

AUSTRALIAN MEDICAL DEVICES GUIDELINES

The Use of Medical Devices in Alternative Therapies

Guidance Document Number 7

Version 1.10

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*, the *Therapeutic Goods (Medical Devices) Regulations 2002* and the *Therapeutic Goods Regulations 1990* 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/devices/devices.htm

Mail: PO Box 100

Woden

ACT 2606

© Commonwealth of Australia 2003

CONTENTS

Disclaimer	2
Further information.....	2
Introduction	6
What are alternative therapies?	8
Examples of alternative therapy products.....	14
The operation of the <i>Therapeutic Goods Act 1989</i>	15
How are medical devices regulated?	16
What schemes are in place to access unapproved medical devices?.....	17
What happens to therapeutic devices and medical devices with the introduction of the new regulatory system in Australia?.....	17
1. Existing therapeutic devices in the ARTG	17
Changes or variations to existing therapeutic devices in the ARTG	18
2. Applications under review by the TGA before 4 October 2002	18
3. New applications for inclusion of a medical device in the ARTG	18
4. Excluded and exempt devices	19
Implications for Australian manufacturers of medical devices during the transition period	21
1. Manufacturers requiring a manufacturing licence	21
2. Manufacturers exempt from licensing.....	21
3. Manufacturers with TGA CE Certification.....	21
4. Manufacturers seeking TGA CE certification.....	22
What is the definition of a therapeutic good?.....	22
What is the definition of therapeutic use?	23
What does supply mean?.....	23
What is a medical device?	23
How are medical devices classified?	24
Who is a sponsor of a medical device?.....	26
Who is a manufacturer of a medical device?.....	26
What is conformity assessment?	27
What are the conformity assessment procedures?	28
Part 1 Full quality assurance procedure for Class AIMD, III, IIb and IIa medical devices	29
Part 2 Type examination for Class AIMD, III and IIb medical devices.....	29
Part 3 Verification procedures for Class AIMD, III, IIa, IIb and I medical devices.....	30

Part 4 Production quality assurance for Class AIMD, III, IIb, IIa, and I (measuring or sterile) medical devices	31
Part 5 Product quality management system for Class IIb, IIa and I (measuring) medical devices	32
Part 6 Declaration of conformity (not requiring assessment by Secretary) procedures for Class IIa, I, and I (measuring and sterile) medical devices	33
Part 7 Conformity assessment procedures for devices used for a special purpose	33
What are the common elements in all of the conformity assessment procedures?	34
Post-market monitoring system.....	34
Quality systems certification surveillance audits.....	34
What is a declaration of conformity?.....	34
Who is responsible for the conformity assessment of a medical device and the declaration of conformity?	35
Choice of conformity assessment procedures and the relevant declaration of conformity.....	35
What are the special conformity assessment procedures?	37
What are the essential principles?	37
How do standards relate to the essential principles?	37
Advertising requirements	38
Some of the principles of the therapeutic goods advertising code.....	39
Prohibited representations.....	39
Restricted representations	39
Obtaining an exemption for a restricted representation.....	40
Consideration of complaints.....	40
Responsibilities and obligations under the <i>Therapeutic Goods Act 1989</i>	41
Responsibilities of sponsors and applicants for inclusion of a medical device in the ARTG.....	41
Requirements and obligations for manufacturers of medical devices	43
Technical documentation for medical devices.....	43
Product description.....	44
Technical requirements	44
Design	45
Applications for a conformity assessment certificate issued by the TGA.....	47
Manufacturers who have been issued a conformity assessment certificate by the TGA.....	47
Conformity assessment procedures for overseas manufacturers who do not have an Australian conformity assessment certificate.....	48
Once a medical device has been approved for supply, what systems are in place for detecting and reporting problems?	49
Offences, penalties and cancellations	50
Offences and penalties	50
Other penalties.....	50
Cancellations	51

Enforcement.....	51
Recalls of therapeutic goods.....	52
Non-Recall actions.....	53

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* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* and the *Therapeutic Goods (Medical Devices) Regulations 2002*. The guidance document should not be relied upon to address every aspect of the legislation. It is recommended that the Act and Regulations be read in conjunction with this document.

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.

It should be noted that three terms “therapeutic goods”, “therapeutic devices” and “medical devices” are used in the legislation. The Act is concerned with therapeutic goods which when the Act was first written described the regulation of medicines and therapeutic devices. At that time many other countries used the term “medical device” and not “therapeutic device”. When the Australian legislation was revised in late 2002 the term “medical device” was introduced. Therefore, for the next five years, the *Therapeutic Goods Act 1989* will regulate medicines, therapeutic devices and medical devices. The therapeutic devices are the registered or listed entries that were in the Australian Register of Therapeutic Goods (ARTG) before 4 October 2002, or which could entered during the 5 year transition period under certain conditions. Medical devices are those products that are entered in the ARTG after 4 October 2002 under the revised legislation. The medical devices in the ARTG will be known as medical devices included in the ARTG, or more colloquially known as inclusions.

If a product supplied in Australia is not a therapeutic good or more specifically, a medical device, it will then be subject to the requirements of consumer legislation such as the *Trades Practices Act 1974* or relevant State consumer legislation. This includes any advertising or labelling requirements set down in that legislation.

When the *Therapeutic Goods Act 1990* (the Act) was implemented in 1991 it was anticipated that some products might not be able to be clearly defined as therapeutic goods. As a result an excluded goods order was prepared which listed a number of products, which although intended for use in humans, have been declared not to be therapeutic goods. A copy of the “Therapeutic Goods (Excluded Goods) Order No. 1 of 1998”, can be downloaded from the Internet at the address “<http://www.tga.gov.au/docs/html/tgeg9801.htm>”. If a product is listed in this order it does not come under the jurisdiction of the Act. However, it will be subject to consumer legislation requirements, such as the *Trade Practices Act 1974*, if sold in Australia. This also includes any advertising or labelling requirements set down in that legislation.

The Act also makes provisions for products, which are considered as being therapeutic goods, but are not required to be entered in the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia. (Refer to Schedules 5 and 5A of the *Therapeutic Goods Regulations 1990* for more detail.) However these exempt goods are still considered as therapeutic goods and therefore still come under the jurisdiction of the Act.

This means that a distinction between excluded goods and exempt goods is that exempt goods are still required to comply with the labelling and advertising requirements for therapeutic goods if they are supplied in Australia. Exempt goods are also subject to the post-market requirements for any therapeutic good including compliance testing, for example.

Many different types of therapy regimes and techniques are used today when a person is sick, injured or unwell. These regimes and techniques include traditional western medical practices, eastern medical practices, naturopathy, reflexology, iridology, meditation and many others. Irrespective of what techniques, therapies or philosophies are utilised, if a product or object is used that meets the definition of a medical device, as stipulated in the Australian legislation, the product or object will be considered as a medical device. Consequently as medical devices they will have to comply with the requirements established by the legislation, such as the essential principles, including the advertising guidelines mentioned below, before they can be supplied in this country. Failure to do so can incur penalties stipulated in the legislation.

In summary, if a person or corporation:

- supplies a product, according to the definition of “supply” in the Act,
- within the operational boundaries of the Act, and
- the product satisfies the definition of a medical device, and
- is not currently exempt or excluded,

the person or corporation will have to have the medical device included in the Australian Register of Therapeutic Goods before it can be supplied in Australia. Otherwise, legislative penalties would be applied.

WHAT ARE ALTERNATIVE THERAPIES?

The National Centre for Complementary and Alternative Medicine (NCCAM), of the United States Food and Drug Administration, defines complementary and alternative medicine as:

“... a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. While some scientific evidence exists regarding some complementary and alternative medicine therapies, for most there are key questions that are yet to be answered through well designed scientific studies – questions such as whether they are safe and whether they work for the diseases or medical conditions for which they are used.”

Complementary medicine and alternative medicine differ from each other in how they relate to conventional medicine. The NCCAM states that “complementary medicine is used together with conventional medicine. An example of a complementary therapy is using aromatherapy to help lessen a patient's discomfort following surgery. Alternative medicine is used in place of conventional medicine. An example of an alternative therapy is using a special diet to treat cancer instead of undergoing surgery, radiation, or chemotherapy that has been recommended by a conventional doctor.”

The NCCAM classifies complementary and alternative medicine therapies into five categories, or domains as:

1. **Alternative Medical Systems** built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach... Examples of alternative medical systems that have developed in Western cultures include homeopathic medicine and naturopathic medicine. Examples of systems that have developed in non-Western cultures include traditional Chinese medicine and Ayurveda.
2. **Mind-Body Interventions** use a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptoms. Some techniques that were considered as complementary or alternative medicine in the past have become mainstream (for example, patient support groups and cognitive-behavioral therapy). Other mind-body techniques are still considered complementary or alternative medicine, including meditation, prayer, mental healing, and therapies that use creative outlets such as art, music, or dance.
3. **Biologically Based Therapies** use substances found in nature, such as herbs, foods, and vitamins. Some examples include dietary supplements, herbal products, and the use of other so-called "natural" but as yet scientifically unproven therapies.
4. **Manipulative and Body-Based Methods** are based on manipulation and/or movement of one or more parts of the body. Some examples include chiropractic or osteopathic manipulation, and massage.

5. Energy Therapies

Energy therapies involve the use of energy fields. They are of two types:

- ⦿ Biofield therapies are intended to affect energy fields that purportedly surround and penetrate the human body. The existence of such fields has not yet been scientifically proven. Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields. Examples include qi gong, Reiki, and Therapeutic Touch.
- ⦿ Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating current or direct current fields.

There are many alternative and complementary therapies. Many, but not all are listed below. The list also demonstrates the diverse range of these therapies. However, the definitions, descriptions and explanations for the various therapies should not be construed as being any form of endorsement or promotion by the TGA.

Acupressure is the application of pressure using beads, seeds or other hard substances to specific pressure points that are associated with desired health benefits, such as weight loss, headache and pain relief, and even the disruptive symptoms of post-addictive withdrawal. It is derived from ancient eastern medicine, which defined the general principles of acupuncture points found throughout the body.

Acupuncture is one form of treatment utilised in the ancient medical practice of Traditional Chinese Medicine, the fundamental cornerstone and basis for the practice of Oriental Medicine, which balances energy levels in the body. Acupuncture uses fine needles that act like antenna to directly manipulate the body's energy levels.

The **Alexander Technique** is a method that works to change movement habits in everyday activities. It is a simple and practical method for improving ease and freedom of movement, balance, support and coordination. The technique teaches the use of the appropriate amount of effort for a particular activity, giving practitioners more energy for all activities. It is not a series of treatments or exercises, but rather a re-education of the mind and body.

Aromatherapy is the technique of using essential oils to relax, balance and stimulate the body, mind and spirit.

Auriculotherapy is a procedure in which stimulation of the auricle of the external ear is utilised to alleviate health conditions in other parts of the body.

Ayurveda places an emphasis on prevention and encourages the maintenance of health through close attention to a balance between right thinking, diet, lifestyle and the use of herbs.

Bach flower treatments are based on 38 remedies directed at a particular characteristic or emotional state.

Biofeedback is a training technique in which people are taught to improve their health and performance by using signals from their own bodies.

Chakra is a Sanskrit word meaning wheel, or vortex, and it refers to each of the seven energy centres of which the consciousness or energy system, is composed. The functioning of the non-physical chakras reflects decisions made in response to conditions encountered in life.

Chi Gung or Qi Gong (pinyin spelling) translates to "Energy Cultivation". There are several different styles of Chi Gung practiced in the world today. Probably the most widely practiced form of Chi Gung is a number of exercises designed to promote health and longevity, increase concentration, vitality and stamina, slow the aging process and enhance sexual functioning.

Chiropractic manipulation is treatment using the therapist's hands to apply body leverage and a physical thrust to one joint or a group of related joints to restore joint and related tissue function. Through the use of manipulation, the aim is to provide relief from symptoms, improve joint and muscle function, and speed recovery. Spinal manipulation is the most common form of manipulation.

Colloidal Mineral Supplements are created by suspending minerals in pure water with a electronic colloidal process that creates liquid mineral suspensions.

Colour Therapy uses the seven colours of the spectrum to balance and enhance the body's energy centres or Chakras and also to help stimulate the body's own healing process.

Cranio-Sacral Therapy involves a very gentle touch of a practitioner's hands, both for diagnosis and for treatment. This light contact may be taken up on the cranium, the sacrum or any other part of the body as appropriate. Through this light touch the practitioner reportedly picks up subtle patterns of motion within the body.

Crystal Healing involves placing crystals of an appropriate colour and energy at corresponding chakra points. It is reported that this process will cleanse and energise the chakras.

Dance or Movement Therapy is the psychotherapeutic use of movement as a process which furthers the emotional, cognitive, social and physical integration of the individual.

Dar' Shem is an ancient healing art in which the initiated reportedly channel energy through their bodies to help others.

Electrotherapy is the application of electricity to the human body in the treatment of disease.

The **Feldenkrais Method** is an educational system that develops a functional awareness of the self in the environment. It is an approach to working with people which expands their repertoire of movements, enhances awareness, improves function and enables people to express themselves more fully.

Feng Shui is part of an ancient Chinese philosophy of nature and is often identified as a form of geomancy, divination by geographic features, but it is mainly concerned with understanding the relationships between nature and ourselves.

Gestalt Therapy is based on two ideas, the proper focus of psychology is the experiential present moment and we are inextricably caught in a web of relationship with all things. Its theory provides a system of concepts describing the structure and organisation of living in terms of aware relations.

Hemi-Sync is a process that reportedly allows people to alter their brainwaves with multi-layered patterns of sound frequencies. When these sounds are heard the brain responds by producing a third, binaural, sound that encourages the desired brainwave activity.

Holotropic Breathwork combines accelerated breathing with evocative music in a special set and setting. A person uses their own breath and the music in the room to enter a non-ordinary state of consciousness.

Homeopathy or the way of similars, is a treatment approach where a person with a particular set of symptoms, is given a minute dose of a substance which in large doses causes similar symptoms in a healthy person.

Huna is system of psychology and religious methods long used by the Kahuna of ancient Hawaii, used to heal the sick, solving personal problems, untangling financial and social difficulties, and changing the future.

Hydrotherapy, or Water Therapy or Pool Therapy, consists of a variety of aquatic-based treatments that are designed to condition and strengthen muscles, and increase the range of motion in affected parts of the body by partially overcoming the effects of gravity with the buoyancy effect of the water.

Hypnosis is a subconscious condition in which the mind is more or less inactive and is sensitive to suggestions made by a hypnotist.

Iridology is the study of the iris of the eye in order to diagnose disease.

Karuna means any action that is taken to diminish the suffering of others and could also be translated as "compassionate action."

Kirlian photography records an image on a photographic plate of an object subjected to a high-voltage electric field. The image looks like a coloured halo or coronal discharge. This image is said to be a physical manifestation of the spiritual aura or "life force" which allegedly surrounds each living thing.

Magnet therapy is based on claims that magnetic fields have healing powers, can help broken bones heal faster, and relieve pain.

Massage Therapy is used for relief from injuries and certain chronic and acute conditions, to help people deal with the stresses of daily life, and to maintain good health.

Meditation is a technique developed to achieve deep relaxation, eliminate stress, promote health, increase creativity and intelligence, and attain inner happiness.

Metamorphosis is a simple approach to healing and transformation in which the spinal reflex points on the feet, hands, head or directly on the spine are used to let go of the underlying genetic and karmic stresses brought in at conception.

Mindfulness is a type of meditation practice, known as vipassana, or insight meditation.

Movement Therapy or Dance Therapy is the psychotherapeutic use of movement as a process that furthers the emotional, cognitive, social and physical integration of the individual.

Music therapy is the prescribed use of music to bring about positive changes in the psychological, physical, cognitive, or social functioning of individuals with health or educational problems.

Naturopathy is a system of therapy and treatment which relies exclusively on natural remedies, such as sunlight, air, water, supplemented with diet and therapies such as massage.

Neuromuscular Integrative Action is a dynamic workout program that motivates people to achieve fitness, health, well-being, potential, and improved self-esteem.

Neuro-Linguistic Programming is a methodology used to explore how people organise their thinking processes, their beliefs and their behaviour so that others can replicate their skills and capabilities in particular areas.

Nutraceuticals (often referred to as phytochemicals or functional foods) are natural, chemical compounds that reportedly have health promoting, disease preventing or medicinal properties.

Oriental Medicine includes the various styles that developed as Traditional Chinese Medicine spread from China to many different countries such as Korea, Japan and then into Europe. It uses ancient diagnostic techniques that evaluate and diagnose a person's imbalance. Once the patient is diagnosed, a treatment protocol using acupuncture, herbal prescriptions as well as other various modalities can be used.

Past Life Regression is the reported journeying into a person's past lives while hypnotised.

The **Pilates Method** is an exercise system focused on improving flexibility and strength for the total body without building bulk.

Polarity Therapy is a health system involving energy-based bodywork, diet, exercise and self-awareness. It works with the reported Human Energy Field, electromagnetic patterns expressed in mental, emotional and physical experience.

Pool Therapy, or Water Therapy or Hydrotherapy, consists of a variety of aquatic-based treatments that are designed to condition and strengthen muscles, and increase the range of motion in affected parts of the body by partially overcoming the effects of gravity with the buoyancy effect of the water.

Psychotherapy is a method of treating disorders, especially nervous disorders, by mental means rather than by using physical intervention techniques.

Qigong is the skill of cultivating internal energy using meditation techniques and external energy through movement patterns.

Reflexology is based on the concept that congestion or tension in any part of the foot mirrors congestion or tension in a corresponding part of the body. The reflex areas on the feet and hands are linked to other areas and organs of the body within the same zone.

Regression therapy is based on the concept that people are eternal beings who carry forward experiences and knowledge from one lifetime to another.

Reiki is a system for channelling the reported universal life-force-energy to someone for the purpose of healing.

Rolfing, or Structural Integration, is a system of soft tissue manipulation and movement education that organises the body in a way to ease pain and chronic stress, and improve physical performance.

Self-Hypnosis is a method of relaxation and introspection similar to meditation intended to attain a level of relaxation and concentration to allow a person's mind to send healing messages to their body.

Shamanism is a primitive religion in which it is believed that good and evil spirits pervade the world and can be influenced only by shamans acting as mediums.

Shiatsu is a traditional hands-on Japanese massage healing therapy to induce deep relaxation that can help in cases of specific injuries and for more general symptoms of poor health.

Sound Therapy examines the effects of low frequency sound and vibration on human health and wellbeing.

Spiritual Healing involves the concept of channelling healing energy from its spiritual source to someone who needs it. The channel is often a person, known as a healer, and the healing energy is usually transferred to the patient through the healer's hands. Praying can also be used to take advantage of spiritual healing.

Stress Management is the skill of dealing with the many stresses, including the psychological stresses of everyday living.

Structural Integration, or Rolfing, is a system of soft tissue manipulation and movement education that organises the body in a way to ease pain and chronic stress, and improve physical performance.

Tai Chi, or Tai Chi Chuan, is an ancient Chinese form of coordinated body movements focusing on the cultivation of internal energy to harmonise the mind, body and spirit, promoting both mental and physical well-being through softness and relaxation. It is also an effective system of self-defence.

Taoist Healing is based on the concepts of a total body-mind-spiritual interaction according to theories explaining the balance of the complementary and antagonistic units which comprise the universe.

Thai Massage is an ancient method of aligning the energies of the body and originates from the time of the Buddha.

Touch Therapy, or healing touch therapy, encompasses a group of non-invasive techniques that utilise the hands to reportedly clear, energise, and balance human and environmental energy fields body to induce deep relaxation and promote self-healing.

Trance Dancing involves moving, breathing and concentration to express the rhythms of music to move energy from the body to other dancers.

Transpersonal Psychotherapy is a therapy combining western psychotherapies and eastern wisdom traditions.

Vedic Vibrations are traditionally believed to be fundamental vibrations that structure the material universe and the human body and reportedly generate "silent whispers" in people's consciousness which can be used to enliven the body's inner intelligence and bring immediate relief of symptoms of poor health.

Vibrational Therapy, or **Vibrational Medicine** and **Energy Medicine**, is based on the concept that all matter vibrates to a precise frequency and that by using resonant vibration, the balance of matter can be restored.

Vipassana which means to see things as they really are, is one of India's most ancient techniques of meditation.

Water Therapy, or **Pool Therapy** or **Hydrotherapy**, consists of a variety of aquatic-based treatments that are designed to condition and strengthen muscles, and increase the range of motion in affected parts of the body by partially overcoming the effects of gravity with the buoyancy effect of the water.

Yoga is a holistic system of self transformation that approaches well-being through balancing the vital energies in the body which harmonise all aspects of the physical, mental, emotional and spiritual aspects of human life.

Zen Buddhism is based on the teachings of Siddhartha Gautama, or Buddha, which contend that everything is subject to change and that suffering and discontentment are the result of attachment to circumstances and things which, by their nature, are impermanent. By ridding oneself of these attachments, including attachment to the false notion of self, people can be free of suffering.

EXAMPLES OF ALTERNATIVE THERAPY PRODUCTS

The list of products below has been included to illustrate some of the types of devices used in alternative therapy regimes and techniques. It should not be considered as a definitive or exhaustive list. Many others are available and are being promoted. Products include:

- acupuncture pressure point equipment,
- battery powered, externally applied, devices claiming to purify blood or remove intestinal parasites,
- bioelectric magnetic therapy equipment,
- bioelectric resonance therapy equipment,
- bioelectric shields,
- colloidal silver generators,
- crystals and crystal therapy devices claiming to harness or emit energy for therapeutic benefits,
- electrodermal screening equipment,
- electromagnetic field therapy equipment,

- external nerve stimulators for weight reduction,
- far infrared therapy equipment,
- full body scanning equipment,
- hologram body alignment devices,
- intrasound equipment,
- ionising devices claiming to redistribute positive and negative ions in the body for therapeutic benefits,
- live blood analysis devices,
- magnetic therapies using garments, mattresses, pillows, innersoles and body adornments making therapeutic claims,
- magnetic water therapy equipment,
- massage devices for weight loss and cellulite reduction,
- metallic alloy devices for alignment of energy meridians,
- multi-frequency electric current therapy equipment,
- multi-wave oscillation equipment,
- program controlled devices combining massage and acupuncture,
- radionic measurement devices,
- silver salts impregnated into garments for therapeutic benefits,
- sound frequency therapy equipment,
- thermographic equipment, and
- water ionisers.

THE OPERATION OF THE *THERAPEUTIC GOODS ACT 1989*

As stated in section 6 of the Act:

“This Act applies to:

- (1) (a) things done by corporations; and
 - (b) things done by natural persons or corporations in so far as those things are done:
 - (i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or
 - (ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or
 - (iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.
- (2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1)(a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities.”

As can be seen the Act applies to things done by corporations in all instances. However in the case of natural persons or unincorporated businesses the Act only applies where the individuals concerned engage in trade or commerce between States and Territories, or between Australia and another country.

Unless complementary legislation is enacted within a State or Territory of Australia to apply the legislative requirements the Commonwealth legislation, the *Therapeutic Goods Act 1989* has no application to activities undertaken by those who trade in therapeutic goods within the borders of a State or Territory.

New South Wales, for example, has enacted the *NSW Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 1994*, and following amendments to the Commonwealth *Therapeutic Goods Act 1989*, it now means that the NSW legislation has the effect of, among others things, applying the Commonwealth's regulatory scheme for therapeutic goods within NSW.

HOW ARE MEDICAL DEVICES REGULATED?

The *Therapeutic Goods Act, 1989* provides the legislative basis for uniform national controls over goods used in the prevention, diagnosis, curing, or alleviation of a disease, ailment, defect or injury.

It is important to know the current regulatory requirements. Copies of the legislation can be obtained from Government Info Shops in each capital city or from Internet web sites such as the Attorney General's Department's law resource at <http://scaleplus.law.gov.au>.

The Therapeutic Goods Administration (TGA), a Division of the Commonwealth Department of Health and Ageing, is responsible for administering the Act. The Office of Devices, Blood and Tissues within the TGA is responsible for regulating medical devices.

The new medical devices legislation incorporates accepted best practice relating to safety, quality and risk management procedures, as well as providing the flexibility and capacity to regulate new and changing technology. The new framework also adopts the principles of the Global Harmonisation Task Force on medical devices.

The new regulatory system has the following features:

- a device classification scheme based on different levels of risk for each class of device;
- essential principles for the quality, safety and performance of the medical device that must be complied with before the product can be supplied;
- options as to how compliance with the essential principles can be satisfied and assessed by manufacturing quality systems, type testing, and design evaluation;
- the use of recognised standards to satisfy the requirements of the essential principles;
- a comprehensive post market surveillance and adverse incident reporting program;
- appropriate regulatory controls for the manufacturing processes of medical devices;
- the use of an Internet-based system, the Devices Electronic Application Lodgement system (DEAL), for applications to have a medical device included in the ARTG. The DEAL system will also be used to lodge details of medical device manufacturers, and the required declarations of conformity, before applications can be submitted to have a medical device included in the ARTG for all classes of medical devices, except for Class I; and
- the continued use of the ARTG as the central point of control for the legal supply of medical devices in Australia. Following the amendments to the Act, an additional part has been created in the ARTG for medical devices. The new part is for medical devices included in the Register. In other words, new medical devices will be known as included

medical devices as opposed to registered or listed devices. The parts of the ARTG for registered and listed goods will remain. Therapeutic goods, which are currently registered or listed in the Register, cannot be transferred to the new part. If these goods satisfy the new regulatory requirements an application to have these goods included in the ARTG must be submitted.

WHAT SCHEMES ARE IN PLACE TO ACCESS UNAPPROVED MEDICAL DEVICES?

The Act provides access to medical devices not entered on the ARTG under the following special access and supply arrangements:

- Clinical trials (either the clinical trial exemption (CTX) scheme or the clinical trial notification (CTN) scheme, where both schemes require human research ethics committee approval;
- The Special Access Scheme (Categories A and B);
- Authorised Prescribers; and
- Importation for personal use.

The Special Access Scheme (SAS) allows access to unapproved products by individual patients, other than by personal importation. Access is dependent on whether the patients are classified as Category A, as defined in the Regulations. The use of a medical device for a Category A patient only requires notification while Category B patients require approval by a TGA delegate.

A detailed document, “Access to Unapproved Therapeutic Goods in Australia” is available from the TGA website, “<http://www.tga.gov.au/docs/html/sasinfo.htm>”.

WHAT HAPPENS TO THERAPEUTIC DEVICES AND MEDICAL DEVICES WITH THE INTRODUCTION OF THE NEW REGULATORY SYSTEM IN AUSTRALIA?

Therapeutic and medical devices fall into 1 of 4 regulatory categories after 4 October 2002:

1. Existing therapeutic devices on the ARTG in either of the registrable or listable categories;
2. Therapeutic devices for which applications for listing or registration were under review by the TGA before 4 October 2002;
3. Medical devices for which applications have been received for inclusion in the ARTG; and
4. Excluded and exempt therapeutic goods.

1. Existing therapeutic devices in the ARTG

Devices that are currently registered or listed in the ARTG can remain in those categories until 4 October 2007, at which time they will be automatically cancelled from the ARTG. However if a successful application has been made for them to become included medical devices in the Register, at any time up to 4 October 2007, the new entry can replace the registrations or listings. The registrations or listings would be cancelled when the included entry is created in the ARTG, permitting supply of the new “included” devices in Australia to continue. It is also possible that the new included entry could replace other registrations or listings as new criteria are being used to

distinguish included entries in the ARTG. Each separate kind of included medical device classified as Class I, Class I Measuring, Class I Sterile, Class IIa and Class IIb will be categorised according to the criteria of:

- same sponsor;
- same manufacturer;
- same Class; and
- same Global Medical Device Nomenclature System (GMDNS) code.

If the medical device is classified as a Class III or an Active Implantable Medical Device (AIMD) an additional characteristic will be used to define a kind of medical device. The characteristic is called the unique product identifier (UPI) which is given to the device by its manufacturer to identify the device and any variants.

The revised criteria may result in each included entry in the ARTG covering more devices than under the previous criteria. This is especially true for the range of devices from Class I to Class IIb.

Until 4 October 2007, the supply of all registered and listed therapeutic devices will remain subject to the conditions imposed when the entries were approved. For example, good manufacturing practice requirements will need to remain current and any and all relevant therapeutic goods orders will remain in force for those entries. The entries could also be subject to any compliance checks by the TGA.

Changes or variations to existing therapeutic devices in the ARTG

Certain changes or variations to existing entries in the ARTG for registrable or listable therapeutic devices will be permitted during the 5-year transition period provided that the change or variation does not require a new entry in the ARTG. If a new entry is required as a result of the change, an application to include the medical device in the ARTG, under the new system, will need to be submitted to the TGA.

2. Applications under review by the TGA before 4 October 2002

If an application was made for the registration or listing of a medical device before 4 October 2002, and the application was not determined or withdrawn before that date, it will still be processed by the TGA. Further, if the application is found satisfactory, an entry for the registered or listed therapeutic device will be created in the ARTG. On 4 October 2007, those entries will be cancelled from the ARTG, if inclusions have not been created to replace them. As stated previously, supply of these registered and listed therapeutic devices will remain subject to the conditions imposed when the entries were approved.

3. New applications for inclusion of a medical device in the ARTG

Applications for inclusion of a medical device in the ARTG made after 4 October 2002 will be subject to the requirements of the new regulatory system.

The new regulatory regime adopts a classification system to categorise medical devices.

The classification of a medical device determines the conformity assessment procedures a manufacturer can choose to ensure that the device is adequately assessed to conform to the particular requirements for the class of device.

Higher class devices undergo a more stringent form of conformity assessment than lower class devices. Certification by the TGA or an overseas notified body is required for higher risk devices.

The responsibility for conformity assessment rests with the manufacturer of a medical device. The role of the TGA, or an overseas notified body, is to issue certification after they have confirmed that the conformity assessment procedures are appropriate and have been applied. This intervention will vary according to the class of the device.

Assessment by the TGA is required for Australian manufacturers of medical devices intended for supply in Australia.

Essential principles of safety and performance have been prescribed for all medical devices. There are two main categories of these principles. The general principles apply to all devices. The applicability of the principles dealing with design and construction will depend on the intended purpose and properties of the medical device.

4. Excluded and exempt devices

When the Act was implemented in 1991 it was anticipated that some products might not be able to be clearly defined as therapeutic goods. As a result an excluded goods order was prepared listing a number of products, which although intended for use in humans, have been declared not to be therapeutic goods. A copy of the “Therapeutic Goods (Excluded Goods) Order No. 1 of 1998”, can be downloaded from the Internet at the address, [“http://www.tga.gov.au/docs/html/tgeg9801.htm”](http://www.tga.gov.au/docs/html/tgeg9801.htm). If a product listed in this order is sold in Australia it will be subject to consumer legislation requirements, such as the *Trade Practices Act 1974*. This also includes any advertising or labelling requirements set down in that legislation.

The Act also makes provisions for products, which are considered as being therapeutic goods, but are exempt from the penalty of being supplied in Australia without being entered in the ARTG. (refer to Sections 18 and 19 of the Act and Schedules 5 and 5A of the *Therapeutic Goods Regulations 1990* for more detail). Some other therapeutic goods are also considered exempt from good manufacturing requirements. (refer to Schedule 7 of the *Therapeutic Goods Regulations 1990*).

It must be emphasised that exempt medical devices under section 19 of the Act, “Exemptions for special and experimental uses”, are only exempt while the clinical trial is being conducted or used for the special purpose.

Therapeutic goods that are medical devices and considered as exempt from registration or listing in the ARTG under sections 18 and 19 of the Act, and the related regulations, will remain exempt until 4 October 2004. After that time, similar provisions under Part 4-7 of the Act are likely to come into effect. These provisions deal with:

- medical devices exempted under the regulations (schedule 4 of *the Therapeutic Goods (Medical Devices) Regulations 2002*);
- approval for medical devices to be used for special treatment of individuals or for experimental purposes; and
- the authorisation of particular medical practitioners to supply specified medical devices.

All exempt goods are still considered as therapeutic goods and therefore still come under the jurisdiction of the Act. This means that a distinction between excluded goods and exempt goods is that exempt goods are still required to comply with the labelling and advertising requirements for therapeutic goods if they are supplied in Australia. Exempt goods are also subject to the post-market requirements for any therapeutic good, including compliance testing, for example.

Components of therapeutic and medical devices and parts of therapeutic devices intended for use in the:

- manufacture,
- installation,
- repair, or
- maintenance

of devices that are not provided separately to the consumer as an accessory or consumable component except for:

- components for artificial limbs; or
- programmers for implantable electronic devices; or
- components of implantable devices that are assembled in the body,

will remain as exempt goods until 4 October 2004.

The devices that are determined to be excluded or exempt will remain so until 4 October 2004.

Applications to list or register exempt therapeutic goods will continue to be accepted until 4 October 2004. The listings for those goods will be automatically cancelled from the ARTG on 4 October 2007 or cancelled if an application for an inclusion in the ARTG, which covers those goods, is successful.

Applications to list or register excluded therapeutic goods will be rejected and the application fees will not be refunded.

IMPLICATIONS FOR AUSTRALIAN MANUFACTURERS OF MEDICAL DEVICES DURING THE TRANSITION PERIOD

A manufacturer based in Australia supplying registered or listed goods will have until 4 October 2007 to adopt the conformity assessment requirements of the new legislation. Until that time the requirements and conditions that were imposed when the products were approved for supply will continue to remain in force. This includes the need for surveillance audits of the manufacturing facilities and compliance to any therapeutic goods orders. The requirements are documented in the publication “Australian Medical Device Requirements Version 4 under the Therapeutic Goods Act 1989” (DR4). This is available on the Internet at “<http://www.tga.gov.au/docs/html/dr4.htm>”.

1. Manufacturers requiring a manufacturing licence

If a licence was required to manufacture a listable or registrable device in the ARTG, the licence will remain in effect until:

- conformity assessment requirements are established by the manufacturer and an application for inclusion in the ARTG is approved for the good before 4 October 2007,
- supply of the good in Australia ceases before 4 October 2007, or
- it is automatically revoked on 3 October 2007.

Until 3 October 2007 variations to existing licences will be permitted for changes to existing processes for registered or listed therapeutic devices so long as the change does not result in or requires a new entry in the ARTG.

Until 3 October 2007 licences to manufacture therapeutic devices will only be issued in connection with currently registered or listed goods and so long as new entries on the ARTG are not required. This may apply, for example, if a manufacturer needs to move their premises.

If a licensed manufacturer introduces new products after 4 October 2002 conformity assessment procedures will have to be applied and an application for inclusion will have to be submitted.

2. Manufacturers exempt from licensing

Manufacturers of therapeutic goods, except for goods supplied as pharmaceutical benefits, satisfying the requirements of Schedule 7 of the *Therapeutic Goods Regulations 1990* did not require a manufacturing licence from the TGA prior to 4 October 2002. Those manufacturers will be able to continue to list or register their products in the ARTG until 4 October 2004. If any products are listed or registered up to this time the products can remain in the ARTG until 4 October 2007. At that time the products will be automatically cancelled unless they are covered by an included entry in the Register, and the listed or registered entries have been cancelled.

3. Manufacturers with TGA CE Certification

If an Australian manufacturer had an assessment carried out by the TGA for CE certification prior to 4 October 2002, a similar assessment will need to be carried out if the products are to be supplied in Australia. This will be required to ensure the conformity assessment procedures for Australia have been carried out correctly. However, reduced assessment fees will be applied to:

- review post market monitoring procedures,

- review conformity with the Australian essential principles, and
- issue conformity assessment certification.

4. Manufacturers seeking TGA CE certification

If an Australian manufacturer wishes to have the TGA carry out an assessment for a CE mark after 4 October 2002, they are advised to consider a number of options. For example, it would be a more productive exercise to have the TGA undertake an assessment for conformity assessment certification for Australia and have the assessment for the CE mark carried out at the same time. This will increase the marketing potential for the manufacturer and save on assessment costs. The charge for the CE mark assessment would be the incremental cost above the fees for the conformity assessment for Australia's requirements. Conformity assessment and CE certification may also be issued to the manufacturer.

If an assessment for CE marking for an Australian manufacturer is undertaken by the TGA before conformity assessment procedures are carried for Australia's requirements full assessment and audit fees will be levied for both procedures.

WHAT IS THE DEFINITION OF A THERAPEUTIC GOOD?

Section 3 of the Act states that "therapeutic goods" "means goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) for therapeutic use; or
 - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii)...

and includes medical devices and goods declared to be therapeutic goods under an order in force under Section 7 but does not include:

- (c) goods declared not to be therapeutic goods under an order in force under section 7; or
- (d) goods" declared under an order in force under section 7 "not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way..."

WHAT IS THE DEFINITION OF THERAPEUTIC USE?

Section 3 of the Act states that therapeutic use “means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.”

WHAT DOES SUPPLY MEAN?

The term “supply” is a fundamental component of the Australian therapeutic goods legislation. It should be noted that as far as medical devices are concerned, the supply of medical devices in Australia has a broader meaning than for medical devices on the market in the European Community.

“Supply” is defined in section 3 in the Act as:

- supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and
- supply, whether free of charge or otherwise, by way of sample or advertisement; and
- supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and
- supply by way of administration to, or application in the treatment of, a person or animal.

WHAT IS A MEDICAL DEVICE?

A medical device is defined in section 41BD of the Act as “any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended by the person under whose name it is to be supplied, to be used for human beings for the purposes of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

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

an accessory to such an instrument, apparatus, appliance, material or other article.”

It should be noted that a key part of this definition is the intended purpose specified by the manufacturer of the medical device.

An accessory, to a medical device, is an article, or articles intended specifically by its manufacturer to be used together with the medical device to enable the medical device to be used as intended by its manufacturer.

HOW ARE MEDICAL DEVICES CLASSIFIED?

The new regulatory regime adopts a classification system to categorise medical devices. The system uses a set of classification rules (see the Guidance Document on the Classification of Medical Devices) based on:

- the manufacturer's intended use
- the level of risk; and
- the degree of invasiveness in the human body.

The five classes of medical devices, starting at the lowest level of risk are:

- Class I
- Class IIa
- Class IIb
- Class III
- Active Implantable Medical Devices (AIMD)

The examples shown in Table 1, below, are included for guidance only. The classification, which has to be determined by the manufacturer of the medical device, may change depending on the site of use, the addition of a medicinal component, or the intended purpose specified by the manufacturer.

Table 1. Examples of typical medical device classifications

Class I	Class IIa	Class IIb	Class III	AIMD
Acupuncture pressure point equipment	Battery powered externally applied devices claiming to purify blood or remove internal parasites	Apnea monitors	Absorbable sutures	Implantable drug infusion devices
Beds	Bioelectric magnetic therapy equipment	Blood bags	Breast implants	Implantable pulse generators
Cervical collars	Bioelectric resonance therapy equipment	Baby incubators	Condoms with spermicides	
Cotton wool	Electrodermal screening equipment	Blood pumps for heart-lung machines	Cortical electrodes	
Crystals and crystal therapy devices claiming to harness or emit energy for therapeutic benefits	Electromagnetic field therapy equipment	Blood warmers	Heart valves	
Dental curing lights	External nerve stimulators for weight reduction	Condoms	Heparin coated catheters	
Examination gloves	Far infrared therapy equipment	Contact lens care products	Implantable electrodes	
External electrodes	Gamma cameras	Contraceptive diaphragms	Intrauterine devices	
Full body scanning equipment	Holographic body alignment devices	Diagnostic X-ray sources	Neurological catheters	
Gauze dressings	Hydrogel dressings	External defibrillators	Temporary pacing leads	
Manual drills and saws	Ionising devices claiming to redistribute positive and negative ions in the body for therapeutic benefits	Haemodialysers	Vascular prostheses	
Ostomy pouches	Magnetic therapies using garments, mattresses, pillows, innersoles and body adornments making therapeutic claims	Instrument grade disinfectants	Vascular stents	
Removable dentures	Magnetic water therapy equipment	Insulin pens		
Scalpels	Massage devices for weight loss and cellulite reduction	Intensive care monitoring systems		
Spectacles	Multi-frequency electric current therapy equipment	Lung ventilators		
Stethoscopes	Single-use catheters	Orthopaedic implants		
Thermographic imagers	Sound frequency therapy equipment	Penile implants		
Walking aids	TENS devices	Peripheral vascular grafts		
Wheelchairs	Thermographic equipment	Sterilants		

WHO IS A SPONSOR OF A MEDICAL DEVICE?

The Act requires that people or corporations supplying a therapeutic good in Australia by way of exporting, importing or manufacturing the product, are held responsible for its quality, safety and efficacy. That person or corporation, being resident in, or doing work in Australia, is called a sponsor. Under section 3 of the Act a sponsor is a “person who:

- exports, or arranges the exportation of therapeutic goods from Australia; or
- imports, or arranges the importation of therapeutic goods into Australia; or
- in Australia, manufactures therapeutic goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere)”.

However, a sponsor is *not* a person who:

- “exports, imports or manufactures therapeutic goods, or
- arranges the exportation, importation or manufacture of the goods,

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in Australia”.

This means that people or companies working as import or export agents, manufacturers contracted to other people or companies, distribution agents acting for people residing in or carrying out business in Australia, for example, are not normally considered as sponsors.

WHO IS A MANUFACTURER OF A MEDICAL DEVICE?

A manufacturer of a medical device is defined as a person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person’s name or business name. This will apply whether or not the person, or someone else acting on their behalf, carries out these operations.

If the above does not apply, according to section 41BG of the Act, the manufacturer is the “person who, with a view to supplying the device under their name, does one or more of the following using ready-made products:

- assembles the device;
- packages the device;
- processes the device;
- fully refurbishes the device;
- labels the device;
- assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:
 - the labelling;
 - the instructions for use;
 - any advertising material.

However, a person is *not* the manufacturer of a medical device if:

- they assemble or adapt the device for an individual patient; and
- the device has already been supplied by another person; and

- the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the labelling, the instructions for use, or any advertising material”.

WHAT IS CONFORMITY ASSESSMENT?

Irrespective of the classification of a medical device it is necessary to be able to demonstrate that the device, or the manufacturing processes used to make the device, conforms to the requirements laid down in the legislation. This is the fundamental process of conformity assessment. Various types of conformity assessment procedures have been developed.

The classification of a medical device determines the conformity assessment procedures a manufacturer can choose to ensure that the device is adequately assessed to conform to the particular requirements for the class of device. Higher class devices undergo a more stringent form of conformity assessment than lower class devices.

The role of the TGA, or an overseas notified body, is to issue certification after audits have confirmed that the conformity assessment procedures are appropriate and have been applied correctly. These audit processes will vary according to the class of the device and the conformity assessment route selected by a manufacturer.

Assessment by the TGA is also required for Australian manufacturers of medical devices intended for supply in Australia. In addition, the TGA will undertake assessments of overseas manufacturers when requested.

The table below shows what kinds of medical devices require a conformity assessment certificate from the TGA.

Table 2. Kinds of medical devices which require a conformity assessment certificate from the TGA

Kinds of Medical Devices	TGA Conformity Assessment Certificate required
Medical devices manufactured in Australia	Yes
Medical devices, manufactured outside Australia, containing non-viable tissues of animal origin, other than those intended to come into contact with intact skin	Yes
Medical devices, manufactured outside Australia, containing tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body	Yes
Medical devices, manufactured outside Australia, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device	Yes
Medical devices, manufactured outside Australia, that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device	Yes
Class I medical devices, or the manufacturers of Class I medical devices, not intended to be supplied in a sterile state or that does not have a measuring function	No
Exempt devices or manufacturers of exempt devices	No
Medical devices approved under section 41HB of the Act or manufacturers of medical devices approved under section 41HB of the Act (ie for use in the treatment of another person or for use solely for experimental purposes in humans)	No
Medical devices subject to an authority under section 41HC of the Act or manufacturers of medical devices approved under section 41HC of the Act (ie authorising a specified medical practitioner to supply specified kinds of medical devices for use in the treatment of humans to a specified class of recipients)	No

WHAT ARE THE CONFORMITY ASSESSMENT PROCEDURES?

A manufacturer, either in Australia or elsewhere, uses a conformity assessment procedure to demonstrate that a medical device conforms to the essential principles of safety and performance defined in Australian legislation. Depending on the procedure chosen, assessment of the final design, the controls implemented for production and the manufacturer’s courses of action may have to be assessed by the TGA or another conformity assessment body acceptable to the TGA.

The conformity assessment procedures are defined in Parts 1 to 8 of Schedule 3 of the Regulations. More information of these procedures can be found in the guidance document, “Conformity Assessment Procedures”.

Part 1 Full quality assurance procedure for Class AIMD, III, IIb and IIa medical devices

Part 1:

- is suitable for manufacturers who produce new models on a regular basis
- is also suitable for manufacturers who improve, modify or correct their devices on a regular basis

A manufacturer may apply this procedure by implementing a full quality management system that takes into account the regulatory requirements for the design, production, packaging, labelling and final inspection processes, and implements a post-production phase monitoring system.

The manufacturer must make an application for an assessment of the quality management system by the TGA or, in most cases for an manufacturer outside Australia, an overseas conformity assessment body. Certification will be issued if the quality management system is satisfactory. The certification will declare that the quality system conforms to the requirements of Part 1 of the Regulations. The certification cannot make a declaration against a conformity assessment standard such as ISO13485, if it had been used, for example. The manufacturer may then prepare a declaration of conformity. A sponsor must use this declaration, together with the quality system certification, as the basis for an application for supply in Australia.

The quality management system certification remains valid only if it is subject to periodic and satisfactory surveillance audits.

Changes to the quality system that broaden the scope of the quality system or alter the approved system will require further assessment and approval by the TGA or another conformity assessment body. Changes to the design or methods of production of a Class AIMD and III devices will also require further assessment and approval.

For Class AIMD and III devices, this procedure will also require the TGA, or in some cases another appropriate conformity assessment body, to examine the design for each device. The manufacturer must make a separate application for the assessment of the design. Re-examination of the design may be required after 5 years. This will be decided on a case-by-case basis.

Part 2 Type examination for Class AIMD, III and IIb medical devices

The options available with this conformity assessment procedure are that:

- the TGA will conduct tests on the device at the manufacturer's site and will supervise or commission the testing;
- the testing can be conducted within the TGA's own laboratories; or
- the TGA will subcontract the testing to an accredited test laboratory (either in Australia or overseas);
- however, as many test procedures need to be designed, established and qualified before testing can begin, the overhead cost of the assessment is usually high when compared to assessment under Part 1.

The manufacturer must make an application for the TGA, or in some cases another appropriate conformity assessment body, to examine a representative sample of the type of device (the 'type'). The type must have been designed and produced according to the essential principles.

The TGA will determine if the design of the type satisfies the essential principles, either through testing by the TGA or by an accredited testing body in Australia or overseas, which has been subcontracted to the TGA. Testing or the supervision of the testing may occur on the manufacturer's premises with the agreement of the manufacturer.

If the type testing has been certified, the manufacturer must seek further certification for the production and final inspection and testing of the device.

For Class AIMD, III or IIb devices:

- that are supplied sterile, the manufacturer must seek further certification against Part 4 – Production Quality Assurance Procedures.
- that are not supplied sterile the manufacturer may seek further certification against either Part 3 – Verification Procedures or Part 4 – Production Quality Assurance Procedures.

For Class IIb devices:

- that are not supplied sterile, the manufacturer may seek further certification against Part 5 – Product Quality Assurance Procedures

Part 3 Verification Procedures for Class AIMD, III, IIa, IIb and I medical devices

This Part:

- has very limited application
- requires that the TGA will need to test each device batch by batch (either on a statistical basis or a 100% sampling rate)
- is a very expensive option
- requires the TGA to provide some indicative costing of the testing as part of the application fee

Manufacturers of Class AIMD, III or IIb devices, that are not supplied sterile, and where Part 2 has been applied may use this procedure.

Manufacturers of Class IIa devices or Class I devices with a measuring function, that are not supplied sterile, and that have followed the procedure described in Part 6 may also use this procedure.

The TGA will conduct examinations and tests, as the manufacturer chooses, on:

- each product (ie 100% testing) or;
- each product selected on the basis of a statistically determined sample of each uniform batch submitted.

In either case the TGA, or an appropriate conformity assessment body, will determine if the device conforms to the 'type'.

Where the manufacturer has self-declared that the device conforms with the essential principles under Part 6, the TGA will determine if the product conforms to the technical documentation

prepared by the manufacturer under that part. Certification will be issued for each device or each batch as appropriate.

When conformity assessment procedures for Class AIMD, III or IIb medical devices have been successfully completed, the manufacturer may prepare a declaration of conformity under this part. This declaration and the certifications issued under Part 2 and this part, form the basis of an application for supply in Australia.

For Class IIa devices or Class I devices with a measuring function, that are not supplied sterile, a declaration of conformity is made under Part 6 on the basis of the procedures in Part 6 and the certification issued under this Part.

The manufacturer is also required to implement a post-production monitoring system.

Part 4 Production quality assurance for Class AIMD, III, IIb, IIa, and I (measuring or sterile) medical devices

This part:

- is suitable for manufacturers who produce new models on a regular basis
- is also suitable for manufacturers who improve, modify or correct their devices on a regular basis

Class AIMD, III, or IIb devices can require Part 2 + Part 4 conformity assessment procedures. However, it may be better to follow the conformity assessment procedures in Part 1 for these devices.

Manufacturers of Class IIa devices or Class I devices with a measuring function that have followed the procedure described in Part 6 may also use this procedure. If any of these devices are supplied sterile the manufacturer must follow these procedures.

In this conformity assessment procedure, the manufacturer must implement a quality management system for the production and final inspection of the device that specifically includes regulatory requirements and a post-production monitoring system.

The manufacturer must make an application for an assessment of the quality management system by the TGA or, in some cases, another appropriate conformity assessment body. Certification will be issued if the quality management system is satisfactory. The certification will declare that the quality system conforms to the requirements of Part 4 of the Regulations and not against a conformity assessment standard (eg. ISO 13485), if one has been used for the implementation and assessment of the system.

When Part 2 has been completed together with this part, manufacturers of Class AIMD, III and IIb devices may then prepare a declaration of conformity. A sponsor can use this declaration and the certifications issued under Part 2 and this part, as the basis for an application for supply in Australia.

For Class IIa and Class I devices a declaration of conformity is made under Part 6 on the basis of the procedures in Part 6 and the certification issued under this Part.

The quality management system certification remains valid only if it is subject to periodic surveillance.

Changes to the quality system that add additional product to the range covered by, or alter, the approved system will require further assessment and approval.

Part 5 Product quality management system for Class IIb, IIa and I (measuring) medical devices

This part is applicable to:

- non-sterile Class IIb, IIa and Class I devices with a measuring function.
- Class IIb devices, which are not supplied sterile and when Part 2 has been applied.
- manufacturers of Class IIa devices or Class I devices with a measuring function, that are not supplied sterile, and that have followed the procedure described in Part 6.

In this conformity assessment procedure, the manufacturer must implement a quality management system for the processes of final inspection and testing for particular identified products, and one that specifically includes regulatory requirements. In particular, the quality system must implement a post-production monitoring system.

Under this procedure the manufacturer performs final inspection and testing on 100% of the product or on a representative sample of each batch according to the quality system.

The manufacturer must make an application for assessment of the quality management system by the TGA, or in some cases, an approved equivalent conformity assessment body. If the quality management system is defined, implemented and effective, certification will be issued for a particular product or range of products. The certification issued will declare conformity with the quality system requirements of Part 5 of the Regulations for particular products and not against a conformity assessment standard (e.g ISO13485) used for the implementation and assessment of the system.

When conformity assessment procedures have been successfully completed for the Class IIb products the manufacturer may prepare a declaration of conformity under this part. This declaration and the certifications issued under Part 2 and this part, form the basis for applying for supply in Australia.

For Class IIa devices or Class I devices that have a measuring function, a declaration of conformity is made under Part 6 on the basis of the procedures in Part 6 and the certification issued under this Part.

Quality management system certification only remains valid if it is subject to periodic surveillance.

Changes to the quality system that add additional product to the range covered by, or alter, the approved system will require further assessment and approval.

Part 6 Declaration of conformity (not requiring assessment by Secretary) procedures for Class IIa, I, and I (measuring and sterile) medical devices

This part:

- can be used for Class I, Class I supplied sterile, Class I with a measuring function and IIa devices.
- also requires Part 3, 4 or 5 conformity assessment procedures to be followed (except Class I devices)

In this conformity assessment procedure, the manufacturer of the device ensures that the device(s) comply with the essential principles and prepares documentation that allows the conformity to be assessed.

When conformity assessment procedures have been successfully completed the manufacturer may prepare a declaration of conformity under this part. This declaration forms the basis of an application for supply in Australia by a sponsor.

The manufacturer is also required to implement a post-production monitoring system.

For Class IIa devices, the manufacturer must seek further certification against either Part 3, 4 or 5.

For Class IIa devices that are supplied sterile the manufacturer must seek further certification against Part 4.

For Class I devices that have a measuring function the manufacturer must seek further certification against either Part 3, 4 or 5.

For Class I devices that are supplied sterile the manufacturer must seek further certification against Part 4.

Part 7 Conformity assessment procedures for devices used for a special purpose

Conformity assessment procedures for these devices are addressed in a separate guidance document.

WHAT ARE THE COMMON ELEMENTS IN ALL OF THE CONFORMITY ASSESSMENT PROCEDURES?

Post-market monitoring system

A manufacturer must implement and maintain a post-market monitoring system to seek and assess information concerning the performance of devices after supply. Any reportable events must be tested against the reporting thresholds defined in the Regulations and conveyed to the TGA, either directly or through the Australian sponsor within:

- 48 hours after becoming aware of a serious threat to public health;
- 10 days after becoming aware of the death, or serious deterioration in the state of health, of a patient, a user of the medical device or another person;
- 30 days after becoming aware of an event, if a recurrence of the event might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or another person.

More information on this issue can be found in the guidance document on post-market monitoring.

When a conformity assessment procedure requires a quality management system the post-production monitoring must be implemented as part of that system.

Quality systems certification surveillance audits

Quality management system certification only remains valid when it is periodically inspected. A re-inspection audit is to be known as a surveillance audit. The audits ensure that the manufacturer is continuing to apply the approved quality system to existing product and to any new product introduced since the previous surveillance or certification audit. A program of surveillance audits will be established for all manufacturers issued with Quality Systems Certification under Parts 1, 4 and 5.

WHAT IS A DECLARATION OF CONFORMITY?

As part of the conformity assessment procedures, the manufacturer of a medical device will be required to make a declaration of conformity which, in most cases, declares that the medical device complies with:

- the applicable provisions of the essential principles;
- the classification rules; and
- the conformity assessment procedures;

before being supplied in Australia.

The declaration also requires the manufacturer to provide:

- their name and address;
- details of the:
 - scope of the declaration (including product identification information);
 - certification;
 - classification;

- ⊙ nomenclature code;
- ⊙ conformity assessment standards (quality management standards); and
- ⊙ medical device standards (product standards);

relevant to the conformity assessment procedure and the manufacture of the medical device covered by the declaration.

The manufacturer of the medical device can sign the declaration of conformity or a person authorised by the manufacturer. Evidence of the authorisation may be required for the declaration to be valid.

WHO IS RESPONSIBLE FOR THE CONFORMITY ASSESSMENT OF A MEDICAL DEVICE AND THE DECLARATION OF CONFORMITY?

The responsibility for the classification and the conformity assessment of a medical device rests with the manufacturer of the medical device. The choice of an appropriate conformity assessment procedure, which will be governed by the class of the medical device, is left to the manufacturer.

Manufacturers are also required to sign a declaration of conformity to Australia's medical device requirements. This declaration is required if requested by the TGA. The wording of the declaration of conformity will depend on the conformity assessment procedure chosen by the manufacturer. Templates for each of the six possible types of declarations of conformity have been included as attachments to the guidance document describing the declarations of conformity.

CHOICE OF CONFORMITY ASSESSMENT PROCEDURES AND THE RELEVANT DECLARATION OF CONFORMITY

The table below summarises the options available to manufacturers when deciding which conformity assessment procedure and which declaration of conformity is appropriate for each class of medical device. The conformity assessment procedures and declarations of conformity are detailed in the parts and clauses of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 3. Comparisons of Alternatives for Conformity Assessment Procedures and the Required Declarations of Conformity under Schedule 3 of the Therapeutic Goods (medical Devices) Regulations 2002, for each Class of Medical Device

Class or Category of Medical Device	Minimum Conformity Assessment Procedures Alternatives	Declaration of Conformity Required under Schedule 3 of Therapeutic Goods (Medical Devices) Regulations 2002
Class AIMD	Part 1 (Full Quality Assurance Procedures)	Clause 1.8
	Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures)	Clause 3.5
	Part 2 (Type Examination Procedures)+ Part 4 (Production Quality Assurance Procedures)	Clause 4.7
Class III	Part 1 (Full Quality Assurance Procedures)	Clause 1.8
	Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures)	Clause 3.5
	Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	Clause 4.7
Class IIb	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Clause 1.8
	Part 2 (Type Examination Procedures)+ Part 3 (Verification Procedures)	Clause 3.5
	Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	Clause 4.7
	Part 2 (Type Examination Procedures) + Part 5 (Product Quality Assurance Procedures)	Clause 5.7
Class IIb (sterile)	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Clause 1.8
	Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	Clause 4.7
Class IIa	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Clause 1.8
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures)	Clause 6.6
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Clause 6.6
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Assurance Procedures)	Clause 6.6
Class IIa (sterile)	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Clause 1.8
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Clause 6.6
Class I	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	Clause 6.6
Class I (measuring)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures)	Clause 6.6
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Clause 6.6
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Assurance Procedures)	Clause 6.6
Class I (sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Clause 6.6
System or Procedure Packs	Part 7 (Procedures for Medical Devices Used for a Special Purpose)	Clause 7.5

WHAT ARE THE SPECIAL CONFORMITY ASSESSMENT PROCEDURES?

Special conformity assessment procedures apply to medical devices that:

- have a special purpose, such as those intended for special and experimental use or used by medical practitioners for specific patients, or
- are exempt.

WHAT ARE THE ESSENTIAL PRINCIPLES?

The essential principles are requirements for all medical devices. There are two main categories. The general principles apply to all devices. The applicability of the principles dealing with design and construction will depend on the intended purpose and properties of the medical device. The essential principles documented in Schedule 1, Part 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* include:

- General Principles
 - the use of a medical device must not compromise health and safety
 - the design and construction of a medical device has to conform with safety principles
 - medical devices are to be suitable for the intended purpose
 - long term safety
 - medical devices are not adversely affected by transport or storage
 - the benefits of medical devices are to outweigh any side effects
- Principles about Design and Construction
 - chemical, physical and biological properties
 - infection and microbial contamination
 - construction and environmental properties
 - medical devices with a measuring function
 - protection against radiation
 - medical devices connected to or equipped with an energy source
 - information to be provided with medical devices
 - clinical evidence

HOW DO STANDARDS RELATE TO THE ESSENTIAL PRINCIPLES?

The essential principles set out the requirements relating to the safety and performance characteristics of medical devices. Compliance with applicable medical device standards is not required, but it is one way to establish compliance with the essential principles. If a manufacturer uses a medical device standard, or a number of medical device standards, this will allow a presumption of conformance with the relevant essential principles. Medical device standards will be identified by orders in the Commonwealth Gazette. Other standards can also be used to demonstrate conformance with the relevant essential principles, however the use of those standards will not allow a presumption of conformance.

ADVERTISING REQUIREMENTS

The advertising of therapeutic goods, including medical devices, is regulated in Australia under an arrangement between the TGA, industry, consumers, health care professionals, and the media. Advertising is considered as part of the information provided with medical devices required by the essential principles (refer to Schedule 1, Part 2, 7 of the Regulations). Unlike medicines, advertisements for medical devices do not have to be approved prior to publication, however the advertisements must comply with:

- Section 22(5) of the Act that specifies advertising of a therapeutic good can only refer to the indications which are included in the Australian Register of Therapeutic Goods (ARTG) for that specific good.
- Part 2 of the Regulations and the Therapeutic Goods Advertising Code Council (TGACC).

An advertisement is defined in section 3 of the Act, as:

“any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly to promote the use or supply of the goods.”

This includes product labels, pamphlets, and instructions for use, promotional samples, promotional seminars, demonstrations and displays.

Advertisements for therapeutic goods, directed to consumers must comply with:

- The *Therapeutic Goods Act, 1989*,
- The *Therapeutic Goods Regulations, 1990*, and
- The Therapeutic Goods Advertising Code (TGAC).

The information in this section of the guidance document is only a brief summary of some of the main parts of the TGAC as it relates to medical devices. The TGAC is regularly revised and therefore it is advisable to refer to a current copy available from the TGACC website, “www.tgacc.com.au”. Information about restricted representations and copies of the exemptions that have been granted are available on the TGA website, “www.tga.gov.au/docs/html/therad.htm”.

It is not feasible to provide details of exactly what advertising requirements will apply to any particular medical device in this guidance document. Many factors need to be considered in conjunction with the TGAC.

The TGAC is based on a set of principles to ensure that advertisements for therapeutic goods, directed to consumers:

- promote the quality use of therapeutic goods,
- are socially acceptable, and
- do not mislead or deceive consumers.

Some of the principles of the therapeutic goods advertising code

Advertisements for therapeutic goods must:

- comply with the statute and common law of the Commonwealth, States and Territories, and
- contain correct and balanced statements only and claims, which the sponsor has already verified.

Advertisements for therapeutic goods must not:

- be likely to arouse unwarranted or unrealistic expectations of the products effectiveness,
- be likely to lead consumers to self-diagnose or inappropriately treat potentially serious diseases,
- mislead directly or by implication or through emphasis, comparisons or omissions,
- abuse or exploit the lack of knowledge of consumers,
- contain any matter which is likely to lead people to believe that are suffering from a serious ailment or that harmful consequences may result if the therapeutic good is not used,
- contain claims, statements or implications that the therapeutic good is infallible, magical, unyielding, miraculous or that it is a certain or guaranteed sure cure,
- contain a claim that it is effective in all cases, and
- contain any claim or implication that the therapeutic good is safe or cannot cause harm or has no side effects.

The TGAC also prohibits to certain disease categories and restricts representations to serious diseases.

Prohibited representations

The TGAC prohibits any representation to abortifacient action and any representation regarding the treatment, cure or prevention of neoplastic diseases, sexually transmitted diseases, HIV, AIDS or HVC or mental illness.

The TGAC prevents any endorsements by any government agency, hospital or facility providing health care or a health care professional.

Restricted representations

The TGAC prevents any reference, either direct or by implication to any serious medical condition, disease, ailment or defect unless a specific exemption has been granted by the TGA. Serious diseases, conditions, ailments or defects are those that cannot be diagnosed, treated or managed without consulting a suitably qualified health care professional and are generally beyond the ability of the average person to evaluate accurately and treat without medical supervision.

For example:

A medical device to relieve pain associated with rheumatoid arthritis could not be advertised to consumers until the advertiser:

- produced credible evidence to demonstrate its effectiveness in relieving pain associated with rheumatoid arthritis,

- complied with all the requirements of the Code, the *Therapeutic Goods Regulations, 1990* and the *Therapeutic Goods Act, 1989* and,
- obtained an exemption from the TGA to make a reference to Rheumatoid Arthritis (this is a restricted representation because Rheumatoid Arthritis is a serious disease).

Obtaining an exemption for a restricted representation

To obtain an exemption for a restricted representation in advertisements for medical devices, including labels, directed to consumers, the advertiser must make a submission to the TGACC and to the Director of the Office of Devices, Blood and Tissues (ODBT) of the TGA.

The request for an exemption should include an explanation as to why the exemption is required and where possible should address the Public Interest Criteria in Appendix 6 of the TGAC. The submission needs to include:

1. a copy of the proposed advertisement,
2. the ARTG entry for the therapeutic good or a letter on TGA letterhead identifying the product as an exempt good,
3. justification for using the restricted representation in an advertisement,
4. evidence validating the claims in the advertisement, and
5. responses to the relevant segments of the public interest criteria in Appendix 6 of the TGAC.

The Code Council will apply the public interest criteria and make a recommendation to the TGA that will be considered prior to making a decision to either grant or deny the request for an exemption.

Consideration of complaints

The Complaints Resolution Panel, established under the Therapeutic Goods Regulations, considers complaints about therapeutic goods (including consumer medicines and devices). A trade practices lawyer chairs this panel and the members represent the industry, consumers and health care professionals. The TGA has observer status. The panel does have the power to impose sanctions and refer unresolved matters to the TGA for further action.

RESPONSIBILITIES AND OBLIGATIONS UNDER THE *THERAPEUTIC GOODS ACT 1989*

Under the Act sponsors and manufacturers of medical devices have separate yet inter-linked responsibilities and obligations. Any differences and similarities need to be clearly understood. This is especially important for medical device manufacturers. If someone carries out activities that would normally be carried by a manufacturer, they would then be considered as a manufacturer. This also refers to rewording or fabricating statements or declarations that should be made by manufacturers about their products, including the intended purpose of use, any instructions, labelling or advertising.

The Act makes an interesting distinction between sponsors and manufacturers. On the whole sponsors have responsibilities while manufacturers mostly have obligations. The distinction means that penalties will be incurred by a sponsor by way of the suspension or cancellation of the sponsor's entry in the ARTG, and/or fines if the manufacturer does not fulfil their obligations. Additionally, if the manufacturer has been issued a conformity assessment certificate by the TGA, breaching conditions of the conformity assessment certificate may lead to the suspension or revocation of the certificate. It may also be an offence that will incur a financial penalty.

Responsibilities of sponsors and applicants for inclusion of a medical device in the ARTG

Before someone can supply a therapeutic good, including a medical device, in Australia, and assuming that the product is not an excluded good, they are required to make an application to have the product entered in the ARTG.

When making the application to include a medical device in the ARTG the person must comply with section 41FD of the Act and certify that:

- the product applied for is a medical device;
- the device is intended for a specific purpose;
- the device is correctly classified;
- the device complies with the essential principles as well as having available and sufficient information to substantiate compliance with the essential principles;
- an appropriate conformity assessment procedure has been applied to the device as well as having available and sufficient information to substantiate the application of the conformity assessment procedures;
- the advertising for the device complies with all requirements;
- the device does not contain any prohibited imports;
- the information included in or with the application is complete and correct

It should be noted that an offence would be committed if the person made a false or misleading statement in connection with the application or a certificate connected with the application. Severe financial penalties will be incurred.

If the application is successful conditions will then be imposed on the supply of the medical device. If the conditions are breached various penalties, ranging from suspension or cancellation of the entry in the ARTG to large fines, can be imposed.

Conditions applying automatically to entries in the ARTG under section 41FN of the Act require the person in whose name the entry has been made to:

- allow an authorised person from the TGA to enter, at any reasonable time, any premises, including premises outside Australia, at which that person, or any other person deals with the medical devices. This is required so that the authorised person can inspect the premises and medical devices and to take samples. It should be noted that the TGA would pay for the samples.

If requested by the authorised person the sponsor will also need to produce any documents relating to the medical device and to allow the documents to be copied by the authorised person.

- deliver a reasonable number of samples of the medical device within a specified period of time and according to any specified requirements from the TGA
- have sufficient information to substantiate compliance with the essential principles
- have sufficient information to substantiate that the conformity assessment procedures have been applied to the medical device
- have available information relating to changes to the medical device including the product range, the quality management system of the manufacturer of the medical device
- give this information to the TGA, if requested
- under section 41MP, give information to the TGA about any malfunction or deterioration in the characteristics or performance of the medical device or any inadequacy in the design, production, labelling, instructions for use or advertising materials for the medical device, or any use in accordance with, or contrary to, the use intended by the manufacturer that:
 - led to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 10 days after becoming aware of the event or occurrence, or
 - led to a serious threat to public health, within 48 hours of becoming aware of the event, or
 - that might lead to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 30 days of becoming aware of the event.

NOTE: a serious threat to public health is considered as a systemic failure of a medical device that may lead to the death of, or serious injury to a patient, user of the device or another person and the severity of the harm caused by the hazard was not previously known or anticipated by the manufacturer, and the manufacturer will be required to take prompt action to eliminate, or reduce the risk, of the hazard.

Note: a serious deterioration in the state of health of a person means a life-threatening illness or injury or a permanent impairment of a bodily function, permanent damage to a body structure, or a condition requiring medical or surgical intervention to prevent the permanent impairment or damage.

This also includes information relating to any technical or medical reason that has led the manufacturer to take steps to recover the medical devices.

- information to the TGA:
 - that indicates that a medical device does not comply with essential principles
 - information to the TGA that indicates that a certificate not issued by the TGA certifying compliance with the essential principles or the application of relevant conformity assessment procedures used to support an application for inclusion in the ARTG has been restricted, suspended, revoked or is no longer valid
- give the manufacturer of the medical device information relevant to the manufacturer's obligations under the conformity assessment procedures, especially the requirements for post-market monitoring, and whether the medical device complies with the essential principles; and
- ensure advertising material used is consistent with the intended purpose for the medical device.

Under section 41FO of the Act other conditions may be imposed which relate to:

- the manufacture of the device;
- custody of the device;
- intended purpose of the device;
- supply of the device;
- disposal or destruction of the device;
- keeping of records relating to the device, including records of the tracking and location of the device;
- any matters concerning the essential principles; and
- any other matters deemed appropriate by the TGA.

Additional conditions may be also imposed and existing conditions can be varied or removed at the sponsor's written request or on the Department's initiative after the medical device has been included in the ARTG.

Requirements and obligations for manufacturers of medical devices

Technical documentation for medical devices

The manufacturer of a medical device is required to prepare technical documentation to demonstrate that the medical device complies with the essential principles. This will vary on a case-by-case basis, depending on the type of product, the risk associated with its manufacture, installation, use and servicing, and the period that it has been on the market. More details for this requirement are set out in the guidance document on technical information.

There are three broad categories of information required in the technical documentation. They are:

- Product Description;
- Technical Requirements; and
- Design

Product description

A description is required to allow an understanding of the design, characteristics, and where appropriate, the performance of the device and to distinguish between any variants of the device. A description of the packaging, where this is relevant to the preservation of the intended characteristics and performances of the device is also necessary.

In many cases, the name of the device(s) will be sufficient. Where the documentation requires evaluation, a general pictorial representation of the device would be required.

A description of the intended purpose and the method of use of the device are required. This may include, where appropriate, details of the patient population and the medical conditions for which the device is intended. This should also identify the intended users of the device, and in particular, if the device is designed for professional use. The information may be given by way of reference to the “instructions for use” or operating manual for the device(s).

Where the device incorporates a medicinal substance, the documentation should make clear the purpose of including the substance and its mode of action in this application. This only applies where the substance is liable to act upon the body with action ancillary to that of the device.

Where the device incorporates non-viable materials of animal origin, the risk analysis in the technical documentation should address the additional risks and benefits associated with incorporation of such materials, and the measures taken to eliminate or inactivate transmissible agents).

A general summary is required of the type of manufacturing methods used for the device and the method of sterilisation, if relevant.

A description of the accessories, adaptors and other devices or equipment and other interfaces that are intended by the manufacturer to be used in combination with the device will be required. In addition the technical documentation should include the description of other devices or equipment etc, which the device is intended to be used with. It should also include data on the verification and validation of the safety and performance of such combinations. The technical documentation should also address any known incompatibilities that may be covered, for example, in the label or the instructions for use.

The technical documentation should include the rule numbers applied, together with a brief rationale for this classification, and reasons why particular rules do not apply, if this is not self-evident.

Technical requirements

The manufacturer should define the technical requirements or specifications that must be satisfied in order to ensure that each of the applicable essential principles are met. Where particular essential principles are deemed not to apply to the device, a brief rationale should be given.

The manufacturer is required to demonstrate how each of the applicable essential principles and any derived technical requirements or specifications for the particular device have been met.

Compliance with medical device standards is voluntary. Where medical device standards are used to comply with relevant essential principles, all that is needed is to demonstrate that the device complies with the relevant clauses of the medical device standards.

Where other methods, including compliance with draft and in-house or industry standards, are used to comply with one of a range of relevant essential principles, the manufacturer should justify that:

- the methods applied adequately address relevant essential principles and
- the device complies with the relevant provisions

The evidence of device compliance with standards may take the form of, for example, test reports or records of application of Standard Operating Procedures intended to assure such compliance.

The use of a checklist may facilitate demonstration of how the solutions adopted meet the relevant requirements. The checklist should:

- list the essential requirements, identifying those which are/are not applicable
- list the standards applied, and
- against each essential principle, give the basis for claiming compliance.

This will either make clear the solutions adopted to fulfil each requirement or refer to stand-alone specifications or reports.

Design

The manufacturer is required to present the documented results of a risk analysis. There are a number of published techniques for performing a risk analysis. It is recommended that the risk analysis performed in connection with conformity assessment procedures should follow ISO 14971. The risk analysis should address all known hazards or reasonably foreseeable for the particular product types and technologies involved, together with the likelihood and consequences of occurrence and measures taken to reduce the resulting risks to acceptable levels. In the case of devices intended and labelled for “single use”, the risk analysis should address the hazards associated with reuse as an example of foreseeable misuse.

The results must demonstrate that an appropriate risk analysis has been performed and provide a conclusion, with appropriate evidence, that the remaining risks are acceptable when weighed against the intended benefits to the patient. The results of the risk analysis should be reviewed and approved by the manufacturer.

The technical documentation should specify the manufacturing and any special processing of materials used in the construction of the device, together with the biological safety and biocompatibility of materials intended to come into contact with the body. Particular reference should be included when materials are invasive and/or will have prolonged contact with the body.

Specifications, drawings, including circuit diagrams for components, sub-assemblies and the complete product, including packaging, need to be provided. The manufacturer should determine what specifications, drawings, diagrams etc. are appropriate and sufficient to enable the proper manufacture, installation, maintenance and servicing of the product to assure that the intended characteristics and performances are achieved and maintained.

The specifications of the checks, tests and trials that are intended to be carried out as part of routine production are required. The procedures and work instructions for the checks, tests and trials form part of the manufacturer's quality system.

The manufacturer is required to identify the characteristics, performances and compatibilities needed to assure the safe and correct operation of the device.

The manufacturer is required to include any product labels in the technical documentation, and where appropriate, the instructions for use, together with any known changes to these during the lifetime of the product. The labelling documentation should make clear where particular information will be provided, for example on the device itself or its component parts, on the packaging for each unit, on the sales packaging, or on the leaflet or user manual supplied with one or more devices.

Identification of the shelf life for the device should be reflected by any 'use by' date, or other 'lifetime' indication. In certain cases, such restrictions on use will reflect a time-related deterioration in characteristics that are important to product safety and performance. In other cases, however, the restrictions could be based on other considerations.

The 'lifetime' of an active device, for example, may be determined by the period for which the manufacturer will support the device by way of availability of spare parts, manuals, training, service/repairs etc.

Testing should follow a pre-defined protocol, which should include the parameters to be measured, measuring and test equipment to be used including calibration arrangements, statistical treatment of results and acceptance criteria, together with the necessary formal approval of the report. Bench testing includes in-vitro/animal studies, simulated use testing and validation of software and the results of special processes.

Clinical data requirements are detailed in the guidance document on that subject.

The technical documentation should include records of each design change and the reasons for these, together with any associated verification and validation data. The documentation should include evidence that the change achieved the desired effect, and that the device continues to comply with the essential principles.

Where the technical documentation or parts have been submitted to the TGA in connection with conformity assessment involving design or type examination, the manufacturer is required to inform the TGA of substantial changes and obtain further approval.

Applications for a conformity assessment certificate issued by the TGA

When an application has been made for a conformity assessment certificate the decision to issue the certificate will depend on several factors:

- if the application procedures in section 41EB have been followed,
- the application of quality management systems,
- the certification of compliance with the essential principles,
- whether the applicant for the certificate:
 - is a fit and proper person,
 - has had a conformity assessment certificate suspended or revoked,
 - has had a conviction for an offence against a Commonwealth, State or Territory law
- whether people who participate, or who are likely to participate in the management of the applicant's affairs:
 - are fit and proper people,
 - have had a conformity assessment certificate suspended or revoked,
 - have had a conviction for an offence against a Commonwealth, State or Territory law
- whether people who have effective control, or who are likely to have effective control over the applicant:
 - are fit and proper people to have effective control over a manufacturer who has been issued a conformity assessment certificate,
 - have had a conformity assessment certificate suspended or revoked
 - have had a conviction for an offence against a Commonwealth, State or Territory law

Manufacturers who have been issued a conformity assessment certificate by the TGA

When a conformity assessment certificate is issued to a manufacturer of a medical device by the TGA, conditions will be imposed on the certificate. Breaching any of these conditions may lead to the suspension or revocation of the certificate.

There are four conditions which will be imposed automatically when a conformity assessment certificate is issued. Other conditions can also be imposed.

The automatic conditions are:

- Entry and inspection powers
 - The manufacturer will allow an authorised person to:
 - enter premises, including premises outside Australia, at which the manufacturer, or any other person deals with the medical devices covered by the certificate; and
 - inspect those premises and the medical devices, and to take samples of the devices (which will be paid for by the TGA); and
 - to see and copy any requested documents relating to the medical device or the manufacturer's quality management system.
- Review
 - The manufacturer will cooperate with any review by the TGA of the application of quality management systems, the compliance with the essential principles and any other conformity assessment procedures specified in the regulations, relating to the certificate.
- Notification of substantial changes
 - The manufacturer will notify the TGA, in writing, of any plan for substantial changes to the:

- quality management systems; or
- product range; or
- the product design
- Fees
 - Any prescribed fees for a review of a conformity assessment certificate will be paid when they are due.

Additional conditions, imposed on a conformity assessment certificate issued by the TGA, could include:

- conditions on the medical devices covered by the certificate; or
- the manufacturer's quality management system; or
- new conditions at the request of the manufacturer or the TGA; or
- varying or removing existing conditions, at the request of the manufacturer or the TGA, if it is necessary to prevent imminent risk of a death, serious illness or serious injury, at the request of the manufacturer or the TGA.

Conformity assessment procedures for overseas manufacturers who do not have an Australian conformity assessment certificate

Overseas manufacturers of medical devices wishing to supply their products in Australia have two avenues to follow to obtain conformity assessment certification. They can either arrange for the TGA to undertake the necessary audits or else have their products CE marked.

The Australian conformity assessment procedures have been modelled on those of the Medical Devices Directive 93/42/EEC. The CE marking under the European system is a declaration of conformity with the Medical Device Directives (MDD). This declaration includes an obligation to report certain events to the competent authorities (Government Authorities) in the European Member State. In Australia reportable events must be reported to the TGA within the timeframes stipulated in the Regulations.

Certification against the MDD Annexes may be used to support the corresponding Australian conformity assessment procedure as shown below. Items included as undertakings in these procedures, such as the implementation and maintenance of the post-production monitoring system, do not require evidence of a third party assessment. In all cases the manufacturer must prepare a specific declaration of conformity to the Australian legislative requirements.

- Schedule 3 Part 1 is equivalent to Annex II (of the MDD)
- Schedule 3 Part 2 is equivalent to Annex III (of the MDD)
- Schedule 3 Part 3 is equivalent to Annex IV (of the MDD)
- Schedule 3 Part 4 is equivalent to Annex V (of the MDD)
- Schedule 3 Part 5 is equivalent to Annex VI (of the MDD)
- Schedule 3 Part 6 is equivalent to Annex VII (of the MDD)
- Schedule 3 Part 7 is equivalent to Annex VIII (of the MDD)

In practice, European conformity assessment certificates from European Notified Bodies can be accepted, provided that the Secretary of the Department is satisfied that the regulatory body has the competence and authority to assess the device. European conformity assessment certificates also include an assessment of the procedure to report adverse events to the European Competent

Authorities. Although the certification includes the assessment of this procedure adverse events must be reported to the Secretary.

ONCE A MEDICAL DEVICE HAS BEEN APPROVED FOR SUPPLY, WHAT SYSTEMS ARE IN PLACE FOR DETECTING AND REPORTING PROBLEMS?

The new legislation includes a mandatory reporting system for adverse events involving all medical devices. The system is known as the Vigilance System and is based on the recommendations of the Global Harmonisation Task Force (GHTF) Study Group 2: Vigilance and Surveillance.

Sponsors are required to report any problem to the manufacturer of the device. Manufacturers are required to report the problem to the TGA. For further information on what types of problems are required to be reported, please refer to the post market guidance document.

The Vigilance System comprises:

- penalties and time frames
- recall and seizure provisions
- voluntary reporting provisions for medical device users
- international information exchange between conformity assessment bodies
- information exchange between inter governmental agencies within Australia (such as Health Care Complaints Commission and coronial inquests)

Post market surveillance of medical devices by the TGA includes the compliance testing of medical devices and a TGA audit of the technical files and certification for products not assessed as part of an application to supply the medical device in Australia.

OFFENCES, PENALTIES AND CANCELLATIONS

Offences and penalties

The offences in the Act include:

- illegal importation, exportation, manufacture or supply of medical devices not included in the register and not subject to an appropriate exemption (section 41MI with maximum penalties for individuals of imprisonment for 12 months or \$110 000, or both, and \$550 000 for corporations);
- non-compliance with the essential principles, unless the Secretary has consented (sections 41MA with maximum penalties for individuals of imprisonment for 12 months or \$110 000, or both, and \$550 000 for corporations);
- non-application of an appropriate conformity assessment procedure (sections 41ME and 41MF with maximum penalties for individuals of imprisonment for 12 months or \$110 000, or both, and \$550 000 for corporations);
- failure to comply with the conditions of entry in the ARTG (section 41MN with maximum penalties of \$26 400 for individuals and \$132 000 for corporations);
- failure to comply with the conditions of a conformity assessment certificate (section 41MN with maximum penalties of \$26 400 for individuals and \$132 000 for corporations);
- failure to notify adverse events (section 41MP with maximum penalties of \$44 000 for individuals and \$220 000 for corporations);
- failure to notify adverse events etc where an application is withdrawn or lapses (section 41MQ with maximum penalties of \$44 000 for individuals and \$220 000 for corporations);
- misuse of medical devices exempted for special or experimental uses (section 41MO with maximum penalties of \$6 600 for individuals and \$33 000 for corporations);
- claims about arranging supplies of medical devices not included in the ARTG (section 41MM with maximum penalties of \$6 600 for individuals and \$33 000 for corporations);
- making false declarations at the time of entry in the ARTG (section 41MH with maximum penalties for individuals of imprisonment for 12 months or \$220 000, or both, and \$1 100 000 for corporations) and;
- making misrepresentations about medical devices (section 41ML with maximum penalties of \$6 600 for individuals and \$33 000 for corporations).

Other penalties

In addition to financial penalties for offences under the Act, other penalties can be applied for a failure to comply with provisions of the Act. These include:

- suspension or cancellation of the medical device from the ARTG (Part 4-6);
- suspension or revocation of conformity assessment certification (Part 4-4 Division 3 and Division 4); and the
- recall of medical devices supplied, either to batch level or all medical devices (section 41MI(1)).

Cancellations

The TGA will cancel products from the register under Part 4-6 of the Act only in those cases where there has been a severe breach of the law or, more often, where there is a safety concern associated with the use of the product. If a sponsor cannot satisfactorily establish the quality, safety or efficacy of their product and a decision to cancel the entries in the ARTG is confirmed, the sponsor will also be required to recall any affected products.

The principles of natural justice are followed by the TGA whenever a proposal to cancel a product in the ARTG is considered. The cancellation proposal will be submitted to a sponsor and they will be allowed a certain period of time to show cause why the cancellation should not take occur. The sponsor may also be given the opportunity to submit any data to support their case. A decision will be made when this time has elapsed and any submitted information has been assessed. If it is decided to cancel the registration, listing or inclusion, sponsors normally have an opportunity to lodge an appeal. The sponsor's rights in the cancellation process are explained in the cancellation letter.

ENFORCEMENT

The Surveillance Unit of the TGA:

- monitors compliance with the Act,
- investigates alleged breaches of the Act, and
- initiates criminal prosecutions where appropriate.

Information regarding the illegal supply of medical devices should be referred to this Unit.

Options available to the TGA include criminal prosecutions under section 5A for offences included in the Act and fines detailed in many other parts. Illicit goods that have been seized during these investigations are forfeited to the Commonwealth and destroyed.

For further information contact:

Manager, Surveillance Unit
Business and Services Branch
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8640
Facsimile: 02 6232 8643

RECALLS OF THERAPEUTIC GOODS

When the need for a recall of a therapeutic good supplied in Australia has been established, the sponsor of the affected goods assumes the responsibility for recovery of the goods, or corrective action, while the Australian Recall Coordinator in the TGA assists by:

- advising the sponsor of the procedures,
- notifying agreed third parties, and
- monitoring the overall action.

Most recalls are conducted on a voluntary basis. However, the *Therapeutic Goods Act 1989* and the *Trade Practices Act 1974* underpin the procedure. Recall provisions can be applied under the *Therapeutic Goods Act 1989* when:

- therapeutic goods are cancelled from the Australian Register of Therapeutic Goods (section 30); or
- where therapeutic goods are unlawfully supplied in Australia (section 30A);
- where therapeutic goods fail to comply with an applicable standard (section 30B); or
- where therapeutic goods have been or could possibly be, subject to actual or potential tampering (section 42T)

The *Trade Practices Act 1974* contains provisions about the safety-related recall of consumer goods. The relevant parts of that Act, which are administered by the Consumer Affairs Division of the Department of Treasury, empower the Commonwealth Minister responsible for consumer affairs to take action when:

- notification is not made of safety related recalls, or
- where the recall has not been satisfactorily completed.

The use of the “Uniform Recall Procedure for Therapeutic Goods” is obligatory for safety related recalls of therapeutic goods. Where a recall is refused, or is not carried out satisfactorily, the Minister may order a mandatory recall. Failure to comply with such an order may result in substantial fines. A corporation convicted of a failure to comply with a mandatory recall may be fined up to \$200,000 and an individual in a contravention up to \$40,000 under section 65L of the *Trade Practices Act 1974*. Relevant parts of the Procedure may also be used by sponsors to disseminate emergency information on the safe use of therapeutic goods. This will normally be restricted to situations involving a significant safety factor and where national distribution of the affected goods has occurred.

Detailed information about recalls can be found in the document “Uniform Recall Procedure for Therapeutic Goods” available from the TGA website at <http://www.tga.gov.au/docs/pdf/urptg.pdf>.

For further information contact:

Australian Recall Coordinator
Office of Devices, Blood and Tissues
TGA
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8637

Facsimile: 02 6232 8687

NON-RECALL ACTIONS

The Uniform Recall Procedure for Therapeutic Goods points out that:

- safety alert,
 - advice about a specific situation where a therapeutic good, while meeting all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions are not observed. Safety alerts are intended only to provide information on the safe use of therapeutic goods.
- product notification,
 - precautionary information about a therapeutic good, when it is unlikely to involve significant adverse health consequences.
- withdrawal, and
 - therapeutic goods removed from supply or use for reasons not related to their quality, safety or efficacy, and
- recovery,
 - therapeutic goods removed from sale or supply by the sponsor that have not left their direct control.

are four actions which are not recall actions, and are therefore not subject to the Procedure.

However, hazard alerts are considered to be recall actions which are subject to the Procedure. The appropriate action to be taken, particularly where patient safety may be a consideration should be discussed with the Australian Recall Coordinator.

Sponsors of therapeutic goods may use appropriate sections of the Procedure to assist disseminating safety alert information. Copies of safety alerts should be forwarded to the Australian Recall Coordinator for distribution to the relevant health authorities for their information.