

AUSTRALIAN MEDICAL DEVICES GUIDELINES

Obligations and Responsibilities of Medical Device Sponsors and Manufacturers

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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* and the *Therapeutic Goods (Medical Devices) Regulations 2002* for legislative requirements.

FURTHER INFORMATION

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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*.

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.

RESPONSIBILITIES AND OBLIGATIONS UNDER THE *THERAPEUTIC GOODS ACT 1989*

Under the *Therapeutic Goods Act 1989* (the Act) sponsors and manufacturers of medical devices have separate yet inter-linked responsibilities and obligations. The 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 Australian Register of Therapeutic Goods (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 associated 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;
 - 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,
- risk associated with its manufacture, installation, use and servicing, and
- 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 provided in a reference to the “instructions for use” or the operating manual.

Where the device incorporates a medicinal substance, the documentation should justify the inclusion of the substance and its mode of action in this application. This only applies where the substance is liable to act upon the body with an 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 as well as the measures taken to eliminate or inactivate transmissible agents.

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

A description of the accessories, adaptors and other devices or equipment and other interfaces that are intended by the manufacturer to be used with the device will be required. In addition the

technical documentation should include the description of other devices or equipment intended to be used with the device. 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. These 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 the classification of the medical device, 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 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 a documented risk analysis. There are a number of published techniques for performing a risk analysis. It is recommended that the risk analysis performed should follow ISO 14971, Medical Devices - Application of Risk Management to Medical Devices. The risk analysis should address all known hazards or those 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 human 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 indicated 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 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 with spare parts, manuals, training, service, or repairs, for example.

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 any applicable 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 associated reasons, together with any related 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,
- whether people who participate, or who are likely to participate in the management of the applicant's affairs are fit and proper people,
- 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.

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.