

EXPLANATORY STATEMENT

Select Legislative Instrument 2013 No. 220

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Advisory Committees) Regulation 2013

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national 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), which is part of the Department of Health and Ageing, is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the regulation is to amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations) to make a number of minor amendments to the arrangements relating to the advisory committees established in Divisions 1-1EB of Part 6 of the Principal Regulations.

These committees are established under the Principal Regulations to provide the Minister for Health and Medical Research and the Secretary of the Department of Health and Ageing with access to specialist expertise in relation to therapeutic goods and include, for example, the Advisory Committee on Prescription Medicines (ACPM), the Advisory Committee on the Safety of Medicines (the ACSOM), the Advisory Committee on the Safety of Medical Devices (the ACSMD) and the Advisory Committee on the Safety of Vaccines (the ACSOV).

The purpose of a number of the amendments is to clarify the circumstances in which the committees provide advice, and make recommendations, to the Minister or Secretary. This role is intended to be triggered when the Minister or the Secretary (or a delegate) requests advice or recommendations about a matter.

This will be consistent with current administrative practices regarding the consulting of these committees.

The regulation also increases the maximum number of members that may be appointed to each of the ACSOM and the ACSMD from the current 15 members to 25, and introduces a number of new fields of expertise to the respective lists of fields from which the Minister may appoint specialists to those committees.

The Minister may, in the case of the ACSOM, appoint persons with expertise in at least one of the fields listed in subregulation 37B(2), and in the case of the ACSMD, appoint persons with expertise in at least one of the fields listed in subregulation 38E(2).

For example, the regulation adds the fields of anaesthetics, toxicology and psychiatry in relation to the ACSOM, and the fields of plastic and reconstructive surgery, obstetrics or gynaecology and ear nose and throat in relation to the ACSMD.

Since the establishment of the ACSOM (in 2009) and the ACSMD (in 2011), the TGA has on occasion needed advice on matters relating to medicines and medical devices safety from specialists whose areas of expertise are not listed in the Principal Regulations.

These changes are therefore an important measure designed to address this, and to ensure that the TGA is able to access an appropriate range of expertise to enable it to properly, and promptly, address matters relating to the safety of medicines and medical devices.

In addition, the regulation makes a minor amendment to correct an inadvertent error in relation to an existing field of expertise for the membership of the ACSOV (changing the field from ‘nurse practitioner’ to ‘registered nurse’), and a small number of minor, editorial changes.

Details of the regulation are set out in the Attachment.

The Act does not specify conditions that need to be met before the power to make the regulation may be exercised.

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on the day after it is registered.

The Chairs of each of the ACSOM and the ACSMD were consulted in relation to the amendments to increase their membership and to add new fields of expertise for those committees.

Consultation was not undertaken in relation to the other measures set out in the Amendment Regulation, as these are considered to be minor and machinery in nature, and do not substantially alter existing arrangements in relation to the affected advisory committees.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

Details of the *Therapeutic Goods Amendment (Advisory Committees) Regulation 2013*

Section 1 – Name of regulation

This section provides for the regulation to be referred to as the *Therapeutic Goods Amendment (Advisory Committees) Regulation 2013*.

Section 2 – Commencement

This section provides for the regulation to commence the day after it is registered.

Section 3 – Authority

This section provides that the regulation is made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedule

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

Item 1 – Subregulation 34A(1)

Subregulation 34A(1) of the Principal Regulations provides that the functions of the Therapeutic Goods Committee (the TGC) are:

- under paragraph 34A(1)(a) of the Principal Regulations, to advise and make recommendations to the Minister about the matters relating to standards for therapeutic goods that are listed at subparagraphs 34A(1)(a)(i) – (vii), (e.g. the adoption of standards); and
- under paragraph 34A(1)(b) of the Principal Regulations, to advise and make recommendations to the Minister, or the Secretary, “*on matters referred to the committee by the Minister or Secretary*”.

Item 1 introduces a new subregulation 34A(1) to the Principal Regulations which, principally, has the effect of implementing the following changes compared to the current subregulation 34A(1) by:

- replacing the current descriptions of the role of the TGC to “advise” the Minister under paragraph 34A(1)(a), or the Minister or Secretary under paragraph 34A(1)(b), with a reference to this role being to “provide advice”; and
- clarifying that the TGC’s role of providing advice and making recommendations to the Minister, or the Minister or Secretary, is only activated where the Minister or Secretary has requested such advice or recommendations.

In relation to the former, this amendment is designed to make clearer the distinction between advice and recommendations, as given or made by the TGC. This is important because, under subregulation 42(12), the Secretary is required to publish the recommendations (but not the

advice) of each of the committees established under Divisions 1-1EB of Part 6 of the Regulations (which includes the TGC), following meetings of that committee.

In relation to the latter, this is intended to clarify that the TGC is only to undertake its functions of giving advice or making recommendations in response to a request from the Minister (paragraph 34A(1)(a)), or from the Minister or Secretary (paragraph 34A(1)(b)).

Item 2 – Subregulation 35A(1)

Subregulation 35A(1) of the Principal Regulations says that the functions of the Advisory Committee on Prescription Medicines (the ACPM) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 35A(1)(a) – (e) (e.g. the inclusion of a prescription medicine in the Australian Register of Therapeutic Goods (the Register)).

Item 2 introduces a new subregulation 35A(1) to the Principal Regulations, which largely contains equivalent changes to those outlined above in item 1, i.e. to refer to “provide advice” rather than “advise”, and to highlight that the ACPM’s role is only activated in response to a request from the Minister or Secretary.

In addition, item 2 replaces the current reference in paragraph 35A(1)(a) to “the Australian Register of Therapeutic Goods (the Register)” with a reference simply to “Register”, as this term is defined in subsection 3(1) of the Act.

Item 2 also implements a minor editorial change to combine current paragraphs 35A(1)(d) and (e) of the Principal Regulations (in a new paragraph 35A(1)(d)), and remove the reference in paragraph (e) to “*any other matter referred to the committee by the Minister or Secretary*”. As the new subregulation 35A(1) makes it clear the ACPM is only to give its advice etc. at the request of the Minister or Secretary, this reference will be redundant.

Item 3 – Subregulation 36A(1)

Subregulation 36A(1) of the Principal Regulations says that the functions of the Advisory Committee on Non-prescription Medicines (the ACNM) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 36A(1)(a) – (e) (e.g. the inclusion of a non-prescription medicine in the Register).

Item 3 introduces a new subregulation 36A(1) to the Principal Regulations.

The new subregulation 36A(1) contains equivalent changes in relation to subregulation 36A(1) to those outlined above in relation to item 2.

Item 4 – Subregulation 37A(1)

Subregulation 37A(1) of the Principal Regulations sets out the functions of the ACSM, being to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 37A(1)(a) – (d) (e.g. risk assessment and risk management of medicines).

Item 4 introduces a new subregulation 37A(1) to the Regulations, which largely contains equivalent changes to those outlined above in items 2 and 3, in relation to referring to “provide advice” rather than “advise” and clarifying that the ACSM’s role is only activated in response to a request from the Minister or Secretary.

Item 4 also makes a minor adjustment to paragraphs 37A(1)(c) and (d). Currently under paragraph 37A(1)(c), one of the ACSOM's functions is to advise and make recommendations about "*other matters related to pharmacovigilance*". In order to clarify the relationship between paragraphs 37A(1)(a) and (b) of the Principal Regulations and paragraph 37A(1)(c), item 4 remove the reference to "*any other matters related to [pharmacovigilance]*" from paragraph 37A(1)(c), with the effect that the paragraph refers simply to "*pharmacovigilance*".

Item 4 also removes the reference in paragraph 37A(1)(d) to "*referred to the committee by the Minister or Secretary*", for the same reasons as outlined above in item 2.

Item 5 – Subregulation 37B(1)

Subregulation 37B(1) of the Principal Regulations currently permits the Minister to appoint up to 15 persons to the ACSOM.

Item 5 amends subregulation 37B(1) to increase this to 25 persons.

Item 6 – Paragraphs 37B(1)(a) to (j)

Subregulation 37B(2) of the Principal Regulations currently lists, at paragraphs 37B(2)(a) – (j), 10 fields of expertise from which suitably qualified members may be appointed ACSOM), e.g. paediatrics, clinical pharmacy and general medical practice in Australia.

Item 6 introduces a new subregulation 37B(2), which incorporates a number of new fields of expertise, e.g. gerontology, intensive care, anaesthetics, toxicology and internal medicine (which itself includes a number of areas of expertise such as haematology, oncology and neurology).

The new subregulation 37B(2) modifies an existing field of expertise (adding a reference to "pharmacokinetics" to existing field "clinical pharmacology") and incorporate some existing fields within new fields ("pharmacology" by "epidemiology", "general medicine" by "internal medicine" and "hepatology" by "gastroenterology and hepatology").

These changes ensure that the ACSOM is able to access a broader range of specialist advice to inform its consideration of matters relating to the safety of medicines.

Item 7 – Subregulation 38A(1)

Subregulation 38A(1) of the Principal Regulations says that the functions of the Advisory Committee on Medical Devices (the ACMD) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 38A(1)(a) – (e) (e.g. the inclusion of a medical device in the Register).

Item 7 introduces a new subregulation 38A(1) to the Principal Regulations.

The new subregulation 38A(1) contains equivalent changes in relation to subregulation 38A(1) to those outlined above in relation to items 2 and 3.

Item 8 – Subregulation 38D(1)

Subregulation 38D(1) of the Principal Regulations says that the functions of the Advisory Committee on the Safety of Medical Devices (the ACSMD) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 38D(1)(a) – (d) (e.g. risk assessment and risk management of medical devices).

Item 8 introduces a new subregulation 38D(1) to the Principal Regulations.

The new subregulation 38D(1) largely contains equivalent changes to those outlined above in items 2, 3, 4 and 7 in relation to referring to “provide advice” rather than “advise” and clarifying that the ACSM’s role is only activated in response to a request from the Minister or Secretary.

Item 8 also makes a minor adjustment to paragraphs 38D(1)(c) and (d). Currently under paragraph 38D(1)(c), one of the ACSMD’s functions is to advise and make recommendations about “*other matters related to performance of medical devices*”. In order to clarify the relationship between paragraphs 38D(1)(a) and (b) of the Principal Regulations and paragraph 38D(1)(c), item 8 removes the reference to “*any other matters related to [performance of medical devices]*” from paragraph 38D(1)(c), with the effect that the paragraph simply refers to “*performance of medical devices*”.

Item 8 also removes the reference in paragraph 38D(1)(d) to “*referred to the committee by the Minister or Secretary*”, for the same reasons as outlined above in item 2.

Item 9 – Subregulation 38E(1)

Subregulation 38E(1) of the Principal Regulations currently permits the Minister to appoint up to 15 persons to the ACSMD.

Item 9 amends subregulation 38E(1) to increase this to 25 persons.

Item 10 – Subregulation 38E(2)

Subregulation 38E(2) currently lists, at paragraphs 38E(2)(a) – (m), 13 fields of expertise from which suitably qualified members may be appointed to the ACSMD, e.g. anaesthetics, cardiology and consumer issues.

Item 10 introduces a new subregulation 38E(2), which incorporates a number of new fields of expertise, e.g. medical or surgical expertise in plastic and reconstructive surgery, respiratory medicine and neurology.

The new subregulation 38E(2) modifies a small number of existing fields of expertise, by referring to “gastroenterology” rather than the current “gastrointestinal surgery”, to “orthopaedics” rather than the current “orthopaedic surgery” and to “biomaterials” rather than the current “biomaterial science”.

The new subregulation 38E(2) also incorporates two existing fields of expertise within new fields - “oro-maxillofacial surgery” by “dentistry or oro-maxillofacial surgery”, and “epidemiology” by “epidemiology or biostatistics”.

These changes ensure that the ACSMD is able to access a broader range of specialist advice to inform its consideration of matters relating to the safety of medical devices.

Item 11 – Subregulation 39A(1)

Subregulation 39A(1) of the Principal Regulations says that the functions of the Advisory Committee on Complementary Medicines (the ACCM) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 39A(1)(a) – (e) (e.g. the inclusion of a complementary medicine in the Register).

Item 11 introduces a new subregulation 39A(1) to the Principal Regulations.

The new subregulation 39A(1) contains equivalent changes in relation to subregulation 39A(1) to those outlined above in relation to items 2, 3 and 7.

Item 12 – Subregulation 39D(1)

Subregulation 39D(1) of the Principal Regulations says that the functions of the Advisory Committee on Biologicals (the ACB) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 39D(1)(a) – (e) (e.g. the inclusion of a biological in the Register).

Item 12 introduces a new subregulation 39D(1) to the Principal Regulations.

The new subregulation 39D(1) contains equivalent changes in relation to subregulation 39D(1) to those outlined above in relation to items 2, 3, 7 and 11 – with the exception of the amendment in those items replacing the relevant reference to “the Australian Register of Therapeutic Goods” with a reference to “the Register”.

That measure is not needed in relation to the ACB, as subparagraph 39D(1)(a) already refers simply to “the Register”.

Item 13 – Subsection 39G(1)

Subregulation 39G(1) of the Principal Regulations says that the functions of the Advisory Committee on Safety of Vaccines (ACSOV) are to advise and make recommendations to the Minister or Secretary about the matters listed at paragraphs 39G(1)(a) – (c) (e.g. risk assessment and risk management of vaccines).

Item 13 introduces a new subregulation 39G(1) to the Principal Regulations.

The new subregulation 39G(1) contains equivalent changes to relevant above items in relation to replacing “advise” with “provide advice”, clarifying that that the ACSOV’s role is only activated upon request by the Minister or Secretary and removing the reference in paragraph 39G(1)(c) to “*referred to the committee by the Minister or Secretary*”.

Item 14 – Subparagraph 39H(3)(1)

Under paragraph 39H(3)(1) of the Principal Regulations, one of the fields of expertise from which the Minister may appoint members to the ACSOV is the provision of immunisation treatment by a nurse practitioner.

This reference was included in the list of fields of expertise for ACSOV members when the Principal Regulations were amended in 2012 to establish that committee and provide for its functions and membership.

However, the reference to expertise in the provision of immunisation treatment by a “nurse practitioner” was intended to refer to such treatment by a “registered nurse” (such as a nurse with experience working in a general practice setting). “Nurse practitioners” are a specific subgroup of registered nurses, and it was not intended to restrict this field of expertise to only such nurses.

Item 14 therefore replaces “nurse practitioner” with “registered nurse”.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Therapeutic Goods Amendment (Advisory Committees) Regulation 2013

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Therapeutic Goods Amendment (Advisory Committees) Regulation 2013* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989*.

The purpose of the Amendment Regulation is to make a small number of minor amendments to the *Therapeutic Goods Regulations 1990* (the Principal Regulations) in relation to the advisory committees established under Divisions 1-1EB of Part 6 of the Principal Regulations to advise the Minister and the Secretary about matters related to therapeutic goods.

The Amendment Regulation increases the number of members able to be appointed to the Advisory Committee on the Safety of Medicines (ACSOM) and the Advisory Committee on the Safety of Medical Devices (ACSMD) (from 15 to 25 in each case) and adds a number of new fields of expertise from which members of those committees may be appointed. These changes enable the ACSOM and ACSMD to access a broader range of expertise to inform their consideration of medicines and medical devices safety matters, and enhances the ability of the Therapeutic Goods Administration to respond promptly to such matters.

The Amendment Regulation also clarifies that the function of the committees to provide advice and to make recommendations is activated in response to a request from the Minister or the Secretary. They also clarify the intent of one of the fields of expertise for the Advisory Committee on the Safety of Vaccines by replacing a reference to ‘nurse practitioner’ with ‘registered nurse’.

Human rights implications

As the Amendment Regulation does not introduce any changes to the Principal Regulations other than to implement the minor changes mentioned above, it does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

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