EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

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/performance and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (TGA), which is part of the Department of Health, 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.

In 2014 and 2015, an independent panel examined Australia's medicines and medical devices regulatory framework – the Expert Review of Medicines and Medical Devices Regulation (the MMDR) and made a number of recommendations.

As part of the response to the MMDR, the Government agreed to rationalise the number of statutory advisory committees currently set out in Part 6 of the Therapeutic Goods Regulations 1990 (the Principal Regulations) from the current nine committees established in Divisions 1-1EB of Part 6 of the Principal Regulations, to a more streamlined structure of five advisory committees. The intention to reduce the number of committees and re-focus their work was announced in the 2016-17 Budget.

The nine committees – the Therapeutic Goods Committee (TGC), the Advisory Committee on Prescription Medicines (ACPM), the Advisory Committee on Non-prescription Medicines (ACNM), the Advisory Committee on the Safety of Medicines (ACSOM), the Advisory Committee on Medical Devices (ACMD), the Advisory Committee on Complementary Medicines (ACCM), the Advisory Committee on Biologicals (ACB) and the Advisory Committee on the Safety of Vaccines – are, under the recommendation, to be replaced with five new committees from 1 January 2017.

The committees that constitute the new structure are the Advisory Committee on Medicines (ACM), the Advisory Committee on Medical Devices (ACMD), the Advisory Committee on Complementary Medicines (ACCM), the Advisory Committee on Biologicals (ACB) and the Advisory Committee on Vaccines (ACV).

The ACM will cover the roles of the current ACPM, ACNM and ACSM, each of which will be replaced. The ACMD will continue (with some changes), and will cover the role of the current ACSMD, which is also replaced. The ACCM and the ACB will continue (with some changes) and the current ACSV is replaced by a broader ACV.

The Therapeutic Goods Committee is also abolished, but its core role of advising and making recommendations about standards for therapeutic goods (other than medical devices) is preserved across relevant new or continuing committees (the ACM, ACCM, ACB and ACV).

The purpose of the Regulation is, principally, to amend the Principal Regulations to implement this recommendation by repealing relevant Divisions of Part 6 of the Principal Regulations, and replacing committees in those Divisions to deliver the new structure. It also makes the changes described above to the continuing committees.

The Regulation also makes a small number of minor, unrelated amendments to the Principal Regulations, including introducing fees for responding to requests from sponsors for advice that their registered over the counter (OTC) medicine is equivalent to a medicine that is listed on the Pharmaceutical Benefit Scheme.

Other minor amendments include updating the definition of the Australian Self Medication Industry (ASMI) to reflect that organisation having become a public company, and the updating of a small number of references to ingredient names for consistency with international practice.

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 *Legislation Act 2003*.

The amendments in the Regulation relating to advisory committees commence on 1 January 2017. All other measures in the Regulation commence the day after registration.

Consultation

Consultation on the committee restructure was carried out during, and as part of, the Expert Review's processes as part of MMDR in 2014-2015.

Key industry bodies ASMI, the Generic and Biosimilar Medicines Association (GBMA) and Accord were consulted in relation to equivalence requests for registered OTC medicines as part of consultations that took place between 2012 and 2015 on the new fee structure that was introduced for these products on 1 January 2016. However, fees for these requests were inadvertently not included in the regulation amendments that established that new structure.

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

ATTACHMENT

Details of the *Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016*

Section 1 – Name of regulation
This section provides for the Regulation to be referred to as the *Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016.*

Section 2 – Commencement
This section provides for the measures in Schedule 1 of the Regulation to commence on 1 January 2017, and for the measures in Schedules 2 and 3 of the Regulation to commence the day after registration.

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 the Regulation has effect according to its terms.

Schedule 1 – Amendments relating to Advisory Committees

Therapeutic Goods Regulations 1990

Item 1 – Paragraph 6AA(a)
Item 1 makes a minor, consequential amendment to regulation 6AA of the Therapeutic Goods Regulations 1990 (the Principal Regulations), to reflect that the Advisory Committee on Non-prescription Medicines is to be replaced (item 13 below refers).

The effect of this item is to substitute the current reference to the Advisory Committee on Non-prescription Medicines in regulation 6AA with a new paragraph 6AA(a) referring to the new Advisory Committee on Medicines.

Amendments relating to abolishing the Therapeutic Goods Committee

Item 2 – Division 1 of Part 6
Item 2 repeals current Division 1 of Part 6 of the Principal Regulations, with the effect of abolishing the Therapeutic Goods Committee (as part of the rationalisation of nine advisory committees to a more streamlined structure of five such committees).

The capacity to provide advice to the Minister on matters relating to standards for the purposes of subsection 10(4) of the *Therapeutic Goods Act 1989* (the Act) will however be preserved across a number of the new or continuing advisory committees - the Advisory Committee on Medicines, the Advisory Committee on Complementary Medicines, the Advisory Committee on Biologicals and the Advisory Committee on Vaccines.

Amendments relating to the new Advisory Committee on Medicines

Item 3 – Division 1A of Part 6 (heading)
This item substitutes a new heading for the current heading of Division 1A of Part 6 of the Principal Regulations, which currently refers to the Advisory Committee on Prescription Medicines, to reflect the replacement of this committee by item 4 below.

Item 4 – Regulation 35
Item 4 substitutes a new regulation 35 for the current regulation 35, with the effect of replacing the current Advisory Committee on Prescription Medicines with a new committee – the Advisory Committee on Medicines.

The Advisory Committee on Medicines is intended, in particular, to, in effect, replace three current committees - the Advisory Committee on Prescription Medicines, the Advisory Committee on Non-prescription Medicines and the Advisory Committee on the Safety of Medicines.

Item 5 – Paragraphs 35A(1)(a) to (d)
This item repeals the current list of the Advisory Committee on Prescription Medicines' functions at paragraphs 35A(1)(a)-(d) with a revised list of functions for the new Advisory Committee on Medicines.

Under this revised list of functions, the principal functions of the new Advisory Committee on Medicines include providing advice and making recommendations about:

- the entry of a medicine in the Australian Register of Therapeutic Goods (the Register), the variation of an entry in the Register for a medicine and the possible removal of a medicine from the Register;
- the safety, quality and efficacy of a medicine, including in relation to pharmacovigilance; and
- any other matter, including in relation to standards.

The new committee thus covers the main functions of the current Advisory Committee on Prescription Medicines and Advisory Committee on Non-prescription Medicines, as well as functions relating to providing advice and making recommendations on post-market monitoring/pharmacovigilance issues, to reflect the adoption of the role of the current Advisory Committee on the Safety of Medicines.

The capacity to advise on matters relating to standards ensures that the role of the Therapeutic Goods Committee is preserved across a number of the new committees including the Advisory Committee on Medicines.

Item 6 – Subregulation 35B(1)
Currently under subregulation 35B(1) of the Principal Regulations, the Minister may appoint up to 32 persons to the membership of the Advisory Committee on Prescription Medicines.

Item 6 amends subregulation 35B(1) to replace this with a more streamlined 20 person maximum membership for the new Advisory Committee on Medicines.

Items 7 Subregulation 35B(1
This item makes a minor amendment to subregulation 35B(1), to reflect the changes introduced by item 8 below.

Item 8 – After subregulation 35B(1)
Item 8 introduces new subregulations 35B(1A) and (1B) to Division 1A of Part 6 of the Principal Regulations.

New subregulation 35B(1A) requires that, to the extent reasonably practicable and subject to new subregulation 35B(1B), membership of the Advisory Committee on Medicines is to represent the widest possible range of the fields of expertise for members listed in subregulation 35B(2). Each member must have expertise in at least one of those fields.

New subregulation 35B(1B), however, highlights that the Minister may appoint as a member of the new committee a person with expertise in consumer health issues.

If appointed, the consumer health expert is not required to have expertise in one of the fields listed in subregulation 35B(2). This is made clear in subregulation (1A) where the requirement for the membership to reflect a wide range of the fields of expertise is subject to the Minister's power to appoint a consumer health expert.

Item 9 – Subregulation 35B(2)
This item makes a minor editorial amendment to subregulation 35B(2) to reflect the changes introduced by item 8 above.

Items 10 and 11 – Paragraphs 35B(2)(b) and (l)
These items amend the list of fields of expertise in subregulation 35B(2) of the Principal Regulations, with the main effect of adding additional fields of expertise for members of the new Advisory Committee on Medicines (other than a member appointed as a consumer health expert under new subregulation 35B(1B)).

These new fields mainly comprise some of the fields of expertise currently set out in Division 1B of Part 6 of the Principal Regulations for the Advisory Committee on Non-prescription Medicines (e.g. microbiology, manufacture of medicines), and a small number of new fields not currently covered in the Principal Regulations (e.g. obstetrics or gynaecology, medical genetics and medicines in pregnancy).

The fields of expertise currently listed in paragraphs 35B(2)(a)-(l) are retained under these amendments.

Item 12 – Subregulation 35B(3)
This item makes a minor amendment to repeal subregulation 35B(3) of the Principal Regulations, to reflect the changes introduced by item 8 above.

Item 13 – Division 1B and 1C of Part 6
This item repeals Divisions 1B and 1C of Part 6 of the Principal Regulations, with the effect of allowing two current committees - the Advisory Committee on Non-prescription Medicines, and the Advisory Committee on the Safety of Medicines - to be replaced by the Advisory Committee on Medicines which will cover the roles currently carried out by those committees.

Amendments relating to the continuing Advisory Committee on Medical Devices

Items 14 and 17 – Before paragraph 38A(1)(a), and paragraphs 38A(1)(c) and (d)
These items amend subregulation 38A(1) of the Principal Regulations, which sets out the functions of the Advisory Committee on Medical Devices to, principally, include two new functions. These are to provide advice, and make recommendations, to the Minister or the Secretary about the safety, performance and manufacturing of a medical device, and about the risk assessment and risk management of medical devices.

The Advisory Committee on Medical Devices is one of the committees that will continue under the streamlined committee structure. The addition of these new functions for the Advisory Committee on Medical Devices principally reflects the adoption of the safety committee's role of providing expert input on post-market issues involving medical devices. The Advisory Committee on the Safety of Medicines would not continue (item 20 below refers).

Items 15 and 16 – Paragraphs 38A(1)(a) and (b)
These items make a minor, editorial amendment to each of paragraphs 38A(1)(a) and (b).

Item 18 – Subregulation 38B(1)
Currently under subregulation 38B(1) of the Principal Regulations, the Minister may appoint up to 32 persons to the membership of the Advisory Committee on Medical Devices.

Item 18 amends subregulation 38B(1) to replace this with a more streamlined 16 person maximum membership, under the revised structure of Division 1D for the new Advisory Committee on Medical Devices.

Item 19 – Subregulations 38B(2) and (3)
Item 19 introduces new subregulations 38B(2) - (5) to Division 1D of Part 6 of the Principal Regulations.

New subregulation 38B(2) requires that, subject to new subregulation new subregulation 38B(2):

- to the extent reasonably practicable, membership of the Advisory Committee on Medicines is to represent the widest possible range of the fields of expertise for members listed in subregulations 38B(4) and (5); and
- each member must have either medical or surgical expertise in one of the fields listed in subregulation 38B(4), or expertise in one of the fields of expertise listed in subregulation 38B(5).

New subregulation 38B(3) highlights that the Minister may appoint as a member of the new committee a person with expertise in consumer health issues. Taken together, subregulations 38B(2) and (3) makes it clear that, if appointed, the consumer health expert is not required to also have expertise in one of the fields listed in subregulations 35B(4) or (5).

Principally, the fields of expertise in new subregulations 38B(4) and (5) reflect the current fields of expertise for the Advisory Committee on Medical Devices, with a small number of additional fields.

These additional fields mainly comprise some of the fields of expertise currently set out in Division 1DA of Part 6 of the Principal Regulations for the Advisory Committee on the

Safety of Medical Devices (e.g. dentistry or oro-maxillofacial surgery, human factors analysis), and a small number of new fields not currently covered in the Regulations (e.g. interventional cardiology, interventional radiology and medical device software engineering). These new fields would reflect advances in technology, and will assist the committee to keep pace with the current state of the art for medical devices.

Item 20 – Division 1DA of Part 6
This item repeals Division 1DA of Part 6 of the Principal Regulations, with the effect that the current Advisory Committee on the Safety of Medical Devices would not continue under the new committee structure. This does, however, make way for the continuing Advisory Committee on Medical Devices to cover the role of the replaced committee.

Amendments relating to the continuing Advisory Committee on Complementary Medicines

Item 21 – Paragraphs 39A(1)(a) to (d)
This item replaces the current list of functions of the Advisory Committee on Complementary Medicines (which is continuing as part of these amendments) in subregulation 39A(1) of the Principal Regulations with a revised list of functions.

This revised list clarifies some of the committee's current functions by making it clearer that the committee may advise or make recommendations to the Minister or Secretary about both registered or listed complementary medicines (or about the proposed registration or listing of such products), as well as about variations to entries in the Register for such products and their possible removal from the Register.

The revised list also adds new functions - in particular, in relation to advising and making recommendations about ingredients that are proposed for use in listed complementary medicines under section 26BB of the Act, and about any requirements that may be specified under section 26BB of the Act in relation to the use of ingredients in such products.

Section 26BB of the Act allows the Minister to make a legislative instrument specifying ingredients that can be included in a medicine listed in the Register listed under section 26A of the Act, and requirements relating to the inclusion of those ingredients in such medicines, e.g. in relation to maximum daily dosages of some ingredients. A person seeking to list a medicine under section 26A must certify, when doing so, that the medicine does not contain an ingredient that is not included in the section 26BB instrument, and does not contravene any requirements in the instrument in relation to the use of that ingredient.

The revised list of functions also includes the capacity to advise on matters relating to standards, which would ensure that the role of the Therapeutic Goods Committee is preserved across a number of the new and continuing committees including the Advisory Committee on Complementary Medicines.

Item 22 – Subregulation 39B(1)
Currently under subregulation 39B(1) of the Principal Regulations, the Minister may appoint up to 12 persons to the membership of the Advisory Committee on Complementary Medicines.

Item 22 amends subregulation 39B(1) to replace this with a more streamlined 8 person maximum membership, under the revised structure of Division 1E for the new Advisory Committee on Complementary Medicines.

Item 23 – Subregulation 39B(1)
Item 23 makes a minor amendment to subregulation 39B(1), to reflect the changes to be introduced by item 24 below.

Item 24 – After subregulation 39B(1)
Item 24 introduces new subregulations 39B(1A) and (1B) to the Principal Regulations, requiring that, to the extent reasonably practicable and subject to new subregulation 39B(1B), membership of the Advisory Committee on Complementary Medicines is to represent the widest possible range of the fields of expertise in subregulation 39B(2). Each member must have expertise in at least one of those fields.

New subregulation 39B(1B) highlights that the Minister may appoint as a member a person with expertise in consumer health issues. If appointed, the consumer health expert is not required to have expertise in one of the fields listed in subregulation 39B(2).

Items 25-27 – Subregulation 39B(2) and subregulations39B(3) and (4)
This item makes minor amendments in relation to subregulation 39B(2), (3) and (4), and paragraph 39B(2)(c), to reflect the changes introduced by item 24 above.

Amendments relating to the continuing Advisory Committee on Biologicals

Item 28 – Before paragraph 39D(1)(a)
This item amends subregulation 39D(1) of the Principal Regulations to add a new function for the continuing Advisory Committee on Biologicals – being, to advise and make recommendations to the Minister or Secretary in relation to the safety or efficacy of a biological.

The inclusion of this new field principally makes it clear that, in addition to continuing to advise on including biologicals in the Register, varying entries in the Register for biologicals or removing biologicals from the Register, the committee may also advise on post-market monitoring issues relating to these products.

Items 29 and 30 – Paragraphs 39D(1)(a) and (b)
These items make a minor, editorial amendment to each of paragraphs 39D(1)(a) and (b).

Item 31 – Paragraphs 39D(1)(c) and (d)
This item amends subregulation 39D(1) of the Principal Regulations, principally to include a reference to the capacity of the Advisory Committee on Biologicals to advise on matters relating to standards.

This reflects the preservation of the core function of the Therapeutic Goods Committee (in relation to providing advice and making recommendations about standards) across relevant new or continuing committees, including the Advisory Committee on Biologicals.

Item 32 – Subregulation 39E(1)

This item makes a minor amendment to subregulation 39E(1) to reflect the changes to be introduced by item 33 below.

Item 33 – After subregulation 39E(1)
Item 33 introduces new subregulations 39E(1A) and (1B) to the Principal Regulations, to require that, to the extent reasonably practicable and subject to new subregulation 39E(1B), membership of the Advisory Committee on Biologicals is to represent the widest possible range of the fields of expertise in subregulation 39E(2). Each member must have expertise in at least one of those fields.

New subregulation 39E(1B) highlights that the Minister may appoint as a member a person with expertise in consumer health issues. If appointed, the consumer health expert is not required to have expertise in one of the fields listed in subregulation 39E(2).

Item 34 – Subregulation 39E(2)
This item makes a minor amendment to subregulation 39E(2) to reflect the changes introduced by item 33 above.

Item 35 – Paragraphs 39E(2)(e) and (f)
This item removes two current fields of expertise for members of the Advisory Committee on Biologicals – 'stem cell transplantation', and 'organ and tissue transplantation'. Separate fields for these areas are not considered necessary, because 'stem cell transplantation' is covered by another current field - 'cellular therapies, including tissue engineering', and 'organ and tissue transplantation' is covered by the current field - 'tissue products'.

Item 36 – Paragraphs 39E(2)(i) and (j)
This item makes a minor amendment to subregulation 39E(2) of the Principal Regulations to remove the current field of 'consumer issues', to reflect that provision for a member of the committee to have expertise in consumer health issues is separately provided for in new subregulation 39E(1B) (item 33 above refers).

Item 37 – Subregulation 39E(3)
This item makes a minor amendment to repeal current subregulation 39E(3), to reflect the changes introduced by item 33 above.

Amendments relating to the new Advisory Committee on Vaccines

Items 38 and 39 – Division 1EB of Part 6 (heading)
Item 38 substitutes a new heading for Division 1EB of Part 6 of the Principal Regulations, to reflect the changes to be introduced by item 39, which replaces the current Advisory Committee on Safety of Vaccines with the new Advisory Committee on Vaccines.

Item 40 – Paragraphs 39G(1)(a) – (c)
This item substitutes a new set of functions for the new Advisory Committee on Vaccines.

The new set of functions preserves the current functions of the Advisory Committee on Safety of Vaccines in providing advice and making recommendations about the safety and risk assessment and risk management of vaccines.

The new functions, however, also add to the committee's role the capacity to advise on the quality and efficacy of vaccines including in relation to pharmacovigilance, the registration of

a vaccine, variations to entries in the Register for vaccines and the possible removal of vaccines from the Register, and matters relating to standards.

Principally, this reflects an intention that the new committee be able to provide expert input in relation to applications for marketing approval of vaccines, as well as a greater emphasis on providing advice and making recommendations about relevant post-market monitoring issues.

The reference to standards in the new functions ensures that the role of the Therapeutic Goods Committee is preserved in relevant new and continuing committees including the Advisory Committee on Vaccines.

Item 41 – Subregulation 39H(1)
This item makes a minor amendment to subregulation 39H(1) of the Principal Regulations to reflect the changes to be introduced by item 42 below.

Item 42 – After subregulation 39H(1)
Item 42 introduces new subregulations 39H(1A) and (1B) to the Principal Regulations.

New subregulation 39H(1A) requires that, to the extent reasonably practicable and subject to both new subregulation 39H(1B) and current subregulation 39H(2), membership of the Advisory Committee on Vaccines is to represent the widest possible range of the fields of expertise in subregulation 39H(3). Each member must have expertise in at least one of those fields.

The effect of these requirements being subject to subregulations 39H(1B) and (2) is that any person appointed who is either a person with expertise in consumer health under new subregulation 39H(1B) or a person from any of the groups mentioned in subregulation (2) (such the Australian Technical Advisory Group on Immunisation, and the National Immunisation Committee), does not need to have expertise in any of the fields listed in subregulation 39H(3).

Item 43 – Subregulation 39H(2)
This item amends subregulation 39H(2) of the Principal Regulations in relation to the appointment of representatives of the groups or committees mentioned in subregulation (2) to the new Advisory Committee on Vaccines.

The effect of this item is that the Minister would not (contrary to the current position) be required to appoint as members one person from each of the bodies mentioned in subregulation 39H(2) to the new Advisory Committee on Vaccines, but instead have the discretion to make an appointment or appointments under that provision.

Item 44 – Paragraph 39H(2)(c)
Item 44 makes a minor amendment to subregulation 39H(2) of the Principal Regulations reflect that fact that the Advisory Committee on the Safety of Medicines will be replaced (see item 13 above).

Item 45 – Subregulation 39H(3)
This item makes a minor amendment to subregulation 39H(3) to reflect the changes introduced by item 42 above.

Item 46 – Paragraphs 39H(3)(d)-(l)
This item amends the list of fields of expertise in relation to the Advisory Committee on Vaccines, principally to add new fields paediatrics and nursing.

Item 47 – Subregulation 39H(4)
This item makes a minor amendment to repeal current subregulation 39H(4) of the Principal Regulations to reflect the changes made by item 42 above.

Amendments to Division 1F – General requirements in relation to advisory committees

Item 48 – Regulation 40
This item makes a minor, consequential amendment to regulation 40 of the Principal Regulations, to reflect the changes made by items 2, 13 and 20 above which, respectively, abolish the Therapeutic Goods Committee and allow the replacement of the Advisory Committee on Non-prescription Medicines, the Advisory Committee on the Safety of Medicines and the Advisory Committee on the Safety of Medical Devices.

Schedule 2 – Amendments relating to fees

Therapeutic Goods Regulations 1990

Items 1 - 8 - Various references in Schedule 9
These items make a number of minor amendments for consistency to reflect the changes to be introduced by item 9 below.

Item 9 – Clause 4 of Schedule 9 (at the end of the table)
This item introduces two new fees to the table in Part 3 of Schedule 9 to the Principal Regulations that would relate to the processing and, where necessary, evaluating of requests from sponsors of registered over the counter (OTC) medicines that their medicine is equivalent to a medicine that is listed on the Pharmaceutical Benefits Scheme (PBS).

This advice is important for sponsors of generic registered OTC medicines, who require it to support their applications to list their generic such medicines on the PBS.

As is the case in relation to prescription medicines (for which a similar fee to that proposed already exists at item 18 of Part 2 of Schedule 9), these fees will only apply in relation to registered OTC medicines that are already registered in the Register – where information about equivalence is included in the letter from the TGA to the sponsor advising them that their product has been approved for marketing, the fee will not apply.

The new fees would be $1530 where the request does not involve clinical data (typically, this is where the medicine the subject of the request is a ‘clone’ of a medicine that is already listed in the PBS, and the main part of responding to such a request is to confirm the relationship with the parent medicine on the PBS), and $7860 for requests involving the evaluation of either clinical data (typically, this will be bioequivalence data) or of a justification as to why such data is not needed. Such justifications are usually accompanied

by physico-chemical data and/or pharmacokinetic data and, in some cases, clinical data in the form of literature reports rather than bioequivalence data.

In relation to the fee of $1530 where the request does not involve clinical data, this fee reflects the Therapeutic Goods Administration's costs which include direct staff time of around 8 hours (on average) in relation to such requests, and the related allocation of support and corporate costs. In relation to the fee of $7860 where the request involves clinical data or a justification as to why such data is not needed, this fee reflects the Therapeutic Goods Administration's costs which include direct staff time of around 40 hours (on average), and the related application of support and corporate costs.

Schedule 3 – Other amendments

Therapeutic Goods Regulations 1990

Item 1 – Regulation 2 (definition of ASMI)
This item updates the definition of the Australian Self Medication Industry (ASMI) in regulation 2 of the Principal Regulations, to reflect ASMI's change in 2015 from an incorporated association to a public company limited by guarantee.

Item 2 – After subregulation 11A(1)
This item amends regulation 11A of the Principal Regulations, which prescribes characteristics in which a biological will be taken to be' separate and distinct' from other biologicals.

Under current subparagraph 11A(1)(a)(ii) of the Principal Regulations, a Class 1 or Class 2 biological is taken to be separate and distinct from other such biologicals if it has a different intended clinical use. Under current subparagraph 11A(1)(b)(iv) of the Principal Regulations, a Class 3 or Class 4 biological is taken to be separate and distinct from other such biologicals if it has a different therapeutic indication.

If a sponsor of a biological applies to the Secretary under subsection 9D(3AA) of the Act for a variation to the entry in the Register for their product and the only effect of the variation would be to reduce the class of persons for whom the biological would be suitable or to add a warning or precaution about the use of it which does not involve a comparison with any other therapeutic goods, the Secretary must vary the entry in accordance with the request – these are regarded as 'safety-related' variations.

However, the provisions in the Principal Regulations referred to above - subparagraphs 11A(1)(a)(ii) and 11A(1)(b0(iv) – could have the unintended effect of making biologicals for which the Secretary has approved a safety-related variation that involves a change of intended clinical use or therapeutic 'separate and distinct' for the purposes of the Act. This would mean that, as varied, the biologicals would require a new entry in the Register, and a new application for marketing approval, the application of fees and obviously delays relating to processing.

To avoid this unintended outcome, item 2 adds a new subregulation 11A(1A) to the Principal Regulations, which makes it clear that a biological is not separate and distinct from other biologicals if it is separate and distinct by reason only of a difference referred to in subparagraphs 11A(1)(a)(ii) or 11A(1)(b)(iv), and the difference is the result of a request

made under subsection 9D(3AA) of the Act. Subsection 9D(2A) of the Act has the same effect in relation to registered and listed therapeutic goods (including medicines).

Item 3 – Paragraph 46A(2)(c)
This item makes a minor amendment to paragraph 46A(2)(c) to reflect recent changes to the name of the Group in the Department in which the TGA is located.

Items 4 and 5 – Part 3 of Schedule 2 (cells at table items 3 and 10, column 2)
These items make minor amendments to change references to two substances in Part 3 of Schedule 2 to the Regulations, to more closely align with international practice. 'Cholecalciferol' is updated to 'colecalciferol', and 'Riboflavine' is updated to 'riboflavin'.

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 and Other Measures) Regulation 2016

The *Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016* (the Amendment Regulation) 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 Amendment Regulation is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). It amends the *Therapeutic Goods Regulations 1990* (the Principal Regulations) mainly to rationalise the number of statutory advisory committees established under the Principal Regulations, as part of the Government's response to the Expert Review of Medicines and Medical Devices Regulation. These amendments take effect on 1 January 2017.

In 2014 and 2015, an independent panel examined Australia's medicines and medical devices regulatory framework – the Expert Review of Medicines and Medical Devices Regulation (the MMDR) - and made a number of recommendations.

As part of the response to the MMDR, the Government agreed to rationalise the number of statutory advisory committees currently set out in Part 6 of the Therapeutic Goods Regulations 1990 (the Principal Regulations) from the current nine committees established in Divisions 1-1EB of Part 6 of the Principal Regulations, to a more streamlined structure of five advisory committees. The intention to reduce the number of committees and re-focus their work was announced in the 2016-17 Budget.

The nine committees – the Therapeutic Goods Committee (TGC), the Advisory Committee on Prescription Medicines (ACPM), the Advisory Committee on Non-prescription Medicines (ACNM), the Advisory Committee on the Safety of Medicines (ACSOM), the Advisory Committee on Medical Devices (ACMD), the Advisory Committee on Complementary Medicines (ACCM), the Advisory Committee on Biologicals (ACB) and the Advisory Committee on the Safety of Vaccines – are, under the recommendation, to be replaced with five new committees from 1 January 2017.

The committees that constitute the new structure are the Advisory Committee on Medicines (ACM), the Advisory Committee on Medical Devices (ACMD), the Advisory Committee on Complementary Medicines (ACCM), the Advisory Committee on Biologicals (ACB) and the Advisory Committee on Vaccines (ACV).

The Amendment Regulation also makes a small number of minor, unrelated amendments including to:

- introduce two fees for responding to requests from sponsors for advice that their registered over the counter (OTC) medicine is equivalent to a medicine that is listed on the Pharmaceutical Benefits Scheme. These fees were inadvertently omitted from earlier TG Regulations amendments that introduced a new fee structure for registered OTC products in January this year;

- updating the definition of the Australian Self Medication Industry (ASMI), to reflect that organisation having become a public company;
- updating two ingredient names for consistency with international practice; and
- ensuring that safety-related changes (those that only involve a reduction of the class of person for whom the biological would be suitable, or that add a warning or precaution about the biological that does not involve comparing it to any other therapeutic good) to entries in the Australian Register of Therapeutic Goods (the Register) for biologicals do not result in the varied biological becoming a separate and distinct therapeutic good that would otherwise need its own, new entry in the Register.

Human rights implications

As the Amendment Regulation does not introduce any changes to the TG Regulations other than to implement the 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.

Sussan Ley, Minister for Health and Aged Care