



Therapeutic Goods Amendment (Advisory Committees) Regulation 2013

Select Legislative Instrument No. 220, 2013

I, Quentin Bryce AC CVO, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation under the *Therapeutic Goods Act 1989*.

Dated 05 August 2013

Quentin Bryce
Governor-General

By Her Excellency's Command

Shayne Neumann
Parliamentary Secretary for Health and Ageing

OPC60147 - A

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No. 220, 2013 *Therapeutic Goods Amendment (Advisory Committees)
Regulation 2013* *i*

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1 Name of regulation

This regulation is the *Therapeutic Goods Amendment (Advisory Committees) Regulation 2013*.

2 Commencement

This regulation commences on the day after it is registered.

3 Authority

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

4 Schedule(s)

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods Regulations 1990

1 Subregulation 34A(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are:
 - (a) at the request of the Minister—to provide advice and to make recommendations to the Minister about one or more of the following matters:
 - (i) the adoption of standards for therapeutic goods;
 - (ii) matters relating to standards for therapeutic goods;
 - (iii) requirements for labelling and packaging of therapeutic goods;
 - (iv) standards for manufacture of therapeutic goods;
 - (v) matters relating to medical device standards;
 - (vi) matters relating to conformity assessment standards;
 - (vii) matters relating to standards for biologicals; and
 - (b) at the request of the Minister or Secretary—to provide advice and to make recommendations to the Minister or Secretary about a matter.

2 Subregulation 35A(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) inclusion of a prescription medicine in the Register;
 - (b) variation of an entry for a prescription medicine included in the Register;
 - (c) removal or continued retention of a prescription medicine in the Register;
 - (d) any other matter (whether or not related to prescription medicines).

3 Subregulation 36A(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) inclusion of a non-prescription medicine in the Register;
 - (b) variation of an entry for a non-prescription medicine included in the Register;
 - (c) removal or continued retention of a non-prescription medicine in the Register;
 - (d) any other matter (whether or not related to non-prescription medicines).

4 Subregulation 37A(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) safety of medicines;
 - (b) risk assessment and risk management of medicines;
 - (c) pharmacovigilance;
 - (d) any other matter (whether or not related to medicines safety).

5 Subregulation 37B(1)

Omit "15", substitute "25".

6 Paragraphs 37B(2)(a) to (j)

Repeal the paragraphs, substitute:

- (a) clinical pharmacology or pharmacokinetics;
- (b) clinical pharmacy;
- (c) general medical practice in Australia;
- (d) complementary medicine;
- (e) paediatrics;
- (f) consumer issues;
- (g) epidemiology or biostatistics;

- (h) gerontology;
- (i) intensive care;
- (j) anaesthetics;
- (k) psychiatry;
- (l) toxicology;
- (m) naturopathy;
- (n) nutrition and nutritional medicine;
- (o) pharmacognosy;
- (p) blood or tissue products;
- (q) cellular therapies, including tissue engineering;
- (r) organ and tissue transplantation;
- (s) stem cell transplantation;
- (t) internal medicine, including the following:
 - (i) haematology;
 - (ii) oncology;
 - (iii) infectious diseases;
 - (iv) cardiology;
 - (v) gastroenterology or hepatology;
 - (vi) renal disease;
 - (vii) endocrinology;
 - (viii) neurology;
 - (ix) immunology;
 - (x) rheumatology;
 - (xi) respiratory disease.

7 Subregulation 38A(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) inclusion of a medical device or other therapeutic goods in the Register;
 - (b) variation of an entry for a medical device or other therapeutic goods in the Register;

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- (c) removal or continued retention of a medical device or other therapeutic goods in the Register;
 - (d) any other matter (whether or not related to medical devices or other therapeutic goods).

8 Subregulation 38D(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) safety of medical devices;
 - (b) risk assessment and risk management of medical devices;
 - (c) performance of medical devices;
 - (d) any other matter (whether or not related to medical device safety).

9 Subregulation 38E(1)

Omit "15", substitute "25".

10 Subregulation 38E(2)

Repeal the subregulation, substitute:

- (2) Each member of the committee must have:
 - (a) medical or surgical expertise in at least one of the following fields:
 - (i) gastroenterology;
 - (ii) anaesthetics;
 - (iii) cardiology;
 - (iv) respiratory medicine;
 - (v) orthopaedics;
 - (vi) neurology;
 - (vii) vascular;
 - (viii) plastic and reconstructive surgery;
 - (ix) obstetrics or gynaecology;
 - (x) pathology;
 - (xi) ophthalmology;

- (xii) dentistry or oro-maxillofacial surgery;
- (xiii) ear, nose and throat;
- (xiv) renal; or
- (b) expertise in at least one of the following fields:
 - (i) consumer issues;
 - (ii) biomedical engineering;
 - (iii) biomaterials;
 - (iv) clinical medicine;
 - (v) epidemiology or biostatistics;
 - (vi) nursing;
 - (vii) human factors analysis;
 - (viii) general medical practice in Australia.

11 Subregulation 39A(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) inclusion of a complementary medicine in the Register;
 - (b) variation of an entry for a complementary medicine in the Register;
 - (c) removal or continued retention of a complementary medicine in the Register;
 - (d) any other matter (whether or not related to a complementary medicine).

12 Subregulation 39D(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) inclusion of a biological in the Register under Part 3-2A of the Act;
 - (b) variation of an entry for a biological included in the Register under Part 3-2A of the Act;

- (c) removal or continued inclusion of a biological in the Register under Part 3-2A of the Act;
- (d) any other matter (whether or not related to a biological).

13 Subregulation 39G(1)

Repeal the subregulation, substitute:

- (1) The committee's functions are, at the request of the Minister or Secretary, to provide advice and to make recommendations to the Minister or Secretary about one or more of the following matters:
 - (a) safety of vaccines;
 - (b) risk assessment and risk management of vaccines;
 - (c) any other matter (whether or not related to vaccine safety).

14 Paragraph 39H(3)(I)

Omit "nurse practitioner", substitute "registered nurse".