Therapeutic Goods (Medical Devices) Regulations 2002 2002 No. 236

EXPLANATORY STATEMENT

STATUTORY RULES 2002 No. 236

Issued by the authority of the Parliamentary Secretary to the Minister for Health and Ageing

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Regulations 2002

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Section 63 of the Act provides that the Governor-General may make regulations required or permitted to be prescribed by the Act, or that are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Amendment (Medical Devices) Act 2002* (the Amendment Act), inserts a new part into the Act to provide for the creation of a new regulatory system for medical devices, harmonising Australia's requirements with the recommendations of the Medical Devices Global Harmonisation Task Force (the five key global regulators of medical devices, Japan, USA, EU, Canada and Australia), which are based on those of the European Community.

The new devices regulatory system has several key features. It provides for specified criteria for safety and performance, (the `essential principles'), with which devices must conform; increased use of internationally recognised standards for devices as a means of demonstrating that a device conforms with the essential principles; a risk based classification of medical devices; conformity assessment procedures to ensure devices meet the essential principles for safety and performance; and increased emphasis on post-market activities such as adverse event reporting and compliance.

The purpose of the Regulations is to provide the detail necessary to implement the new regulatory system for medical devices detailed in the Amendment Act. The Regulations:

- describe the administrative procedures necessary to implement the provisions of the Amendment Act (Parts 4, 5, 6, 8 and 10);

- set out the essential principles for safety and performance for all medical devices (Part 2 and Schedule 1);

- detail the rules by which medical devices are to be classified according to the degree of risk involved in using the device (based on the degree of invasiveness in the human body, duration of use, location of use and whether or not the device is powered) (Division 3.1 and Schedule 2);

- set out the procedures for conformity assessment of medical devices, in accordance with the classification of the device (the level of assessment will be commensurate with the level and nature of risks posed by the device to the patient or user, ranging from manufacturer self assessment for low risk devices through to full TGA assessment with respect to high risk devices). The procedures allow flexibility as to how devices are assessed and require that

documentation be held and made available as evidence to verify conformity with the essential principles (Division 3.2 and Schedule 3);

- set out when a manufacturer must hold a TGA issued conformity assessment certificate (regulation 4.1);

- specify the offences that apply in addition to those specified in the Act where there has been non-compliance with particular regulatory requirements (regulations 4.11, 8.2, 10.2 and 10.3);

- specify the kinds of medical devices, such as those imported for personal or experimental uses, that are exempt from entry on the Australian Register of Therapeutic Goods (the Register) (Part 7 and Schedule 4); and

- prescribe the fees payable in respect of matters dealt with in these regulations, such as fees for carrying out a conformity assessment or an application audit (Part 9 and Schedule 5).

Details of the Regulations are set out in the Attachment.

Two related Regulations, The Therapeutic Goods Amendment Regulations 2002 (No. 4) and the Therapeutic Goods (Charges) Amendment Regulations 2002 (No. 2), will commence operation with these Regulations.

A copy of the regulatory impact statement for the scheme is attached. Extensive consultation has been undertaken with the medical devices industry in developing this new regulatory scheme since that statement was prepared. The fees prescribed for the purposes of this legislation have been developed based upon expected workloads and work input required to implement the legislation. The industry consultation process included agreement on adoption of the optimal model for fees and charges. The transitional arrangements incorporated under section 15A of the Act have been provided to assist industry with implementation.

The Regulations commence on the date of commencement of the *Therapeutic Goods Amendment (Medical Devices) Act 2002*, ie 4 October 2002.

ATTACHMENT 1

Part 1 - Preliminary

Regulation 1.1 states that these Regulations are entitled the *Therapeutic Goods (Medical Devices) Regulations 2002.*

Regulation 1.2 provides that these Regulations will commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002*. This will be on 4 October 2002, 6 months after Royal Assent.

Regulation 1.3 introduces the dictionary at the end of the Regulations that defines certain words and expressions, including signpost definitions that are defined in the *Therapeutic Goods Act 1989* (`the Act') or elsewhere in these Regulations. The dictionary is part of these Regulations.

Regulation 1.4 defines when a device has a "measuring function" (it is intended by the manufacturer to measure specified parameters, or to deliver to or remove from the human body a quantity of energy or substance, and the measurement given by the device is displayed, or compared to at least one point of reference in specified units of measurement approved by the Secretary, and it is essential that the measurements are accurate for the device to perform as intended by the manufacturer).

Regulation 1.5 defines "refurbishment" for purposes of subsection 3(1) of the Act. To refurbish an already used medical device for the purpose of supplying the device again is the act of a manufacturer under subsection 41BG(2) of the Act. Such persons will be required to affix their name to the device and represent themselves as the manufacturer. Refurbishment is taken to have occurred if a medical device is rebuilt

- to an extent that exceeds normal use (that is, exceeding the manufacturer's recommendation for routine maintenance and servicing),

- using the original components of the device and/or components from another device of the same kind,

- to produce a new device suitable for use for the intended purpose assigned by the manufacturer of the original device, and

- intended to be supplied for that use under the name of the new manufacturer (ie the person responsible for refurbishing).

Refurbishment will normally involve, but is not limited to, activities related to

- stripping the device

- checking its component parts for suitability for re-use

- replacing components or parts that are not suitable for re-use

- assembling reclaimed or replacement components or parts

- testing the re-assembled device against the specifications of the original device, or revised specifications, if the manufacturer of the original device has revised those specifications, and

- identifying the device as a refurbished device.

Regulation 1.6 This definition is for the purposes of a determining if a medical device is of the same `kind' as another medical device under paragraph 41BE(1)(e) of the Act. It defines a characteristic in relation to a Class III medical device or a Class AIMD medical device. The characteristic is defined as the unique product identifier.

The unique product identifier is given to the device by its manufacturer to identify the device and its variants. "Variants" are design variations made to accommodate differing patient anatomical requirements, relating to shape, size, length, diameter, gauge, or any other variation approved by the Secretary that does not change the intended purpose of the device. (A definition of a variant appears in the dictionary.)

Regulation 1.7 introduces the Global Medical Device Nomenclature System Code (GMDNS), as set out in the international standard ISO 15225:2000 (E), and specifies the terms in the GMDNS assigned for each Class of medical device. The device nomenclature system code is required for the purposes of section 41BE of the Act, to define a kind of medical device.

Subregulation (2) provides definitions for ISO 15225:2000(E), and the expressions "relevant preferred term" and "relevant template term", used in subregulation (1).

Part 2 - Essential principles

This Part explains that the essential principles relating to the safety and performance characteristics of medical devices, for the purposes of section 41CA of the Act, are included as Schedule 1 of these Regulations.

Part 3 - Conformity assessment procedures

Division 3.1 - Medical device classifications

Regulation 3.1 specifies the medical device classifications for purposes of section 41DB of the Act, as Class I, Class IIa, Class IIb, Class III and Class AIMD (active implantable medical devices). Class I is the lowest level of classification and Classes III and AIMD are the highest levels of classification.

Regulation 3.2 introduces the rules for determining the classification of a medical device, which are set out in Schedule 2 of these Regulations.

Regulation 3.3 sets out the principles to be used in applying the classification rules. It provides that

- a medical device is classified on the basis of its intended purpose (assigned by the manufacturer),

- where a medical device is intended to be used in combination with another medical device, each device in that combination is classified in its own right, ie in accordance with its intended purpose (medical devices that are *supplied* together for use in combination as a system or for use in the context of a procedure are defined as a system or procedure pack under section 41BF of the Act. Such a collection of products is defined to be a single medical device in its own right, and hence cannot be considered a combination of devices. This is necessary as the intended purpose of the system or procedure pack may be different from the intended purpose of the individual parts of the system or procedure pack. This principle for the application of the classification rules is therefore not applicable to systems and procedure packs.),

- an accessory to a medical device is classified also in its own right, ie in accordance with its intended purpose, separate from the device to which it is an accessory,

- software used to drive or influence a medical device has the same classification as the medical device,

- a medical device that may be used in different parts of a patient's body is to be classified taking into account the most critical intended use of the device, and

- if, on the basis of intended use, two or more classification rules apply, the device is to be classified at the highest level applying. (This is the appropriate principle to apply to determine the class of a medical device that is a collection of products supplied together for use in the context of a procedure or in combination as a system)

Division 3.2 - Conformity assessment procedures

Regulation 3.4 specifies, for the purpose of s41DA of the Act, that the requirements relating to obligations on manufacturers, namely the conformity assessment procedures, are set out in Schedule 3 of these Regulations. Subregulation (2) specifies that the process for application of the conformity assessment procedures is set out in this Division.

Subregulation (3) specifies that the manufacturer of a Class IIb, Class IIa or Class I medical device must apply the minimum conformity assessment procedures applicable. However, it allows a manufacturer of these classes of device to choose to apply a conformity assessment procedure that is normally available to a higher class of medical device.

Regulation 3.5 allows the Secretary to accept the performance of functions and powers carried out by an overseas body or authority in relation to conformity assessment procedures for a kind of medical device manufactured overseas. However the Secretary must be satisfied that the overseas body has the authority and the expertise to exercise the power or perform the functions necessary for each of the assessments undertaken under the conformity assessment procedures. This subregulation provides the means by which the Secretary may accept overseas certification as evidence of compliance with the conformity assessment procedures, where suitable. It requires that the assessment be performed at the location of the manufacturer and at the site of manufacturing if these should differ.

Subregulation (2) requires the manufacturer to give to the Secretary information in relation to adverse events and of a kind required under paragraph 41 MP (2) (a) or (b) of the Act, regardless of whether the information has been given to the authority or body who carried out an assessment on behalf of the Secretary under the conformity assessment procedures.

Regulation 3.6 sets out the requirements for conformity assessment procedures for Class III and Class AIMD medical devices. It excludes medical devices used for a special purpose that may fall into these Classes. The manufacturer must apply one of the procedures specified in this clause, but has a choice as to which is applied. Unless the device is intended by the manufacturer to be supplied in a sterile state, the manufacturer must apply either

- the full quality assurance procedures (Part 1 of Schedule 3), or

- the type examination procedures (Part 2 of Schedule 3), together with

- the verification procedures (Part 3 of Schedule 3), or

- the production quality assurance procedures (Part 4 of Schedule 3).

The type examination procedures cannot be used alone; they must be used in conjunction with either the verification procedures or the production quality assurance procedures.

If a medical device, subject to this regulation, is to be supplied as sterile, then the manufacturer cannot choose to apply the verification procedures; the options that apply are

- the full quality assurance procedures (Part 1 of Schedule 3), or

- the type examination procedures (Part 2 of Schedule 3), together with the production quality assurance procedures (Part 4 of Schedule 3).

Regulation 3.7 sets out the requirements for conformity assessment procedures for Class IIb medical devices, excluding medical devices used for a special purpose. The manufacturer must apply one of the procedures specified in this regulation, but has a choice as to which is applied. Unless the device is intended by the manufacturer to be supplied as sterile, the manufacturer must apply either:

- the full quality assurance procedures (Part 1 of Schedule 3), except for clause 1.6 which requires examination of the design aspects, or

- the type examination procedures (Part 2 of Schedule 3), together with

- the verification procedures (Part 3 of Schedule 3), or

- the production quality assurance procedures (Part 4 of Schedule 3), or

- the product quality assurance procedures (Part 5 of Schedule 3).

The type examination procedures cannot be used alone; they must be used in conjunction with the verification procedures, the production quality assurance procedures, or the product quality assurance procedures.

If a medical device, subject to this regulation, is to be supplied as sterile then the manufacturer cannot choose to apply the verification procedures or the product quality assurance procedures; the minimum procedures that apply are

- the full quality assurance procedures (Part 1 of Schedule 3), except for clause 1.6, or

- the type examination procedures (Part 2 of Schedule 3), together with the production quality assurance procedures (Part 4 of Schedule 3).

Regulation 3.8 sets out the requirements for conformity assessment procedures for Class IIa medical devices, excluding medical devices used for a special purpose. The manufacturer must apply one of the procedures specified in regulation, but has a choice as to which is applied. Unless the device is intended by the manufacturer to be supplied as sterile, the manufacturer must apply either

- the full quality assurance procedures (Part 1 of Schedule 3), except for clause 1.6 which requires examination of the design aspects, or

- the declaration of conformity (not requiring assessment by the Secretary) procedures (Part 6 of Schedule 3) and

- the verification procedures (Part 3 of Schedule 3), except for clause 3.5 which relates to a declaration of conformity in relation to that Part, or

- the production quality assurance procedures (Part 4 of Schedule 3), except for clause 4.7 which relates to a declaration of conformity in relation to that Part, or

- the product quality assurance procedures (Part 5 of Schedule 3), except for clause 5.7 which relates to a declaration of conformity in relation to that Part.

The declaration of conformity (not requiring assessment by the Secretary) procedures cannot be used alone for this class; they must be used in conjunction with the applicable parts of the verification procedures, the production quality assurance procedures, or the product assurance system procedures. As the declaration of conformity requires a manufacturer to make a Declaration of Conformity, the declarations required by clause 3.5, 4.7 and 5.7 need not be made.

If a medical device, subject to this regulation, is to be supplied as sterile then the manufacturer cannot choose to apply the verification procedures or the product quality assurance procedures; the minimum procedures that apply are

- the full quality assurances procedures (Part 1 of Schedule 3), except for clause 1.6, or

- the declaration of conformity (not requiring assessment by the Secretary) procedures and the production quality assurance procedures (Part 4 of Schedule 3), except for clause 4.7.

Regulation 3.9 sets out the requirements for conformity assessment procedures for Class I medical devices, excluding medical devices used for a special purpose. The manufacturer must apply the declaration of conformity (not requiring assessment by the Secretary) procedures (Part 6 of Schedule 3). If the manufacturer intends the device to be supplied as sterile the production quality assurance procedures (Part 4 of Schedule 3), except for clause 4.7, must also be applied. If the device has a measuring function, the declaration of conformity procedures must be applied in conjunction with

- the verification procedures (Part 3 of Schedule 3) except for clause 3.5, or

- the production quality assurance procedures (part 4 of Schedule 3), except for clause 4.7, or

- the product quality assurance procedures (Part 5 of Schedule 3), except for clause 5.7.

As the declaration of conformity (not requiring assessment by the Secretary) procedure requires a manufacturer to make a Declaration of Conformity, the declarations required by clause 3.5, 4.7 and 5.7 need not be made.

Regulation 3.10 sets out the requirements for conformity assessment procedures for medical devices used for a special purpose. This includes devices exempt from the prohibitions on dealing in medical devices that are not included in the Australian Register of Therapeutic Goods (`the Register') in three circumstances:

a) exempt under Division 7.1 of the Regulations;

b) a medical device subject to an approval under section 41HB of the Act for experimental use in a clinical trial or for use in an individual; and

c) a medical device which is the subject of an authority under section 41HC of the Act, ie authorisation of a specific medical practitioner to use a specified kind of medical device;

A system or procedure pack that meets the particular conditions set out in subregulation (3) is also a medical device used for a special purpose. Those packs not meeting these conditions are classified and the conformity assessment procedures applied, as relevant, in the usual manner.

The conformity assessment procedures that apply to these devices are those set out in Part 7 of Schedule 3. If a system or procedure pack is to be supplied as sterile, the production quality assurance procedures of Part 4 of Schedule 3 (except for clause 4.7) must also be applied. The Secretary will limit the assessment to those aspects of the manufacturing process that relate to ensuring the sterility of the device. If the package contains a medicine, the manufacturer of the system or procedure pack must ensure that the sterilisation process is appropriate for the medicine.

The regulation notes that the requirements for custom-made medical devices do not come into force for a period of two years after the commencement of these Regulations, and the procedures for medical devices for a special purpose do not need to be applied during this time.

Regulation 3.11 requires that the clinical evaluation procedures (of Part 8 of Schedule 3) must be applied by the manufacturer to all medical devices, in addition to the other conformity assessment procedures that apply in order to show compliance with the essential principles. The regulation does not apply to

a) a device exempt under Division 7.1 of the Regulations, except for devices described in Schedule 4, item 1.3 (sample) or 1.5 (custom made);

b) a medical device subject to an approval under section 41HB of the Act for experimental use in a clinical trial or for use in an individual; and

c) a medical device which is the subject of an authority under section 41HC of the Act, ie authorisation of a specific medical practitioner to use a specified kind of medical device

Regulation 3.12 requires that all records (including correspondence) of conformity assessment provided by the manufacturer must be in English.

Regulation 3.13 allows for a person to request that the Secretary carry out assessment or verification of the application of the conformity assessment procedures at any stage of the manufacturing process. This allows assessment at an intermediate stage of manufacture. This request may be made independent of whether an application for a conformity assessment certificate, or an application for inclusion on the Register, has been made. The person must pay the prescribed fee for this assessment. Intermediate products are not medical devices as they are manufactured for use in further manufacture, not for use in humans. Assessment of products at an intermediate stage of manufacture provides a benefit to medical device manufacturers further down the manufacturing chain. Manufacturers may rely on an assessment at an intermediate stage of manufacture as a foundation for their own declaration of conformity.

Part 4 Conformity assessment certificates

Division 4.1 Issuing conformity assessment certificates

This Division relates to the issue by the Secretary of a conformity assessment certificate under part 4-4 of the Act, in respect of certain kinds of medical device. It allows for particular devices, such as those sourced from animal tissue, to be assessed by officers of the Therapeutic Goods Administration (`TGA') (as delegates of the Secretary) so that an application for inclusion in the Register can be considered valid. Equivalent assessment by an overseas body or authority will not be accepted where a conformity assessment certificate is required. The Division also prescribes the kinds of manufacturers of medical devices who must have their quality management systems assessed by the TGA. This is the provision under which manufacturers of medical devices in Australia must have their compliance with the conformity assessment procedures assessed by the TGA, rather than a third party.

Regulation 4.1 relates to paragraphs 41EA (a) and 41EA (b) of the Act. Subregulation (1) defines the kind of manufacturer required to have a conformity assessment certificate issued before an application is made to include a kind of medical device on the Register, as a manufacturer who manufactures medical devices in Australia.

Subregulation (2) details the kinds of medical devices for which a conformity assessment certificate must be issued by the Secretary before an application is made for inclusion on the Register. These are medical devices, manufactured outside Australia, that

- contain tissues of animal origin that are rendered non-viable except for those that are intended to come into contact with intact skin only;

- contain tissues, cells or substances of microbial or recombinant origin, and are intended for use on or in the human body;

- incorporate stable derivates of human blood or blood plasma; or

- incorporate or will incorporate, as an integral part, a medicinal substance.

Subregulation (3) exempts from the requirement to have a conformity assessment certificate

- Class I medical devices that are not to be supplied in a sterile state and do not have a measuring function;

- devices exempt by Regulation;

- medical devices that are covered by an approval under section 41HB (exemption for special and experimental purposes) or an authority under section 41HC of the Act (exemptions for medical practitioners);

- system or procedure packs to which conformity assessment procedure 7.5 applies; and

- a manufacturer of any of these devices.

Regulation 4.2 clarifies that, for purposes of subsection 41EC (2) of the Act, the other requirements for the conformity assessment procedures relate to the establishment and maintenance of a system for post-market monitoring, reporting and corrective action, and the keeping of records. This is to ensure that overseas manufacturers who rely on evidence of conformity from a body or authority acceptable to the Secretary, establish and maintain a post-market monitoring system that reports adverse events to the Secretary.

Regulation 4.3 specifies the time-frame for determining an application for a conformity assessment certificate where examination of the design of the device is required. The Secretary is required to make a decision on the application within 255 working days after the application is received.

The regulation allows periods of time to be disregarded in relation to calculating the number of working days taken to make a decision on the application where

- the Secretary sends a request for information to the sponsor, the time between the day on which the request is sent and the day on which a complete response is received, or

- an appeal is lodged concerning the application, the time between the day on which the appeal is lodged and the day on which the appeal is finally disposed of, or

- the applicant or sponsor agree in writing to any other period.

Division 4.2 Suspension of conformity assessment certificates

Regulation 4.4 specifies the time-frame for determining an application to revoke the suspension of a conformity assessment certificate under paragraph 41EP (2) (a) of the Act, as 40 working days after the application is received.

Division 4.3 Transfer of conformity assessment certificates

Regulation 4.5 clarifies that this Division applies to the manufacturer of a medical device to whom a conformity assessment certificate has been issued.

Regulation 4.6 identifies the persons to whom responsibility for the conformity assessment certificate falls in the event of death, bankruptcy or winding up of the manufacturer, and defines the responsibilities for notifying the Secretary of the situation.

Regulation 4.7 provides that**,** if the name of the manufacturer is changed in circumstances where the manufacturer

a) disposes of the business concerned with the manufacture of medical devices, and the disposal involves a transfer of the conformity assessment certificate, or

b) if the manufacturer is a body corporate, amalgamates with another body corporate under a name different to that on the conformity assessment certificate

the person to whom the business is disposed of, or the body corporate with whom the manufacturer amalgamates, has 3 months to apply for the name of the manufacturer to be changed and in the meantime is taken to be the person in respect of whom the original certificate was issued.

Regulation 4.8 requires that, where the name of the manufacturer is changed, the manufacturer must notify the Secretary of the new name and the circumstances that brought about the change, within 3 months of it occurring. The manufacturer, as renamed, is taken to be the person to whom the conformity assessment certificate is issued. (Regulations 4.10 and 4.11 are also relevant.)

Regulation 4.9 provides that, if conditions described under Regulation 4.6, 4.7 or 4.8 are in operation, the certificate of conformity has effect as if it had been issued to the person who takes on the responsibility, and the medical devices to which that certificate relates may continue to be manufactured.

Regulation 4.10 requires that, if a person is required to notify the Secretary of an event under this Division, the relevant documentary evidence must be supplied. If the Secretary becomes aware that an event has not been notified as required, the Secretary may revoke or suspend the relevant conformity assessment certificate. Such a decision is reviewable under regulation 10.7.

Regulation 4.11 requires the Secretary to notify the manufacturer of a change to the name of a manufacturer on a conformity assessment certificate or a suspension or revocation of a conformity assessment certificate. The Secretary must also ask the manufacturer to return the conformity assessment certificate given before the change of name, revocation or suspension occurred. If the manufacturer receives such notification from the Secretary, the certificate must be returned as soon as practicable after receiving the notice. Failure to comply is an offence of strict liability, with a penalty of 5 points.

Where strict liability applies to an offence the prosecution does not have to prove fault on the part of the defendant (see section 6.1 of the Criminal Code). The prosecution need only prove that the physical element of the offence did occur. However, there is a defence of mistake of fact under section 9.2 of the Criminal Code. Section 9.2 provides that the person is not criminally responsible for an offence of this nature if, at or before the time of the conduct, the person considered whether or not a relevant fact existed and is under a mistaken but reasonable belief about the fact and, had that fact existed, the conduct would not constitute an offence. If there is a mistake of fact, the evidential burden of proof is on the defendant who has to adduce or point to the evidence that suggests a reasonable possibility that the fact exists or does not exist. If the defendant is able to do this, the prosecution is required to prove beyond a reasonable doubt that there was no such mistake.

The return of the original certificate is required to ensure that there is no misuse of an outdated or invalid certificate.

Part 5 Including medical devices in the Register

Division 5.1 Including medical devices in the Register

Regulation 5.1 is intentionally not used.

Regulation 5.2 specifies 20 working days as the period for obtaining from the manufacturer, information to substantiate compliance with the essential principles or conformity assessment procedures.

Regulation 5.3, subregulation (1), prescribes, for the purposes of paragraph 41FH (1)(a) of the Act, the applications for a kind of medical device to be included in the Register that must always be selected for auditing. These are applications for medical devices that are:

- barriers indicated for contraception or for prevention of the transmission of disease in the course of penile penetration during sexual intercourse, other than condoms;

- implantable contraceptive devices;

- implantable breast prostheses containing material of fluid consistency other than water only or a saline solution only;

- to be used specifically for disinfecting another medical device, other than those used for disinfecting contact lenses;

- Class AIMD;

- prosthetic heart valves;

- implantable intra-ocular lenses;

- intra-ocular visco-elastic fluids; or

- other Class III medical devices that have not been assessed under the Mutual Recognition Agreements.

Subregulation (2) states that subregulation (1) does not apply to an application for a device for which a conformity assessment certificate has been issued, and that certificate has not been suspended or revoked.

Subregulation (3) defines the Mutual Recognition Agreements referred to in subregulation (1).

Regulation 5.4 specifies that for purposes of paragraph 41FK (e) of the Act, the period for payment of assessment fees before an application for inclusion in the Register lapses is 40 working days after the applicant is notified of the decision to include the device in the Register.

Division 5.2 Conditions

This Division contains the regulations pertinent to Part 4-5 Division 2 of the Act, the conditions that apply when a medical device is included in the Register. These conditions automatically apply to each inclusion in the Register.

Regulation 5.5 is intentionally not used.

Regulation 5.6 specifies 20 working days as the period for obtaining from the manufacturer, information to substantiate compliance with the essential principles or conformity assessment procedures.

Regulation 5.7 defines the periods for giving information to the Secretary about adverse events, as required in 41FN (3) (d) of the Act. The prescribed times are

- 48 hours for an event that represents a serious threat to public health

- 10 days for an event that has led to the death or serious deterioration in the state of health of the patient, user of the device or other person, and

- 30 days if a recurrence of the event might lead to the death or serious deterioration in the state of health of the patient, user of the device or other person.

subregulations (2) and (3) define the terms "represents a serious threat to public health" and "serious deterioration".

Regulation 5.8 details the information required to be given by the sponsor to the manufacturer under 41FN (3) (e). This information should allow the manufacturer to carry out the post-market activities required under the conformity assessment procedures.

Part 6 Suspension and cancellation from the Register

Regulation 6.1 this regulation defines the time period within which the Secretary must make a decision on an application to revoke the suspension of a kind of medical device from the Register as 40 working days after the application for revocation is received.

Part 7 Exempting medical devices from inclusion in the Register

Division 7.1 Exempt devices

This Division relates to section 41HA of the Act, which specifies that the regulations may exempt particular medical devices from the requirement to be included in the Register. Breach of this requirement would otherwise constitute an offence under Division 3 of Part 4-11 of the Act.

Regulation 7.1 exempts, for the purposes of paragraph 41HA (1) (b), a kind of medical device mentioned in Part 1 of Schedule 4. Subregulation (2) exempts a kind of medical device mentioned in Part 2 of Schedule 4 subject to the conditions specified in that Schedule.

Subregulation (3) provides that, if a kind of medical device that is exempt, ceases to be exempt, and an application was made for inclusion in the Register before the device ceased to be exempt, the device is taken to be exempt until the application is determined.

Regulation 7.2 exempts a kind of medical device that is to be used on a Category A patient, under specified conditions. Subregulation (2) defines the terms "Category A patient" and "informed consent" for the purposes of this Regulation.

Division 7.2 Exemptions for experimental uses

This Division relates to section 41HB of the Act, which allows the Secretary to grant written approval for a person to import, export or supply a specified medical device or kind of medical device for use in the treatment of another person, or for experimental purposes in humans.

Regulation 7.3 details, for the purposes of subsection 41HB (3) of the Act, the conditions that apply to an approval to use a medical device for experimental use in humans. These are that, prior to the commencement of a clinical trial for a kind of medical device, the person to whom the approval is granted, and the principal investigator of the trial, must give to the TGA

- a written assurance that each clinical trial will be conducted in accordance with the specified ethical standards, and

- a written undertaking to comply with a request from an authorised person for information about the conduct of the trial, and that the person will allow an authorised person to do any of the things mentioned in Regulation 7.4.

Regulation 7.4 defines the powers of an authorised person in relation to a clinical trial including search and entry, inspecting records and asking questions. An authorised person is defined in regulation 10.1 and subsection 3(1) of the Act.

Regulation 7.5 defines, for the purposes of subsection 41HB (7) of the Act, the conditions that apply to the use of a medical device for experimental use by a person other than the person to whom the approval for use has been given. These include compliance with the approved procedural protocol and specified ethical standards.

Division 7.3 Exemptions for medical practitioners

This Division relates to section 41HC of the Act, which allows the Secretary to authorise a specified medical practitioner to supply specified kinds of medical devices to a specified class of recipients.

Regulation 7.6 defines, for purposes of paragraph 41HC (4) (a) of the Act, specialist medical practitioners with relevant ethics committee endorsement as the class of medical practitioners to whom an authority may be granted, and the class of recipients. Subregulation (3) defines the conditions under which a medical practitioner may be authorised without the approval of an ethics committee.

Regulation 7.7 defines, for the purposes of subsection 41HC (5), the circumstances under which medical devices may be supplied under an authority.

Part 8 Obtaining information

This Part relates to Part 4-8 of the Act, which is about the powers of the Secretary to seek information or documents relating to the application of conformity assessment procedures, compliance with the essential principles and other requirements, and matters related to medical devices covered by exemptions under Part 4-7.

Regulation 8.1 provides that the power to require information under section 41JA of the Act extends to persons who previously had a device on the Register during the notice period specified in this regulation as

- 5 years if the information requested by the Secretary relates to manufacturing records,

- 10 years if the information relates to distribution records for a Class AIMD, Class III or Class IIb implantable medical device, or

- 5 years if the information relates to distribution records relating to any other device,

and ending on the day before the Secretary gives the notice requesting information.

Regulation 8.2 specifies the information that must be included in a statement by a medical practitioner in relation to the use of an exempt device in or on a Category A patient, as required under subsection 41JD (2) of the Act. The practitioner must send a copy of the statement to the Secretary within 20 working days of signing it, and failure to do so is an offence of strict liability with 10 penalty points. For the purposes of this regulation, the terms "Category A patient" and "informed consent" are defined.

The offence is one of strict liability because the provision of a statement by a medical practitioner about the use of an unapproved exempt device in or on a Category A patient is integral to TGA's monitoring of the use of such devices, in particular, it is necessary to ensure that the conditions on the use of such devices have been complied with. These conditions include a requirement that the patient give informed consent to the use of the unapproved device.

Where strict liability applies to an offence the prosecution does not have to prove fault on the part of the defendant (see section 6.1 of the Criminal Code). The prosecution need only prove that the physical element of the offence did occur. However, there is a defence of mistake of fact available under section 9.2 of the Criminal Code.

Part 9 Fees

Regulation 9.1 prescribes the assessment fees and other fees set out in Schedule 5.

Regulation 9.2 specifies that for purposes of section 41LB of the Act, a fee for application audit assessment is due and payable on the day that the application to be audited is received (by TGA). Application audit fees are to be paid for auditing applications but only where the audit is required under paragraph 41FH (1) (a) of the Act.

Regulation 9.3 specifies that the fee for consideration of an application for a conformity assessment certificate is due and payable in full on the day specified in a notice given to the applicant by the Secretary. If the application is withdrawn before a decision is made in relation to the application, and within the 255 days specified for determining particular applications under subregulation 4.3 (2), the fee is due and payable in full on the day the application is withdrawn.

Subregulation (2) applies if an applicant has paid three-quarters of the applicable fee and the application is withdrawn within the 255 days specified in subregulation 4.3 (2), but before a decision is made to determine the application. In this situation, the part of the fee that remains unpaid is due and payable on the day that the application is withdrawn.

Subregulation (3) requires that any fees imposed in relation to additional assessment work required in relation to an application for a conformity assessment certificate become due and payable on the day specified in a notice given to the applicant. The fee for any additional work carried out in accordance with this Regulation is prescribed in item 1.12 of Schedule 5.

Regulation 9.4 provides for an abridged conformity assessment fee if the Secretary has undertaken a full assessment of the device under the Mutual Recognition Agreements, prior to the commencement of these Regulations. In these circumstances, if the Secretary considers that there is sufficient information relating to the device to allow an abridged assessment, the fee to be charged is $2 500.

Regulation 9.5 allows the Secretary to approve payment of an assessment fee in instalments in a case of financial hardship where the circumstances specified in subregulation (1) are met. These include the applicant providing reasons and supplying documentation to support the application. Applications must be decided within 30 days of the application and supporting documentation being received. The decision is reviewable under regulation 10.7. If an application is approved, and any amount of the instalment is not paid when it becomes due, the balance of the fee then becomes due for payment. If other assessment or evaluation fees are outstanding this regulation does not apply (subregulation 7).

Part 10 Miscellaneous

Regulation 10.1 clarifies that an authorised person under subsection 3 (1) of the Act may exercise the powers given to an authorised person under the provisions of these Regulations.

Regulation 10.2 addresses the question of sponsors name and address in relation to the label of a medical device. It requires that the sponsor of a medical device imported into Australia must ensure that information about the sponsor is provided in a way that allows the sponsor to be identified. The regulation does not require that the sponsor's name and address to appear on a label, but the intent is that the sponsor be identifiable when matters arise as the result of the use of a medical device.

Subregulation (2) requires that if the sponsor does attach a label to the device in order to comply with this requirement (or for any other purpose), the label must not interfere with the device or obscure the information that the manufacturer has provided with the device. Although the actions of the sponsor may involve labelling, sponsors are not considered to be manufacturers by virtue only of complying with this regulation. The penalty for non-compliance with this regulation is 10 penalty units.

Regulation 10.3 requires an Australian manufacturer of custom-made devices to give to the Secretary information about the manufacturer's name and address and a description of the kinds of devices being manufactured. The sponsor of imported custom-made devices has a similar obligation. Failure to comply with the requirements of this regulation invokes a penalty of 10 penalty units. The requirements of this regulation will not take effect until two years after the commencement of the Regulations as custom made devices remain for that time exempt goods under Chapter 3 of the Act.

Regulation 10.4 specifies, for the purposes of paragraph 41MP (1) (c) of the Act, the period for notifying the Secretary about adverse events as the relevant period specified in regulation 5.7.

Regulation 10.5 allows the Secretary to delegate functions or powers under these Regulations to an officer of the Department or to the National Manager of the TGA.

Regulation 10.6 relates to delegation of the Secretary's powers under paragraph 41HB (1) (d) of the Act, to approve the use of a specified unapproved medical device for use in the treatment of a person. The conditions under which the delegation may be made under subsection 57(3) of the Act include specifying to whom it may be given, and the circumstances under which the power may be used.

Regulation 10.7 provides for review by the Minister of particular decisions of the Secretary. The Minister may delegate a power or function under this regulation to an officer of the Department, or to the National Manager of the TGA. The regulation sets out the conditions under which a person whose interests are affected by the decision may request a review, and the administrative procedures to be followed in reviewing the decision. The Minister's decision may be reviewed by the Administrative Appeals Tribunal.

Schedule 1 - Essential principles

This Schedule details the essential principles for safety and performance of medical devices, for the purposes of section 41CA of the Act and regulation 2.1.

Part 1 - General principles

Essential Principle (EP) 1 specifies that a medical device must be designed and produced in a way that ensures that, when used as intended, by a person with appropriate knowledge, experience, training or education, it does not compromise the safety or health of a patient or the user. It also requires that the intended benefit to the patient outweighs any risks associated with the use of the device, and that a high level of protection of health and safety is in place to counter possible risks.

EP 2 requires that conformance with safety principles be taken into account during the design and construction phases for a medical device, and that a medical device should be designed and constructed in accordance with state of the art procedures and requirements (in relation to the device and the technology). State of the art in this context refers to, for instance, published standards or other authoritatively endorsed literature relevant to the device.

The EP further requires that in developing the design and construction solutions for a medical device, the manufacturer conducts a risk analysis to identify the risks that may arise from the use of the device. The risk analysis should take into account not only use of the device according to its intended purpose, but also any risks that may arise from misuse situations, if these situations can be foreseen. Any risks identified should be eliminated as far as possible. Any risks that cannot be eliminated should be mitigated by the use of other protection measures, such as alarms or fail-safe mechanisms. Users should be informed of any residual risks that may arise if protection measures are not fully effective.

EP 3 requires that a medical device must perform in the way intended by the manufacturer. The device must also be designed, produced and packaged in a way that ensures it is suitable for one or more of the functions within the scope of the definition of medical device in subsection 41BD (1) of the Act, ie for

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

EP 4 requires that the device be designed and produced in such a way as to ensure the characteristics and performance for safety of the device, as described in EPs 1, 2 and 3, are maintained throughout the period of safe use as indicated by the manufacturer. This requirement is subject to the provision that the device is not subject to abnormal stress, and the device is regularly maintained and calibrated in accordance with the manufacturer's instructions.

EP 5 requires that a medical device must be designed, produced and packaged in a way that ensures that its characteristics and performance are not adversely affected by conditions of transport and storage, when that transport and storage is carried out in accordance with the manufacturer's instructions and information.

EP 6 complements and supplements EP 1, in requiring that the benefits to be gained by use of the device in accordance with its intended purpose outweigh any undesirable side-effects that may arise from its use. In this context undesirable side-effects are distinguished from adverse events. A side-effect is an anticipated consequence of the way a device achieves its purpose or the way that it must be used. Such effects must not outweigh the benefits derived from the use of the device. Adverse events are not anticipated. The risk of such adverse events occurring must be minimised.

Part 2 - Principles about design and construction

This part sets out the essential principles for design and construction of a medical device, and covers chemical, physical and biological properties, infection and microbial contamination issues, construction and environmental properties, special requirements for devices with a measuring function, protection against radiation, requirements for devices connected to, or equipped with, an energy source, and labelling.

EP 7 - Chemical, physical and biological properties

EP 7.1 requires that, in order to ensure safety of the device in accordance with Part 1, the manufacturer must pay particular attention to the materials used in construction, particularly with regard to chemical and physical properties of the materials. The manufacturer must pay particular attention also to the compatibility between the materials to be used and biological tissues, cells and body fluids. In considering these matters, the intended purpose of the device must be taken into account.

EP 7.2 requires that the device be designed, produced and packed in a manner that minimises any risks associated with contaminants and residues, that may affect persons involved in transport, storage or use of the device, or the patient on whom it is to be used. The risk minimisation strategy should take into account the likely levels of human exposure, in terms of time and frequency, during transport, storage or use.

This essential principle has particular application to devices with a chemical or biological formulation, such as disinfectants, enzymatic cleaners or tracing dyes.

EP 7.3 requires the manufacturer to take into account the environment in which a device is to be used, to ensure that it can be used safely with any materials, substances or gas with which it is likely to come into contact during normal conditions of use. In particular, if a device is to be used to administer medicines, it must be designed and manufactured in a way that ensures that it is compatible with the medicines to be administered, and it does not affect the performance of the medicine.

EP 7.4 relates to device that incorporates, or is intended to, incorporate a medicinal substance that has an effect ancillary to that of the device (and for the purposes of this clause, stable derivatives of human blood and human plasma are considered to be a medicine). In these devices, the safety and quality of the medicinal substance must be verified in accordance with the procedures applied to medicines. This has the effect of requiring assessment of the medicinal substance in accordance with the requirements of Chapter 3 of the Act.

In addition, the ancillary action of the medicinal substance, for instance in terms of enhancing or complementing the intended purpose of the device, must be verified.

EP 7.5 requires that a device be designed and produced in a way that minimises any risks associated with substances that may leach from the device. For example, such substances may include chemical manufacturing residues or components of the materials used.

EP 7.6 requires that a device must be designed and produced in such a way as to minimise the risks posed by the unintentional ingress or egress of substances into or from the device, taking into account the environment in which the device is to be used.

EP 8 - Infection and microbial contamination

EP 8.1 requires that a device be designed and produced in such a way as to eliminate or minimise the risk of infection to patients, users or any other person. The design should

- allow easy handling; and

- minimise contamination of the device by the patient, or contamination of the patient by the device, during use.

EP 8.2 relates to a medical device that contains tissues, cells or substances of animal origin that have been rendered non-viable, and to those that contain tissues, cells or substances of microbial or recombinant origin. It is not intended to apply to plant cells or substances.

It requires, for materials of animal origin, that

- the animals are subjected to the appropriate veterinary controls and supervision, taking into account the intended use of the material, and

- a record be kept of the country of origin of each animal from which the material was derived.

For all material covered by this clause, the processing, preservation, testing and handling must be carried out in such a way as to ensure the highest standards of safety for the patient, the user of the device and any other person. In particular, the production process must incorporate validated methods for elimination or inactivation of viruses and other transmissible agents.

EP 8.3 applies to a medical device that is intended by the manufacturer to be supplied as sterile. The device must be designed, produced and packaged in a way that maintains the sterility of the device from the point of supply until the package is opened (unless damaged) provided that the device is stored and transported in accordance with the manufacturer's directions. The device must be produced and sterilised using an appropriate validated method and must be produced in appropriately controlled conditions, eg in an environment that maintains the required microbial integrity of the device.

EP 8.4 applies to a medical device that is intended by the manufacturer to be supplied as non-sterile. It must be packed in such a way to ensure that the level of cleanliness stipulated by the manufacturer is maintained. Further, if the intention is that the device be sterilised before it is used, then it must be packed in a way that ensures that the risk of microbial contamination is minimised, and the packaging must be suitable for the intended method of sterilisation. Such a device must also be produced in controlled conditions as appropriate to maintain the required level of cleanliness.

EP 8.5 requires that if a medical device is supplied as both sterile and non-sterile, the information supplied with the device must clearly indicate whether it is sterile or non-sterile.

EP 9 - Construction and environmental properties

EP 9.1 applies to a medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment, including a connection system. The device must be designed and produced in a way that ensures that both the device and the equipment to which it is connected continue to perform in a safe manner and that the intended performances are not impaired.

EP 9.2 details a number of possible risks that must be removed or minimised during the design and production of a medical device, for example the risk:

- of injury arising from the physical features of the device eg, sharp corners or protrusions; or

- associated with reasonably foreseeable environmental conditions eg if a device may be used outdoors in unfavourable weather conditions, such as devices used by ambulance paramedics, then it should not be affected by rain.

EP 10 relates to devices with a measuring function, and requires that

- such devices be designed and produced in a way that ensures that, for the intended purpose of the device, the measurements are accurate, precise and stable, within the limits indicated by the manufacturer;

- ergonomic principles be taken into account in the design and production of the measurement, monitoring and display scale of the device, where relevant to the intended purpose of the device; and

- the measurements must be expressed in Australian legal units of measurement (ie in accordance with the *National Measurement Act 1960*), or if the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed, the units used must be approved by the Secretary for that device.

EP 11 - Protection against radiation

EP 11.1 requires that a medical device must be designed and produced in a way that minimises the exposure to radiation of the patient, the user, or any other person, taking into account the levels of radiation needed to enable the device to perform its intended functions.

EP 11.2 applies to a medical device that, in accordance with its intended purpose, emits hazardous levels of visible or invisible radiation, and the benefit of the device outweighs the risks inherent in the emission. The device must be designed and produced in a way that ensures that the user can control the level of the emission, and that ensures the reproducibility and tolerance limits of relevant variable parameters. If practicable, the device must be fitted with audible and/or visual alarms that operate if potentially hazardous levels of radiation are emitted.

EP 11.3 requires that a medical device be designed and produced in a way that minimises the exposure of the patient, the user or any other person to the emission of stray, scattered or unintended radiation.

EP 11.4 requires that the operating instructions for a device that emits radiation should give detailed information on

- the nature of the radiation emitted;

- the means of protecting patients and users from the radiation;

- ways of avoiding misuse; and

- ways of eliminating risks inherent in installation of the device.

EP 11.5 contains requirements additional to those of EPs 11.1 to 11.4, for a medical device that is intended to emit ionising radiation. It includes requirements for control of the radiation, and particular requirements for devices used in diagnostic radiology and those used in therapeutic radiology.

EP 12 - Medical devices connected to or equipped with an energy source

EP 12.1 applies to medical devices incorporating an electronic programmable system. These are devices that incorporate microprocessor systems that rely on software for their performance. The clause contains requirements for performance, reliability and repeatability of the system and minimisation of risk associated with the device when it is designed to withstand the occurrence of a single fault.

EP 12.2 applies to a medical device in which the safety of the patient is dependent upon an internal power supply for the device. It requires that there be a system for determining the state of the power supply, ie to warn of a hazardous situation in the event of a failure of the power supply.

EP 12.3 applies to a medical device in which the safety of the patient depends on an external power supply for the device. It requires that the device be fitted with an alarm system to indicate whether a power failure has occurred.

EP 12.4 applies to a medical device intended for use in measuring clinical parameters in a patient. It requires that the device be fitted with an appropriate alarm system to warn the user if a situation develops that could severely harm the patient.

EP 12.5 requires that the risks consequent upon the creation of an electromagnetic field be minimised.

EPs 12.6 to 12.12 require that a medical device must be designed and produced in a way that ensures protection against

- accidental electrical shock,

- mechanical risks,

- risks associated with vibration generated by the device,

- risks associated with noise emitted by the device,

- risks associated with terminals and connectors, where a device is intended to be connected to an electric, gas, hydraulic, pneumatic or other energy supply,

- risk associated with heat generated in accessible parts of the device (except where a part is intended to supply heat or reach a given temperature),

- risk associated with administration of energy or substances (eg radiant heat or medicines).

EP 12.13 applies to active implantable medical devices (eg pacemakers) and requires that they display a code identifying the device, the manufacturer and the year of manufacture. The code

must be able to be read without the need for surgery. This requirement is intended to facilitate tracking of implantable devices.

EP 13 - Information to be provided with medical devices

This section sets out the requirements for information to be provided with medical devices, in the labelling, instructions for use or other literature provided with the medical device.

EP 13.1 specifies

- the information that must be provided with a medical device;

- that the information be provided in English (although any other language may also be provided);

- that the format, content and location must be appropriate for the intended purpose of the device; and

- requirements for the legibility and height of numbers, letters and symbols used in the information.

It also requires that the meaning of any symbols or identification colour not included in a medical device standard must be explained in the information or instructions provided with the device.

EP 13.2 specifies that information to be provided with a device must be provided on the device itself, unless that is impractical or inappropriate (subclause (1)). Subclause (2) allows information to be provided on the packaging if it is not practicable to comply with subclause (1). If it is impracticable or inappropriate to comply with subclauses (1) and (2), subclauses (3) and (4) allow for particular information to be provided on a leaflet, in printed documents or other appropriate media.

EP 13.3 sets out in a table particular requirements for information to be provided with a medical device. This information should be provided by the manufacturer. A separate requirement is given in regulation 10.2, requiring the sponsor to ensure the sponsor of a medical device can be identified.

EP 13.4 requires that instructions for use be provided with a medical device. Subclause (2) allows exemption from the provision of instructions for use, or abbreviated instructions for use, if the device falls into Class I or Class IIa, and the device can safely be used for its intended purpose without instructions. Subclause (3) details in a table the information that must be included in the instructions for use, as applicable.

EP 14 requires clinical evidence for all medical devices as appropriate to the use and classification of the device. Further requirements for the assessment of clinical data are included in Regulation 3.11.

Schedule 2 Classification rules

This schedule details the rules for classification for the purposes of Regulation 3.2. Regulation 3.1 classifies devices as Class I, Class IIa, Class IIb, Class III or Class AIMD (active implantable medical device), in a system where Class I is specified as the lowest level of risk, and Class III and Class AIMD at the highest level. Regulation 3.3 provides a set of principles for applying the classification rules.

Part 1 - Interpretation

Rule 1.1 clarifies the terms "transient", "short-term" and "long-term" use for the purposes of classification of medical devices in this Schedule. Transient use is continuous use for less than 60 minutes. Short-term use is continuous use for at least 60 minutes, but not more than 30 days. Long-term use is continuous use for more than 30 days. Period of use is defined in terms of the manufacturer's intended purpose.

Part 2 - Rules for non-invasive devices

Rule 2.1 classifies non-invasive devices as Class I, unless another clause in this Part, or Part 4 or 5 of this Schedule applies to classify the device at a higher level.

Rule 2.2 applies to a non-invasive device that is intended for use in

- channelling or storing blood or body liquids that are to be re-introduced to a patient by some means, or

- storing an organ, part of an organ or body tissue that is later to be introduced into a patient, or

- channelling or storing a liquid or gas that is to be introduced into a patient.

These devices are classified as Class IIa.

Rule 2.3 classifies a non-invasive device used to modify the biological or chemical composition of blood, other body fluids, or other fluids for infusion into a patient, as Class IIb. However, if the treatment of the blood or fluid is limited to filtration, centrifugation or exchange of gases or heat, the device is Class IIa.

Rule 2.4 applies to a non-invasive device that is intended for use in contact with injured skin, including a device that as its main purpose manages the micro-environment of a wound. These devices include topical gels and other wound care devices intended for primary contact with an open wound. Such a device is classified as Class IIa, unless

- it is intended for use as a mechanical barrier, or for compression, or for the absorption of exudates, in which case it is Class I, or

- it is intended for wounds that breach the dermis, and the wounds can only heal by secondary intent (ie by growth of tissue), in which case it is Class IIb. An example of this type of device is one used in contact with diabetic ulcers.

Part 3 - Rules for invasive devices and implantable devices

Rule 3.1 classifies invasive devices where the intention is that the device penetrates through a body orifice (not surgically). The classification assigned depends upon whether the device is intended for connection to an active medical device, and if not, whether it is for transient, short term or long term use, and the part of the body where it is intended that the device be used. The rule particularly classifies as Class IIa any device that is intended for connection to an active medical device that is Class IIa or higher.

Rule 3.2 classifies a surgically invasive device intended for transient use as Class IIa, except where

- it is intended specifically for use in diagnosing, monitoring or correcting a defect of the heart or central circulatory system, in which case it is Class III, or

- it is a reusable surgical instrument, in which case it is Class I, or

- it is intended for a number of other specified purposes, for example supplying energy in the form of ionising radiation, where it is Class IIb.

Rule 3.3 classifies a surgically invasive device intended for short term use as Class IIa, except under specified circumstances, such as use in administering a medicine, or where it comes into direct contact with the central nervous system, in which case a higher classification applies. The rule specifies that a device to be placed in the teeth is Class IIa, except where it is intended to penetrate a tooth and enter the gum or bone beyond.

Rule 3.4 classifies a surgically invasive device intended for long term use, and an implantable device, as Class IIb, except where

- it is intended to be placed in the teeth, in which case it is Class IIa (see Rule 3.3), or

- it is intended for use in one of a number of specified circumstances, for example where it is intended to have a biological effect, in which case it is Class III.

Part 4 - Special rules for active medical devices

Rule 4.1 specifies that active medical devices are in general classified as Class I, unless higher classification is required under another rule in this Part, or Parts 2, 3 or 5.

Rule 4.2 classifies an active medical device used for therapy, and intended to administer energy to a patient, or exchange energy to or from a patient, as Class IIa, unless

- the administration or exchange of energy occurs in a potentially hazardous way; or

- the device is an active medical device intended to control, monitor, or directly influence the performance of an active device for therapy where the administration or exchange of energy occurs in a potentially hazardous way,

in which case the device is classified as Class IIb.

Rule 4.3 classifies active medical devices for diagnosis as Class IIa or Class IIb, depending upon the circumstances of use. Devices of this kind used for instance to monitor parameters such as variations in cardiac performance, respiration or activity of the nervous system where the variations could result in immediate danger to the patient, are in the higher class.

Rule 4.4 classifies an active medical device intended to administer or remove a medicine, body liquid or other substance to or from a patient as Class IIa, unless the administration or removal is potentially hazardous to the patient, in which case the device is Class IIb. An example of a Class IIb device under this Rule is a powered drug infusion system.

Part 5 - Special rules for particular kinds of medical devices

Rule 5.1 classifies as Class III a medical device that will incorporate a substance that if used separately, would be a medicine, and where the substance is intended to have an action ancillary to that of the device. An example of such a device is a catheter incorporating an antibiotic for the purposes of reducing catheter-related sepsis. For the purposes of this rule, stable derivatives of human blood or blood plasma are considered to be medicines.

Rule 5.2 classifies a medical device intended for contraception or the prevention of sexually transmitted diseases as Class IIb, unless it is implantable or an invasive device intended for long term use (eg an intra-uterine contraceptive device), in which case it is classified as Class III.

Rule 5.3 classifies as Class IIb a medical device specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses, or for disinfecting another medical device. For the purposes of this rule, a sterilant is taken to be a type of disinfectant. The rule excludes a medical device intended only to be used to clean another device (except for contact lenses) by means of physical action, which is classified as Class I, under rule 2.1.

Rule 5.4 classifies a non-active medical device intended for use in recording X-ray diagnostic images (eg X-ray film) as Class IIa.

Rule 5.5 classifies as Class III a medical device that is manufactured using tissues, cells or substances of

- animal origin that have been rendered non-viable;
- microbial origin; or
- recombinant origin; or
- a combination of these.

There is an exception for devices of animal origin, rendered non-viable, where they are intended only for contact with intact skin, in which case they are classified as Class I, under rule 2.1. This exception does not apply to devices containing material of microbial or recombinant origin; these are to be classified as Class III even if they only come into contact with intact skin.

Rule 5.6 classifies blood bags as Class IIb.

Rule 5.7 classifies an active implantable medical device as Class AIMD. An implantable accessory to an active implantable medical device is classified as Class III; for example a device such as a cardiac pacing lead.

An active medical device that is used to control or monitor, or directly influence, the performance of an active implantable device is classified as Class III. For example, a programmer used to set the treatment delivered by a cardiac pacemaker.

Rule 5.8 classifies a medical device that is intended for export from Australia, and not for supply in Australia, as Class I.

Rule 5.9 classifies a medical device that is a mammary implant as Class III.

Schedule 3 Conformity assessment procedures

This Schedule sets out, for the purposes of regulation 3.4, the requirements relating to obligations of manufacturers of medical devices, to be known as conformity assessment procedures. Manufacturers have a choice of conformity assessment procedures, or combination of procedures, depending upon the classification of the medical device being manufactured, as provided in regulations 3.5 to 3.10.

Part 1 - Full quality assurance procedures

This Part relates to demonstration of conformity with the essential principles through the implementation of a full quality assurance system for production of a kind of medical device.

Clause 1.1 specifies that the conformity assessment procedures set out in this Part may be applied to medical devices of Class AIMD, Class III, Class IIb and Class IIa. However, clause 1.6 need not be applied to a medical device that is Class IIa or Class IIb. The procedures specified in this Part provide for the manufacturer to implement a quality management system for design, production, packaging, labelling and final inspection of the kind of medical device and to arrange for the Secretary to assess the system, and carry out other activities as specified. The manufacturer then makes a declaration of conformity in relation to the medical device, and undertakes to notify of changes to the system, to have those changes assessed, and to establish and maintain a post-market system for monitoring, reporting and corrective action.

Clause 1.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 1.3 requires a manufacturer to implement the quality management system as described in Clause 1.1, and details the information and undertakings that the manufacturer must have available, in writing, in order that the assessment of the quality management system can be carried out.

Clause 1.4 details the requirements that a quality management system must meet if it is to be assessed under Clause 1.3.

Clause 1.5 details the obligations on a manufacturer who has had a quality management system assessed under Clause 1.3, and who then plans to make a substantial change to the system or a change to the kinds of medical device to which the system is to be applied.

Clause 1.6 relates to the requirements for examination of the design for medical devices that are Class III or Class AIMD, if the quality management system to be applied to the manufacture of the devices is to be assessed under Clause 1.3. It requires that the manufacturer arrange for the examination of the design or intended performance of the kind of device, details the information and documentation that the manufacturer must have available, and specifies the obligations on the manufacturer in relation to changes to the design or intended performance.

Clause 1.7 specifies that in response to a request by an authorised person, the manufacturer must supply certain information in relation to the quality management system or the kinds of medical device to which the system is applied. It also specifies that the manufacturer must arrange for tests to be carried out for the purpose of checking that the quality management system is operating correctly, if requested. The clause further stipulates that if the authorised person carries out inspections or tests in relation to the manufacturer's premises, or medical devices produced by the manufacturer, the manufacturer may ask to be given a report of the inspection or test findings.

Clause 1.8 requires that a manufacturer applying a quality management system to the manufacture of a kind of medical device under this Part must make a declaration of conformity in relation to the kind of device. Subclause (2) specifies the contents of the declaration.

Clause 1.9 specifies the records that must be kept by the manufacturer of a medical device to which a quality management system assessed in accordance with this Part has been applied. The specified records must be kept for at least five years after the manufacture of the last medical device to which the quality management system was applied, and the manufacturer must make the records available to the Secretary on request.

Part 2 - Type examination procedures

This Part relates to demonstration of conformity with the essential principles through the examination of a representative sample of the kind of medical device.

Clause 2.1 specifies that the conformity assessment procedures set out in this Part may be applied to medical devices of Class AIMD, Class III and Class IIb. The procedures specified in this Part provide for the manufacturer to arrange for the Secretary to examine a representative sample of a kind of medical device (ie, the type). In the context of this Part, examination will usually involve testing of the type to demonstrate compliance with the essential principles.

Clause 2.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 2.3 requires that for the purposes of this Part, the manufacturer must arrange for examination of the type by the Secretary, and specifies the information, documentation and samples that the manufacturer must have or make available in order that the examination can be carried out. Subclause (5) specifies that if the type is intended for connection to another medical device, the manufacturer must make available, or arrange access to, a sample of the medical device, if requested to do so.

Clause 2.4 details the obligations of a manufacturer if the manufacturer plans to make a substantial change to the design or intended performance of a medical device to which the type relates, after the type examination has been carried out.

Clause 2.5 specifies the records that must be kept by the manufacturer of a type that has been examined under this Part. The specified records must be kept for at least five years after the manufacture of the last medical device of that type, and the manufacturer must make the records available to the Secretary on request.

Part 3 - Verification procedures

This Part relates to demonstration of conformity with the essential principles through examination and testing of each device or a representative sample of a batch of devices, in conjunction with other procedures.

Clause 3.1 specifies the requirements for a manufacturer to arrange for the examination and testing of the kind of medical device in order to verify that

a) the device conforms to the approved type, if the type examination procedures of Part 2 have been applied, or

b) the device is in accordance with the technical documentation prepared under Part 6, clause 4, if the device is of a kind to which the declaration of conformity (not requiring assessment by the Secretary) procedures of Part 6 have been applied.

The clause specifies that the conformity assessment procedures set out in this Part may be applied to medical devices of Class AIMD, Class III and Class IIb, to which the type examination procedures detailed in Part 2 have been applied, except where the device is to be supplied as sterile. The procedures set out in this Part may also apply to Class IIa medical devices except those intended to be supplied sterile and Class I medical devices that have a measuring function, if the declaration of conformity (not requiring assessment by the Secretary) procedures (as set out in part 6) have been applied.

The clause exempts the manufacturer of a Class IIa or Class I medical device, to which these procedures are applied, from preparation of the declaration of conformity required under clause 3.5. Class IIa and Class I medical devices using this procedure will be required to make a

declaration of conformity under the declaration of conformity (not requiring assessment by the Secretary) procedures (as set out in Part 6).

Clause 3.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 3.3 sets out the responsibilities of the manufacturer in arranging the examination and testing of each device of the kind, or a representative sample of a batch under this Part. It details the information, undertakings and documentation to be available in relation to the examination and testing, and the devices that must be made available for examination and testing.

Clause 3.4 sets out the obligations of the manufacturer in relation to the process used to manufacture a kind of medical device that is assessed under this Part.

Clause 3.5 requires that the manufacturer of a Class AIMD, Class III or Class IIb medical device that has been verified under this part must make a declaration of conformity in relation to the kind of device. It details the information that must be included in the declaration.

Clause 3.6 specifies the records that must be kept by the manufacturer of devices that have been verified under this Part. The specified records must be kept for at least five years after the manufacture of the last medical device to which the verification relates, and the manufacturer must make the records available to the Secretary on request.

Part 4 - Production quality assurance procedures

This Part relates to demonstration of conformity with the essential principles through the implementation of a quality management system for the production and final inspection of a kind of medical device, in conjunction with other procedures.

Clause 4.1 outlines the requirements for the manufacturer of a kind of medical device to implement a quality management system for the production and final inspection of that kind of device and to have that system assessed by the Secretary. The procedures of this Part may be applied to

a) Class AIMD, Class III and Class IIb medical devices to which the type examination procedures of Part 2 have been applied; or

b) Class IIa medical devices to which the declaration of conformity (not requiring assessment by the Secretary) procedures of Part 6 have been applied; or

c) Class I medical devices that are to be supplied as sterile, or that have a measuring function, and to which the declaration of conformity (not requiring assessment by the Secretary) procedures of Part 6 have been applied.

The manufacturer of a Class IIa or Class I medical device to which these procedures are applied, does not need to prepare the declaration of conformity required under clause 4.7. Class IIa and Class I medical devices using this procedure will be required to make a declaration of conformity under the declaration of conformity (not requiring assessment by the Secretary) procedures, as set out in Part 6.

Clause 4.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 4.3 sets out the responsibilities of the manufacturer in implementing and enabling the assessment of a quality management system for the production and final inspection of the kind

of device. It details the information, undertakings and documentation that must be available to enable the assessment to be carried out.

Clause 4.4 details the requirements that a quality management system must meet if it is to be assessed under clause 4.3.

Clause 4.5 details the obligations on a manufacturer who has had a quality management system assessed under Clause 4.3, and who then plans to make a substantial change to the system.

Clause 4.6 specifies that in response to a request by an authorised person, the manufacturer must supply certain information in relation to the quality management system or the kinds of medical device to which the system is applied. It also specifies that the manufacturer must arrange for tests to be carried out for the purpose of checking that the quality management system is operating effectively, if requested. The clause further stipulates that if the authorised person carries out inspections or tests in relation to this clause, the manufacturer may ask to be given a report of the inspection or test findings.

Clause 4.7 stipulates that the manufacturer of a Class AIMD, Class III or Class IIb medical device for which a quality management system has been assessed under this Part must make a declaration of conformity in relation to the kind of device. Subclause (2) specifies the contents of the declaration.

Clause 4.8 specifies the records that must be kept by the manufacturer of a kind of medical device to which this Part has been applied. The specified records must be kept for at least five years after the manufacture of the last medical device to which the quality management system was applied, and the manufacturer must make the records available to the Secretary on request.

Part 5 - Product quality management system procedures

This Part relates to demonstration of conformity with the essential principles through the implementation of a product-related quality management system for the final inspection and testing of a kind of medical device, in conjunction with other procedures.

Clause 5.1 sets out the requirements for the manufacturer of a kind of medical device to implement a quality management system for the final inspection and testing of the kind of device, and to have that system assessed by the Secretary. The procedures set out in this Part may be applied to

a) Class IIb medical devices to which the type examination procedures of Part 2 have been applied, unless the devices are to be supplied as sterile;

b) Class IIa devices to which the declaration of conformity (not requiring assessment by the Secretary) procedures of Part 6 have been applied, unless the devices are to be supplied as sterile; and

c) Class I devices that have a measuring function.

The manufacturer of a Class IIa or a Class I medical device to which these procedures are applied does not need to prepare the declaration of conformity required under clause 5.7.

Clause 5.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 5.3 sets out the responsibilities of the manufacturer in implementing a quality management system for the final inspection and testing of a kind of medical device and enabling

the assessment of the system by the Secretary. It details the information, undertakings and documentation that must be available to enable the assessment to be carried out.

Clause 5.4 details the requirements that a quality management system must meet if it is to be assessed under clause 5.3.

Clause 5.5 details the obligations on a manufacturer who has had a quality management system assessed under Clause 5.3, and who then plans to make a substantial change to the system or a change to the kinds of medical device to which the system is to be applied.

Clause 5.6 specifies that in response to a request by an authorised person, the manufacturer must supply certain information in relation to the quality management system or the kinds of medical device to which the system is applied. It also specifies that the manufacturer must arrange for tests to be carried out for the purpose of checking that the quality management system is operating effectively, if requested. The clause further stipulates that if the authorised person carries out inspections or tests in relation to this clause, the manufacturer may ask to be given a report of the inspection or test findings.

Clause 5.7 stipulates that the manufacturer of a Class IIb medical device for which a quality management system has been assessed under this Part must make a declaration of conformity in relation to the kind of device. Subclause (2) specifies the contents of the declaration.

Clause 5.8 specifies the records that must be kept by the manufacturer of a kind of medical device to which this Part has been applied. The specified records must be kept for at least five years after the manufacture of the last medical device to which the quality management system was applied, and the manufacturer must make the records available to the Secretary on request.

Part 6 - Declaration of conformity (not requiring assessment by the Secretary) procedures

This Part relates to the procedure by which a manufacturer of low risk medical devices may self-assess the conformity of those medical devices with the essential principles and, where required, in conjunction with other procedures, make a declaration in relation to the conformity of the kinds of medical devices.

Clause 6.1 outlines the requirements for a manufacturer of a kind of medical device to prepare technical documentation to enable assessment of the device, and to make a declaration of conformity in relation to that kind of medical device. The procedures set out in this Part can be applied to

a) Class IIa medical devices; and

b) Class I medical devices.

For Class IIa devices, and Class I devices that are to be supplied sterile, or that have a measuring function, other conformity assessment procedures must also be applied, in compliance with regulations 3.7 and 3.8 of Division 4.3.

Clause 6.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 6.3 sets out the responsibilities of the manufacturer in preparing the technical documentation for a kind of medical device in a form that would, if selected, allow the assessment of the device by the Secretary. It details the information and undertakings that must be available to enable the assessment to be carried out.

Clause 6.4 details the information that must be included in the technical documentation, and sets out the obligations if a manufacturer makes a change to the design or production of a kind of medical device after the technical documentation has been prepared.

Clause 6.5 sets out the obligations on a manufacturer of a medical device to which the provisions of this Part are applied, to establish and maintain a post-market system for monitoring and reporting and corrective action in relation to the post-production phase of the device.

Clause 6.6 stipulates that the manufacturer of a kind of medical device for which technical documentation is prepared under this Part must make a declaration of conformity in relation to the kind of device. Subclause (2) specifies the contents of the declaration.

Clause 6.7 specifies the records that must be kept by the manufacturer of a kind of medical device to which this Part has been applied. The specified records must be kept for at least five years after the manufacture of the last medical device to which the technical documentation prepared under clause 6.4 applies, and the manufacturer must make the records available to the Secretary on request.

Part 7 - Procedures for medical devices used for a special purpose

Clause 7.1 introduces the conformity assessment procedures to be applied to medical devices used for a special purpose. It provides for the manufacturer of such medical devices to prepare a written statement in relation to the device, and to prepare and maintain particular documentation in relation to the device.

Clause 7.2 sets out the obligations on a manufacturer of a custom-made medical device to

a) prepare a written statement containing specified information;

b) prepare and maintain documentation relating to the device, including information relating to the design, production and intended purpose;

c) take all measures necessary to ensure that the manufacturing process results in the device complying with the specifications for design, production and intended performance; and

d) notify the Secretary of specified information relating to performance or use in the post-production phase.

The clause notes that the requirements for custom-made medical devices do not come into force for a period of two years after the commencement of these Regulations. During this period, the provisions of Chapter 3 of the Act continue to apply to these devices; they continue to be exempt goods, or are declared, by order published in the *Gazette* under subsection 41BD(3) of the Act, not to be medical devices for the purposes of the Act.

Clauses 7.3 and 7.4 are intentionally not used.

Clause 7.5 sets out the obligations on the manufacturer of a system or a procedure pack to

a) make a declaration of conformity in relation to the pack,

b) include specified information in the declaration, and

c) establish and maintain a post-marketing system for use in relation to the pack.

Subclause (4) details the elements that the post-marketing system must require of the manufacturer in order to comply with the requirements of this clause.

Clause 7.6 requires the manufacturer to keep the statement and documentation required under these clauses relevant to the kind of medical device. The statement and documentation must be kept for at least five years after the manufacture of the last medical device to which they relate, and the manufacturer must make them available to the Secretary on request.

Part 8 - Clinical evaluation procedures

Essential Principle 14 states that all medical devices require clinical evidence, appropriate to the nature and classification of the device. This Part requires that clinical evaluation procedures must be applied to medical devices (except for those specified in regulation 3.10), in addition to the conformity assessment procedures that must be applied.

Clause 8.1 applies the procedures of this Part to all medical devices except those specified, and requires the manufacturer of a kind of medical device to obtain and evaluate clinical data in relation to the device.

Clause 8.2 clarifies that where this Part refers to a kind of medical device the reference includes an individual medical device.

Clause 8.3 specifies that the manufacturer must obtain the clinical data in the form of either or both

a) clinical investigation data as defined in clause 8.4;

b) a literature review in accordance with clause 8.5,

taking into account any medical device standard or conformity assessment standard that may apply to the device.

Clause 8.4 defines ***clinical investigation data*** for the purposes of clause 8.3, and sets criteria for the form of the documentation, records or reports that are included in the clinical investigation data. It also requires the investigation that produced the data, if collected inside Australia, to have been conducted in accordance with the specified National Health and Medical Research Council publication. If the data is collected outside Australia, the investigation must have been conducted in accordance with the principles of the Declaration of Helsinki.

Clause 8.5 defines a ***literature review*** for the purposes of clause 8.3.

Clause 8.6 requires that the manufacturer must ensure that competent clinical experts evaluate the clinical data, and that the clinical evidence that the device complies with the essential principles is documented in writing.

Schedule 4 Exempt devices

This Schedule specifies, for the purposes of regulation 7.1, the kinds of medical devices that are exempt from the operation of Division 3 of Part 4-11 of the Act (offences relating to medical devices that have not been included in the Register).

Part 1 Exempt devices - general

This Part specifies the kinds of medical devices that are to be exempt devices:

- Item 1.1 exempts a medical device that is imported into Australia for use in the treatment of the importer, or the importer's immediate family, provided that specified conditions are met.

- Item 1.2 exempts a medical device that is exported from Australia, provided it is not intended for commercial supply, does not contain a substance prohibited from export, and is not intended for use for experimental purposes in humans.

- Item 1.3 exempts samples of devices imported, exported or manufactured or supplied in Australia for one of the purposes specified and not to be supplied for use in or on a human being.

- Item 1.4 exempts a medical device that is imported solely for the purposes of export and remains subject to the control of the Australian Customs Service, and provided that it is not subject to manufacture or related activities, as mentioned in section 41BG, by a manufacturer in Australia.

- Item 1.5 exempts a custom-made medical device (defined in the dictionary).

Part 2 Exempt devices - exemption subject to conditions

This Part specifies the kinds of medical devices that are to be exempt devices where the exemption is subject to specified conditions. It sets out items 2.1 - 2.5, and specifies in column 2 the kind of medical device to which the item applies, and in column 3 the conditions that apply to each exemption. These exempt devices include imported devices awaiting further action, devices to be used under the clinical trial notification scheme and devices imported by visiting sporting or military groups.

Schedule 5 Fees

This Schedule sets out the fees specified in Part 9 of these Regulations, for the purposes of Part 4-10 of the Act. The Schedule also specifies the fees payable in respect of activities carried out under other provisions of the Act. For each item the matter to which the fee relates is specified in column 2, the relevant provision of the Act or regulations that applies is set out in column 3, and the prescribed fee in column 4. These fees have been set based on the expected workload and work input required for each activity. An independent consultancy firm worked with the TGA to develop an "options" model for fees and charges, and the preferred model, as included here, was adopted in consultation with industry. The TGA is a 100% cost recovery organisation. The fees have been set in accordance with the Government's cost recovery principles.

Part 1 tables general fees for the activities provided for in the Act or these regulations.

Part 2 allows for additional fees to be imposed in specific circumstances.

Item 2.1 provides for fees additional to the assessment fee mentioned in item 1.2, 1.3, 1.9 or 1.10 of this Schedule. The additional fee is an amount that reimburses the costs and reasonable expenses of travel for each assessor involved in an assessment activity, including travel both in and outside Australia. It also provides for an amount for assessments to be conducted outside Australia, calculated at the rate of $255 for each hour of preparation by each assessor involved.

Item 2.2 provides for fees additional to those mentioned in paragraph 1.3 (b), 1.9 (c) or (d), or paragraph 1.10 (c) of this Schedule, for an amount that reimburses the costs of testing the relevant kind of medical device, or quality management system, wherever testing is required.

Dictionary

This part contains the definitions of certain words and expressions used in these Regulations, and includes references to certain words and expressions (known as "sign-post definitions") that are defined in the Act or elsewhere in these Regulations. The dictionary only includes a signpost definition for a word or expression that is defined elsewhere in the Regulations if the word or expression is used in more than one regulation.

REGULATION IMPACT STATEMENT

Background

The Government response to the Industry Commission Medical and Scientific Equipment Industries Report of 1997 supported harmonising Australia's regulatory requirements for medical devices with those of the European Commission.

Medical devices encompass a wide range of products such as bandages, syringes, gloves, tampons, condoms, pacemakers, X-ray equipment, surgical lasers, dialysis equipment and baby incubators. The current Australian system for the regulation of medical devices is based on the *Therapeutic Goods Act 1989* (the Act). The Act establishes a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia. The Act is administered by the Therapeutic Goods Administration (TGA).

A number of shortcomings have been identified with the present Australian system for the regulation of medical devices. The current system classifies medical devices into three categories, registrable, listable and exempt according to an arbitrary list contained in the Act. Medical devices have to be included on the Australian Register of Therapeutic Goods (ARTG) before they can be legally marketed in Australia.

Only 12 types of medical devices are currently classified as "high risk" (`registrable') and subject to detailed pre-market evaluation for quality, safety and efficacy. These include pacemakers, heart valves, breast implants and HIV and Hepatitis C in vitro diagnostic test kits.

Presently, manufacturers must hold a Good Manufacturing Practice (GMP) license for all registrable devices and for listable devices that are implantable or sterile, and for a few selected non-sterile devices.

The Industry Commission Report also recommended that the Commonwealth Government should accredit eligible bodies in the public or private sector to assess the conformance of medical devices, their manufacturers and their sponsors, to the therapeutic goods legislation.

This Regulation Impact Statement identifies options for private sector conformity assessment of medical devices.

The Industry Commission suggestion regarding the establishment of a statutory authority for the regulation of medical devices is inconsistent with government policy and is not supportable at this time, and so options have not been identified in this document.

Regulation of medical devices

Problem

The current Australian regulatory requirements for medical devices require amendment to align them with international best practice. In light of this there are a number of identified problems with the current medical device regulatory system the Government is trying to address:

(a) There are numerous examples of medical devices, considered to be high risk, that are not subject to comprehensive assessment for quality, safety and efficacy.

(b) Classification of medical devices is rigidly prescribed in the Regulations, with lists of registrable and listable devices, exemptions and exclusions in Schedules. Consequently the Regulations cannot readily handle technological change, as they have to be amended for each

type of new medical device. New medical devices are treated as listable regardless of their level of risk, until the legislation is amended to re-classify them as registrable, where appropriate.

(c) All other medical devices (`listable') are approved for supply in Australia following a brief assessment of labelling and product information, and, for a limited number of medical devices, compliance with mandatory standards.

(d) There are Australian specific standards for some medical devices, however for many medical devices there are no specific standards under the current regulatory system.

(e) There are critical medical devices, such as surgical lasers and endoscopes, which are currently not required to be manufactured using a quality system (GMP) standard.

(f) Australia's medical device requirements differ from those of our major trading partners. Consequently Australian medical device importers and exporters have to comply with a number of different regulatory regimes, with the attendant increase in compliance costs.

(g) Under current legislation sponsors of a medical device on the Australian Register of Therapeutic Goods are required to report device problems which have caused or may cause serious injury or death. However, it is estimated that only a small percentage of medical device problems are actually reported.

Objectives

In introducing a new regulatory system for medical devices the Commonwealth seeks to address the problems of the current system (as stated above), to allow better protection of public health and timely access to new medical technology, while avoiding excessive and costly restraint on industry.

Alternatives

Several options were considered for the regulation of medical devices to achieve the objectives.

Option A - No regulation

Option B - Retention of the current system

Option C - Adoption of the US FDA regulatory system

Option D - Adoption of an internationally harmonised medical device regulatory system.

Option A would entail totally deregulating the medical devices industry leaving the industry and the protection of public health at the discretion of market forces. Without regulation, it would be possible to market in Australia medical devices that failed to meet overseas regulatory requirements and internationally accepted standards. Before the introduction of legislation regulating medical devices in Australia there were a number of serious problems with medical devices, such as heart valves and intraocular lenses.

Option B would retain the current regulatory system for medical devices.

Option C entails adoption of the United State's Food and Drug Administration regulatory system for medical devices.

This option would entail:

(a) adopting the more stringent USA requirements for product approval for marketing;

(b) adopting a classification of medical devices based on increasing controls required, into classes I, II or III, where the classification is done individually by type;

(c) providing manufacturers no choice of methods to demonstrate product compliance with requirements;

(d) retaining national regulatory control over the supply of medical devices by retaining the Australian Register of Therapeutic Goods; and

(e) establishing a demanding compulsory sponsor postmarket surveillance scheme with a legislative basis.

Option D is the recommended option and entails the adoption of an internationally harmonised medical device regulatory system for medical devices.

This option enshrines the world's best practice for safety, quality and risk management, and provides the capacity to accommodate new technology. The proposed framework would be based on the EC system and adopt the philosophies of the GHTF to introduce the harmonised model agreed by Australia, Canada, the EC, Japan and the United States of America. Industry is an essential player in the development of the Global Harmonisation Task Force (GHTF) recommendations for the regulation of medical devices. It is anticipated the proposed new regulatory system will comprise:

(a) a device classification scheme with pre-market requirements based on risk for each class of device;

(b) essential requirements for quality, safety and performance, based on the intended purpose of the device that must be met before the product can be placed on the market;

(c) options as to how conformity with the essential requirements is assessed - manufacturer quality systems, type testing, and design evaluation;

(d) use of international harmonised standards as a means to demonstrate conformance;

(e) comprehensive manufacturer post market surveillance and adverse incident reporting program;

(f) appropriate regulatory controls will be maintained over the manufacturing process; and

(g) the ARTG would remain the central point of control for the legal supply of medical devices in Australia.

Australia will not automatically adopt decisions taken in other countries (including the EC) relating to the regulation or the conformity assessment of medical devices. This is in line with recommendations of both the Baume review and the 1996 TGA Review.

Impact Analysis

Option A

The option of having no regulation for medical devices is not appropriate because it would place public health at an unacceptable risk. For example, prior to the development of the current Act there was a major problem with the Bjork-Shilley heart valves, which caused the death of several

Australians; this was due to a manufacturing/design defect which caused the leaflets of the valve to fracture. It should be noted that most developed countries regulate medical devices to protect public health.

Impact on Consumers

(a) No guarantee of the safety, quality and efficacy of medical devices in Australia.

Impact on Business

(a) Sole responsibility for the safety, quality and efficacy of medical devices.

(b) Reduced public confidence in Australian made medical devices,

(c) No evaluation fees or annual charges.

Impact on Government

(a) Criticism for abrogating responsibility to uphold public health and safety.

Option B

Retaining the current system would have no new impact on consumers or business. However this option would not address the problems (see Problem) identified in the current system. By retaining the current system Australia would not gain the benefits of an internationally harmonised system, and thus not come into line with international best practice.

Impact on Consumers

(a) Current system does not allow timely full assessment of all high risk devices, especially new technologies.

Impact on Business

(a) Australian specific requirements resulting in products having to undergo at least two assessment procedures for entry into overseas markets.

Impact on Government

(a) Public health risks due to the lack of appropriate assessment of medical devices.

(b) Need to respond to the Industry Commission Report.

Option C

The US FDA option is not considered an appropriate way to address Australia's problems with the current devices regulation system. The current Australian evaluation requirements are generally modelled on the USA system with less assessment for listable devices. The USA is actively involved in the GHTF and is starting to adopt a more harmonised system of regulation for medical devices. The USA system has complex assessment procedures and is thus highly resource intensive.

Impact on Consumers

(a) Increased costs due to resource intensive system.

(b) Delays in availability of new products.

Impact on Business

(a) Increased costs due to resource intensive system

(b) the USA system provides manufacturers with no choice of methods to demonstrate product compliance and therefore provides less flexibility for industry compliance; and

(c) the USA system has a demanding compulsory post-market surveillance scheme with a legislative basis, which places the onus on industry.

Impact on Government

(a) Increased resources.

(b) If the USA system changes in light of global harmonisation then Australia will again have a unique system.

Option D

Impact on Consumers

(a) Improvement in Public Health as all medical devices must comply with the essential principles for quality, safety and performance on a risk based assessment;

(b) Greater confidence in the quality and safety of high risk devices;

(c) More consumer protection as a wider range of devices would be subject to premarket requirements and postmarket surveillance;

(d) Capacity to accommodate new technology at an appropriate level of risk classification.

(e) Potentially higher costs for some products.

Impact on Business

(a) Easier and faster introduction of new products that have been assessed in the EC onto the Australian market.

(b) Savings due to streamlined process and less delay in placing products on the market;

(c) Savings resulting from greater flexibility in the choice of routes to conformity assessment;

(d) Savings due to elimination of Australian specific requirements;

- reduced costs associated with exporting to EC;

- reduce costs as EC approved products can be introduced to the market;

(e) Will facilitate Australian exports;

(f) Economies of scale resulting from the ability to access larger markets;

(g) Some manufacturers may face costs of implementing a quality systems approach to manufacturing;

(h) Possible additional costs to Australian manufacturers who do not export;

(i) Some medical devices, currently exempt, would have to be to be registered on the ARTG;

(j) Due to the TGA's 100% cost recovery policy there will be a review of fees and charges.

Impact on Government

(a) Fulfil responsibilities to public by the greater protection of public health;

(b) Current system inadequacies are addressed;

(c) Conformity assessment resources focussed more appropriately due to provision for classification of new devices without need for legislative amendments;

(d) Potentially faster notification of device problems and recalls due to improved capacity to share information with overseas regulatory agencies;

(e) Active involvement of Australian government in global discussions and strategies for regulation of medical devices in an environment of increasing harmonisation and reduction in trade barriers.

(f) Costs incurred in the implementation of a new regulatory system: staff training, administration changes, legal amendments, communication/education campaign for stakeholders.

Conclusion and recommended option for the regulation of medical devices

There are a number of identified problems with the current Australian system for the regulation of medical devices. It is recommended that Option D be adopted to address these problems. Option D would bring Australian regulatory requirements for medical devices into line with international best practice. The other options do not offer a method of addressing the problems with the current system, do not offer an appropriate means of removing Australian specific requirements, do not allow improved access to high quality and safe medical devices and do not allow Australia to move to a more internationally harmonised regulatory system for medical devices.

Conformity assessment of medical devices

Background/problem

Medical devices impact on public health and safety. There is a prima facie case for Government regulation of the conformity assessment of medical devices. This regulation can be of assessment by government agency or private sector. The latter occurs in the EU, where competition is allowed between third party conformity assessors which are regulated by government agencies.

Alternatives

The alternatives for the conformity assessment of medical devices, as broadly outlined in the independent Monash University Report `An Economic Analysis of Proposed Changes to the Conformity Assessment of Medical Devices', are as follows:

1 Conformity assessment of all medical devices to be undertaken by the private sector;

2 Conformity assessment of all low to medium risk medical devices to be undertaken by the private sector, and conformity assessment of all high risk medical devices to be retained by the TGA; and

3 Conformity assessment of all medical devices to be retained by the TGA.

The parties affected by the options for the conformity assessment of medical devices are the TGA, potential private sector assessors, medical device manufacturers and consumers.

Option 1

Costs

The Monash University study broadly found that the market for private sector pre-market evaluation of medical devices was, at best, very small and was therefore not financially viable in Australia as the total estimated conformity assessment market in Australia is between $A390,000 and $A1.3 million per annum.

The study found that:

"The potential cost savings were therefore found to be very modest, estimated to be between only $22,00 and $117,000 per year. Even allowing the potential size of the private sector market to be presented in a very optimistic light, cost savings would almost certainly be less than $100,000 per year." [*An Economic Analysis of Proposed Changes to the Conformity Assessment of Medical Devices, 1999]*

The Monash study sought to quantify the opportunity costs of public health:

"Literature based estimates of the value of reduced mortality risk suggest that there would need to be savings in excess of $3,000,000 per year if there was an expectation of one additional death a year as a result of any (regulatory) changes." [*An Economic Analysis of Proposed Changes to the Conformity Assessment of Medical Devices, 1999]*

As well as the additional costs of accreditation and auditing of the private sector, questions have been raised as to whether private sector expertise is available in Australia for the conformity assessment of medical devices.

The study concluded that the potential risks to public safety in moving to private sector conformity assessment in Australia did not justify the very small potential savings that may be achieved.

"The overriding and decisive consideration is the trivial magnitude of the potential benefits from regulated competition, and the likelihood that these would be very quickly exceeded by even a modest increase in administrative costs. Loss of scale economies, private sector failure to deliver the product, or increased mortality and/or morbidity would result in a large net loss from the introduction of regulated competition." [*An Economic Analysis of Proposed Changes to the Conformity Assessment of Medical Devices, 1999]*

It should be noted, however that some growth in assessment activity may arise as a result of the proposed changes. For example, the adoption of the harmonised model based on the EU system would result in a wider range of medical devices being subject to comprehensive premarket assessment and postmarket monitoring and more manufacturers being required to comply with quality systems. This may increase the size of the potential assessment market for conformance of medical devices.

Benefits

Competition may result in efficiency benefits such as delivery of conformity assessment services in a cost effective and timely manner, however this can not be quantified at this point.

While there is some doubt about a local market in assessors, EU assessors are potentially available.

Option 2

Costs

The Monash University study broadly found that the market for private sector pre-market evaluation of medical devices was, at best, very small and was therefore not financially viable in Australia:

(a) the total estimated conformity assessment market in Australia is between $A390,000 and $A1.3 million per annum;

(b) the estimated conformity assessment market for high risk products is between $A136,000 and $A725,000 per annum; and

(c) the estimated conformity assessment market for low risk products is between $A254,000 and $A571,000 per annum.

See Option 1 for further information.

Benefits

As for Option 1, although limited to the low risk segment of the market.

Option 3

This option involves TGA retaining the conformity assessment of all medical devices.

As well as the additional costs of accreditation and auditing of the private sector, questions have been raised as to whether private sector expertise is available in Australia for the conformity assessment of medical devices. The peak industry body in this sector (the Medical Industries Association of Australia) believe that:

"there is insufficient work available to sustain an industry of notified bodies in Australia (and) we do not believe that the academic community in Australia would have the experience in industry that would be a required background for the assessment of manufacturing portions of submissions". [*MIAA response to An Economic Analysis of Proposed Changes to the Conformity Assessment of Medical Devices, 1999]*

At the same time, the Industry Commission report points out that conformance bodies currently operating elsewhere may be interested in operating in Australia. There may also be Australian organisations which assess products other than medical devices that might be interested in evaluating medical devices.

Consumer representatives have also expressed concern about the use of private sector conformity assessment organisations for pre-market assessment. Consumers therefore support the TGA continuing to conduct all evaluation of medical devices in Australia.

Conclusion and recommended option for the conformity assessment of medical devices

In order to maintain public confidence and safety, and given that the benefits of using the private sector do not outweigh the attendant risks, the pre-market conformity assessment of medical devices should continue to be undertaken by the TGA at this stage, subject to Cabinet endorsement. A review of the conformity assessment contestability issue should be performed within 5 years of the date of implementation to examine any changed circumstances.

Consultation

The consultation process on the proposal for the new harmonised medical device regulatory system has involved a number of elements.

These elements include:

(a) Industry surveys on the likely cost impact of the proposal, including one by an independent body;

(b) A working party called the Medical Devices European Harmonisation Working Party, established to provide stakeholder views and advice to the TGA, was convened with representatives from Medical Industry Association of Australia, Australian Dental Industry Association, Consumers Health Forum, an Australian manufacturer, State government and the Department of Industry, Science and Resources;

(c) Articles have been published in the Australian Therapeutic Device Bulletin and the TGA News. These publications are distributed to industry and other stakeholders;

(d) Presentations have been given to industry and professional bodies.

(e) An information paper, for comment, sent out to medical device industry groups and appropriate health professional organisations.

(f) Papers have been presented to a number of ministerial advisory and Commonwealth / State liaison committees, such as Therapeutic Devices Evaluation Committee (TDEC), Therapeutic Goods Committee (TGC), National Coordinating Committee on Therapeutic Goods (NCCTG) and Australian Health Ministers Advisory Committee (AHMAC).

To date both industry and consumers have been supportive of the proposal to move to a new harmonised regulatory system for medical devices. Comments made during the consultations were taken into account and changes made where appropriate.

Consumers have welcomed the move to improve the standard and availability of medical devices in Australia including the prospect of lower prices achieved through a reduction in regulatory duplication. However, representatives have expressed concern about the use of private sector conformity assessment organisations for pre-market assessment. Consumers therefore support the TGA continuing to conduct all conformity assessment of medical devices in Australia.

Implementation, Monitoring and Review

It is proposed that all medical devices currently entered on the ARTG be given 5 years to meet the new requirements. At the end of this period they have to meet requirements or be removed from the ARTG. All new applications for entry on the ARTG have to meet the new requirements. Products also have to meet the postmarket problem reporting requirements.

The new legislation will be monitored closely by the TGA in cooperation with industry and consumers through TDEC, TGC, and NCCTG.

An interim review to highlight any major deficiencies or problems will be performed by a working party and where appropriate, will make recommendations for implementing change. The review will allow fine-tuning of the proposal during its early phase of implementation.

A later, more substantive review will be performed by a working party. The criteria (for example the timely availability of medical devices) for the review will be developed before the implementation of the harmonisation proposal. The review will involve wide consultation with key stakeholders.

A review of the conformity assessment contestability issue should be performed within 5 years of the date of implementation to examine any changed circumstances.

Regular review of the effectiveness of a reformed regulatory scheme will also be effected through TGA's strong advisory/expert committee structure (which includes TDEC, TGC, NCCTG and the TGA-Industry Consultative Committee (TICC)), regular reporting to the public through annual reports, and other consultative arrangements already in place.

Information Strategy

An information strategy to ensure that both providers and users of medical devices are able to access details regarding the new arrangements will include:

(a) Media announcement by Minister;

(b) Mail out to all industry groups and sponsors;

(c) Article in Therapeutic Device Bulletin and TGA News;

(d) Information on TGA internet site; and

(e) Information seminars.