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**Therapeutic Goods Amendment (Medical Devices)
Bill 2001**

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I N F O R M A T I O N A N D R E S E A R C H S E R V I C E S

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No. 149 2000–01

Therapeutic Goods Amendment (Medical Devices) Bill
2001

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7 June 2001

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Therapeutic Goods Amendment (Medical Devices) Bill 2001

Date Introduced: 29 March 2001

House: House of Representatives

Portfolio: Health and Aged Care

Commencement: Schedule 1 commences on Proclamation, or 6 months after Royal Assent, whichever is the earlier. Schedule 2 commences five years after Schedule 1 commences.

Purpose

To introduce a comprehensive new system for the classification, risk management assessment and approval of medical devices.

Background

Current regulation of therapeutic devices

The *Therapeutic Goods Act 1989* establishes a uniform national system of controls on the availability within Australia of therapeutic goods. Therapeutic goods are divided broadly into two classes - medicines and therapeutic devices. The current legislation employs the terminology 'therapeutic devices', whereas the Bill uses the term 'medical devices'. *Medicines* include items such as prescription medicines and vaccines, non-prescription medicines including vitamins and sunscreens, and traditional or alternative medicines such as herbal products, aromatherapy and homeopathic products. *Therapeutic devices* include a wide range of products such as pacemakers, heart valves, medical gloves, bandages, syringes, condoms, contact lenses, X-ray equipment, heart rate monitors, surgical lasers, dialysis equipment, and baby incubators.¹

There are currently about 24,000 product entries on the Register for medical devices. The Australian medical devices industry was valued at \$1.5 billion in 1996,² and represents approximately one per cent of the global market. Approximately 90 per cent (by dollar value) of medical devices used by Australians are imported.³

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Currently, the same regime of registration or listing, and the same manufacturing standards apply to both medicines and therapeutic devices. Under the legislation, therapeutic goods may be imported into, supplied in, or exported from, Australia only if they fall into one of four categories:⁴

- goods ‘registered’ on the Australian Register of Therapeutic Goods (the Register), which have been assessed as having a higher level of risk and require rigorous and detailed examination and evaluation by the Therapeutic Goods Administration (TGA) for quality, safety and efficacy⁵
- goods ‘listed’ on the Register, which are generally lower risk products⁶
- goods ‘exempt’ from the registration and listing process (generally, drugs requested by a medical practitioner to treat terminally ill patients,⁷ or drugs imported for personal use under the Personal Import Scheme⁸) or
- goods given a specific approval or authority by the Secretary of the Department, which do not have to undergo registration or listing.⁹

The system is administered by the TGA, which maintains the Register and assesses applications for registration or listing.

Harmonisation with Europe

On 24 June 1998 Australia signed the Mutual Recognition Agreement with the European Community (the EC MRA). The EC MRA is a binding bilateral treaty that covers a number of industry sectors which are subject to government regulation and conformity assessment, including the medical device sector. It permits conformity assessment (testing, inspection and certification) of medical devices traded between Europe and Australia to be undertaken in the exporting country rather than requiring it to be carried out in the importing country.¹⁰

The EC MRA does not require the harmonisation of Australian and European technical regulations, nor does it involve recognition of each other’s standards. It merely requires that Australia will accept statements that designated conformity assessment bodies in the European Community have checked that products comply with Australian standards, and vice versa.¹¹ The aim of this is to facilitate trade by allowing testing for compliance with both European and Australian standards to be carried out simultaneously, rather than require multiple testing and certification. The accuracy of these conformity assessment procedures can still be monitored by post-market surveillance programs.

In July 1998, in response to the Industry Commission report on the *Medical and Scientific Equipment Industries*, the Minister for Industry, Science and Tourism announced the Government’s intention to harmonise the regulation of medical devices with the regulatory standards of the European Union.¹²

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At the same time as pursuing harmonisation with Europe, Australia has been a principal member of a broader project, the Global Harmonisation Task Force for medical devices. The Task Force comprises Australia, the European Community, the USA, Canada and Japan.¹³ The European system is the basis for the new global model being developed by the Task Force.¹⁴

The Bill

This Bill aims to introduce a new system for regulation of medical devices, incorporating elements of the European Community's regulatory requirements. The European regulatory system is considered to be world's best practice and 'is being adopted by many comparable countries'.¹⁵ It is envisaged that the new system will be comprehensive and integrated, dealing with the classification of medical devices, the essential principles for safety and performance with which all medical devices must comply, conformity assessment procedures, manufacturing standards, post-market surveillance and monitoring. The new system will also apply to medical devices which are not covered by the European Community's medical device legislation, such as tampons and hospital and commercial grade disinfectants.¹⁶ The Bill will not affect the existing system governing medicines.¹⁷

The harmonisation is aimed at achieving:¹⁸

- a reduction in unnecessary or duplicatory regulation, with associated
 - price benefits for consumers from reducing regulatory costs, and
 - competitiveness for Australian manufacturers in international markets,
- faster access for consumers to new medical devices as they come onto the world market, and
- confidence in the safety and efficacy of medical devices, arising from the comprehensive quality and performance requirements which will be applied to all medical devices used in Australia.

Since 1998, the proposed new scheme for regulating medical devices has been the subject of extensive consultation with consumers, the medical devices industry, professional groups and the States and Territories. According to the second reading speech, there is 'strong support for the proposed new regulatory reforms amongst all these groups.'¹⁹

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Main Provisions

The *Therapeutic Goods Act 1989* has been restructured into Chapters and Parts. This has necessitated changing a number of headings and cross-references in the Act,²⁰ but has not effected any substantive change to the existing regulatory regime. The Register will continue to exist,²¹ although the sections dealing with it will be grouped together in a new Chapter 2 and renumbered.²² A number of other amendments reflect changes in terminology, for example adding references to ‘inclusion’ in the Register in addition to ‘registration’ or ‘listing’.²³

The new scheme for regulating medical devices will be in a separate Chapter of the Act, Chapter 4 (**inserted by item 59 of Schedule 1**). The current standards, registration and listing procedures, and manufacturing requirements for therapeutic goods will continue to apply to medicines, but will not apply to medical devices (**proposed section 10A, subsection 15A(1) and section 33A**). However, the current arrangements will continue to apply to medical devices during the transitional period. The transitional provisions are described below.

Throughout this digest, reference has been made to the Exposure Draft of the Therapeutic Goods (Medical Devices) Regulations 2001 (‘the Draft Regulations’), as the regulations have a significant role to play under the proposed new scheme in supplying much of the regulatory detail.

Reference is also frequently made to the role and powers of the TGA, although technically both the *Therapeutic Goods Act 1989* and the Bill confer functions and powers on the ‘Secretary’. In practice, these functions are usually exercised by the TGA rather than the Secretary.²⁴

What is a ‘medical device’?

A complex definition of ‘*medical device*’ is provided in **proposed section 41BD**. The definition is similar to the current definition of ‘therapeutic device’, although it now focuses on the purpose for which devices are intended to be used. Devices will fall within the definition if their purpose is the:

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

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The intended use can be ascertained by looking at the label, instructions for use or advertising of the device (**proposed subsection 41BD(2)**).

An accessory to a medical device will be a medical device in its own right (**proposed paragraph 41BD(1)(b)**).

Other definitions included in the new scheme are based on the definitions in the European Community's medical device directives.²⁵

Classification scheme for medical devices

Currently, there are only two classes for therapeutic devices – registrable and listable. Under the Bill, medical device classifications will be set out in the regulations (**proposed section 41DB**). The Draft Regulations propose five medical device classifications: Class I, Class IIa, Class IIb, Class III and Class AIMD (active implantable medical devices).²⁶

Under the detailed system of classification rules set out in Schedule 2 of the Draft Regulations, classification will be according to the degree of risk posed by use of the device, which in turn depends on criteria such as:

- the level of its invasiveness of the body,
- the duration of use of the medical device, and
- contact with the central nervous or circulatory system.

There are particular rules for the classification of invasive and implantable devices, active medical devices (those that are powered by electricity or another energy source), and some specific types of medical devices, such as contraceptives, blood bags, disinfectants and devices containing animal tissue or derivatives.

The following examples give some indication of the types of medical devices which will be covered by each of the proposed classifications:²⁷

- **Class I** – low risk devices which are non-invasive, or invasive and for transient use,²⁸ such as hospital beds, walking aids, wheelchairs, simple surgical and dental instruments such as scalpels and manual drills, examination gloves, gauze dressings and stethoscopes;
- **Class IIa** – intermediate risk medical devices, including devices which are invasive and for short-term use,²⁹ such as hearing aids, dental filling materials, ECG machines, hospital grade disinfectants, and devices for storage and transport of organs, cornea, sperm and embryos;
- **Class IIb** – intermediate risk medical devices, including some invasive or implantable devices, such as baby incubators, external pacemakers, surgical lasers, ventilators,

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haemodialysers, condoms, contraceptive diaphragms, blood bags, healing wound dressings, contact lens care products and instrument grade disinfectants;

- **Class III** – high risk devices, including surgically invasive devices and animal-derived products, such as absorbable sutures, heart valves, vascular prostheses and stents, condoms with spermicides and IUDs; and
- **AIMDs** – implantable pulse generators, implantable electrodes and implantable drug infusion devices.

The Government has also indicated that it proposes to include *in vitro* diagnostic products – which include pathology tests – in the new regulatory system within the next couple of years. The TGA will continue to consult with stakeholders on this issue.³⁰ There will be a small number of products, which are specifically excluded by the European Community directives, which would not be regulated as medical devices under the proposed system.³¹

The Government claims that under the new classification system there will be more medical devices categorised in the high risk classes, resulting in ‘better coverage and scrutiny of these important, often highly invasive medical devices’.³² Certainly, almost³³ all of the medical devices that are currently required to be registered will be classified either as AIMDs,³⁴ Class III³⁵ or Class IIb.³⁶ In addition, a number of devices that currently do not require registration will be included in Classes IIb and III.

Quality and safety standards

The Bill proposes mandatory safety standards, known as ‘essential principles’, and mandatory quality assurance standards, known as ‘conformity assessment procedures’. Compliance with both will be required before a medical device may be considered for inclusion on the Register. In addition, there are non-compulsory standards for safety – ‘medical device standards’, and for quality control – ‘conformity assessment standards’.

Safety standards – ‘essential principles’ and ‘medical device standards’

According to the Government, under the current regime ‘only 50 per cent of manufacturers are required to meet quality systems standards’.³⁷ All registrable and some listable therapeutic devices must demonstrate compliance with quality or safety standards, which are specified either in the regulations³⁸ or in Therapeutic Goods Orders issued by the Minister.³⁹ However, for many therapeutic devices there are presently no applicable standards.⁴⁰

Under the Bill, by contrast, it is proposed that manufacturers of all medical devices will be required to meet certain general standards for safety and performance, which will be called ‘*essential principles*’. These principles will be contained in the regulations (**proposed section 41CA**). The current draft contained in Schedule 1 of the Draft Regulations sets the principles at a high level of generality. For example:

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- medical devices should be designed and manufactured in a way that ensures that their use will not compromise the health and safety of patients,
- design and construction of medical devices must conform with safety principles,
- medical devices should be safe to use for the full period of use indicated in the instructions,
- medical devices should be fit for their intended purpose, and
- the benefits of using medical devices should outweigh any undesirable side effects.

In addition to these, the Minister may issue ‘*medical device standards*’ for particular kinds of medical devices.⁴¹ These standards will be published in the *Gazette* and will be disallowable instruments (**proposed section 41CB**). The standards may be, but need not be, specified by reference to certain British, European, United States or international standards (**proposed section 41CC**). Compliance with the medical device standards will not be mandatory, but will be a way of demonstrating conformity with the essential principles (**proposed subsection 41BH(2)**).⁴²

Quality control – ‘conformity assessment procedures’

Although the Minister has power to determine manufacturing principles, including quality assurance and quality control procedures,⁴³ under the existing system the majority of listable therapeutic devices are exempt from compliance with these manufacturing standards. Only registrable and certain types of listable therapeutic devices must comply with manufacturing standards.⁴⁴

Under the Bill, the manufacturer or sponsor of all medical devices will have to demonstrate that appropriate quality management procedures have been applied during the manufacture of a medical device before it can be included on the Register (**proposed paragraph 41FD(f)**). These procedures are known as ‘*conformity assessment procedures*’, and will be contained in the regulations (**proposed subsections 41DA(1) and (2)**).

Quality management systems for the manufacture of medical devices will be the focus of the conformity assessment procedures. The regulations may provide a mechanism for certification of compliance with either the essential principles or the quality management systems, and may permit manufacturers to declare, and/or to place a mark on devices indicating that conformity assessment procedures have been applied to the devices. The regulations may also deal with monitoring of design, manufacturing and performance of medical devices, record-keeping, notification of changes in design or quality management and corrective action (**proposed subsection 41DA(4)**).

The conformity assessment procedures may apply to a number of medical device classifications, or only to a particular classification, or even to a particular kind of medical

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device or manufacturer (**proposed subsection 41DA(3)**). There are currently no regulations in the Draft Regulations dealing with conformity assessment. However, the Government's information indicates that different levels of conformity assessment will apply to different classifications of medical device, ranging from self-assessment for Class I, to full comprehensive quality assessment for Classes IIb, III and AIMD.⁴⁵

The Minister may also issue '*conformity assessment standards*' for quality management systems for particular kinds of medical device. Although compliance with these standards will be optional, a medical device manufactured in accordance with a quality management system which complies with the conformity assessment standard will be treated as having complied with the applicable conformity assessment procedure (**proposed section 41BI**).⁴⁶ These standards will be published in the *Gazette* and will be disallowable instruments (**proposed section 41DC**).

Pre-market assessment of medical devices

Under the current regulatory system, only registrable therapeutic devices (of which there are 12) require detailed pre-market assessment by the TGA prior to registration and entry on the Register. This assessment evaluates the quality, safety and efficacy of the goods, conformity with any applicable standards, manufacturing and quality control procedures and presentation.⁴⁷ The TGA conducts a much briefer assessment of the quality and safety of listable therapeutic devices, based on labelling and product information supplied by the manufacturer or sponsor in the application for listing.⁴⁸ The Government contends that there 'are numerous examples of high risk technologies that are not subject to comprehensive pre-market assessment.'⁴⁹

The Bill contains flexible options for pre-market assessment of medical devices. It will be mandatory for all medical devices to be certified to comply with the essential principles and conformity assessment procedures. Applications may be subject to audit prior to inclusion on the Register. In addition, certain high-risk classes of medical devices may be required to obtain a conformity assessment certificate from the TGA prior to inclusion on the Register.

Inclusion on the Register

The Register, which is currently divided into two parts, will be divided into three parts (**proposed subsection 9A(3)**):

- the existing part for *registered* therapeutic goods, including some therapeutic devices during the transitional period,
- the existing part for *listed* therapeutic goods, including some therapeutic devices during the transitional period, and
- a new part for medical devices '*included*' in the Register.

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All classes of medical devices will be required to be ‘included’ on the Register. The applicant for inclusion of a kind of medical device must, among other things (**proposed section 41FD**):

- certify that the devices comply with the essential principles for safety and performance,
- certify that an appropriate conformity assessment procedure has been applied to the devices,
- either hold information to substantiate compliance with the essential principles and application of conformity assessment procedures, or have a procedure in place to obtain this information from the manufacturer, and
- if the medical devices are marketed in Australia, also comply with any applicable advertising requirements.

The TGA must include a kind of medical device on the Register if an effective application is made, accompanied by a document certifying the required matters, unless the application has been selected for audit (**proposed section 41FF**). A unique ‘*device number*’ is assigned to each kind of medical device which is included in the Register (**proposed section 41FL**).

Auditing of applications

Auditing of applications will be mandatory for kinds of medical device prescribed in the regulations, and at the TGA’s discretion in all other cases (**proposed section 41FH**). Although there are currently no regulations made under the existing equivalent of this provision, the Government has indicated that a ‘quality systems audit’ will be mandatory prior to inclusion on the Register of any Class III or AIMD medical device, and ‘some form of production audit or sample examination’ will be required prior to inclusion of Class IIb devices.⁵⁰

The audit may consider whether the application complies with the formal requirements, and whether the matters certified are in fact correct (**proposed section 41FI**). If the TGA is satisfied on all aspects of the audit, the kind of medical device must be included in the Register (**proposed subsection 41FI(2)**). But if the application does not satisfy the Secretary in all respects, the kind of medical device cannot be included in the Register (**proposed subsection 41FI(3)**).

Conformity assessment certificates

The TGA has power to issue ‘*conformity assessment certificates*’ on application and payment of the prescribed fee (**proposed section 41EB**). When the regulations so provide, a conformity assessment certificate must be obtained before a person applies to have a kind of medical device included on the Register (**proposed section 41EA**). If a conformity

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assessment certificate is required, this would mean that international conformity assessment pursuant to a mutual recognition agreement between Australia and the other country would not on its own be sufficient to warrant inclusion on the Register. An applicant would have to obtain a conformity assessment certificate from the TGA, in addition to complying with the essential principles and applying the relevant conformity assessment procedures.

Currently there are no Draft Regulations making conformity assessment certificates mandatory. The Government has indicated that this provision can be used to require full pre-market assessment by the TGA of certain high risk devices, such as products that may contain contaminated animal material, such as bovine-sourced material from countries identified as having mad cow disease.⁵¹

In determining whether to issue a certificate, the TGA must consider whether the applicant has complied with the conformity assessment procedures relating either to the application of quality management systems or to the certification of compliance with the essential principles. The TGA must also consider any other matters prescribed by the regulations (**proposed section 41EC**). The TGA may also require an inspection of the manufacturing premises before determining whether to issue a certificate (**proposed subsection 41EB(4)**).

Exemptions

Three classes of exemptions from the requirement that medical devices be included in the Register are proposed. These directly parallel the existing exemptions for therapeutic goods. Kinds of medical devices will be exempt from inclusion in the Register if they are:

- listed in the regulations as exempt (**proposed section 41HA**). This provision will cover use of medical devices to treat terminally ill patients, or importation for personal use under the Personal Import Scheme⁵²
- given written approval by the TGA to be used for special treatment or experimental purposes (**proposed section 41HB**). This provision will permit medical devices to be included in a scheme covered by a ‘clinical trial approval’ or a ‘special treatment approval’,⁵³
- covered by an ‘authorised prescriber authority’ given by the TGA to a medical practitioner (**proposed section 41HC**).⁵⁴

Exemptions may be subject to conditions, and may apply only to specified classes of persons. Currently, no exemptions are listed in the Draft Regulations.

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Post-market monitoring

The Bill provides for a wide range of post-market mechanisms to enforce compliance with safety and quality control standards. These range from administrative arrangements, such as the production of documentation, random inspections and sampling, and notification of adverse events, through to administrative sanctions such as suspension or cancellation of a conformity assessment certificate or even of inclusion in the Register.

Inspection, sampling and testing

All kinds of medical devices included on the Register will be subject to a condition that the person who obtained inclusion on the Register submit to inspections and sampling of the devices by authorised persons as required (**proposed section 41FN**). This is also a condition imposed on the manufacturers of all kinds of medical devices which hold conformity assessment certificates (**proposed section 41EJ**). This condition parallels an existing condition applicable to all registered or listed therapeutic goods.⁵⁵

The existing powers of entry, search and seizure which apply to therapeutic goods will also cover medical devices, whether included in the Register or exempt from inclusion.⁵⁶

Obtaining information

The provisions relating to production of information and documents, including the offences of non-compliance, closely parallel existing provisions relating to registered or listed therapeutic goods. Curiously, the maximum penalties applicable to offences relating to medical devices are considerably lighter than those which are currently applicable to and will continue to apply to therapeutic goods. This is discussed below.

All kinds of medical devices included on the Register will be subject to a condition that the person who obtained the inclusion produce documentation relating to the device or the quality management system, if required (**proposed paragraph 41FN(1)(b)**). This is also a condition imposed on the manufacturers of all kinds of medical devices that hold conformity assessment certificates (**proposed section 41EJ**).⁵⁷

In addition, once a medical device is included on the Register, the person who obtained the inclusion must at all times maintain sufficient documentation (or a procedure to obtain such documentation from the manufacturer) to demonstrate compliance with the essential principles and application of the conformity assessment procedures, and give the information to the TGA if required (**proposed subsection 41FN(3)**).⁵⁸

Reinforcing these conditions, the TGA has explicit statutory power to require information or documents to be provided by applicants for, or holders of, a conformity assessment certificate, applicants for inclusion in the Register, and sponsors of a device included in the Register (**proposed section 41JA**).⁵⁹ The information required may relate to:

- compliance with the essential principles,

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- application of the conformity assessment procedures,
- compliance with conditions imposed on a conformity assessment certificate,
- compliance with applicable advertising regulations, or
- whether the kind of medical device is still being supplied in, imported into or exported from Australia.

The TGA also has power to require information or documents to be provided in relation to the supply, handling, monitoring of and results of the supply of kinds of medical devices which are exempt for any one of the three reasons described above (**proposed sections 41JD, 41JE, and 41JF**).⁶⁰

It is an offence to fail to provide information as and when required (**proposed subsections 41JB(3) and 41JG(3) and (4)**). The maximum penalty is \$3 300. This fine is lower than the maximum \$6 600 applied to the parallel offence which already exists in relation to therapeutic goods.⁶¹

It is also an offence to provide false or misleading information or documents (**proposed subsection 41JB(4) and proposed sections 41JH and 41JI**). The maximum penalty is \$6 600. This penalty is considerably lighter than the maximum sentence of 12 months imprisonment which applies to the parallel offences which already exist in relation to therapeutic goods.⁶² No explanation is provided for the lighter penalty.

It is a defence to a charge of providing false or misleading documents if the document is accompanied by a statement setting out the particulars in which the information is false or misleading (**proposed subsection 41JI(2)**).⁶³ This defence only applies to the provision of documents, not of information.

A person cannot refuse to provide information or documents on the ground of potential self-incrimination. However, any information provided cannot be used against the person in any criminal proceedings, except for the offence of providing false or misleading information (**proposed sections 41JC and JJ**).⁶⁴

Public notification and recall

The TGA will have power to require public notification and/ or recall of kinds of medical devices which have been supplied when they did not comply with the requirements of the Bill. This may be because of non-compliance with the essential principles, non-application of the conformity assessment procedures, suspension or cancellation from the Register (**proposed section 41KA**). Any requirements imposed under this provision must be notified in the Gazette as soon as practicable (**proposed section 41KB**).

This power is a new power not currently possessed in relation to therapeutic goods generally.⁶⁵ It is an offence, punishable by a fine of up to \$6 600, to contravene this requirement (**proposed section 41KC**).

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Notification of adverse events

Manufacturers and sponsors must report adverse events involving their medical devices within specified time frames. A person who has obtained the inclusion of a kind of medical device in the Register must notify the TGA of any information (**proposed subsection 41MP(2)**):

- relating to any malfunction, deterioration, design, manufacture or labelling inadequacy, or use of a kind of medical device which may lead to death or a serious deterioration in the health of a patient or user of the device,
- relating to a technical or medical reason for a malfunction or deterioration which has led the manufacturer to recall the kind of devices,
- that indicates that a device of that kind does not comply with the essential principles, or
- that indicates that a certificate of compliance with the essential principles or application of the conformity assessment procedures has been restricted, suspended, or revoked.

It is an offence not to notify the TGA of any of these adverse matters within the period specified in the regulations (**proposed subsection 41MP(1)**). Although the Draft Regulations do not specify the time frames, the Government has indicated that the proposed maximum time allowed before providing an initial report would be 10 days after the manufacturer first becomes aware of a serious problem.⁶⁶ The maximum penalty is a fine of \$44 000, as it is for the comparable offence relating to therapeutic goods.⁶⁷ A person must provide information concerning each occurrence of an adverse event, not just the first of such incidents.

The TGA may require notification of any such information even if a person has withdrawn an application for inclusion on the Register or allowed the application to lapse. It is an offence not to provide any information a person is aware of, or to provide false or misleading information. The maximum penalty for this offence is also \$44 000 (**proposed section 41MQ**).⁶⁸ This is also identical to the maximum penalty imposed for the parallel offence relating to therapeutic goods.

Other administrative arrangements for conformity assessment certificates

All conformity assessment certificates are subject to a condition that the manufacturer cooperate in a review to determine whether the conformity assessment procedures relating to the application of quality management systems, certification of compliance with the essential principles, or other matters prescribed by the regulations have been applied. The holder of a conformity assessment certificate must also notify the TGA in writing of any plan for substantial changes to the quality management systems, product range or product

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design of the kinds of medical devices covered by the certificate (**proposed subsections 41EJ(2) and (3)**).

The TGA may impose other conditions on a conformity assessment certificate or on inclusion in the Register, either at the time (**proposed sections 41EK and 41FO**) or at any time after issue (**proposed sections 41EL and 41FP**).

The TGA has power to suspend a conformity assessment certificate for up to six months if it is satisfied that there are likely to be grounds for revoking the certificate (**proposed section 41EM**). Unless suspension is immediately necessary to prevent imminent risk of death, serious illness or serious injury, the TGA must give written notice of the reasons for the proposed suspension and give the person a reasonable opportunity to make submissions (**proposed section 41EN**). The suspension must be revoked if the ground on which it was issued no longer applies, and there is no other ground for suspension (**proposed section 41EP**).

The TGA must revoke a conformity assessment certificate if it has been suspended and the period of the suspension expires and there remain grounds for revocation which have not been addressed (**proposed section 41ER**). The TGA also has discretion to revoke a conformity assessment certificate⁶⁹ without first suspending it if (**proposed section 41ET**):

- the relevant conformity assessment procedures have not been applied to the kind of medical devices,
- the manufacturer refuses or fails to comply with a condition of the certificate,
- the certificate holder fails to provide the TGA with information relating to a kind of medical device or quality management system after being required to, or
- the manufacturer no longer manufactures any of the kinds of medical devices covered by the certificate.

Suspension of a conformity assessment certificate is significant, as it may lead to suspension of a medical device from the Register. Cancellation of a conformity assessment certificate automatically leads to cancellation of an entry for a medical device in the Register. Suspension and cancellation from the Register are discussed further below.

Suspension or cancellation

Under the present regulatory system the TGA has power to cancel the registration or listing of a therapeutic good for a number of reasons. These grounds carry over in relation to medical devices to be included in the Register under the new scheme. In addition, the Bill proposes giving the TGA an additional power to suspend kinds of medical devices from the Register, rather than cancelling them, in certain circumstances. According to the

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second reading speech, this ‘will allow manufacturers and sponsors to investigate any problems that may arise and take appropriate action.’⁷⁰

Suspension from the Register

The TGA will have power to suspend a kind of medical device for up to six months if:

- it is satisfied that there are likely to be grounds for cancellation (**proposed paragraph 41GA(1)(b)**), or
- it is satisfied that there is a potential risk of death, serious illness or serious injury if the kind of device continues to be included in the Register, and that risk is likely to be remediable (**proposed paragraph 41GA(1)(a)**), or
- the conformity assessment certificate for that kind of device has been suspended (**proposed section 41GF**).

Where the suspension is based on the existence of likely grounds for cancellation, the TGA must give written notice of the reasons for the proposed suspension and give the person a reasonable opportunity to make submissions (**proposed section 41GB**).⁷¹

Suspension of a medical device from the Register must be revoked if the initial reason no longer applies, and there is no other ground for suspension (**proposed sections 41GD, 41GH**).

Cancellation of an entry in the Register

Entry of a medical device in the Register will be liable to cancellation for a number of reasons relating to non-compliance with the regulatory requirements. Some grounds result in automatic cancellation, but most grounds give the TGA discretion to cancel an entry. A number of grounds require that a person be given an opportunity to make submissions before the entry is cancelled. Many of the grounds of cancellation relating to medical devices replicate existing grounds for cancellation of the registration or listing of therapeutic devices, although some of the grounds are novel, including the powers of automatic cancellation.⁷²

Automatic cancellation

The TGA must cancel an entry in the Register if (**proposed section 41GK**):

- that kind of device has been suspended, and the period of the suspension expires and there remain grounds for cancellation which have not been addressed, or
- the conformity assessment certificate applying to that kind of device is revoked.

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Discretionary cancellation

The TGA will have discretion to immediately cancel an entry of a kind of device in the Register (without first suspending it) on a number of grounds, including (**proposed section 41GL**):

- an imminent risk of death, serious illness or serious injury if the kind of device continued to be included in the Register,
- where a false or misleading statement has been made in relation to the application for inclusion on the Register, or
- where there has been non-compliance with a direction or requirement relating to the Therapeutic Goods Advertising Code, or there has been a serious breach of the applicable advertising regulations.

These grounds for cancellation largely duplicate the existing grounds for cancellation of the registration or listing of a therapeutic good.⁷³

The TGA will also have power to cancel an entry if a request for information under **proposed section 41JA** is not complied with, and the purpose of the request was to determine whether the kind of medical device should have been included on the Register, or is still being supplied in, imported into or exported from Australia (**proposed section 41GM**). This is a novel power.

Discretionary cancellation after receiving submissions

The TGA will also have power to cancel an entry after giving notice of proposed cancellation and giving the person an opportunity to make submissions, for a number of reasons (**proposed section 41GN**):

- the medical devices have changed kind,
- failure to comply with a condition of inclusion on the Register,
- failure to comply with a requirement to provide information,
- failure to report an adverse event,
- safety or performance of the kind of medical device is unacceptable, or
- the certification provided on application is incorrect or no longer correct.

Again, these grounds for cancellation largely duplicate the existing grounds for cancellation of the registration or listing of a therapeutic good, after giving the person an opportunity to make submissions.⁷⁴ The power to cancel for failure to provide information on request is, however, new.

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All cancellations of entries of kinds of medical devices shall be notified in the *Gazette* (**proposed section 41GP**).⁷⁵

Offences

In addition to these administrative monitoring and enforcement provisions, and the powers to suspend or cancel the inclusion of a kind of medical device on the Register, the Bill contains a range of criminal offence provisions carrying varying monetary penalties. The majority of offences replicate existing offences relating to therapeutic goods, although there are some novel offences related to new requirements, such as the essential principles and conformity assessment procedures.

Existing offences

It is an offence to make false or misleading statements in connection with an application for inclusion on the Register (**proposed section 41FE**).⁷⁶ The maximum penalty is \$44 000. This penalty is the same as that specified for making a false or misleading statement in connection with an application for *registration* of a therapeutic good,⁷⁷ but significantly greater than the \$6 600 for the same offence in relation to an application for *listing* of a therapeutic good.⁷⁸

It is also an offence to make false or misleading statements that a kind of medical device is either included in the Register, or is exempt or the subject of a specific approval, when in fact it is not (**proposed subsections 41ML(1) and (2)**). The maximum penalty is a fine of \$6 600, the same maximum penalty as applies to the comparable offence relating to therapeutic goods.⁷⁹

Another category of offences, some of which carry significant monetary penalties, concerns importation, exportation or supply of medical devices. All of these offences carry identical maximum penalties to those imposed for the parallel offence relating to therapeutic goods. The offences are:

- import, export, supply or manufacture of a medical device which is neither included in the Register nor exempt (**proposed section 41MI**). The maximum penalty is a fine of \$26 400.⁸⁰
- wholesale supply of medical devices which are neither included in the Register nor exempt (**proposed section 41MK**). The maximum penalty is a fine of \$13 200.⁸¹
- claiming to be able to arrange the supply of medical devices which are neither included in the Register nor exempt (**proposed section 41MM**). The maximum penalty is a fine of \$6 600.⁸²

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There are also offences related to breaches of conditions. The maximum penalty for each of the following offences, as it is for the cognate offences relating to therapeutic goods, is a fine of \$6 600:

- breach of a condition applying to inclusion of a kind of medical device on the Register (**proposed subsection 41MN(1)**)⁸³
- breach of a condition of an applicable conformity assessment certificate (**proposed subsection 41MN(2)**)
- breach of a condition of an exemption, or a special treatment or clinical trial approval (**proposed subsection 41MN(3)**)⁸⁴
- supply of a medical device otherwise than in accordance with an authorised prescriber authority, or any conditions or regulations which apply to the authority (**proposed subsection 41MO(1)**),⁸⁵ and
- use of a medical device otherwise than in accordance with a special treatment approval or a clinical trial approval (**proposed subsection 41MO(2)**).⁸⁶

It is also an offence to advertise a medical device as being for a purpose other than the purpose which was accepted when it was included on the Register (**proposed subsection 41ML(3)**). Like the identical offence relating to therapeutic goods,⁸⁷ the maximum penalty is a fine of \$6 600.

Devices that do not comply with the essential principles, or that are neither included on the Register nor exempt, may be forfeited to the Crown.⁸⁸

New offences

There are also novel offences relating to non-compliance with the essential principles or non-application of the conformity assessment procedures, both of which will be mandatory under the Bill. According to the *Explanatory Memorandum*, the level of the penalties indicates recognition of ‘the significant threat to public health and safety where there are dealings in medical devices which do not meet the fundamental safety and performance requirements’⁸⁹ prescribed in the essential principles and the conformity assessment procedures.

It is an offence for manufacturers to make false or misleading statements relating to the application of conformity assessment procedures (**proposed section 41MH**). The maximum penalty is \$44 000. It is also an offence to make false or misleading statements in connection with an application for a conformity assessment certificate (**proposed section 41EI**). The maximum penalty is \$6 600.

It is an offence for manufacturers or sponsors to supply or export a medical device to which the conformity assessment procedures have not been applied. The maximum penalty is a fine of \$26 400 (**proposed sections 41ME and 41MF**).

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It is also an offence to import, supply or export a medical device which does not comply with the essential principles.⁹⁰ The maximum penalty is \$26 400 (**proposed section 41MA**). However, it will not be an offence if the TGA has consented to the importation, supply or export. No criteria are established to guide the TGA's discretion as to the circumstances in which it may be appropriate to permit the importation or supply in Australia of medical devices which do not comply with the essential principles. The only guidance given relates to export – the TGA must not consent to the export of non-complying medical devices from Australia unless there are 'exceptional circumstances' (**proposed subsection 41MA(5)**). It is unclear what will constitute 'exceptional circumstances'.⁹¹

The TGA may impose conditions on the consent to import, export or supply a medical device which does not comply with the essential principles. It is an offence to breach a condition of that consent, punishable by a fine of up to \$13 200 (**proposed section 41MC**).

Fees

Fees are payable for applications for a conformity assessment certificate, and for audit assessment if an audit is ordered prior to consideration of an application for inclusion on the Register. The regulations may set differential fee rates for different kinds of manufacturers, different kinds of medical devices, or different levels of assessment (**proposed section 41LA**). Fees may also be payable in instalments if that is permitted in the regulations (**proposed section 41LC**).

The conformity assessment fee is reduced by a quarter where a decision on an application is not made within the statutory time period (**proposed section 41LE**).

Review of decisions

The majority of decisions of the TGA will be reviewable on application to the Minister (**item 96 of Schedule 1**). The decision to select certain applications for auditing prior to considering whether they should be included on the Register will not be reviewable, but the ultimate outcome of the audit will be a reviewable decision (**proposed paragraph 60(1)(f)**). A person who is not satisfied with the Minister's decision will be able to apply to the Administrative Appeals Tribunal for review.⁹²

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Transitional period

Some medical devices will have five years within which to comply with the requirements of the new scheme. These are:

- currently approved devices which are already registered or listed on the Register as ‘therapeutic devices’ (**proposed subsections 15A(2) and 9B(2)**), and
- devices in respect of which applications for registration or listing are pending at the time the Bill commences, which subsequently become registered or listed (**proposed subsection 15A(3)**).

These registered or listed medical devices will need to go through the process for ‘inclusion’ on the Register in the new separate part for medical devices within five years from the commencement of the new scheme. Once they are included in the Register, their registration or listing is cancelled. If they are not included in the Register within five years, registration or listing will automatically be cancelled (**proposed subsection 9B(2)**).

In addition, some other medical devices will have two years to comply with the harmonised requirements:

- certain classes of new medical devices, which will be specified in the regulations, will be able to apply for registration or listing under the current regulatory regime during the first two years after the new scheme commences (**proposed subsection 15A(5)**). This registration or listing will be valid for a maximum of two years after the new scheme commences, and after that the medical devices will need to be included in the Register, or their registration or listing will automatically be cancelled (**proposed subsection 9B(1)**),
- medical devices which are currently exempt goods will continue to be exempt for two years after the new scheme commences (**proposed subsection 15A(6)**),
- medical devices which are given a special treatment or clinical trial approval within the two years after the new scheme commences will continue to be governed by the current scheme during those two years (**proposed subsection 15A(8)**).

Finally, medical devices which are the subject of an existing special treatment or clinical trial approval will continue to be governed by the current regime for the duration of the approval (**proposed subsection 15A(7)**).

After five years, ‘therapeutic devices’ will cease to exist as a separate category, and will be regulated either as ‘medical devices’ or as ‘therapeutic goods’.⁹³

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Concluding Comments

The Bill proposes the introduction of a new and comprehensive system for classifying medical devices according to the degree of risk their use will pose to patients. The introduction of five classes of medical device, as opposed to the present two, should enhance the ability to develop safety and quality standards and levels of testing which are appropriate to the level of risk.

A key initiative contained in the Bill is the introduction of essential principles of safety and performance, and conformity assessment procedures for demonstrating quality management, both of which must be complied with before a medical device may be included in the Register. Having minimum, enforceable standards for quality and safety is an improvement on the current regulatory regime, pursuant to which many therapeutic devices are not required to comply with any quality or safety standards. Although the essential principles contained in the Draft Regulations are expressed in broad, general terms, more detailed requirements for particular kinds of medical devices may be specified in the medical device standards.

The TGA's power to audit applications, and to require a conformity assessment certificate, and hence to do its own compliance checks prior to inclusion of medical devices on the Register are also useful powers. However, whether these will result in comprehensive and effective pre-market assessment for all high-risk devices and an improvement on the current system, as the Government claims, depends on the circumstances in which the TGA decides to exercise those powers. The Draft Regulations currently prescribe no situations in which either of these procedures will be mandatory.

The inclusion of a medical device in the Register may be cancelled for a variety of reasons, most of which are already grounds for cancellation of the registration or listing of a therapeutic good. There are also some additional grounds of cancellation, including where a conformity assessment certificate relating to a medical device has been revoked, or where a medical device has been suspended and the defect warranting suspension has not been rectified during the period of the suspension.

Many of the features of the proposed scheme for the regulation of medical devices replicate existing provisions of the *Therapeutic Goods Act 1989* currently applicable to therapeutic goods, including therapeutic devices. For example, the classes of exemptions from inclusion on the Register reproduce current exemptions for therapeutic goods. Similarly, many of the enforcement mechanisms, including inspection and sampling, obtaining information, notification of adverse events, and the majority of offences, parallel existing regulatory measures. It remains unclear why the maximum penalties applicable to offences relating to the provision of information and documents are significantly lower for medical devices than the penalties for the corresponding offences relating to other therapeutic goods.

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The TGA will be given additional enforcement powers in relation to medical devices which it does not possess in relation to therapeutic goods. These include the power to suspend a medical device from the Register prior to cancellation, and the power to require public notification and recall of medical devices which do not comply with the essential principles or the conformity assessment procedures, or have been suspended or cancelled from the Register. There are also some new offences designed to punish non-compliance with the essential principles and conformity assessment procedures.

The majority of the measures contained in the Bill either represent no change to the existing regulatory system applicable to therapeutic devices, or represent a strengthening of that system.

Endnotes

- 1 Therapeutic Goods Administration, *Medical Devices – A New Approach to Regulation: General Information*, 15 February 2001, <http://www.health.gov.au/tga/docs/pdf/devinfo2.pdf> (accessed 4 May 2001) (hereafter ‘*General Information*’).
- 2 *ibid.*
- 3 The Hon Peter McGauran, MP, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 4 Subsection 20(1) of the *Therapeutic Goods Act 1989*.
- 5 Registration occurs under subsection 25(3) of the *Therapeutic Goods Act 1989*. Schedule 3 of the Therapeutic Goods Regulations 1990 includes the types of substances required to be registered on the Register.
- 6 Listing occurs under subsection 26(1) of the *Therapeutic Goods Act 1989*. Schedule 4 of the Therapeutic Goods Regulations 1990 contains goods required to be listed. They only contain well known established ingredients, usually with a long history of use, such as vitamin, herbal and mineral products or sunscreens, which are not scheduled poisons. Some over-the-counter medicines are also listed goods rather than registered goods. The majority of listed medicines are self-selected by consumers and used for self-treatment. See further the TGA publication *Medicines Regulation and the TGA* (December 1999), <http://www.health.gov.au/tga/docs/html/medregs.htm> (accessed 23 May 2001).
- 7 Section 18 of the *Therapeutic Goods Act 1989* permits therapeutic goods specified in the Therapeutic Goods Regulations 1990 to be exempt from registration or listing. For example, drugs to treat a Category A patient (a patient who is seriously ill and likely to die within months) are exempt if the treating medical practitioner signs a statement and sends it to the Secretary: regulation 12A of the Therapeutic Goods Regulations 1990. This is because in a life-threatening situation it is often impractical to wait months or years until the drug can be evaluated and entered on the Register.

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- 8 Under the Personal Import Scheme, individuals can legally import most therapeutic goods for personal use, subject to restrictions on the quantity that can be imported in any twelve-month period, without the goods being entered on the Register. Therapeutic goods prohibited by Customs legislation or injections that contain material of human or animal origin cannot be imported under the scheme, unless an import permit has been obtained: subregulation 12(1) and Schedule 5 of the Therapeutic Goods Regulations 1990.
- 9 Approval may be granted to import, export or supply a particular therapeutic good for use in the treatment of an individual (*special treatment approval*) or for use in experiments in humans (*clinical trial approval*): subsection 19(1) of the *Therapeutic Goods Act 1989*. Approval may also be granted where similar registered goods are in short supply or are unavailable (*substitute product approval*): section 19A of the *Therapeutic Goods Act 1989*. Where a particular medical practitioner is likely to treat a significant number of patients with the same condition with the same therapeutic good, he or she may apply to the Secretary for approval to supply a specified therapeutic good to a specified class of patients (*authorised prescriber authority*): subsection 19(5) of the *Therapeutic Goods Act 1989*. This removes the need for the medical practitioner to obtain a separate approval for every patient.
- 10 See Department of Industry, Science and Resources, *Technical and Regulatory Barriers to Trade: Australia-EC Mutual Recognition Agreement*, http://www.isr.gov.au/industry/tbt/mra/ec_mra/index.html (accessed 7 May 2001).
- 11 *ibid.*
- 12 The Hon John Moore, MP, Minister for Industry, Science and Tourism, 'Government Responds to IC Report on Medical and Scientific Equipment Industries', *Media Release*, 24 July 1998.
- 13 See Senator Grant Tambling, Parliamentary Secretary for Health and Aged Care, 'Better International Access for Australian Medical Devices', *Media Release*, 17 September 1999, <http://www.health.gov.au/mediarel/yr1999/gt/gt99032.htm> (accessed 4 May 2001).
- 14 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 15 *General Information*, *op. cit.* n. 1.
- 16 Therapeutic Goods Administration, *Background and Information on the Proposed New Harmonised Regulatory Requirements For Medical Devices*, February 2000, <http://www.health.gov.au/tga/docs/pdf/deveudoc.pdf> (accessed 10 May 2001), p. 2 (hereafter '*Background and Information*').
- 17 Therapeutic Goods Administration, *Medical Devices – A New Approach to Regulation: Proposed New Legislation*, 15 February 2001, <http://www.health.gov.au/tga/docs/pdf/devinfo1.pdf> (accessed 4 May 2001).
- 18 See *General Information*, *op. cit.* n. 1.
- 19 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.

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- 20 **Items 1, 5, 14, 15, 16, 19, 26, 31, 34, 39, 42, 48, 49, 50, 51, 52, 53, 56, 60, 61, 62, 64, 72, 77, 78, 79, 87, 107, 111, 112, 113 of Schedule 1.**
- 21 Section 17 of the *Therapeutic Goods Act 1989*, which establishes the Register, is repealed by **item 45 of Schedule 1**, and becomes **proposed section 9A**.
- 22 Current provisions dealing with inspection of the Register, variation of entries and the annual publication of a list of therapeutic goods included in the Register, will remain unaltered in substance. Sections 32 and 33 of the *Therapeutic Goods Act 1989*, dealing with these matters, are repealed by **item 54 of Schedule 1**, and become **proposed sections 9C, 9D and 9E**.
- 23 **Items 65-71, 74, 75, 86, 108, 110 of Schedule 1.**
- 24 Pursuant to section 57 of the *Therapeutic Goods Act 1989*, the Secretary may delegate any or all of his or her powers to an officer of the Department of Health and Aged Care, or an officer in another Department or Commonwealth authority with functions relating to therapeutic goods.
- 25 Attachment 2 of *Background and Information*, op. cit. n. 16.
- 26 Proposed regulation 3.1.
- 27 See Attachments 2 and 5 of *Background and Information*, op. cit. n. 16.
- 28 Medical devices will be treated as for ‘transient’ use if they are used for less than one hour, subclause 1.1(a) of Schedule 2.
- 29 Medical devices will be treated as for ‘short-term’ use if they are used for more than an hour but less than 30 days, subclause 1.1(b) of Schedule 2.
- 30 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 31 These are: human tissues for direct donor to host transplantation; medicinal products where device and drug form a single integral product which is intended exclusively for use in the given combination and is not reusable; drug-device combinations where the principal intended purpose is reliant on the drug component (such as an IUD with hormone release); cosmetic products and personal protective equipment. Artificial tears, artificial saliva, preservatives for transplants/transport media (other than for IVF) which are currently regulated as devices, would be regulated as drugs. See Attachment 5 of *Background and Information*, op. cit. n. 16.
- 32 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 33 The exceptions are hospital and household or commercial grade disinfectants (which will be Class IIa) and HIV/HCV *in vitro* diagnostics (the inclusion of which is still under consideration). See Attachment 6 of *Background and Information*, op. cit. n. 16.
- 34 Active implantable medical devices, including implantable infusion systems, cardiac pacemakers and accessories.

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- 35 Intrauterine contraceptive devices (not drug releasing), prosthetic heart valves, intra ocular fluids made from non-viable animal tissue, devices of animal origin.
- 36 Synthetic intra ocular fluids for transient use, intra ocular lenses, non-implantable powered drug infusion systems, breast implants, barrier contraceptive devices, sterilents and instrument grade disinfectants.
- 37 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 38 For the purposes of paragraph 26(1)(k) of the *Therapeutic Goods Act 1989*, Schedule 11 of the Therapeutic Goods Regulations 1990 prescribes quality and safety criteria for certain wound dressings, surgical absorbents, hydrogels and sterile items such as bandages and gauzes.
- 39 Therapeutic Goods Orders are made under section 10 of the *Therapeutic Goods Act 1989*, and prescribe quality standards with which registrable and listable therapeutic devices must comply, by virtue of paragraphs 25(1)(f) and 26(1)(f) of the *Therapeutic Goods Act 1989* respectively. Currently, standards are issued for sterile therapeutic devices, contraceptive diaphragms, condoms, insulin syringes, barium lime, sutures, pyrogen and endotoxin products, menstrual tampons, examination and surgical gloves, disinfectants and sterilants, dental restorative materials, polymer catheters, and diagnostics containing material of human origin. See the TGA publication, *Therapeutic Goods Orders and Standards applicable to Therapeutic Devices* (May 1998) <http://www.health.gov.au/tga/docs/pdf/dr4/dr4app13.pdf> (accessed 17 May 2001).
- 40 The standards specified in British Pharmacopoeia have limited application to devices. See *Background and Information*, op. cit. n. 16, p. 5.
- 41 The Bill commonly refers to 'kinds of medical devices'. Medical devices are of the same kind if they have the same sponsor, manufacturer, classification and device nomenclature system code, as well as any other characteristics which the regulations say must be the same (**proposed section 41BE**).
- 42 Compliance with a medical device standard is deemed to be compliance with the essential principles even if the standard contravenes a part of the essential principles, so long as the standard specifically refers to the part of the essential principles (**proposed section 41BH**).
- 43 Section 36 of the *Therapeutic Goods Act 1989*.
- 44 Schedule 7 of the Therapeutic Goods Regulations 1990 exempts most therapeutic devices manufactured in Australia from complying with the manufacturing standards. Schedule 6 of the Therapeutic Goods Regulations 1990 exempts most therapeutic devices manufactured outside Australia from having to comply with manufacturing and quality control procedures.
- Registrable therapeutic devices, or listable devices which are supplied as pharmaceutical benefits, are sterile, are used for contraception, are dental restorative materials, soft contact lenses, lubricants for insertion into body cavities or orifices, implantable therapeutic devices and *in vitro* diagnostics are required to comply with manufacturing standards.
- 45 See Attachment 2 of *Background and Information*, op. cit. n. 16.

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- 46 Compliance with a conformity assessment standard is deemed to be compliance with the conformity assessment procedures even if the standard contravenes a part of the conformity assessment procedures, so long as the standard specifically refers to the part of the conformity assessment procedures (**proposed section 41BI**).
- 47 Subsection 25(1) of the *Therapeutic Goods Act 1989*.
- 48 See Block 3 of 'DR4', *Australian Medical Device Requirements under the Therapeutic Goods Act 1989*, Version 4, (May 1998) at <http://www.health.gov.au/tga/docs/pdf/dr4/dr4v1s3.pdf> (accessed 17 May 2001).
- 49 See Attachment 2 of *Background and Information*, op. cit. n. 16.
- 50 See Attachment 2 of *Background and Information*, op. cit. n. 16.
- 51 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 52 Compare section 18 of the *Therapeutic Goods Act 1989*.
- 53 Compare section 19 of the *Therapeutic Goods Act 1989*.
- 54 Compare subsection 19(5) of the *Therapeutic Goods Act 1989*.
- 55 Paragraph 28(5)(a) of the *Therapeutic Goods Act 1989*.
- 56 Part 5A of the *Therapeutic Goods Act 1989*, which is renumbered Part 6-2, applies to medical devices, see **items 73, 74 and 75 of Schedule 1**.
- 57 Compare paragraph 28(5)(b) of the *Therapeutic Goods Act 1989*.
- 58 Compare subsection 28(6) of the *Therapeutic Goods Act 1989*.
- 59 Compare section 31 of the *Therapeutic Goods Act 1989*, although the categories of information which may be required vary as between medical devices and therapeutic goods.
- 60 Compare sections 31A and 31B of the *Therapeutic Goods Act 1989*.
- 61 Section 31C of the *Therapeutic Goods Act 1989*.
- 62 Sections 31D and 31E of the *Therapeutic Goods Act 1989*.
- 63 Compare subsection 31E(3) of the *Therapeutic Goods Act 1989*.
- 64 Compare section 31F of the *Therapeutic Goods Act 1989*.
- 65 The power contained in section 42V of the *Therapeutic Goods Act 1989* to order public notification and/ or recall relates only to therapeutic goods that are, or could have been, tampered with.
- 66 See Attachment 2 of *Background and Information*, op. cit. n. 16.
- 67 Compare section 29A of the *Therapeutic Goods Act 1989*, although the specific information which must be notified is different as between therapeutic goods and medical devices.
- 68 Compare section 29B of the *Therapeutic Goods Act 1989*.

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- 69 The Secretary may also revoke a conformity assessment certificate in its application to some kinds of medical devices but not others covered by the certificate (**proposed section 41EU**).
- 70 The Hon Peter McGauran, MP, Minister for the Arts and the Centenary of Federation, Second reading speech on the Therapeutic Goods Amendment (Medical Devices) Bill 2001, House of Representatives, *Hansard*, 29 March 2001, p. 22261.
- 71 There is no comparable provision in relation to suspension based on the suspension of a conformity assessment certificate, possibly because an opportunity to make submissions is provided prior to suspension of the certificate (**proposed section 41EN**).
- The lack of an opportunity to be heard when suspension is proposed on the ground of a potential risk of death, serious illness or serious injury is presumably because the urgency of preventing the risk eventuating does not allow time for consideration of submissions. This is reinforced by the fact that suspension on this ground takes effect immediately, whereas suspensions because of likely grounds for cancellation take effect after 20 working days (**proposed section 41GC**).
- 72 The mandatory cancellation of registration or listing if protected information was used when evaluating the goods for registration, subsection 30(4A) of the *Therapeutic Goods Act 1989*, only applies to therapeutic goods which are not medical devices, subparagraph 25A(2)(a)(i) of the *Therapeutic Goods Act 1989*.
- 73 Compare subsection 30(1) of the *Therapeutic Goods Act 1989*. Other grounds for cancellation, which apply both to therapeutic goods and medical devices, are where the device is no longer a therapeutic good or a medical device, the person requests cancellation, or the annual charges are unpaid. Similar grounds also exist in relation to therapeutic goods.
- 74 Compare subsection 30(2) of the *Therapeutic Goods Act 1989*.
- 75 Compare paragraph 30(6)(b) of the *Therapeutic Goods Act 1989*.
- 76 The offence includes making a false or misleading statement in the certificate of compliance which accompanies the application for inclusion on the Register.
- 77 Section 22A of the *Therapeutic Goods Act 1989*.
- 78 Subsection 22(2) of the *Therapeutic Goods Act 1989*.
- 79 Compare subsection 22(4) of the *Therapeutic Goods Act 1989*.
- 80 Compare section 20 of the *Therapeutic Goods Act 1989*. As is the case for therapeutic goods, the legal onus is on the defendant to prove that he or she was not the sponsor of the medical device at the time of the alleged offence (**proposed subsection 41MI(3)**).
- 81 Compare section 21 of the *Therapeutic Goods Act 1989*.
- 82 Compare subsection 22(6) of the *Therapeutic Goods Act 1989*.
- 83 Compare subsection 22(3) of the *Therapeutic Goods Act 1989*.
- 84 Compare subsection 22(7) of the *Therapeutic Goods Act 1989*.
- 85 Compare subsection 22(7A) of the *Therapeutic Goods Act 1989*.

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- 86 Compare subsection 22(8) of the *Therapeutic Goods Act 1989*.
- 87 Compare subsection 22(5) of the *Therapeutic Goods Act 1989*.
- 88 **Proposed sections 41MD and 41MJ** give the Secretary the discretion to issue a notice to the Chief Executive Officer of Customs to treat such medical devices as ‘prohibited imports’ or ‘prohibited exports’ under the *Customs Act 1901*. Section 229 of the *Customs Act 1901* would then apply to forfeit these devices to the Crown. Compare subsection 20(3) of the *Therapeutic Goods Act 1989*.
- 89 *Explanatory Memorandum* to the Therapeutic Goods Amendment (Medical Devices) Bill 2001, p. 21.
- 90 Consistent with **proposed section 41BH**, it is not an offence to import, export or supply a medical device which complies with a medical device standard and fails to comply with part of the essential principles only by conforming to that medical device standard, **proposed section 41MB**.
- 91 The term ‘exceptional circumstances’ is also used in the existing subsection 14(3) of the *Therapeutic Goods Act 1989*, which corresponds to the **proposed subsection 41MA(5)**. There have been no cases interpreting this provision.
- 92 Under subsection 60(8) of the *Therapeutic Goods Act 1989*.
- 93 **Proposed Schedule 2** makes a number of amendments repealing definitions and removing references to ‘therapeutic devices’. These amendments will commence five years after the Bill is enacted.

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