

Therapeutic Goods Amendment Regulations 2002 (No. 4) 2002 No. 234

EXPLANATORY STATEMENT

STATUTORY RULES 2002 No. 234

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

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2002 (No. 4)

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.

The *Therapeutic Goods Amendment (Medical Devices) Act 2002*, inserts a new part into the Act to provide for the creation of a new regulatory system for medical devices. The Act has been restructured into separate chapters and part numbers have been renumbered as a consequence. There is a separate chapter (Chapter 4) for regulation of medical devices and a separate chapter for medicines and other therapeutic goods that are not medical devices (Chapter 3). The remaining chapters deal with matters common to all therapeutic goods.

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 purpose of the Regulations is to amend the *Therapeutic Goods Regulations 1990* to reflect changes made by the *Therapeutic Goods Amendment (Medical Devices) Act 2002*. The Regulations:

- reflect renumbering of some sections and parts of the Act (Schedule 1, items 4, 5, 55, 71, 73, 75, 76, & 77, Schedule 2, item 1);
- create a new part of the Australian Register of Therapeutic Goods (the Register) for medical devices (Schedule 1, item 3);
- create a new Medical Devices Evaluation Committee to replace the Therapeutic Devices Evaluation Committee (Schedule 1, item 35);
- insert some new fee items, for example for variation of a medical device entry on the Register;
- make consequential amendments in relation to the inclusion of medical devices in the Register and the issuing of conformity assessment certificates to manufacturers.

Details of the Regulations are set out in the Attachment.

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

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

ATTACHMENT 1

Regulation 1 names the Regulations as the *Therapeutic Goods Amendment Regulations 2002 (No. 4)*.

Regulation 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 3 provides that Schedule 1 amends the *Therapeutic Goods Regulations 1990* and that Schedule 2 further amend those regulations by relocating certain provisions.

Schedule 1 Amendments

Item 1 inserts into regulation 2 a definition of 'ASMI', the Australian Self-Medication Industry Incorporated, an organisation previously known as PMAA.

Item 2 removes the definition of ASMI from regulation 5B, as ASMI is now referred to in other areas of the regulations, not just Part 2.

Item 3 inserts a new Part 2C after Part 2B. Part 2C is to contain matters relating to the Australian Register of Therapeutic Goods.

Division 2C.1 relates to registered and listed therapeutic goods.

A new regulation 10 is inserted for the purposes of paragraph 9A (4) (a) of the Act, to prescribe the therapeutic goods, or classes of therapeutic goods, that are required to be included in each part of the Register. The regulation requires that therapeutic goods of a kind mentioned in Schedule 3 are to be included in the part of the register for registered goods and therapeutic goods of a kind mentioned in Part 1 of Schedule 4 are to be included in the part of the Register for listed goods.

A new regulation 10D is inserted to require that the Secretary must give written notice to a person in whose name therapeutic goods or kinds of therapeutic goods are registered or listed if a registration or listing number is assigned under regulation 10C (current regulation 14A). This regulation rewords and replaces the current regulation 14C.

Division 2C.2 relates to medical devices included in the Register under Chapter 4.

Regulation 10E requires that, for purposes of paragraph 9A (4) (a) of the Act, therapeutic goods that are medical devices and that are included in the Register under Chapter 4 of the Act are to be included in the part of the Register for medical devices.

Regulation 10F sets out the responsibilities if, for specified reasons, there is a change of person in relation to whom a medical device is included in the Register under Chapter 4 of the Act. This regulation is the equivalent requirement for medical devices included in the Register to that for listed or registered goods under regulation 13. There is a right of review of a decision to cancel an entry for failing to notify a change of name (see item 69).

It is an offence of strict liability, attracting a penalty of 5 penalty units, for not returning a certificate of inclusion if requested to do so where there has been a name change or the entry has been cancelled. The return of the original certificate is required to ensure that there is no misuse of a cancelled or outdated certificate. 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.

Item 4 allows for regulation 10A to be renumbered as regulation 11.

Item 5 omits regulations 10, 11 and 11A. Regulations 10 and 11 are replaced by new regulation 10. Regulation 11A is no longer necessary, as intra-ocular lenses are medical devices under Chapter 4 of the Act, and subject to the provisions of that Chapter.

Item 6 amends paragraph 12AD (b) to limit the condition for use of goods for experimental purposes to compliance with a procedural protocol approved by the ethics committee that has the function of monitoring the conduct of the trial. The reference to the ethics committee giving approval for the trial itself has been removed as this was an inaccurate description of the committee's role.

Item 7 inserts, after regulation 12B, regulation 12C.

Regulation 12C is made for the purposes of section 15A of the Act. It specifies that where an application is made under Part 3-2 of the Act, for the registration or listing of therapeutic goods during the 2 years after the commencement of section 15A, relating to a medical device of a kind that is currently manufactured in Australia by an exempt person under the circumstances set out in Schedule 8 of the Regulations, the provisions in Chapter 3 continue to apply for 2 years after commencement, unless the registration or listing is cancelled earlier.

Item 8 amends subregulations 14 (1) and (5), to limit the provisions of those subregulations to goods other than medical devices. The subregulations relate to transfers within the Register.

Item 9 substitutes new wording for sub-regulation 14 (6), and inserts a new sub-regulation (7).

Sub-regulation (6) provides that if goods are included in the Register under Chapter 4 as a kind of medical device, and the goods cease to be a medical device because of a declaration under subsection 41BD (3) of the Act, the person to whom the medical device is included may apply to transfer the entry to the part of the Register for listed or registered goods, as applicable.

Sub-regulation (7) rewords and replaces current sub-regulation (6).

Item 10 omits regulations 14B and 14C. The content of regulation 14B is now contained in subsection 9D(1) of the Act. New regulation 10D replaces regulation 14C.

Item 11 amends subregulation 23 (1), by rewording the definition of *relevant test*, and inserting a new clause to cover tests relevant to the analysis of a medical device, as a test mentioned under new subregulation 28 (2).

Item 12 amends subparagraph 23 (2) (a) (ii) by inserting a reference to 41FN (2) (this relates to the condition of inclusion of a medical device in the Register that the person to whom the kind of device is included will deliver samples of the device to the Secretary if requested to do so).

Item 13 expands paragraph 24 (1) (a) to allow an authorised officer to enter the premises of a manufacturer in respect of whom a conformity assessment certificate has been issued.

Item 14 amends subregulation 24 (2) to replace the words "registration or listing of goods" with the words "entry of goods in the Register", to cover included medical devices.

Item 15 expands subregulation 24 (2) to extend the powers of an authorised person to a sponsor, as if the sponsor were a manufacturer, where an entry on the Register is subject to a condition that the sponsor comply with this regulation.

Item 16 amends paragraphs 25 (3) (b) and (c) to insert a reference to 41FN (2). Subsection 41FN (2) relates to the condition of inclusion of a medical device in the Register that the person to whom the kind of device is included will deliver samples of the device to the Secretary if requested to do so.

Items 17, 19 & 20 amend regulation 26A to replace the word "medicine" with the words "therapeutic goods", to extend the operation of the regulation to all therapeutic goods.

Item 18 amends subregulation 26A (1) to extend the requirement for Secretary to deal in the prescribed way with a sample of medicines delivered under subsection 28 (5A) of the Act, to a sample of a kind of medical device delivered under subsection 41FN (2).

Item 21 amends subparagraph 27 (2) (a) (ii) to reword and renumber the existing text as paragraph (A) and to insert a new paragraph (B) which provides that for medical devices, the goods from which a sample is taken must comply with the applicable provisions of the essential principles and any conditions relating to the matters mentioned in paragraph 41FO (2) (d) of the Act, ie matters additional to those dealt with in the essential principles.

Item 22 amends regulation 28 by rewording and renumbering the existing text as paragraph (1) and relating it to therapeutic goods other than medical devices.

Item 23 inserts into regulation 28 a new paragraph (2) that specifies the relevant tests for determining whether a particular kind of medical device complies with the applicable provisions of the essential principles.

Item 24 amends and expands subregulation 29 (4) to insert wording to allow for a review of the test results for a medical device that is found not to comply with the applicable provisions of the essential principles or applicable requirements under regulation 27. The requirements for the statement referred to in subregulation 29 (4) are now placed into a new subregulation (4A).

Items 25 - 27 substitute new wording in regulation 30, to extend the provisions for review of the findings of the official analyst to medical devices that are found not to comply with the applicable provisions of the essential principles or applicable requirements under regulation 27.

Item 28 amends subregulation 31 (1A) to cover therapeutic goods, rather than medicines only and extends the requirement for the Commonwealth to pay for samples of medicines delivered under subsection 28 (5A) of the Act, to samples of a kind of medical device delivered under subsection 41FN (2).

Item 29 amends subregulation 31 (2) to include a reference to samples of a kind of medical device delivered under subsection 41FN (2) of the Act.

Item 30 amends the heading of Part 6, Division 1, to delete the reference to the Therapeutic Device Evaluation Committee (TDEC) and insert a reference to the new Medical Devices Evaluation Committee, which replaces TDEC.

Items 31 & 32 are technical drafting amendments.

Item 33 inserts new subparagraphs 34 (2) (a) (v) and (vi), to allow for the Therapeutic Goods Committee to consider matters relating to the adequacy of a medical device standard or a conformity assessment standard, in relation to the essential principles or the conformity assessment procedures.

Items 34, 36, 45, 49 & 50 replace references to 'therapeutic devices' with 'medical devices and other therapeutic goods' in recognition of the terminology under the new scheme.

Item 35 substitutes new wording for regulation 35, to establish the Medical Devices Evaluation Committee in place of the Therapeutic Devices Evaluation Committee, to prescribe the functions and membership of the Medical Devices Evaluation Committee, and to allow for the appointment of subcommittees.

Item 37 expands subregulation 38 (2A) to prescribe the limits of eligibility for tenure of office for core members of the Medical Devices Evaluation Committee.

Item 38 amends paragraph 41 (2) (c) to refer to the Medical Devices Evaluation Committee rather than the Therapeutic Devices Evaluation Committee, and prescribes the number and type of members who constitute a quorum.

Item 39 inserts into subregulation 41 (2A) a reference to the Medical Devices Evaluation Committee, in relation to the eligibility of an associate member to attend a meeting only at the invitation of the chairperson.

Item 40 amends subregulation 41 (2C) to refer to the Medical Devices Evaluation Committee rather than the Therapeutic Devices Evaluation Committee.

Items 41-44, & 46-48 make amendments to refer to the ASMI (Australian Self-Medication Industry Incorporated) rather than the PMAA (Proprietary Medicines Association of Australia). ASMI is the new name for PMAA.

Item 51 inserts into subparagraph 42ZCAB (1) (b) (i) a reference to subsection 41FN (5) of the Act, for the purposes of allowing complaints to be made to the Complaints Resolution Panel regarding advertisements about medical devices.

Item 52 is a technical drafting amendment.

Item 53 inserts after paragraph 42ZCAI (4) (f), new paragraphs (g) and (h). Paragraphs (g) and (h) allow the Complaints Resolution Panel for advertising matters to recommend that the Secretary suspend or cancel the entry of a kind of medical device from the Register under Part 4-6 of the Act.

Item 54 amends regulation 43A to insert the existing text as paragraph (1), in order to allow the insertion of a new paragraph (2) inserted by item 56.

Item 55 amends paragraph 43A (a) to allow for renumbering of regulation 14 as regulation 10B.

Item 56 inserts into regulation 43A, a subregulation (2), providing for non-application of the fee under item 2 or 3 of Schedule 9

- if a device ceases to be a medical device because of a declaration under subsection 41BD (3) of the Act; and
- as a result of that declaration an application is made to transfer the entry of the kind of medical device from the part of the Register for medical devices to the part of the Register for registered goods, or the part of the Register for listed goods.

Item 57 rewords and extends subregulation 45AA (7) to specify that the payment of fees in instalments regulation does not apply while another evaluation fee, or an assessment fee payable under section 41LA of the Act (or part of either of those kinds of fee) that is due for payment by the applicant is unpaid.

Item 58 replaces paragraph 46 (2) (a) with new wording that allows for included devices release of information about the device number, the date when the device was included in the register, and the class in which the goods are included in the Register.

Item 59 inserts new wording before subparagraph (i) of paragraph 46 (2) (e), to refer to medical devices and devices that are medicine combination products. This change is to align with the language used in Chapter 4 of the Act.

Item 60 amends paragraph 46 (2) (f) with new wording to specify the information that may be released in relation to a kind of medical device, as the intended purpose of the device, the device nomenclature system code specified for the device and the medical device classification applying to the device.

Item 61 inserts subregulation 46 (4) which provides for the Secretary to release, for the purposes of subsection 61 (6) of the Act, information of a kind that a court, tribunal, authority, or other body or person may require to be given or produced under a law of the Commonwealth, or of a State or Territory. Where an application is received for release of information under subsection 61 (6), the applicant may be charged a fee under item 16 of Schedule 9 of the Regulations. This amendment will, for instance, enable TGA to recover some of the often substantial costs involved in responding to subpoenas.

Item 62 amends the heading of regulation 47B, to refer to medical devices rather than therapeutic devices.

Item 63 expands the reporting requirements to medical practitioners authorised to supply unapproved medical devices under subsection 41HC (1).

Items 64, 65 & 66 replace the words "therapeutic devices" in paragraphs 47B (3) (a), 47B (3) (b) and 47B (4) respectively with the words "medical devices".

Item 67 amends subregulation 47B (5) to clarify that "sponsor" means the "sponsor of therapeutic goods" referred to in paragraph 47B (1) (c).

Item 68 amends subparagraphs 47B (5) (b) (i) to (iv) by adding references to sections 41HA, 41HB (1) (d), 41HB (1) (e) and 41HC (1) of the Act to provide a requirement for reports by sponsors in relation to medical devices supplied under the special exemptions and authorisations in Part 4-7 of the Act.

Item 69 amends subregulation 48 (1) by

- substituting subregulation 10A (7) for renumbered subregulation 13 (7);

- providing for renumbering of subregulation 14A as 10C
- inserting a reference to subregulation 10F (7) (which replaces regulation 13).

These changes relate to the decisions of the Secretary under any of these provisions being defined as 'initial decisions' for the purpose of reviewing those decisions.

Item 70 omits Schedule 2, Part 1, item 6A, which prohibits a representation for instrument disinfectants that certain apparatus or instruments may be stored in the disinfectant after use. This representation is removed as such a claim may be allowed if the manufacturer of the disinfectant is able to demonstrate that such use is in accordance with the essential principles.

Item 71 amends the heading of Schedule 4, to allow for the omission of regulations 11 and 11A (Item 5), and the insertion of regulation 10 (Item 3). Schedule 4 is now made for the purposes of regulation 10.

Item 72 amends Schedule 4, Part 1, item 14, paragraph (b) to omit the reference to guidelines made under regulation 11A, and substitute a reference to guidelines approved by the Secretary. Regulation 11A has been omitted (Item 5).

Items 73, 75 & 76 amend Schedule 9 to omit the references to subsections 32 (3), (4), or (5), and substitute a reference to subsection 9D (1), (2) or (3). Section 32 of the Act has been replaced with section 9D.

Item 74 inserts a paragraph (g) into Schedule 9, item 2A, to provide for a fee of \$280 for variation of an entry for a medical device in the Register under section 9D.

Item 77 contains a table of amendments to those regulations in which a reference is made to Parts 2, 3 and 4 of the Act, which have been renumbered as Part 3-1, Part 3-2 and Part 3-3 respectively.

Schedule 2 Amendment

Item 1 relocates regulations 13, 14 and 14A as regulations 10A, 10B and 10C after regulation 10, as inserted by Item 3 of Schedule 1 to these regulations.