Therapeutic Goods Amendment Regulations 2000 (No. 1)

Statutory Rules 2000 No. 1

29

I, WILLIAM PATRICK DEANE, 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 22 MAR 2000 2000

WILLIAM DEANE
Governor-General

By His Excellency's Command

GRANT TAMBLING
Parliamentary Secretary to the Minister for Health and Aged Care

Therapeutic Goods Amendment Regulations 2000 (No. 1)[1]

Statutory Rules 2000 No. 29[2]

made under the

Therapeutic Goods Act 1989

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1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2000 (No. 1)*.

2 Commencement

These Regulations commence as follows:

(a) on gazettal — regulations 1 and 2, subregulation 3 (1) and Schedule 1;

(b) on 31 March 2000 — subregulation 3 (2) and Schedule 2.

3 Amendment of *Therapeutic Goods Regulations 1990*

(1) Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

(2) Schedule 2 amends the *Therapeutic Goods Regulations 1990*.

Schedule 1 Amendments commencing on gazettal

(subregulation 3 (1))

[1] Regulation 2, after definition of *pharmaceutical benefit*

insert

Poisons Standard has the same meaning as ***current Poisons Standard***.

[2] Part 3A, heading

substitute

Part 3A Applications for evaluation

[3] Part 3A, before regulation 16A

insert

Division 1 Goods mentioned in Part 1 of Schedule 10

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[4] After regulation 16G

insert

Division 2 Applications for evaluation of substances

16GA Evaluation other than evaluation under subsection 24 (1) or 32 (3), (4) or (5) of Act

(1) At the request of a person, and on payment of the prescribed fee, the Department may evaluate data submitted by the person concerning the following substances:

(a) a substance that is not an ingredient in listed goods or registered goods for supply in Australia, but that may be an ingredient in goods for which an application may be made for entry in the Register as listed goods or registered goods for supply in Australia;

(b) a new excipient in therapeutic goods for dermal application, being a substance not in use as an ingredient in any other listed goods or registered goods for supply in Australia at the time of conditional listing or conditional registration of those goods under section 28 of the Act.

(2) An evaluation under this regulation may be made, although an application under section 23 or subsection 32 (3), (4) or (5) of the Act is not current.

Exemption from fee

(3) No fee is payable for an evaluation under paragraph (1) (b) if the evaluation is in respect of a new excipient introduced for use as an ingredient, in compliance with a condition under section 28 of the Act, imposed before the commencement of this regulation but not earlier than 6 months before the application for evaluation is made.

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[5] Schedule 9, paragraph 2 (a)

substitute

(a)	for an application relating to a medicine to which item 4 of Schedule 9 does not apply	650
(b)	for an application relating to a therapeutic device of a kind mentioned in Part 2 of Schedule 3	540
(ba)	for an application relating to a medicine to which item 4 applies	the lesser of 5,000 and the amount that is 10% of the relevant fee under item 4

[6] Schedule 9, paragraph 2 (d)

omit

paragraphs (e) and

insert

paragraph

[7] Schedule 9, paragraph 2A (b)

omit

540

insert

650

[8] Schedule 9, item 4

after

for therapeutic goods

insert

in respect of therapeutic goods of a kind mentioned in Part 1 of Schedule 10 that are

[9] Schedule 9, item 4

Provision	*omit*	*insert*
Subparagraph (a) (i)	5,200	5,400
Subparagraph (a) (ii)	16,000	16,500
Subparagraph (a) (iii)	38,000	39,500
Subparagraph (a) (iv)	70,000	72,500
Subparagraph (a) (v)	80,000	83,000
Subparagraph (a) (vi)	85,000	88,500
Subparagraph (a) (vii)	90,000	93,500
Subparagraph (b) (i)	3,000	3,125
Subparagraph (b) (ii)	10,250	10,650
Subparagraph (b) (iii)	37,000	38,500
Subparagraph (b) (iv)	55,000	57,000
Subparagraph (b) (v)	60,000	62,500
Subparagraph (b) (vi)	65,000	67,500
Subparagraph (c) (i)	700	725
Subparagraph (c) (ii)	6,000	6,200
Subparagraph (c) (iii)	13,250	13,750
Subparagraph (c) (iv)	18,000	18,500
Subparagraph (c) (v)	28,000	29,000

Provision	*omit*	*insert*
Subparagraph (c) (vi)	37,000	38,500
Subparagraph (c) (vii)	45,000	47,000

[10] Schedule 9, item 4A

omit

[11] Schedule 9, item 5

substitute

5	evaluation fee:	
	(a) under subsection 24 (1) of the Act — in respect of a medicine to which item 4 does not apply, if the evaluation documentation does not contain clinical or toxicological information	4,300
	(b) under subsection 24 (1) of the Act — in respect of a medicine to which item 4 does not apply, if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	4,300
	(ii) over 50 pages, but not over 250 pages	5,500
	(iii) over 250 pages, but not over 500 pages	7,500
	(iv) over 500 pages, but not over 1,000 pages	10,000
	(v) over 1,000 pages, but not over 2,000 pages	15,000

	(vi) over 2,000 pages, but not over 3,000 pages	20,000
	(vii) over 3,000 pages	30,000
(c)	under subsection 32 (3), (4) or (5) of the Act — in relation to an entry in the Register relating to a medicine (other than an entry for goods in relation to which a fee specified in item 4 applies), if the evaluation documentation does not contain clinical or toxicological information	1,550
(d)	under subsection 32 (3), (4) or (5) of the Act — in relation to an entry in the Register relating to a medicine (other than an entry for goods in relation to which a fee specified in item 4 applies), if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	1,550
	(ii) over 50 pages, but not over 250 pages	5,500
	(iii) over 250 pages, but not over 500 pages	7,500
	(iv) over 500 pages, but not over 1,000 pages	10,000
	(v) over 1,000 pages, but not over 2,000 pages	15,000
	(vi) over 2,000 pages, but not over 3,000 pages	20,000
	(vii) over 3,000 pages	30,000

[12] Schedule 9, after item 7

insert

7A	fee for evaluation under paragraph 16GA (1) (a):	
	(a) if the evaluation documentation does not contain clinical or toxicological information	4,300
	(b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:	
	(i) not over 50 pages	4,300
	(ii) over 50 pages, but not over 250 pages	5,500
	(iii) over 250 pages, but not over 500 pages	7,500
	(iv) over 500 pages, but not over 1,000 pages	10,000
	(v) over 1,000 pages, but not over 2,000 pages	15,000
	(vi) over 2,000 pages, but not over 3,000 pages	20,000
	(vii) over 3,000 pages	30,000

7B	fee for evaluation, under paragraph 16GA (1) (b), in relation to 1 or more new excipients for use in particular therapeutic goods:		
	(a) if the evaluation documentation does not contain clinical or toxicological information		4,300
	(b) if the evaluation documentation contains clinical or toxicological information, and the total number of pages is:		
		(i) not over 50 pages	4,300
		(ii) over 50 pages, but not over 250 pages	5,500
		(iii) over 250 pages, but not over 500 pages	7,500
		(iv) over 500 pages, but not over 1,000 pages	10,000
		(v) over 1,000 pages, but not over 2,000 pages	15,000
		(vi) over 2,000 pages, but not over 3,000 pages	20,000
		(vii) over 3,000 pages	30,000

Schedule 2 Amendments commencing on 31 March 2000

(subregulation 3 (2))

Part 1 Amendments

[1] Regulation 2, after definition of *orphan drug*

insert

OTC medicine means therapeutic goods mentioned in Part 3 of Schedule 10.

[2] Paragraph 42ZE (1) (d)

substitute

(d) therapeutic goods referred to the Committee, by the Minister or the Secretary, for this regulation.

[3] Paragraph 42ZF (2) (f)

omit

applies, the advice may also include:

insert

applies:

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[4] Subregulation 42ZQ (1)

omit

at a meeting of the Committee.

insert

at, or before, the meeting of the Committee.

[5] Subregulation 42ZQ (3)

substitute

(3) When the Committee is making a determination under subregulation (2) about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not:

(a) be present during any deliberation of the Committee; or

(b) take part in making the determination.

(4) A member of a sub-committee under regulation 42ZG, who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the sub-committee must, without delay, disclose the nature of the interest at, or before, the meeting of the sub-committee.

[6] Regulation 42ZX

omit

if

insert

when at least

[7] Part 6, after Division 4

insert

Division 5 Medicines Evaluation Committee

Subdivision 1 Interpretation

42ZZA Definitions

In this Division:

Committee means the Medicines Evaluation Committee established by subregulation 42ZZB (1).

consultant physician has the meaning given in section 3 of the *Health Insurance Act 1973*.

medical practitioner has the meaning given in section 3 of the *Health Insurance Act 1973*.

Subdivision 2 Establishment of Committee

42ZZB Establishment and constitution of Committee

(1) A committee called the Medicines Evaluation Committee is established.

(2) The Committee has the functions mentioned in Subdivision 3 of this Division.

(3) The Committee must be constituted in accordance with Subdivision 4 of this Division.

(4) The Committee must hold meetings, and make decisions, in accordance with Subdivision 5 of this Division.

Subdivision 3 Functions of Committee

42ZZC Committee's evaluating function

(1) The Committee may evaluate, and report to the Minister or Secretary about, any of the following:

(a) an OTC medicine;

(b) an ingredient in an OTC medicine;

(c) a kind of ingredient in an OTC medicine;

(d) therapeutic goods identified by the Committee;

(e) therapeutic goods referred to the Committee, by the Minister or the Secretary, for this regulation.

Example

Examples of OTC medicines that the Committee may evaluate, and report about, include:

- OTC medicines that are included in the Register
- OTC medicines for which an application for inclusion in the Register has been made.

(2) The matters to be included in a report for subregulation (1) include, if appropriate, a recommendation about whether or not a particular kind of therapeutic goods should be included in the part of the Register for listed goods.

42ZZD Committee may give advice to Minister or Secretary

(1) The Committee may, in relation to a thing mentioned in subregulation 42ZZC (1), give to the Minister or Secretary scientific and policy advice about the following matters, as applicable:

(a) the import or export of the OTC medicine, ingredient, kind of ingredient or kind of therapeutic goods;

(b) registration or listing of the OTC medicine, ingredient, kind of ingredient or kind of therapeutic goods;

(c) the manufacture, supply and use of the OTC medicine, ingredient, kind of ingredient or kind of therapeutic goods.

Note For the definition of ***supply***, see subsection 3 (1) of the Act.

(2) An advice given about a thing mentioned in subregulation (1) may include, as applicable:

(a) the Committee's opinion about its safety; and

(b) an assessment of short-term and long-term risks and claimed benefits of its use; and

(c) the Committee's opinion about its quality; and

(d) the Committee's opinion about its efficacy; and

(e) if the advice is about therapeutic goods — the Committee's opinion about the indications of the therapeutic goods; and

(f) if the advice is about therapeutic goods in relation to which a claim has been made to which subsection 28 (6) of the Act applies:

(i) the Committee's opinion about the claim; and

(ii) the Committee's opinion about the amount, standard or type of information or evidence used to support a claim.

Note For the definition of ***indications***, see subsection 3 (1) of the Act.

42ZZE Committee may establish sub-committees

(1) The Committee may appoint sub-committees, consisting of members of the Committee and other persons.

(2) The function of a sub-committee is to inquire into, and report to the Committee on, any matter that is within the functions of the Committee.

42ZZF Minister or Secretary may seek further advice

(1) If the Committee gives advice, under this Division, to the Minister or the Secretary, the Minister or the Secretary may give a copy of that advice to another committee established under the Act.

(2) A Committee to which a copy of an advice is given may make comments to the Minister or the Secretary about that advice.

Example

Examples of Committees to which the Minister or Secretary may give a copy of advice include:

- the Complementary Medicines Evaluation Committee
- the National Drugs and Poisons Schedule Committee
- a committee established under Division 1 of this Part.

42ZZG Committee may seek advice and assistance

The Committee may, in performing its functions under this Division, seek advice from other persons.

Subdivision 4 Constitution of Committee

42ZZH Establishment and membership of Committee

The Committee is constituted in accordance with this Subdivision.

42ZZI Appointment of Committee members

(1) The Minister must appoint members of the Committee in accordance with this regulation.

(2) An appointment of a member must be in writing.

(3) The Committee must include at least 8, but no more than 12, members.

42ZZJ Expertise and experience of members

In deciding whether to appoint a person to be a member of the Committee, the Minister must take into account the person's expertise and experience in the following fields:

(a) general medical practice;

(b) specialist medical practice of a kind relevant to the Committee's functions;

(c) pharmaceutical chemistry;

(d) pharmacology;

(e) toxicology;

(f) microbiology;

(g) community pharmacy;

(h) manufacture of medicines;

(i) government regulation.

Example

For paragraph (b), the Minister would need to take into account candidates' expertise and experience in medical specialties, including paediatric and geriatric medicine.

42ZZK Appointment of Chair

The Minister must, in writing, appoint a member of the Committee to be its Chair.

42ZZL Minister may nominate expert advisers

(1) The Minister may nominate a person to give expert advice to the Committee to assist it in the performance of its functions.

(2) If the Minister nominates a person under subregulation (1), the Committee may ask that person for advice about performing a function of the Committee.

(3) The Committee may have no more than 8 such advisers.

(4) Regulations 42ZZM, 42ZZN, 42ZZO and 42ZZP apply to a person nominated under this regulation as if he or she were a member of the Committee.

42ZZM Term of appointment

(1) A Committee member is appointed for the term stated in the appointment.

(2) The term stated in an appointment must not be greater than 3 years.

(3) However, a Committee member may be reappointed for further terms of up to 3 years each.

(4) The Chair of the Committee is appointed as Chair for the term stated in the Chair's appointment.

(5) The Chair may be reappointed for further terms while he or she is a member of the Committee.

42ZZN Resignation

A Committee member may resign by signed notice of resignation given to the Minister.

42ZZO Disclosure of interests

(1) A Committee member who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.

(2) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines:

(a) be present during any deliberation of the Committee about the matter; or

(b) take part in any decision of the Committee about that matter.

(3) When the Committee is making a determination under subregulation (2) about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not:

(a) be present during any deliberation of the Committee; or

(b) take part in making the determination.

(4) A member of a sub-committee under regulation 42ZZE, who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the sub-committee must, without delay, disclose the nature of the interest at, or before, the meeting of the sub-committee.

42ZZP Termination of appointment

(1) The Minister may terminate a Committee member's appointment on the grounds of:

(a) physical or mental incapacity; or

(b) misbehaviour; or

(c) incompetence; or

(d) inefficiency; or

(e) failing to comply, either recklessly or intentionally, with regulation 42ZZO.

(2) The Minister must terminate the member's appointment if the member:

(a) is convicted of an offence punishable by imprisonment for 1 year or longer; or

(b) is absent without leave of absence from 3 consecutive meetings of the Committee.

42ZZQ Leave of absence

(1) The Minister may grant leave of absence to the Chair of the Committee.

(2) The Chair may grant leave of absence to another Committee member.

Subdivision 5 Committee procedures

42ZZR Committee procedures

This Subdivision sets out the procedures that the Committee must follow in holding meetings.

42ZZS Committee procedures generally

(1) In performing its functions, the Committee:

(a) must act according to these Regulations; and

(b) must act with as little formality and as quickly as the requirements of these Regulations, and a proper consideration of the issues before the Committee, allow; and

(c) is not bound by rules of evidence; and

(d) may obtain information about an issue in any way that it considers appropriate; and

(e) may receive information or submissions orally or in writing.

(2) In addition, the Committee must comply with any directions given, in writing, to the Committee by the Minister or the Secretary about the Committee's performance of its functions.

42ZZT Meetings

(1) The Chair of the Committee may, by written notice to the Committee, direct the Committee to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

(2) Subject to these Regulations, the procedure of a Committee's meeting is as decided by the Committee.

42ZZU Presiding member

(1) The Chair of the Committee must:

(a) preside at a Committee meeting; or

(b) nominate, in writing, a member of the Committee to preside at the meeting.

(2) If the Chair is temporarily absent from a meeting, the member chosen by the members present must preside.

42ZZV Quorum

At a Committee meeting, a quorum exists when at least half of the members are present.

42ZZW Voting

(1) A decision made at a Committee meeting by a majority of the votes of the members present and voting is a decision of the Committee.

(2) The member presiding at a Committee meeting has a deliberative vote and, in the event of an equality of votes, also has a casting vote.

42ZZX Records and reports

(1) The Committee must keep a record of its proceedings.

(2) The Committee must prepare any other report about its activities that is requested by the Minister or the Secretary.

[8] Schedule 10, Part 3, heading

substitute

Part 3 Evaluation by OTC Medicine Evaluation Section of the Department

Part 2 Additional amendments

[9] Table of additional amendments

Provision	*omit*	*insert*
paragraph 42ZF (1) (a)	therapeutic good	kind of therapeutic goods
paragraph 42ZF (1) (b)	therapeutic good	kind of therapeutic goods
paragraph 42ZF (1) (c)	therapeutic good	kind of therapeutic goods
paragraph 42ZF (2) (e)	a therapeutic good	therapeutic goods
paragraph 42ZF (2) (e)	the good	therapeutic goods
paragraph 42ZF (2) (f)	a therapeutic good	therapeutic goods
subregulation 42ZN (1)	performances	performance
subregulation 42ZN (2)	for this section	for this regulation

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.

2. Made by the Governor-General on 22 March 2000, and notified in the *Commonwealth of Australia Gazette* on 23 March 2000.