

CONTENTS

INTRODUCTION

This guidance document is one of a series that has been produced to help explain the new regulatory system for medical devices in Australia that commenced on 4 October 2002. The new system has been established by the *Therapeutic Goods Act, 1989* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations, 2002.*

Many other guidance documents are available in this series. The series was developed to assist a wide-ranging audience and additional documents can be included if there is enough demand. A separate guidance document is available describing the series.

Although each guidance document has been developed to provide information about particular aspects of the new medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

DEVICE AND MEDICINE DISTINCTIONS

- This document supersedes the TGA Device & Drug Distinctions document of February 1998, which is Appendix 5 of the Australian Medical Device Requirements Version 4, dated May 1998.

- These guidelines are to assist sponsors in determining the status of therapeutic goods that are not readily identified as medicines or devices. In developing the list, the status of each product as determined by the USA FDA and European Union was considered with the desire that 'internationally' recognised distinctions be adopted as far as possible.

- The distinctions in this document were implemented on 21 April 2004 and products applying for entry on the Australian Register of Therapeutic Goods (ARTG) will have to meet the new requirements from this date. However, products that were already on the ARTG on the date the Section 41BD(3) Order was gazetted will have until 4 October 2007 to meet the new requirements.

- The distinctions in this document do not preclude assessment of either the medicine or device component or both in combined products.

- In most cases the status of a product will follow this guidance. However, there may be exceptions where a particular product will not follow this guidance. In all cases the status of a product will be determined by the manufacturer's intended purpose for the product and whether this means the product fits better within the definition of a medicine or a medical device. If in doubt sponsors should consult the TGA regarding the status of their product.

DEFINITIONS

Medical Device

Medical devices are defined as:

(a) any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, including any *in vitro* diagnostic device, intended by the person under whose name it is or is to be supplied, to be used, alone or in combination, for human beings for the specific purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
(iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) control of conception;
(vi) disinfection of medical devices;
(vii) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

The Secretary may, by order published in the Gazette, declare that a particular instrument, apparatus, appliance, material or other article, or that a particular class of instruments, apparatus, appliances, materials or other articles, are not, for the purposes of the Act, medical devices. The Section 41BD(3) Order for the purposes of Subsection 41BD(3) of the Act is available on the TGA website at: www.health.gov/tga/devices/devices.htm.

Medicine

Medicines are defined as:

(a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and
(b) any other therapeutic goods declared by the Secretary, by a notice published in the Gazette, not to be medical devices.

Registrable, listable or included goods

The Act**,** the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002* provide that the ARTG has 3 parts, one relating to registrable goods, one relating to listable goods and the other relating to included medical devices.

Registrable and listable goods, including therapeutic devices, are regulated under Chapter 3 of the Act. Registrable goods undergo a more rigorous evaluation of their quality, safety and efficacy, before being entered into the ARTG, than listable therapeutic devices.

Medical devices are regulated under Chapter 4 of the Act and can be included in the ARTG if they comply with the essential principles, have undergone an appropriate conformity assessment procedure and certain other requirements are complied with.

Exemptions from the registration and listing provisions of the regulations are published in Schedules 5 and 5A of the Therapeutic Goods Regulations (exempt goods).

Excluded goods

Goods may be declared by the Secretary, by Order published in the Gazette, to be or not to be therapeutic goods and thereby excluded from the jurisdiction of the Act.

These products are detailed in the **Therapeutic Goods (Excluded Goods) Order No 1 of 1998** was gazetted in the Commonwealth of Australia Gazette S79 of 25 February 1998 and effective from the date of gazettal. An amended Order (No 2 of 1998) was signed on 12 March 1998 and was gazetted in GN 12 of 25 March 1998. This Order is currently undergoing review and, when finalised the new Order will be available on the TGA website as per the above address.

THERAPEUTIC GOODS PURPOSES	STATUS FOR ARTG
1. Absorbable, with shape, used in surgery:	
· sutures ……..……	Medical Device
· staples ……..	Medical Device
· bone fixation devices ……...	Medical Device
· sponges ……...	Medical Device
· tissue adhesives (may include fibrin based adhesives) ..	Medical Device
2. Absorbable, without shape, used in surgery:	
· visco-elastic fluids	
- intra-ocular …….	Medical Device
- synovial *(animal origin)* …….	Medical Device
· haemostatic agents *(collagen)* ……	Medical Device
· haemostatic agents *(fibrin)* ……	Medicine
3. Absorbable 'long-term':	
· collagen injections …….	Medical Device
4. Body 'cleaning' substances:	
· bulk laxatives ……	Medicine
· salt solution laxatives ……	Medicine
· enema solutions ……	Medicine
· medicated mouthwashes ……...	Medicine
· douches ……	Medical Device
· solutions for irrigation …….	Medical Device
· activated charcoal used internally ……	Medicine
5. Body fluid replacements and nutrients:	
· electrolyte solutions ……	Medicine
· plasma expanders ……	Medicine
· total parenteral nutrition solutions ……...	Medicine
· blood substitutes …….	Medicine
· peritoneal dialysis solutions & substances prepacked for their preparation ……...	Medicine
· haemodialysis solutions …….	Medical Device
· artificial tears for use with/without contact lenses ...	Medical Device
· artificial saliva ……...	Medical Device
· soft contact lens lubricants ……	Medical Device
· hard contact lens lubricants ……...	Medical Device
· contact lens solutions ……	Medical Device
· oxygen & other medical gases *(except cryogenic gases and gases for mechanical use)* ……...	Medicine
· oxygen – chemical generators ……...	Medicine

THERAPEUTIC GOODS PURPOSES	STATUS FOR ARTG
6. Diagnostic imaging or similar agents *(in vivo)* for use in conjunction with:	
· positron emission tomography …….	Medicine
· computerised axial tomography ……...	Medicine
· nuclear magnetic resonance …….	Medicine
· ultrasonography ……...	Medicine
· X-Ray …….	Medicine
· gas mixtures for pulmonary function testing devices	Medicine
· radionucleotide scanning …….	Medicine
7. Agents injected, ingested, or otherwise instilled into or applied to the body for use in device therapy:	
· laser fluorescent dyes ……..	Medicine
· laser/UV light activated agents ……	Medicine
· lithotripsy imaging agents ……...	Medicine
· pharmaceuticals ……..	Medicine
· antiseptics ……...	Medicine
· radioactive sources and implants ……	Medical Device
· electrode gels …….	Medical Device
· lubricants ……	Medical Device
· lubricants with spermicide/viricide …….	Medical Device
· refrigerant sprays ……	Medical Device
· cryogenic and refrigerant gases ……...	Medical Device
· gases for mechanical use only …….	Medical Device
8. Diluents and preservatives for medicines:	
· water for injections ……	Medicine
· saline for injections ……	Medicine
· blood anti-coagulants and preservatives (for subsequent *in vivo* use) ……	Medicine
9. External use without added active substance:	
· emollient & moisturising preparations, formulated & presented for therapeutic use ……	Medicine
· Uncompounded emollients, moisturisers presented for therapeutic use ……..	Medical Device
· barrier protectants which claim prevention of transmission of infectious disease …….	Medical Device
· any of above three with non-therapeutic presentation	Not Therapeutic Good
· non medicated skin cleansers and adhesives …..	Not Therapeutic Good
· non medicated soaps …….	Not Therapeutic Good
· adhesive removers ……	Not Therapeutic Good
· skin adhesive and adhesive enhancers ……..	Medical Device

THERAPEUTIC GOODS PURPOSES	STATUS FOR ARTG
10. Other:	
· gums *(as adhesives or lubricants)* [1] ……	Medical Device
· polyhydroxy compounds ……..	Medical Device
· cellulose derivatives ……	Medical Device
· petroleum jelly ……	Medical Device
· dusting powders, non therapeutic ……	Not Therapeutic Good
· dusting powders, therapeutic uses ……...	Medicine
· ostomy dressings ……	Medical Device
· dextranomer dressing …….	Medical Device
11. Medicated devices - external or short-term internal use with an active additive:	
· condom with spermicide …….	Medical Device
· condom with viricide ……...	Medical Device
· catheter with heparin coating ……...	Medical Device
· catheter with antibiotic coating ……	Medical Device
12. Implantable non-absorbable with an active additive:	
· bone cement with antibiotic ……	Medical Device
· active implantable medical device lead, steroid eluting	Medical Device
· intra ocular lens heparin coated ……...	Medical Device
· devices albumin coated ……..	Medical Device
· copper intra uterine contraceptive device ……	Medical Device
· dental cement with antibiotic/adrenalin ……...	Medical Device
13. Sunscreens having SPF 4 or greater …….	Medicine (Listable)
14. Sunscreens having SPF less than 4 ……	Medicine (Exempt)
15. Tissue replacements of biological origin: [2]	
· 'manufactured' from human tissue ……	Therapeutic Device (Registrable)
· ‘manufactured’ from animal tissue ……	Medical Device
· direct transplants ……..	Excluded
· blood & blood components manufactured by the Australian Red Cross Blood Service …….	Medicine (Exempt)
· blood & blood components - other, and blood products	Medicine (Exempt)
· blood substitutes and expanders ……..	Medicine (Exempt)

[1] Note ingested demulcents, gums and absorbents are classified as Medicines

[2] Note the status and regulatory requirements for this group of products is currently being reviewed

THERAPEUTIC GOODS PURPOSES	STATUS FOR ARTG
16. Pre-filled or pre-loaded devices intended to deliver a medicine:	
· syringe *(other than prefilled with sterile water for catheter inflation)* ……..	Medicine
· transdermal patch ……	Medicine
· hormone eluting IUD ……..…….	Medicine
· blood bags *(which contain & deliver an anticoagulant/preservative)* ……	Medical Device
· blood bags without anticoagulant/preservative	Medical Device
· preservative solutions for use in blood bags	Medical Device
· IV nutrition etc. bags *(filled)* ……...	Medicine
· parenteral nutrition bags *(filled)* ……..	Medicine
· peritoneal dialysis bags *(filled)* ……...	Medicine
· IV nutritional etc. bags *(unfilled)* ……	Medical Device
· parenteral nutrition bags *(unfilled)* …….	Medical Device
· peritoneal dialysis bags *(unfilled)* ……...	Medical Device
· oxygen & medical gas containers *(filled)* or delivery units …….	Medicine
· oxygen & medical gas containers *(empty)* ….	Medical Device
· internal sponge, membrane or similar for delivery of spermicide or STD virucide ……	Medicine
· styptics *(pencils, wool etc.)* ……..	Medicine
· corn, callus removal pads with medication ...	Medicine
· analgesic plasters …….	Medicine
· medicated paste bandages ……	Medicine
· gingival retraction cords coated with adrenalin	Medicine
· gingival retraction cords coated with astringent	Medical Device
17. System or procedure packs, or kits *(comprise a medicine(s) and/or device(s) and include procedural trays, first aid kits etc)*:[3]	
· kits, procedural tray, procedural packs, first aid kits, if it contains:	
- medicine(s) only ……...	Medicine
- device(s) only ……...	Medical Device
- both device(s) & medicine(s) …….....	Medical Device
18. Dual treatment goods:	
· lithotripter …….	Medical Device
· dissolution agent used with lithotripter …...	Medicine

[3] Note: All medicines contained in a kit are required to be separately registered or listed. Devices supplied separately to the consumer are required to be entered individually on the ARTG. Also refer to Schedule 5A of the Therapeutic Goods Regulations.

THERAPEUTIC GOODS	STATUS FOR ARTG PURPOSES
19. Diagnostic goods for *in vitro* use:	
· that incorporate material of human origin ..	Therapeutic Device (Listable)
· for self diagnosis *(home use)* …….	Therapeutic Device (Listable)
· supplied under Pharmaceutical Benefits Scheme	Therapeutic Device (Listable)
· for diagnosis of HIV or HCV infection	Therapeutic Device (Registrable)
· professional/laboratory use without products of human origin ……..	Therapeutic Device (Exempt)
· *In vitro* test kits other than above ……..	Therapeutic Device (Exempt)
20. Extra-corporeal therapies:	
· immunoadsorption columns	
- charcoal activated ……	Medical Device
- monoclonal antibodies ……	Medical Device
· haemoperfusion columns ……..	Medical Device
21. Tissue storage and transport solutions:	
· *In vitro* fertilisation media ……	Medical Device
· other storage & transport solutions containing ingredients of animal origin	Medical Device
· other storage & transport solutions containing ingredients of non-animal origin …….	Medical Device
22. Apheresis Solutions ……	Medical Device
23. Diagnostic goods for *in vivo* use:	
· Allergen skin tests	
- scratch test ……...	Medicine
- patch ……	Medicine (Exempt)
24. Antiseptics, disinfectants, cleaners, soaking solutions:	
· antiseptics and skin disinfectants …….	Medicine
· antiseptic 'wipe' ……...	Medicine
· paper tissue with:	
- antiseptic ……..	Medicine
- viricide ……..……	Medicine
· alcohol swab (with antiseptic claim) ……	Medicine
· alcohol swab (with no claims other than cleaning the skin) ……	Medical Device
· fabric dressing with antiseptic …….	Medicine/Medical Device *(dependent on manufacturer's intended purpose)*
· toothpaste *(SUSDP scheduled or with therapeutic claims beyond permitted oral hygiene claims)*	Medicine
· toothpaste other …….	Not Therapeutic Good
· tooth whitener …….	Excluded

THERAPEUTIC GOODS PURPOSES	STATUS FOR ARTG
· contact lens cleaning solutions ……..	Medical Device
· sterilants (except sterilant gases) for use on medical devices ……	Medical Device
25. Antiseptics, disinfectants, cleaners, soaking solutions:	
· instrument grade disinfectants ……..	Medical Device
· hospital grade disinfectants with specific claims*	Therapeutic Device (Registrable)
· household/commercial grade with specific claims*	Therapeutic Device (Registrable)
· hospital grade disinfectants with non-specific claims*	Therapeutic Device (Listable)
· household/commercial grade disinfectants with non-specific claims* ……	Therapeutic Device (Exempt)
· ostomy appliance detergents, deodorisers	Not Therapeutic Good
· cleaners and sanitisers not making disinfectant claims	Not Therapeutic Good

***** *Refer to Therapeutic Goods Order No. 54/54A & Guidelines - Standard for composition, packaging, labelling and performance of disinfectants and sterilants*

Specific claim in relation to disinfectants -

Is a claim which covers virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity. Except where claims of activity against fungi (yeast and mould) for excluded products are concerned, such claims lift a product into the registrable category of goods.

Non-specific claim in relation to disinfectants -

Is a claim which includes general antibacterial action or activity against bacteria covered by the battery of test organisms included in the specified test, or bacteria of the same family. Claims for bacteria other than these are allowable and do not cause the product to become registrable, but the specific organism against which activity is claimed must be included as an extra organism in the test battery eg. E. coli 0157, Salmonella spp, Streptococcus spp, etc.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au