EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2017 Measures No.2) Regulations 2017

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 (the 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.

The *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* (the Amendment Act) amended the Act to support the implementation of several key recommendations of the Expert Panel Review of Medicines and Medical Device Regulation (the Review) agreed to by the Australian Government. The Expert Panel was established to, principally, identify areas of the regulation of medicines and medical devices which could be streamlined while maintaining the safety and quality of therapeutic goods in Australia, and made 58 recommendations. The Australian Government supported 56 of the 58 recommendations for reform. The Amendment Act addressed a first tranche of these recommendations, and the *Therapeutic Goods Legislation Amendment (2017 Measures No.1) Regulations 2017* supported a number of the Review measures in the Amendment Act that required regulations to be in place by 1 July 2017 – for example, in relation to providing a new pathway for the priority review of prescription medicines that represent a major therapeutic advance.

Additional regulations are now needed to support the second tranche of Review measures in the Amendment Act which include:

- providing a new pathway for the priority review by the Secretary of medical devices that represent either a breakthrough technology, or a major clinical advantage over existing alternatives in the Australian Register of Therapeutic Goods (the Register);
- providing an equivalent pathway for the priority review by the Secretary of applications for conformity assessment certificates, in relation to the manufacture of medical devices that meet the same criteria as the above new pathway; and
- allowing industry sponsors of medicines and biologicals that are currently registered or included in the Register to make straightforward, low-risk variations (notifiable variations) to their products (where product safety, quality or efficacy is not impacted) by notification to the Secretary rather than such changes needing to be pre-approved.

The *Therapeutic Goods Legislation Amendment (2017 Measures No.2) Regulations 2017* (the Regulations) amend both the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and the *Therapeutic Goods Regulations 1990* (the TG Regulations) for the above purposes, and to implement two Review measures that do not require principal legislation:

- providing a pathway for the Secretary to evaluate an application for the registration of a prescription medicine within 120 working days, based on the provision of a recent assessment of the same medicine conducted by a comparable international regulator; and
- enhancing the ability of interested parties to have input into the process for the scheduling of medicines and chemicals, by allowing persons interested in a proposed amendment to the Poisons Standard to comment on an interim decision to amend the Poisons Standard (this is currently limited to persons who provided a submission in response to the initial invitation for public submissions, i.e. before the interim decision) and allowing a longer period to submit such comments than the current 10 days.

The Regulations also make one minor amendment to the TG Regulations not related to the Review, principally to allow senior medical officers of the Department of Health's Health Products Regulation Group to approve access to unapproved medicines, biologicals and medical devices where alternatives are unavailable or in short supply.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The measures in the Regulations that relate to notifiable variations would commence on 4 December 2017, those that relate to priority pathways and the evaluation of prescription medicines would commence on 1 January 2018 and all other measures would commence the day after registration.

Consultation

Extensive consultation was undertaken in 2014-15 with consumers, industry and health professionals as part of the Review. Further public consultation on the proposed details for the new priority pathway for medical devices– including proposed criteria for qualifying for the pathway – was undertaken between November 2016 and January 2017. Thirteen submissions were received (6 from industry and regulatory consultants, 2 from industry representative groups, 3 from health practitioner groups and 2 from consumer groups), with broad support for the proposed approach and some modifications suggested in relation to timeframes and the publication of decisions. These suggestions have been incorporated into the final makeup of the scheme. Targeted consultation with industry was undertaken in June 2017 on the proposed notifiable variations for registered medicines and biologicals, with all respondents supporting the proposals. Public consultation was undertaken in late 2016 on shorter evaluation timeframes where a report from a comparable international regulator is available, with general acceptance of the proposed criteria for when the shorter timeframe will apply.

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

ATTACHMENT

Details of the proposed *Therapeutic Goods Legislation Amendment (2017 Measures No.2) Regulations 2017*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (2017 Measures No.2) Regulations 2017.*

Section 2 – Commencement
This section provides for Schedules 1 and 3 of the Regulations to commence on 1 January 2018, Part 2 of Schedule 2 of the Regulations to commence on 4 December 2017 and Part 1 of Schedule 2, and Schedule 4, of the Regulations to commence the day after registration.

Section 3 – Authority
This section provides that the Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 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 the Regulations has effect according to its terms.

Schedule 1 – Approval of medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1– After Division 4.1
This item introduces a new Division 4.1A to the MD Regulations, titled "Conformity assessment (priority applicant) determinations", and provides for the following matters:

- the application of new Division 4.1A;
- requirements for applying for a conformity assessment (priority applicant) determination (new regulation 4.3B);
- the making of such determinations by the Secretary (new regulation 4.3C);
- the period during which such determinations will be in force (new regulation 4.3D); and
- revocation of such determinations (new regulation 4.3E).

Application of new Division 4.1A – new regulation 4.3A
New regulation 4.3A makes it clear that Division 4.1A makes provision for, and in relation to, the making of conformity assessment (priority applicant) determinations for the purposes of subsection 41ECA(1) of the Act.

Applications for conformity assessment (priority applicant) determinations – new regulation 4.3B
New regulation 4.3B sets out the requirements for persons applying to the Secretary for a conformity assessment (priority applicant) determination – principally, these are that the application must be in accordance with the relevant form approved by the Secretary, and must be accompanied by sufficient supporting information to allow the Secretary to properly

consider the application. If these steps are not met, or if the prescribed application fee has not been paid (item 7 below refers), the application will be taken not to have been made.

Making of conformity assessment (priority applicant) determinations – new regulation 4.3C

New subregulation 4.3C(1) makes it clear that on receiving an application for a conformity assessment (priority applicant) determination that is in accordance with new regulation 4.3B, the Secretary must consider the application and decide either to make the determination or refuse to do so.

New subregulation 4.3B(2) sets out the criteria for qualifying for conformity assessment (priority applicant) determination, and would enable the Secretary make a determination if (after having regard to any matter the Secretary considers relevant) he or she is satisfied that:

- the intended purpose of the medical device to which the application for the conformity assessment (priority applicant) determination relates is for the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition; and
- either there are no medical devices with that intended purpose in the Register or, if there are, there is substantial evidence showing that the safety or performance of the new device (when used for that intended purpose) provides a significant improvement compared to those other devices;
- either the medical device to which the application for the conformity assessment (priority applicant) determination relates is a breakthrough technology and there is evidence it offers a major clinical advantage over existing technology, or there is evidence that it offers a major clinical advantage over existing alternative products included in the Register or it is an in vitro diagnostic medical device and its early availability in Australia would provide a major public health benefit.

An example of a medical device that would likely constitute a breakthrough technology would be a nanorobotics device able to be injected into the body and record and/or measure biomarkers (e.g. the presence of a particular enzyme) *in vivo*.

Where the Secretary makes a conformity assessment (priority applicant) determination, the determination must set out the name of the applicant, the medical device to which it relates and the manufacturer's intended purpose of the device.

The Secretary must also notify the applicant in writing as soon as practicable after making the decision and, in the case of a refusal, provide reasons. Review and appeal rights would apply for manufacturers whose applications are refused (items 5 and 6 below refer).

Period during which conformity assessment (priority applicant) determination is in force – new regulation 4.3D

New regulation 4.3D sets out that a conformity assessment (priority applicant) determination comes into force on the day the Secretary notifies the applicant of the decision to make the determination.

Where a person in relation to whom the Secretary makes a conformity assessment (priority applicant) determination applies under section 41EB of the Act for a conformity assessment certificate within 6 months of the determination coming into effect, their determination will remain in force until either of the following occurs:

- a decision by the Secretary on the application for the conformity assessment certificate is finally determined – i.e. when the Secretary issues the certificate under section 41EC of the Act, or where there Secretary decides not to issue the certificate under that provision and there is no longer any possibility of a change in outcome of that decision; or
- the person withdraws that application; or
- that application lapses in accordance with section 41EG of the Act (e.g. because the person did not comply with a request of the Secretary to provide samples of the relevant device, or did not pay the relevant conformity assessment fee for the application).

Where the person does not apply for a conformity assessment certificate within 6 months of the conformity assessment (priority applicant) determination coming into force, the determination will remain in force until the end of that 6 month period.

This is designed to avoid delays and to support the efficient processing of conformity assessment certificates for which these determinations are made, so that they can assist with the medical devices to which they relate being available for patients as soon as possible.

Revocation of conformity assessment (priority applicant) determinations – new regulation 4.3E

New regulation 4.3E sets out the instances in which the Secretary may revoke a conformity assessment (priority applicant) determination – principally these are where:

- either the person has not yet applied for a conformity assessment certificate under section 41EB of the Act, or has done so but that application is not effective for the purposes of subsection 41EB(2) of the Act (e.g. if they have not paid the relevant application fee); and
- the Secretary is satisfied that the criteria for a conformity assessment (priority applicant) determination (outlined above) are no longer satisfied in relation to the medical device to which the conformity assessment (priority applicant) determination relates.

Items 2 and 3 – Before regulation 5.2, and after regulation 5.3

These items makes minor amendments to headings to reflect in particular the introduction of new Subdivision D of Division 5.1 of Part 5 of the MD Regulations in relation to medical devices (priority applicant) determinations by item 4 below.

Item 4 – At the end of Division 5.1 – medical devices (priority applicant) determinations

Item 4 amends the MD Regulations to introduce a new Subdivision D of Part 5.1 of the MD Regulations to provide for and in relation to medical devices (priority applicant) determinations.

New regulations 5.4A – 5.4D set out equivalent arrangements in respect of medical devices (priority applicant) determinations as new regulations 4.3B – 4.3E above do for conformity assessment (priority applicant) determinations including, in particular, setting out identical criteria for making medical devices (priority applicant) determinations (new regulation 5.4B refers).

Items 5 and 6 – Regulation 10.7

These items amend regulation 10.7 of the MD Regulations, to make it clear that a decision of the Secretary to refuse to make a conformity assessment (priority applicant) determination or a medical devices (priority applicant) determination, or a decision of the Secretary to revoke

either such determination, is subject to review and appeal rights for the unsuccessful applicant or holder of the determination.

Items 7 and 8 – Part 1 of Schedule 5 (after table items 1.1 and 1.5)
These items introduce an application fee for persons applying for a conformity assessment (priority applicant) determination and for persons applying for a medical devices (priority applicant) determination – in each case, of $9,660. This fee reflects the staff effort required for pre-submission, application assessment and administrative activities associated with processing and assessing these applications, with an average expected effort to perform these elements of approximately 40 hours.

Items 9-11 - Dictionary
These items principally introduce definitions for a conformity assessment (priority applicant) determination (which would have the meaning given by subsection 41ECA(2) of the Act) and for a medical devices (priority applicant) determination (which would have the meaning given by subsection 41FKA(2) of the Act).

Schedule 2 – Variation of entries in the Register

Part 1 – Prescription medicines

Therapeutic Goods Legislation Amendment (2017 Measures No.1) Regulations 2017

Item 1 – Subsection 2(1) (table item 3, columns 2 and 3)
This item amends the table of commencement dates in subsection 2(1) of the *Therapeutic Goods Legislation Amendment (2017 Measures No.1) Regulations 2017*, with the effect of bringing forward the commencement of Part 2 of Schedule 1 to those regulations from 1 January 2018 to 4 December 2017.

Part 2 of Schedule 1 to those regulations sets out variations to existing entries in the Australian Register of Therapeutic Goods (the Register) that a sponsor of a prescription medicine (encompassing both prescription medicines that are, and that are not, biological medicines) may make to their products by notification to the TGA rather than (as would otherwise be the case) those requiring the Secretary's pre-approval.

Part 2 – Registered complementary medicines, registered over the counter (OTC) medicines, prescription medicines and biologicals

Therapeutic Goods Regulations 1990

Item 2 – Regulation 2
This item introduces a definition of 'TGA notifications process guidance document' which would define that term by reference to the TGA document entitled '*Notifications process – requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected*', as in force on 4 December 2017 (a copy of this document is available without charge from the TGA's website www.tga.gov.au).

Item 3 – Paragraph 10AAA(2)(b)
This item amends paragraph 10AAA(2)(b) of the TG Regulations to, principally, replace a reference to the title of the document mentioned above with a reference to the new definition that relates to that document as in force on 4 December 2017.

Item 4 – Subregulation 10AAA(2) (note)
This item makes a minor amendment to subregulation 10AAA(2) of the TG Regulations to repeal the note under that subregulation. This note is no longer needed in light of the new definition introduced by item 2 above.

Item 5 – Subregulation 10AAA(2) (at the end of the table)
Regulation 10AAA of the TG Regulations specifies kinds of variations for which the Secretary must vary the entry in the Register on request by a person in relation to whom OTC medicines or complementary medicines are registered. Currently the table in subregulation 10AAA(2) lists 16 such notifiable variations.

This item amends subregulation 10AAA(2) to add a further 8 such variations including, for example, a variation to reflect a change to the font, letter height or text size on a product label for the medicine, other than a change on the main label for the medicine, and the addition of a new pack size within a medicine's pack size range.

Items 6-8 – Regulation 10AAB
Regulation 10AAB of the TG Regulations, which was to commence on 1 January 2018 (as introduced by Part 2 of Schedule 1 of the *Therapeutic Goods Legislation Amendment (2017 Measures No.1) Regulations 2017*) but which would now commence on 4 December 2017 as part of these proposed Regulations (item 1 of this Schedule refers), specifies kinds of variations for which the Secretary must vary the entry in the Register on request by a person in relation to whom prescription medicines other than biological medicines are registered. Currently the table in subregulation 10AAB(2) lists 52 such variations.

Item 6 amends paragraph 10AAB(2)(b) of the TG Regulations to, principally, replace a reference to the title of the document mentioned above in item 2 with a reference to the new definition that relates to that document as in force on 4 December 2017.

Item 7 makes a minor amendment to subregulation 10AAB(2) to repeal the note under that subregulation. This note is no longer needed in light of the new definition introduced by item 2 above.

Item 8 amends subregulation 10AAB(2) to add a further 13 notifiable variations for prescription medicines other than biological medicines including, for example, a variation to reflect a change to a label for the medicine to include information about a patient support program.

Items 9 – 11 – Regulation 10AAC
Regulation 10AAC of the TG Regulations, which was to commence on 1 January 2018 (as introduced by Part 2 of Schedule 1 of the *Therapeutic Goods Legislation Amendment (2017 Measures No.1) Regulations 2017*) but which now commences on 4 December 2017 as part of these proposed Regulations (item 1 of this Schedule refers), specifies kinds of variations for which the Secretary must vary the entry in the Register on request by a person in relation to whom prescription medicines that are biological medicines are registered. Currently the table in subregulation 10AAB(2) lists 10 such variations.

Item 9 amends paragraph 10AAC(2)(b) of the TG Regulations to, principally, replace a reference to the title of the document mentioned above in item 2 with a reference to the new definition that relates to that document as in force on 4 December 2017.

Item 10 makes a minor amendment to subregulation 10AAC(2) to repeal the note under that subregulation. This note is no longer needed in light of the new definition introduced by item 2 above.

Item 11 amends subregulation 10AAC(2) to add a further 20 notifiable variations for prescription medicines that are biological medicines including, for example, a variation to reflect a minor change to a physiochemical test method used for testing the medicine.

Item 12 – After regulation 10AAC

This item amends the TG Regulations to introduce new regulation 10AAD, with the effect of allowing specified notifiable variations for biologicals (note that biologicals are defined in section 32A of the Act, are regulated under Part 3.2A of the Act are distinct from biological medicines). Where a person in relation to whom a biological is included in the Register requests that their entry be varied to record one of these variations, the Secretary will be required, under subsection 9D(3AC)(b) of the Act, to vary the entry accordingly.

The table in subregulation 10AAD(2) introduces 12 such notifiable variations for biologicals including, for example, a variation to reflect the introduction of more stringent limits to an in-process control test applied during the manufacture of the biological.

Schedule 3 – Evaluations in relation to prescription medicines

Therapeutic Goods Regulations 1990

This Schedule contains amendments to change the evaluation timeframes for prescription medicines. This gives effect to Review Recommendations 3, 4, 5 ,6 and 7 – that the TGA implement a pathway for the registration of prescription medicines that relies on the review of an assessment prepared by a competent regulatory authority of a foreign country or foreign jurisdiction (e.g. in relation to the latter, of the European Union), provided by the applicant to the TGA, as an alternative to the TGA conducting a *de novo* evaluation of that applicant's data.

As part of the Government's response to the Review, it agreed that where an application for registration meets certain requirements, including for example that the applicant provides a single assessment report that is un-redacted and is for a medicine that is identical to that intended for supply in Australia, the applicable timeframe for processing the evaluation of the medicine would be reduced from the existing statutory timeframe of 255 working days. After consultation, the TGA has determined that an appropriate timeframe would be 120 working days. In circumstances where a single international assessment can be provided but not all such requirements can be met, some limited additional evaluation work will need to be performed by the TGA, and it is intended that a timeframe of 175 working days would apply in this situation. This alternative amends the current requirement that two international reports are required for an application to be evaluated within that timeframe.

Item 1

Item 1 amends regulation 2 to insert a definition of ***generic product***. The definition is substantively the same as the definition of the same term currently located in subclause 1(1) of Schedule 9 to the Regulations. The term is proposed to be used in new regulation 16DA (see item 6) with the same meaning as the current use of the term in Schedule 9.

Items 2 and 3

Item 3 amends regulation 10AA to prescribe, for the purposes of subparagraph 9D(7)(b)(ii) of the Act, requests under subsection 9D(3) of the Act to vary information included in an entry in the Register that relates to a medicine that is a product of a kind specified in Part 1 of Schedule 10 to the Regulations.

This ensures that, if a form for the making of such a request, and the manner of making such a request, are approved under subsection 9D(6) of the Act, such a request of that kind is not effective unless it is in accordance with the approved form, it contains the information required by the approved form, it is made in the approved manner, any prescribed application fee is paid, and it is accompanied by any information determined under subsection 9D(8) of the Act.

Item 2 makes a consequential change to add a subsection number to the existing section.

Items 4 and 5
Item 4 replaces the heading to Division 1 of Part 3A of the Regulations, and item 5 inserts a new Division heading after regulation 16A, so that regulation 16A comprises a separate Division within Part 3A. This reflects the role of regulation 16A in setting out an interpretation provision applying to the Part as a whole.

The remainder of the old Division 1 comprises Division 1A (subject to the amendments made by items 6 to 10), and the new heading to Division 1A is the same as the old heading to Division 1.

Item 6
Item 6 repeals regulations 16B to 16D of the Regulations, and replaces them with new regulations 16C, 16D and 16DA in Division 1A of Part 3A.

Regulation 16C
As with the old regulation 16C, the new regulation 16C applies to applications under section 23 of the Act for the registration of a medicine that is a product of a kind specified in Part 1 of Schedule 10 to the Regulations, if regulation 16G does not apply to the application.

However, unlike the old regulation 16C, the new regulation 16C is not limited to applications that require an evaluation under section 25 of the Act.

The new regulation 16C sets out the periods within which:

- the Secretary must give notice to the applicant stating whether the application is effective (subregulation 16C(2)), and
- within which, if the application is effective, an evaluation of those goods must be completed (subregulation 16C(3)).

The new subregulation 16C(2) replaces, in relation to applications to which regulation 16C applies, the old regulation 16B, which currently sets out a requirement to give notice, within a specified period, to the applicant stating whether the application has been accepted or rejected. Unlike the old regulation 16B, the period under the proposed subregulation 16C(2) will be 40 days in all cases.

The old subregulation 16C(3) set out two periods within which an evaluation would have to be completed, depending on whether the application met certain conditions (set out in the old subregulation 16C(4)) – a standard period of 255 working days, or a shortened period of 175

working days. In contrast the new subregulation 16C(3) sets out three periods – a standard period of 255 working days, 175 working days if certain conditions (set out in the new subregulation 16DA(1)) are met, or 120 working days if additional conditions (set out in the new subregulation 16DA(2)) are also met. In each case, this period begins when a notice under subregulation 16C(2) is sent stating that the application is effective.

Regulation 16D
As with the old regulation 16D, the new regulation 16D applies to applications under subsection 9D(3) of the Act to vary information included in the Register in relation to a medicine that is a product of a kind specified in part 1 of Schedule 10 to the Regulations, if regulation 16F does not apply to the application.

The new regulation 16D sets out the periods within which:

- the Secretary must give notice to the applicant stating whether the application is effective (subregulation 16D(2)), and
- within which, if the application is effective, an evaluation of those goods must be completed (subregulation 16D(3)).

The new subregulation 16D(2) replaces, in relation to applications to which regulation 16D applies, the old regulation 16B. Unlike the old regulation 16B, the period under subregulation 16D(2) will be 40 days in all cases.

As with the old subregulation 16C(3), the old subregulation 16D(3) set out two periods within which an evaluation would have to be completed, depending on whether the application met certain conditions (set out in the old subregulation 16D(4)) – a standard period of 255 working days, or a shortened period of 175 working days. In contrast, the new subregulation 16D(3) sets out three periods – a standard period of 255 working days, 175 working days if certain conditions (set out in the new subregulation 16DA(1)) are met, or 120 working days if additional conditions (set out in the new subregulation 16DA(2)) are also met. In each case, this period begins when a notice under subregulation 16D(2) is sent stating that the application is effective.

Regulation 16DA
The new regulation 16DA sets out the conditions for the shortened periods in subregulations 16C(3) and 16D(3).

The new subregulation 16DA(1) sets out the conditions for the 175 day periods. In each case this involves the evaluation relating to a medicine that is the same as a medicine that has been approved by a competent regulatory authority of a foreign country or foreign jurisdiction determined in a notice on the TGA's website. This is a change from the conditions under the old subregulations 16C(4) and 16D(4), each of which required that the evaluation had been accepted in two acceptable countries.

The new subregulation 16DA(2) sets out the additional conditions that apply, on top of the conditions for the 175 day period, to an application that must be evaluated within 120 working days.

The new subregulation 16DA(3) provides that the Secretary may, determine the foreign countries or foreign jurisdictions for the purposes of regulation 16DA. This is consistent with the current process under which acceptable countries are notified on the Department's

website. The foreign countries and jurisdictions to be determined will be ones whose authorities are comparable to the TGA.

Item 7
Item 7 replaces the heading to regulation 16E to clarify that it applies only in relation to an application for a variation as mentioned in regulation 16D and to be consistent with the style adopted for the headings of the new regulations 16C, 16D and 16DA.

Item 8
Item 8 makes a consequential amendment to regulation 16E to update a reference to regulation 16D.

Items 9 and 10
Items 9 and 10 replace the headings to regulations 16F and 16G to be consistent with the style of the headings of the new regulations 16C, 16D and 16DA.

Item 11
Item 11 repeals the definition of ***generic product*** from subclause 1(1) of Schedule 9, as substantively the same definition is proposed to be included in regulation 2 for application to the whole Regulations.

Item 12
Item 12 replaces the note to the heading of Schedule 10 to reflect the amendments to the provisions giving effect to the Schedule.

Schedule 4 – Miscellaneous amendments

Part 1 – Procedure for amending the current Poisons Standard

Therapeutic Goods Regulations 1990

Item 1 – Regulation 42ZCZI (definition of second closing date)
This item makes a minor amendment to the definition of 'second closing date' in regulation 42ZCZI of the TG Regulations, to reflect the change to be made by item 2 below.

Item 2 – Regulation 42ZCZP
This item amends regulation 42ZCZP of the TG Regulations to, in effect, place existing paragraphs 42ZCZ(a) – (c) into a new subregulation 42ZCZ(1).

Item 3 – Paragraph 42ZCZP(c)
Regulation 42ZCZP of the TG Regulations sits in Subdivision 3D.2 of Part 6 of those regulations, which sets out the procedure to be followed for amending the Poisons Standard if a person applies to the Secretary under section 52EAA of the Act for such an amendment and the Secretary decides to refer the matter to an expert advisory committee (either, the Advisory Committee on Chemicals Scheduling or the Advisory Committee on Medicines Scheduling), or if the Secretary decides to amend the Poisons Standard on the Secretary's own initiative and refers the proposed amendment to one of those committees.

Currently under this Subdivision, the Secretary must publish a notice relating to the relevant committee that has been asked to consider the matter, the details of the proposed amendment

and inviting the public to make submissions to the committee on relation to the proposed amendment.

After the committee considers the matter, they are required to provide their advice or recommendations to the Secretary, and the Secretary must make an interim decision in relation to the proposed amendment.

Under the current regulation 42ZCZP, as soon as practicable after making the interim decision, the Secretary must publish a notice setting out that interim decision and the reasons for it, the proposed date of effect of the decision and inviting persons who made a submission in response to the original invitation to make further submissions to the Secretary about the interim decision within 10 business days.

In order to provide greater opportunities for interested parties to have input into the scheduling process, this item amends regulation 42ZCZP by substituting a new paragraph 42ZCZ(1)(c), with the effect that the current limitation on persons who may be invited to make submissions on an interim decision to only persons who commented on the initial invitation would be removed, with the Secretary being required to invite all interested parties to make submissions on an interim decision.

Item 4 – At the end of regulation 42ZCZP
This item also amends regulation 42ZCZP, with the effect of replacing the current requirement for persons invited to make submissions on an interim decision having 10 business days to make such submissions with a new requirement for them to be given at least 10 business days in which to do so (after publication of the notice required under that regulation).

Part 2 – Delegation under the Act

Therapeutic Goods (Medical Devices) Regulations 2002

Item 5 – Paragraph 10.6A(c)
Regulation 10.6A of the MD Regulations specifies the positions in the Department's Health Products Regulation Group (HPRG) to whom the Secretary's powers to approve the importation and supply of medical devices that are unavailable or in short supply may be delegated, for the purposes of subsection 57(9) of the Act.

This item makes a minor amendment to paragraph 10.6A(c) to reflect a recent change of title of the Principal Medical Advisor of the HPRG (from Principal Medical Advisor to Chief Medical Advisor), and to allow Medical Officer Class 5s in the HPRG to also exercise this power. Medical Officer Class 5s are considered to be appropriately senior and skilled personnel to exercise this power.

Therapeutic Goods Regulations 1990

Item 6 – Paragraph 46A(2)(c)
This item makes equivalent amendments to the TG Regulations to item 5 above, in respect of medicines and biologicals.

Part 3 – Supply of unapproved therapeutic goods

Items 7-9 – Regulations 7.2 and 8.2

Regulation 7.2 of the MD Regulations has the effect that, for the purposes of paragraph 41HA(1)(b) of the Act, a kind of medical device is exempt from the requirement to be included in the Register if used in or on a person who is a Category A patient (principally, one who is critically ill with a condition that is reasonably likely to lead to their death in less than a year or to their premature death without early treatment), if the person or their guardian has given informed consent and the person's medical practitioner has signed a statement in accordance with regulation 8.2 of the MD Regulations.

Regulation 8.2 specifies kinds of information that must be included in the medical practitioner's statement including, for example, a description of the device and the diagnosis of the person's condition.

These items repeal regulation 8.2 and move its requirements relating to the content of such statements into new subregulation 7.2(1A). These items also require such statements to be in the form approved by the Secretary and allow an approval of such forms to require information to be provided electronically, and allow a health practitioner (such as, for example, a nurse or a pharmacist) to complete the statement on the treating medical practitioner's behalf. This is designed in particular to assist medical practitioners in busy hospital environments where unapproved medical devices are being used.

These items also have the effect of replacing the current strict liability offence in subregulation 8.2(3) for a medical practitioner who does not send a signed statement to the Secretary about their supply of an unapproved device to a Category A patient within 28 days of that supply (maximum penalty 10 penalty units) with an equivalent offence for a person who completes a statement as required under new subregulation 7.2(1A) and does not send that statement to the Secretary within 28 days after the use of the device.

This offence is consistent with the criteria outlined in the Attorney-General's Department's Guide to Framing Commonwealth Offences in relation to when it is appropriate for strict liability offences to apply, given that:

- the offence in new subregulation 7.2(1C) is not punishable by imprisonment;
- the maximum penalty is less than 60 penalty units for an individual – it is only 10 penalty units;
- the offence will enhance the effectiveness of the regulatory scheme by deterring practitioners from failing to notify the Secretary of the details the Secretary needs to verify compliance with the rules relating to accessing unapproved therapeutic goods and ensure that such products are being supplied to the kinds of patients they are authorised for under the regulations; and
- without such notifications, the TGA will not be able to ensure that such arrangements are operating safely for patients.

Item 10 – In the appropriate position in Part 11

This item introduces transitional provisions for the purposes of the above amendments, with the effect that the amendments of regulations 7.2 and 8.2 of the MD Regulations would apply in relation to the use of a medical device in or on a person on or after the commencement of Part 3 of Schedule 4 of the Proposed Regulations (noting that Schedule 4 of the proposed Regulations is to commence the day after registration).

Therapeutic Goods Regulations 1990

Items 11-14 – Regulation 12A
These items amend regulation 12A of the TG Regulations, principally to make equivalent amendments in relation to the supply of unapproved medicines and biologicals to items 7-10 above.

Part 4- Narcotic drugs

Therapeutic Goods Regulations 1990

Items 15-17 – Schedule 5(table item 6), Schedule 5A (table item 5) and Schedule 8 (table item 2)
These items make minor amendments to the above table items in Schedules 5, 5A and 8 to the TG Regulations to remove a small number of references to provisions of the TG Regulations that no longer exist as a result of the disallowance earlier this year of certain amendments made to those regulations by the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* – returning the effect of those items back to what it was before the making of the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016*.

Statement of Compatibility with Human Rights

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

The *Therapeutic Goods Legislation Amendment (2017 Measures No.2) Regulations 2017* (the Regulations) are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act) and amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). The measures in the Regulations that relate to notifiable variations would commence on 4 December 2017, those that relate to priority pathways and the evaluation of prescription medicines would commence on 1 January 2018 and all other measures would commence the day after registration.

The *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* (the Amendment Act) amended the Act to support the implementation of several key recommendations of the Expert Panel Review of Medicines and Medical Device Regulation (the Review) agreed to by the Australian Government. The Expert Panel was established to, principally, identify areas of the regulation of medicines and medical devices which could be streamlined while maintaining the safety and quality of therapeutic goods in Australia, and made 58 recommendations. The Australian Government supported 56 of the 58 recommendations for reform. The Amendment Act addressed a first tranche of these recommendations, and the *Therapeutic Goods Legislation Amendment (2017 Measures No.1) Regulations 2017* supported a number of the Review measures in the Amendment Act that required regulations to be in place by 1 July 2017 – for example, in relation to providing a new pathway for the priority review of prescription medicines that represent a major therapeutic advance.

The purpose of the Regulations is to amend the TG Regulations and MD Regulations to support the second tranche of Review measures in the Amendment Act which include:

- providing a new pathway for the priority review by the Secretary of medical devices that represent either a breakthrough technology, or a major clinical advantage over existing alternatives in the Australian Register of Therapeutic Goods (the Register);
- providing an equivalent pathway for the priority review by the Secretary of applications for conformity assessment certificates, in relation to the manufacture of medical devices that meet the same criteria as the above new pathway; and
- allowing industry sponsors of medicines and biologicals that are currently registered or included in the Register to make straightforward, low-risk variations (notifiable variations) to their products (where product safety, quality or efficacy is not impacted) by notification to the Secretary rather than such changes needing to be pre-approved.

The Regulations also implement two Review measures that do not require principal legislation:

- providing a pathway for the Secretary to evaluate an application for the registration of a prescription medicine within 120 working days, based on the provision of a recent assessment of the same medicine conducted by a comparable international regulator; and
- enhancing the ability of interested parties to have input into the process for the scheduling of medicines and chemicals, by allowing persons interested in a proposed amendment to the Poisons Standard to comment on an interim decision to amend the Poisons Standard (this is currently limited to persons who provided a submission in

response to the initial invitation for public submissions, i.e. before the interim decision) and allowing a longer period to submit such comments than the current 10 days.

The Regulations also make a small number of minor amendments to the TG Regulations and MD Regulations not related to the Review, to:

- allow senior medical officers of the Department of Health's Health Products Regulation Group to approve access to unapproved medicines, biologicals and medical devices where alternatives are unavailable or in short supply;
- reduce regulatory burden for treating medical practitioners supplying unapproved therapeutic goods to Category A patients (principally, these are persons who are seriously ill). Currently medical practitioners supplying unapproved goods to such persons must complete and provide a signed statement of having done so to the Secretary within 28 days. The Regulations would allow a health practitioner (e.g. a nurse or pharmacist) to do so on the treating medical practitioner's behalf, and allow for the electronic notification of this information; and
- remove a small number of references to provisions of the TG Regulations that no longer exist as a result of the disallowance earlier this year of certain amendments made to those regulations by the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* – returning the effect of those items back to what it was before the making of the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016*.

Human rights implications

As the Amendment Regulations do not introduce any changes to the TG Regulations or MD Regulations other than to implement the changes outlined above, they do not appear to 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.

Greg Hunt, Minister for Health