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2002B00235

Therapeutic Goods Amendment Regulations 2002 (No. 4)¹

Statutory Rules 2002 No. 4²

234

I, PETER JOHN HOLLINGWORTH, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated - 3 OCT 2002 2002

PETER HOLLINGWORTH
Governor-General

By His Excellency's Command

TRISH WORTH
Parliamentary Secretary to the Minister for Health and Ageing

Regulation 1

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2002 (No. 4)*.

4

2 Commencement

These Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002*.

3 Amendment of *Therapeutic Goods Regulations 1990*

- (1) Schedule 1 amends the *Therapeutic Goods Regulations 1990*.
- (2) Schedule 2 amends those Regulations as amended by Schedule 1.

Schedule 1 Amendments

(subregulation 3 (1))

[1] Regulation 2, after definition of *antiseptic*

insert

ASMI means Australian Self-Medication Industry Incorporated (ABN 55 082 798 952).

[2] Regulation 5B, definition of *ASMI*

omit

[3] After Part 2B*insert***Part 2C Australian Register of
Therapeutic Goods****Division 2C.1 Registered and listed therapeutic
goods****10 Goods to be included in parts of the Register
(Act s 9A)**

For paragraph 9A (4) (a) of the Act:

- (a) therapeutic goods, and classes of therapeutic goods, of a kind mentioned in Schedule 3 that are included in the Register are to be included in the part of the Register for registered goods; and
- (b) therapeutic goods, and classes of therapeutic goods, of a kind mentioned in Part 1 of Schedule 4 that are included in the Register are to be included in the part of the Register for listed goods.

**10D Notice of reassignment of registration or listing
numbers**

The Secretary must give notice, in writing, 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 to the goods under regulation 10C.

**Division 2C.2 Medical devices included in the
Register under Chapter 4****10E Goods to be included in part of the Register for
medical devices (Act s 9A)**

For paragraph 9A (4) (a) of the Act, therapeutic goods, and classes of 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.

10F Change of person in relation to whom a medical device is included in the Register under Chapter 4 of the Act

- (1) If a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act dies, the legal personal representative of the person:
 - (a) is taken to be the person in relation to whom the kind of device is included in the Register under that Chapter; and
 - (b) must notify the Secretary, in writing, of the death within 3 months after it occurred.
- (2) If a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act becomes bankrupt, the trustee in bankruptcy of the estate of the bankrupt:
 - (a) is taken to be the person in relation to whom the kind of device is included in the Register under that Chapter; and
 - (b) must notify the Secretary, in writing, of the bankruptcy within 3 months after the person became bankrupt.
- (3) If a body corporate in relation to which a kind of medical device is included in the Register under Chapter 4 of the Act is wound up, the liquidator of the body corporate:
 - (a) is taken to be the person in relation to whom the kind of device is included in the Register under that Chapter; and
 - (b) must notify the Secretary, in writing, of the winding up within 3 months after the body corporate is wound up.
- (4) If a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act:
 - (a) changes his, her or its name; or
 - (b) being a corporation, amalgamates with another corporation under a name that is different from the name entered in the Register;

the person must, within 3 months after the change of name or amalgamation:

- (c) notify the Secretary, in writing, of the new name of the person and the circumstance giving rise to it; and
 - (d) return the certificate of the inclusion of the kind of device in the Register given under subsection 41FF (2) of the Act.
- (5) If a person notifies the Secretary of an event under paragraph (1) (b), (2) (b) or (3) (b), or a change of name under subregulation (4), the person must send to the Secretary sufficient documentary evidence to establish the matter asserted in the notification.
- (6) If, under subregulation (4), the Secretary is notified of a new name for a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act, the Secretary must:
- (a) enter the new name in the Register as the name of the person in relation to whom the kind of device is included in the Register under that Chapter; and
 - (b) as soon as practicable after entering the new name, give to the person a new certificate of the inclusion of the kind of device in the Register under that Chapter.
- (7) If, at any time, the Secretary becomes aware that he or she has not been informed of a change in the name of a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act, the Secretary may cancel the entry in the Register in relation to the kind of device.
- (8) If, under this regulation, the Secretary:
- (a) changes the name of a person in relation to whom a medical device is included in the Register under Chapter 4 of the Act; or
 - (b) cancels an entry in the Register in relation to a kind of medical device;

the Secretary must, as soon as practicable after changing the name or cancelling the entry:

- (c) notify the person in relation to whom the kind of device was included in the Register that the name has been changed or the entry in the Register has been cancelled; and
 - (d) ask the person to return to the Secretary the certificate of the inclusion of the kind of device in the Register given under subsection 41FF (2) of the Act.
- (9) If a person in relation to whom a kind of device is included in the Register under Chapter 4 of the Act receives a notice under subregulation (8), the person must return to the Secretary, as soon as practicable after receiving the notice, the certificate of the inclusion of the kind of device in the Register under that Chapter that was given before the change of name or cancellation.

Penalty: 5 penalty units.

- (10) An offence against subregulation (9) is an offence of strict liability.

Note For *strict liability*, see section 6.1 of the *Criminal Code*.

[4] Regulation 10A

renumber as regulation 11

[5] Regulations 10, 11 and 11A

omit

[6] Paragraph 12AD (b)

substitute

- (b) the use must comply with a procedural protocol approved by the ethics committee that has the function of monitoring the conduct of the trial at each trial site;

[7] After regulation 12B*insert***12C Application of Part 3-2 to medical devices (Act s 15A)**

For subparagraph 15A (5) (a) (ii) of the Act, a kind of medical device is specified if:

- (a) it is a medical device of a kind that is manufactured in Australia by a person mentioned in column 2 of Schedule 8, as in force immediately before the commencement of the *Therapeutic Goods Amendment (Medical Devices) Act 2002*; and
- (b) it is manufactured in the circumstances set out in column 3 of that Schedule, as in force immediately before that commencement.

Note Schedule 8 identifies persons who are exempt from the operation of Part 3-3 of the *Therapeutic Goods Act 1989* in relation to the manufacture or a step in the manufacture of therapeutic goods or a class of therapeutic goods — see subsection 34 (2) of the Act and regulation 18.

[8] Subregulations 14 (1) and (5)*omit*

If goods

insert

If goods (other than medical devices)

[9] Subregulation 14 (6)*substitute*

- (6) If:
 - (a) goods are included in the Register under Chapter 4 as a kind of medical device; and
 - (b) the goods cease to be a medical device because of a declaration under subsection 41BD (3) of the Act;
 the person in relation to whom the kind of device is included in the Register may apply to the Secretary to transfer the entry in relation to the goods to the part of the Register for registered

goods or the part of the Register for listed goods, as the case requires.

- (7) An application to transfer an entry in relation to goods from a part of the Register to the part of the Register for registered goods, or the part of the Register for listed goods, is to be treated as an application for registration or listing of the goods, as the case requires.

[10] Regulations 14B and 14C

omit

[11] Subregulation 23 (1), definition of *relevant test*

substitute

relevant test:

- (a) in relation to the analysis of therapeutic goods (other than medical devices), means a test that, under subregulation 28 (1), is a relevant test for the purpose of determining whether goods of a class in which the first-mentioned goods are included are goods that conform with a standard applicable to the goods; and
- (b) in relation to the analysis of a medical device, means a test that, under subregulation 28 (2), is a relevant test for the purpose of determining whether a medical device of that kind complies with the applicable provisions of the essential principles.

[12] Subparagraph 23 (2) (a) (ii)

after

subsection 28 (5A)

insert

or 41FN (2)

[13] Paragraph 24 (1) (a)

omit

licence holder

insert

licence holder, manufacturer in respect of whom a conformity assessment certificate has been issued, or

[14] Subregulation 24 (2)

omit

registration or listing of goods

insert

entry of goods in the Register

[15] Subregulation 24 (2)

omit

licence holder.

insert

licence holder or a manufacturer in respect of whom a conformity assessment certificate has been issued.

[16] Paragraphs 25 (3) (b) and (c)

after

subsection 28 (5A)

insert

or 41FN (2)

[17] Subregulation 26A (1)

omit

a medicine

insert

therapeutic goods

[18] Subregulation 26A (1)

after

subsection 28 (5A)

insert

or 41FN (2)

[19] Subparagraph 26A (1) (b) (ii)

omit

the medicine,

insert

the goods,

[20] Subregulation 26A (2)

omit

the medicine.

insert

the goods.

[21] Subparagraph 27 (2) (a) (ii)

substitute

(ii) any other matter relevant to determining whether:

(A) for goods other than medical devices — the goods from which the sample was taken conform with any standard applicable to the goods and any conditions relating to matters mentioned in paragraph 28 (2) (d) of the Act; and

(B) for medical devices — the goods from which the sample was taken comply with the applicable provisions of the essential principles and any conditions relating to matters mentioned in paragraph 41FO (2) (d) of the Act; and

[22] Regulation 28

omit everything before paragraph (a), insert

- (1) Each of the following is a relevant test for determining whether particular therapeutic goods (other than medical devices) are goods that conform with a standard applicable to the goods:

[23] Regulation 28

insert

- (2) Each of the following is a relevant test for determining whether a particular kind of medical device complies with the applicable provisions of the essential principles:
 - (a) a test specified in a medical device standard or conformity assessment standard for the kind of device;
 - (b) a test accepted for the purpose of issuing a conformity assessment certificate in respect of the kind of device;
 - (c) a test required under paragraph 41FO (2) (d) of the Act as a condition of inclusion of the kind of device in the Register;
 - (d) any other suitable test that the Secretary requires to be carried out in respect of the kind of device for the purpose of demonstrating compliance with the applicable provisions of the essential principles.

[24] Subregulation 29 (4)

substitute

- (4) If the certificate referred to in subregulation (1) states:
 - (a) for relevant goods other than medical devices — that the goods do not conform with a specified standard or comply with a requirement that is applicable to the goods under regulation 27; or

- (b) for medical devices — that the goods do not comply with the applicable provisions of the essential principles or a requirement that is applicable to the goods under regulation 27;

the certificate, and the copy of it referred to in subregulation (2), must be accompanied by a notice that complies with subregulation (4A).

- (4A) For subregulation (4), the notice must:
 - (a) state that the person to whom the certificate or copy is sent may ask for the results of the analysis referred to in the certificate to be reviewed in accordance with regulation 30; and
 - (b) specify the time within which a request for a review of the results may be made; and
 - (c) state that the person may ask for an extension of that time if it is not reasonable to expect the person to comply with regulation 30 within the specified time.

[25] Subregulation 30 (1)

substitute

- (1) A person:
 - (a) to whom a certificate, setting out the results of an examination and analysis of goods, is issued under subregulation 29 (1); and
 - (b) who sends to the Secretary evidence in writing establishing that the goods do conform with the specified standard or comply with an applicable requirement, or, for medical devices, do comply with the applicable provisions of the essential principles or an applicable requirement;may ask for the results of the analysis to be reviewed.

[26] Subregulation 30 (4)

omit

conform to a particular standard

insert

conform with a specified standard or comply with an applicable requirement, or, for medical devices, comply with the applicable provisions of the essential principles or an applicable requirement,

[27] Subregulation 30 (5)

omit

conform to the standard

insert

conform with a specified standard or comply with an applicable requirement, or, for medical devices, comply with the applicable provisions of the essential principles or an applicable requirement,

[28] Subregulation 31 (1A)

substitute

- (1A) If a sample of therapeutic goods delivered under subsection 28 (5A) or 41FN (2) of the Act is sent to a laboratory for analysis, the Commonwealth is liable to pay to the person in relation to whom the goods are entered on the Register an amount equal to the value of the sample.

[29] Subregulation 31 (2)

after

subsection 28 (5A)

insert

or 41FN (2)

[30] **Part 6, Division 1, heading**
substitute

**Division 1 Therapeutic Goods Committee,
Medical Devices Evaluation
Committee and Australian Drug
Evaluation Committee**

[31] **Subparagraph 34 (2) (a) (i)**
omit
goods;
insert
goods; and

[32] **Subparagraph 34 (2) (a) (iv)**
omit
use;
insert
use; and

[33] **After subparagraph 34 (2) (a) (iv)**
insert
(v) matters relating to the adequacy of a medical device standard in so far as it relates to a part or parts of the essential principles; and
(vi) matters relating to the adequacy of a conformity assessment standard in so far as it relates to a part or parts of the conformity assessment procedures;

[34] Paragraph 34 (4A) (d)

omit

therapeutic devices;

insert

medical devices and other therapeutic goods;

[35] Regulation 35

substitute

35 Medical Devices Evaluation Committee

- (1) The Medical Devices Evaluation Committee is established.
- (2) The functions of the Committee are:
 - (a) to give medical and scientific advice to the Minister or the Secretary in relation to any medical device that the Minister or the Secretary refers to it; and
 - (b) to give medical and scientific advice to the Minister or the Secretary in relation to any medicines that the Minister or the Secretary refers to it; and
 - (c) to give medical and scientific advice to the Minister or the Secretary in relation to any other therapeutic goods that the Minister or the Secretary refers to it; and
 - (d) to give advice to the Minister or the Secretary about the importation into, exportation from, and manufacture, distribution and supply in Australia, of therapeutic goods that have been assessed by the Committee; and
 - (e) to give advice that has been given to the Minister or the Secretary under paragraph (d) to persons or bodies as the Minister may direct.
- (3) Membership of the Committee consists of:
 - (a) at least 8, and not more than 12, core members; and
 - (b) at least 8, and not more than 20, associate members.

- (4) The Minister must appoint to the Committee:
- (a) as core members:
 - (i) at least 3 persons, each of whom is a medical practitioner eminent in the medical profession and at least 2 of whom are specialists in clinical medicine; and
 - (ii) at least 1 person with expertise in consumer issues; and
 - (iii) at least 1 person with expertise in industry issues; and
 - (iv) at least 1 person who is a biomedical engineer, or who holds a university degree in biomedical engineering; and
 - (v) at least 1 person with expertise in biomaterials, or who holds a university degree in biomaterial science; and
 - (b) as associate members:
 - (i) at least 1 person who is a medical practitioner eminent in the medical profession; and
 - (ii) at least 1 person who is a biomedical engineer, or who holds a university degree in biomedical engineering; and
 - (iii) at least 1 person with expertise in biomaterials, or who holds a university degree in biomaterial science.
- (5) The Minister must appoint, in writing, a member of the Committee to be its chairperson.
- (6) The Committee may appoint sub-committees, consisting of members of the Committee and other persons, to inquire into, and report to the Committee on, any matter within the Committee's functions.

[36] Paragraph 36 (2) (c)

omit

therapeutic devices

insert

medical devices and other therapeutic goods

[37] Subregulation 38 (2A)

after

serve

insert

as a member of the Medical Devices Evaluation Committee
or

[38] Paragraph 41 (2) (c)

substitute

(c) in the case of the Medical Devices Evaluation Committee — 6 members, of whom at least 4 are core members, constitute a quorum.

[39] Subregulation 41 (2A)

substitute

(2A) An associate member of the Australian Drug Evaluation Committee, or the Medical Devices Evaluation Committee, is eligible to attend a meeting of the relevant Committee only at the invitation of the chairperson of that Committee.

[40] Subregulation 41 (2C)

omit

Therapeutic Device Evaluation Committee

insert

Medical Devices Evaluation Committee

[41] Subparagraph 42C (1) (a) (ii)

substitute

(ii) the ASMI;

[42] Subregulation 42E (2)

omit

PMAA.

insert

ASMI.

[43] Paragraph 42K (a)

omit

PMAA;

insert

ASMI;

[44] Subparagraph 42T (1) (b) (ii)

substitute

(ii) the ASMI;

[45] Subregulation 42T (1A)

omit

therapeutic device

insert

medical device or other therapeutic goods

[46] Subregulation 42T (3)

omit

PMAA,

insert

ASMI,

[47] Subregulation 42T (3)

omit

PMAA

insert

ASMI

[48] Paragraph 42Y (c)

omit

PMAA;

insert

ASMI;

[49] Paragraph 42Y (f)

omit

therapeutic device

insert

medical device or other therapeutic goods

[50] Paragraph 42ZCAB (1) (b)

omit

therapeutic devices

insert

medical devices or other therapeutic goods

[51] Subparagraph 42ZCAB (1) (b) (i)

substitute

(i) subsection 22 (5) or 41FN (5) of the Act; or

[52] Paragraph 42ZCAI (4) (f)

omit

information.

insert

information;

[53] After paragraph 42ZCAI (4) (f)

insert

(g) suspend a kind of medical device from the Register under Part 4-6 of the Act;

(h) cancel the entry of a kind of medical device from the Register under Part 4-6 of the Act.

[54] Regulation 43A

omit

A fee

insert

(1) A fee

[55] Paragraph 43A (a)

omit

regulation 14

insert

regulation 10B

[56] Regulation 43A

insert

- (2) The applicable fee under item 2 or 3 of Schedule 9 for an application to transfer an entry of a 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, is not payable if the device ceases to be a medical device because of a declaration in force under subsection 41BD (3) of the Act.

[57] Subregulation 45AA (7)

substitute

- (7) This 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.

[58] Paragraph 46 (2) (a)

substitute

- (a) whether the goods are included in the Register and, if so:
- (i) the registration number, listing number or device number of the goods; and
 - (ii) the date when the goods were registered, listed or included in the Register; and
 - (iii) the class in which the goods are included in the Register;

[59] Paragraph 46 (2) (e)

omit everything before subparagraph (i), insert

- (e) if the goods are medicines, medical devices that contain medicines, or medical devices that incorporate, or are intended to incorporate, as an integral part, a medicine that is intended to act on a patient in a way that is ancillary to the device:

[60] Paragraph 46 (2) (f)

substitute

- (f) if the goods are a kind of medical device:
- (i) the intended purpose of the device; and
 - (ii) the device nomenclature system code specified for the device under subsection 41BE (3) of the Act; and
 - (iii) the medical device classification applying to the device;

[61] After subregulation 46 (3)

insert

- (4) For the purposes of subsection 61 (6) of the Act, the Secretary may release therapeutic goods 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.

[62] Regulation 47B, heading

substitute

47B Provision of information concerning medicines and medical devices

[63] Paragraph 47B (1) (b)

substitute

- (b) a person authorised under subsection 19 (5) or 41HC (1) of the Act to supply a medicine or medical device;

[73] Schedule 9, item 2A*omit*

subsections 32 (3), (4) or (5)

insert

subsection 9D (1), (2) or (3)

[74] Schedule 9, item 2A, after paragraph (f)*insert*

(g) a medical device 280

[75] Schedule 9, item 5, paragraphs (c) and (d)*omit*

subsection 32 (3), (4) or (5)

insert

subsection 9D (1), (2) or (3)

[76] Schedule 9, items 6AB, 6A, 6B and 12*omit*

subsection 32 (3), (4) or (5)

insert

subsection 9D (1), (2) or (3)

[77] Further amendments — references to Parts 2, 3 and 4 of the Act

<i>Provision</i>	<i>omit</i>	<i>insert</i>
Subparagraph 6 (1) (g) (i)	Part 3 of the Act;	Part 3-2 of the Act;
Subregulations 12 (1) and (1A)	Part 3 of the Act	Part 3-2 of the Act
Paragraph 12 (2) (a)	Part 3 of the Act,	Part 3-2 of the Act,
Subregulation 12A (1)	Part 3 of the Act	Part 3-2 of the Act

Schedule 2 Amendment

(subregulation 3 (2))

[1] Regulations 13, 14 and 14A

relocate as regulations 10A, 10B and 10C after regulation 10, as inserted by item [3] of Schedule 1 to these Regulations

Notes

1. These Regulations amend Statutory Rules 1990 No. 394, as amended by 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332, 370 and 430; 1993 No. 141; 1994 Nos. 150, 222 and 364; 1995 Nos. 33, 111, 192, 208, 253, 320 and 328; 1996 Nos. 9, 25 (disallowed by the House of Representatives on 10 September 1996), 131, 200 and 208; 1997 Nos. 162, 398, 399, 400 and 401 (disallowed by the Senate on 31 March 1998); 1998 Nos. 227, 247 and 369; 1999 Nos. 62, 209 and 324; 2000 Nos. 29, 48, 70, 123, 124, 267 and 358; 2001 Nos. 159, 160, 252 and 343; 2002 Nos. 9, 84, 114 and 143.

2. Notified in the *Commonwealth of Australia Gazette* on L 2002. 4 October