Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation.

Dated 13 October 2016

Peter Cosgrove
Governor-General

By His Excellency's Command

Sussan Ley
Minister for Health and Aged Care

OPC62209 - A

Contents

1 Name

This is the *Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	15 October 2016
2. Schedule 1	1 January 2017.	1 January 2017
3. Schedules 2 and 3	The day after this instrument is registered.	15 October 2016

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments relating to Advisory Committees

Therapeutic Goods Regulations 1990

1 Paragraph 6AA(a)

Repeal the paragraph, substitute:

(a) Advisory Committee on Medicines;

2 Division 1 of Part 6

Repeal the Division.

3 Division 1A of Part 6 (heading)

Repeal the heading, substitute:

Division 1A—Advisory Committee on Medicines

4 Regulation 35

Repeal the regulation, substitute:

35 Establishment

The Advisory Committee on Medicines is established.

5 Paragraphs 35A(1)(a) to (d)

Repeal the paragraphs, substitute:

(a) the safety, quality and efficacy of medicines, including in relation to pharmacovigilance;
(b) the entry of a medicine in the Register;
(c) the variation of an entry for a medicine in the Register;
(d) the continued retention of a medicine in, or the removal of a medicine from, the Register;
(e) risk assessment and risk management of medicines;
(f) any other matter (whether or not related to a medicine), including a matter related to standards.

6 Subregulation 35B(1)

Omit "32", substitute "20".

7 Subregulation 35B(1)

Omit "(2) and (3)", substitute "(1A) and (1B)".

8 After subregulation 35B(1)

Insert:

(1A) Subject to subregulation (1B):

(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (2); and

(b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

9 Subregulation 35B(2)

Omit all the words before paragraph (a), substitute:

(2) For the purposes of subregulation (1A), the fields are as follows:

10 Paragraph 35B(2)(b)

Repeal the paragraph, substitute:

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

11 Paragraph 35B(2)(l)

Repeal the paragraph, substitute:

(l) pharmaceutical chemistry;

(m) microbiology;

(n) community or clinical pharmacy;

(o) manufacture of medicines;

(p) dermatology;

(q) obstetrics or gynaecology;

(r) ophthalmology;

(s) radiology;

(t) medical genetics;

(u) developmental or reproductive toxicology;

(v) medicines in pregnancy;

(w) medical ethics.

12 Subregulation 35B(3)

Repeal the subregulation.

13 Divisions 1B and 1C of Part 6

Repeal the Divisions.

14 Before paragraph 38A(1)(a)

Insert:

(aa) the safety, performance and manufacturing of a medical device;

15 Paragraph 38A(1)(a)

Before "inclusion", insert "the".

16 Paragraph 38A(1)(b)

Before "variation", insert "the".

17 Paragraphs 38A(1)(c) and (d)

Repeal the paragraphs, substitute:

(c) the continued retention of a medical device or other therapeutic good in, or the removal of a medical device or other therapeutic good from, the Register;

(d) risk assessment and risk management of medical devices;

(e) any other matter (whether or not related to a medical device or other therapeutic goods).

18 Subregulation 38B(1)

Omit "32", substitute "16".

19 Subregulations 38B(2) and (3)

Repeal the subregulations, substitute:

(2) Subject to subregulation (3):

(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulations (4) and (5); and

(b) each member of the committee must have either or both of the following:

(i) medical or surgical expertise in one of the fields mentioned in subregulation (4);

(ii) expertise in at least one of the fields mentioned in subregulation (5).

(3) One member of the committee may have expertise in consumer health issues.

(4) For the purposes of paragraph (2)(a) and subparagraph (2)(b)(i), the fields are as follows:

(a) anaesthetics;

(b) cardiology;

(c) cardiothoracic surgery;

(d) dentistry or oro-maxillofacial surgery;

(e) ear, nose and throat;

(f) gastroenterology;

(g) neurology;

(h) obstetrics or gynaecology;

(i) ophthalmology;

(j) orthopaedics;

(k) pathology;

(l) plastic and reconstructive surgery;

(m) renal;

(n) respiratory medicine;

(o) vascular medicine;

(p) any other medical or surgical field of expertise that is relevant to the committee's functions.

(5) For the purposes of paragraph (2)(a) and subparagraph (2)(b)(ii), the fields are as follows:

(a) biomedical engineering or biomaterials;

(b) epidemiology or biostatistics;
(c) general medical practice in Australia;
(d) human factors analysis;
(e) interventional cardiology;
(f) interventional radiology;
(g) manufacture of medical devices;
(h) medical device software engineering;
(i) nursing;
(j) any other clinical or technical field of expertise that is relevant to the committee's functions.

20 Division 1DA of Part 6

Repeal the Division.

21 Paragraphs 39A(1)(a) to (d)

Repeal the paragraphs, substitute:

(a) the safety, efficacy and manufacturing quality of a complementary medicine;
(b) the safety and quality of ingredients that are, or are proposed to be, included in a determination under subsection 26BB(1) of the Act for a listed complementary medicine;
(c) any requirements that are, or are proposed to be, included in a determination under subsection 26BB(1) of the Act in relation to ingredients for a listed complementary medicine;
(d) the registration or listing of a complementary medicine;
(e) the variation of an entry for a complementary medicine in the Register;
(f) the continued retention of a complementary medicine in, or the removal of a complementary medicine from, the Register;
(g) any other matter (whether or not related to a complementary medicine), including a matter related to standards.

22 Subregulation 39B(1)

Omit "12", substitute "8".

23 Subregulation 39B(1)

Omit "(2), (3) and (4)", substitute "(1A) and (1B)".

24 After subregulation 39B(1)

Insert:

(1A) Subject to subregulation (1B):
(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (2); and
(b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

25 Subregulation 39B(2)

Omit all the words before paragraph (a), substitute:

(2) For the purposes of subregulation (1A), the fields are as follows:

26 Paragraph 39B(2)(c)

Repeal the paragraph.

27 Subregulations 39B(3) and (4)

Repeal the subregulations.

28 Before paragraph 39D(1)(a)

Insert:

(aa) the safety and efficacy of a biological;

29 Paragraph 39D(1)(a)

Before "inclusion", insert "the".

30 Paragraph 39D(1)(b)

Before "variation", insert "the".

31 Paragraphs 39D(1)(c) and (d)

Repeal the paragraphs, substitute:

(c) the continued retention of a biological in, or the removal of a biological from, the Register;

(d) any other matter (whether or not related to a biological), including a matter related to standards.

32 Subregulation 39E(1)

Omit "(2) and (3)", substitute "(1A) and (1B)".

33 After subregulation 39E(1)

Insert:

(1A) Subject to subregulation (1B):

(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (2); and

(b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

34 Subregulation 39E(2)

Omit all the words before paragraph (a), substitute:

(2) For the purposes of subregulation (1A), the fields are as follows:

35 Paragraphs 39E(2)(e) and (f)

Repeal the paragraphs.

36 Paragraphs 39E(2)(i) and (j)

Repeal the paragraphs, substitute:

(i) toxicology.

37 Subregulation 39E(3)

Repeal the subregulation.

38 Division 1EB of Part 6 (heading)

Repeal the heading, substitute:

Division 1EB—Advisory Committee on Vaccines

39 Regulation 39F

Repeal the regulation, substitute:

39F Establishment

The Advisory Committee on Vaccines is established.

40 Paragraphs 39G(1)(a) to (c)

Repeal the paragraphs, substitute:

(a) the safety, quality and efficacy of vaccines, including in relation to pharmacovigilance;
(b) the registration of a vaccine;
(c) the variation of an entry for a vaccine in the Register;
(d) the continued retention of a vaccine in, or the removal of a vaccine from, the Register;
(e) risk assessment and risk management of vaccines;
(f) any other matter (whether or not related to a vaccine), including a matter related to standards.

41 Subregulation 39H(1)

Omit "(2), (3) and (4)", substitute "(1A), (1B) and (2)".

42 After subregulation 39H(1)

Insert:

(1A) Subject to subregulations (1B) and (2):
(a) to the extent reasonably practicable, membership of the committee is to represent the widest possible range of fields mentioned in subregulation (3); and
(b) each member of the committee must have expertise in at least one of those fields.

(1B) One member of the committee may have expertise in consumer health issues.

43 Subregulation 39H(2)

Omit "must", substitute "may".

44 Paragraph 39H(2)(c)

Repeal the paragraph.

45 Subregulation 39H(3)

Omit all the words before paragraph (a), substitute:

(3) For the purposes of subregulation (1A), the fields are as follows:

46 Paragraphs 39H(3)(d) to (l)

Repeal the paragraphs, substitute:

(d) infectious diseases in adults or children;
(e) public health;
(f) epidemiology or biostatistics;
(g) vaccine program implementation;
(h) the provision of immunisation treatment by an individual;
(i) paediatrics;
(j) nursing.

47 Subregulation 39H(4)

Repeal the subregulation.

48 Regulation 40

Omit "1, 1A, 1B, 1C, 1D, 1DA,", substitute "1A, 1D,".

Schedule 2—Amendments relating to fees

Therapeutic Goods Regulations 1990

1 Clause 2 of Schedule 9 (heading)

Repeal the heading, substitute:

2 Part 2 fees do not apply in relation to applications etc. covered by Part 3

2 Clause 2 of Schedule 9

Omit "and evaluations", substitute ", evaluations and requests".

3 Part 2 of Schedule 9 (heading)

Repeal the heading, substitute:

Part 2—Table of fees other than for applications etc. covered by Part 3

4 Clause 3 of Schedule 9

Omit "and evaluations", substitute ", evaluations and requests".

5 Part 3 of Schedule 9 (heading)

Repeal the heading, substitute:

Part 3—Table of fees for applications etc. in relation to certain OTC medicines

6 Clause 4 of Schedule 9 (heading)

Repeal the heading, substitute:

4 Table of fees

7 Clause 4 of Schedule 9

Omit "application and evaluation fees", substitute "fees for applications, evaluations and requests".

8 Clause 4 of Schedule 9 (table heading)

Repeal the heading, substitute:

Fees

9 Clause 4 of Schedule 9 (at the end of the table)

Add:

7	Fee for providing advice in relation to a registered OTC medicine at the request of the sponsor of the medicine for the purpose of listing the medicine as a pharmaceutical benefit:	
	(a) if the request does not contain clinical data	1 530
	(b) if the request contains clinical data or a justification as to why such data is not needed	7 860

Schedule 3—Other amendments

Therapeutic Goods Regulations 1990

1 Regulation 2 (definition of *ASMI*)

Repeal the definition, substitute:

ASMI means Australian Self-Medication Industry Limited (ACN 607 233 116).

2 After subregulation 11A(1)

Insert:

(1A) However, a biological is not separate and distinct from other biologicals under subregulation (1) if:

(a) the biological is separate and distinct from other biologicals under that subregulation by reason only of a difference in a characteristic mentioned in subparagraph (1)(a)(ii) or (1)(b)(iv); and

(b) the difference in that characteristic is the result of a request made under subsection 9D(3AA) of the Act to vary the entry of the biological in the Register.

3 Paragraph 46A(2)(c)

Omit "Regulatory Services Group", substitute "Health Products Regulation Group".

4 Part 3 of Schedule 2 (cell at table item 3, column 2)

Repeal the cell, substitute:

riboflavin

5 Part 3 of Schedule 2 (cell at table item 10, column 2)

Repeal the cell, substitute:

colecalciferol