EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020

The principal purpose of the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2020* (the MD Regulations) to support measures recently introduced into the *Therapeutic Goods Act 1989* (the Act) by the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020* (the Amendment Act).

The object of 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, 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 Regulations update a number of medical device definitions to more closely align with European Union terminology, and identify matters in relation to which the Secretary may provide scientific advice about a prescription medicine to assist sponsors to better understand the information needed to support a successful application for marketing approval (focussing on the in vitro bioequivalence of such medicines for oral ingestion). The Regulations also support the Amendment Act by identifying circumstances in which a medical practitioner may supply unapproved therapeutic goods to their patients under the authorised prescriber pathway without the need for an ethics committee approval, and by reflecting the introduction of preliminary assessment procedures for applications for the approval of new ingredients for use in listed and assessed listed medicines.

The Regulations make a number of other amendments, to:

- reflect the impact of the public health emergency caused by the outbreak of the disease known as coronavirus disease (COVID-19) by delaying the commencement or effect of reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No .1) Regulations 2019* in relation to medical devices that are or that utilise software, personalised medical devices such as custom-made devices, the reclassification of certain kinds of devices and faecal microbiota transplant products (FMT products);
- amend the timeframes within which the Secretary must decide to make a recommendation to the Minister in relation to an application for the approval of a new ingredient for use in listed or assessed listed medicines, to address the situation in which more than one person applies for approval of the same ingredient;
- exempt oxygen hoods used in hyperbaric chambers for hyperbaric oxygen therapy, and Class 4 in-house in vitro diagnostic (IVD) medical devices used to detect transmissible agents in blood, stool or other specimens from a person's body to assess a person's suitability to donate human stool for use in the manufacture of an FMT product, from the requirement to be included in the Australian Register of Therapeutic Goods; and
- make a number of other, more minor changes and corrections, such as to introduce a timeframe within which a medical device sponsor must notify the Secretary that an

overseas-issued certificate or other document they are relying on to demonstrate their device's compliance with the essential principles or conformity assessment procedures has been restricted, suspended or revoked, correct a fee item in relation to disinfectants and to remove spent and redundant references to therapeutic devices.

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 Regulations commence on various dates. In particular, sections 1-4, Schedules 2-4 and 7 and Part 1 of Schedule 8 (delay of the medical device and FMT reforms) commence on the day after registration, and Schedules 1, 5 and 6 commence at the same time as the commencement of particular Schedules of the Amendment Act.

Consultation

In relation to consultation:

- the TGA consulted publicly between January and February 2019 on proposed changes to a number of specific medical device definitions. 21 submissions were received, with broad support for aligning the Australian definitions with the EU;
- the TGA consulted publicly between February and March 2019 on the proposal to allow the Secretary to provide early scientific advice to prescription medicine sponsors, with a focus on particular bioequivalence aspects. 23 submissions were received, with strong support for the measure. Targeted consultation in August 2019, with parties who provided a submission to the earlier consultation, again indicated support;
- in relation to identifying circumstances in which supply of unapproved therapeutic goods may occur under the authorised prescriber pathway without the need for an ethics committee approval, the TGA consulted with the Australian Medical Association and the Royal Australian College of General Practitioners in June 2020 on circumstances relating to where a medicine contains the active ingredient nicotine, with support for the proposal;
- the TGA discussed and received representations in 2020 from the Medical Technology Association of Australia and device sponsors in relation to the commencement of medical device reforms on software, personalised medical devices and reclassification, both in light of COVID-19 and (for reclassification) the delay of EU reforms;
- the TGA recently consulted Australian manufacturers of FMT products on delaying the effect of reforms relating to FMT products, with support for the proposal;
- the TGA consulted on the issue of timeframes for new ingredient applications for listed and assessed listed medicines at the October 2019 and May 2020 meetings of the TGA-industry working group, the Complementary and Over the Counter Medicines Regulatory and Technical Forum, and industry representative bodies Complementary Medicines Australia and the Consumer Healthcare Products Australia supported the proposal; and
- the TGA consulted in June 2020 with FMT manufacturers, the National Association of Testing Authorities and the Royal College of Pathologists of Australasia in relation to the proposed exemption of Class 4 in-house IVDs for the testing of samples to support donor screening in relation to FMT products. These stakeholders supported this proposal.

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

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* (the Regulations).

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after the Regulations are registered, except for Schedule 1 which commences at the same time Part 1 of Schedule 1 to the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020* (the Amendment Act) commences, Schedules 5 and 6 which commence at the same time as Schedules 2 and 4 (respectively) to the Amendment Act commence and Part 2 of Schedule 8, which commences on 25 November 2021.

Section 3 – Authority

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

Section 4 – Schedules

This section provides that 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 instrument has effect according to its terms.

Schedule 1 – Medical device definitions and system or procedure packs

Summary

On 5 April 2017, the EU adopted two new regulations to introduce significant reforms for medical devices and in vitro diagnostic medical devices, to better address the technological and scientific developments that have occurred in the devices sector over the last 20 years:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) (the EU Regulations); and
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746) (the EU IVD Regulations).

These regulations entered into force in the EU on 25 May 2017 and have various transitional arrangements affecting their commencement.

Recommendation 20 of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review) recommended that, wherever possible and appropriate, the regulation of medical devices in Australia should align with the EU framework.

To support the implementation of Recommendation 20, some measures in the Amendment Act amended a number of device-related definitions in the Act to more closely align with the EU Regulations, and to modernise the terminology of the Act in a similar manner to the EU approach. The measures in this Part also align the definition of 'instructions for use', 'reusable surgical instrument' and 'user' with the EU definitions of those terms.

The *Therapeutic Goods Amendment (2020 Measures No.1) Act 2020* (the Amendment Act) also introduced a new definition for 'system or procedure pack' to the Act. The amendments in Part 1 of this Schedule include minor amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to reflect the updated definition of 'system or procedure pack' introduced by the Amendment Act, and to improve the clarity of a small number of provisions dealing with 'system or procedure packs' (without introducing any new requirements for such products).

The TGA consulted publicly between January and February 2019 on proposed changes to a number of specific medical device definitions. 21 submissions were received, including from industry representative bodies (e.g. the Medical Technology Association of Australia (MTAA)), consumer advocacy bodies (e.g. the Consumer Health Forum (CHF)), sponsors (e.g. Cochlear Limited) and healthcare professionals (e.g. the Royal Australian and New Zealand College of Ophthalmologists (RANZCO)), with broad support for aligning the Australian definitions with the EU.

Part 1 – Medical device definitions

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – Dictionary

This item inserts a definition for 'instructions for use' in relation to a medical device, in centring on information provided by the manufacturer of the device to inform a device user about its intended purpose, proper use and any precautions to be taken in relation to its use.

The definition is an inclusive definition, and as such may cover other information as well. The requirements relating to instructions for use of a medical device are in clauses 13.1 and 13.4 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) which deal with the information that must be included in instructions for use for medical devices. The note to the definition of 'instructions for use' explains this.

Item 2 – Dictionary (paragraph (b) of the definition of *reusable surgical instrument*)
This item amends the definition of 'reusable surgical instrument' in the Dictionary of MD Regulations to insert a reference to cleaning, disinfection and sterilisation in paragraph (b). This amendment makes it clear that a reusable surgical instrument includes a medical device that is intended by the manufacturer to be reused after appropriate procedures, such as cleaning, disinfection and sterilisation (as specified by the manufacturer in the instructions for use) have been carried out. This clarification brings this definition into closer alignment with the EU definition.

Item 3 – Dictionary
This item inserts a definition for 'user' of a medical device in the Dictionary of the MD Regulations. This definition aligns with the EU definition of 'user' and means any person (including a health professional) who uses the device. A user of a medical device may include a patient, a parent or guardian, a carer or a health professional.

Part 2 – System or procedure packs

Therapeutic Goods (Medical Devices) Regulations 2002

Item 4 – Paragraphs 3.10(1)(d) and (e)
This item repeals paragraphs 3.10(1)(d) and (e) of the MD Regulations and substitute these paragraphs with a single paragraph referring to a system or procedure pack to which subregulation (3) applies. This amendment effectively removes paragraph 3.10(1)(e), which is not required as the system or procedure packs covered by paragraph 3.10(1)(e) would already fall within the scope of subregulation 3.10(3).

Item 5 – Subregulation 3.10(1) (notes)
This item repeals and replace the notes to subregulation 3.10(1) of the MD Regulations. While the content of the notes remains unchanged, their formatting is updated to reflect the repeal of paragraph 3.10(1)(e) by item 4 above. Note 1 deals with exempt devices. Note 2 provides that a system or procedure pack that contains a medical device (that is not an IVD medical device) and an IVD medical device is classified in accordance with Division 3.1 and either Schedule 2 or 2A and that the conformity assessment procedures to be applied are those for a medical device used for a special purpose in clause 7.5 of Schedule 3. Note 3 provides that if paragraph 3.10(1)(d) does not apply to a system or procedure pack, the system or procedure pack is classified in accordance with Division 3.1 and either Schedule 2 or 2A and the conformity assessment procedure to be applied are those that apply to the relevant classification.

Item 6 – Subregulation 3.10(1A)
This item repeals and replaces subregulation 3.10(1A) of the MD Regulations, to clarify that paragraphs 3.10(1)(a), (b) and (c) do not apply to a Class 1, 2 or 3 in house IVD medical device.

Item 7 - Paragraph 3.10(3)(a)
This item amends subregulation 3.10(3) of the MD Regulations, by replacing paragraph 3.10(1)(a) with two new paragraphs, to provide that the subregulation only applies to a system or procedure pack where conformity assessment procedures have been applied to the medical devices in the system or procedure pack and, if medicines, biologicals or other therapeutic goods are included in the system or procedure pack, those therapeutic goods are on the Australian Register of Therapeutic Goods (the Register). This amendment ensures consistency with the new definition of 'system or procedure pack' in the Act, that does not require the goods in a system or procedure pack to be packaged together in all cases.

If a system or procedure pack does not meet the requirements in the new paragraphs 3.10(3)(a) and (aa) – i.e. if relevant conformity assessment procedures have not been applied to each medical device in such a pack or if any medicines, biologicals or other therapeutic goods in such a pack are not entered on the Register, the system or procedure pack would not fall within the scope of subregulation 3.10(1) and the applicable conformity assessment procedures for such a system or procedure pack would not be those mentioned in subregulation 3.10(2).

Item 8 – Subregulation 3.10(4) (note)
This item amends the note to subregulation 3.10(4) to remove references to a system or procedure pack being contained in a package. Under the definition of a 'system or procedure pack' in the Act, as introduced by the Amendment Act, the contents of a system or procedure pack may not always be contained in a single package.

Items 9 to 18 – Paragraphs 7.5(2)(c), (d), (e)(i) and (ii), (f), (g), (h)(i), (i), (j) and (k) of Schedule 3
These items amends paragraphs 7.5(2)(c) to (k) in Schedule 3 to the MD Regulations to remove references to a system or procedure pack being contained in a package. Under the definition of a 'system or procedure pack' in the Act, as introduced by the Amendment Act, the contents of a system or procedure pack may not always be contained in a single package.

Schedule 2 – Exemption of hyperbaric oxygen therapy hoods

Summary
This Schedule deals with the exemption of certain hyperbaric oxygen therapy hoods from the requirement to be included in the Register.

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – Part 1 of Schedule 4 (after table item 1.3)
This item inserts item 1.3A in Part 1 of Schedule 4 to the MD Regulations to provide an exemption from the operation of Division 3 of Part 4-11 of the Act (this Division sets out criminal offences and civil penalty provisions, principally in relation to importing, exporting, supplying or manufacturing a medical device that is not included in the Register) for oxygen administration hoods for use in hyperbaric chambers for hyperbaric oxygen therapy.

Hyperbaric oxygen therapy involves breathing pure oxygen in a pressurised room or tube, and is a well-established treatment for decompression sickness, which is a hazard of scuba diving. It is also used to treat other conditions such as serious infections, bubbles of air in blood vessels, wounds that will not heal (as a result of diabetes or radiation injury), carbon monoxide poisoning, sudden vascular threat to vision and hearing and overwhelming soft tissue infections.

Oxygen administration hoods are consider low risk, Class 1 medical devices when supplied for use in hyperbaric chambers for hyperbaric oxygen therapy. Their low supply volume does not make them commercially viable for inclusion in the Register, and they are currently only available through access pathways for therapeutic goods that are not on the Register or exempt. Exempting these medical devices from inclusion in the Register is designed to support the continued availability of these devices in Australia, while ensuring that they will continue to be regulated as medical devices that are subject to the Act and MD Regulations should any safety or manufacturing issues arise.

Schedule 3 – Period for notifying adverse events

Summary
This Schedule provides for the introduction of a specific timeframe for medical device sponsors to notify the Secretary if an overseas certificate or other document (or a certificate issued by an Australian conformity assessment body) is suspended, revoked, restricted or is no longer in effect, for the purposes of the condition of inclusion of a kind of medical device in the Register set out in paragraph 41FN(3)(d) of the Act.

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – Subregulation 5.7(1)
This item amends subregulation 5.7(1) of the MD regulations to include a reference to section 41MPA(2) of the Act.

Item 2 – At the end of subregulation 5.7(1)
This item introduces paragraph (d) in subregulation 5.7(1) to provide a timeframe of 60 days for providing certain information to the Secretary. Section 41MP of the Act provides a criminal offence for failing to notify the Secretary of information of a kind mentioned in subsection 41MP(2) of the Act within the timeframe specified in the regulations. It is also a condition of inclusion of a medical device in the Register, under paragraph 41NF(3)(d) of the Act, that the information be given to the Secretary within the timeframe specified in the regulations. The information specified in subsection 41MP(2) of the Act mainly relates to adverse event information.

However, it also includes other information, including (in particular) information that indicates that a certificate or other document (other than a certificate or other document issued by the Secretary under this Act), that is used for the purposes of an application under section 41FC(1) for the inclusion of a kind of medical device in the Register to signify the kind of device's compliance with the essential principles or the application of relevant conformity assessment procedures (or comparable requirements) to a device of that kind, has been suspended, revoked, restricted or is no longer in effect (paragraph 41MP(2)(d)(ii) of the Act refers).

Regulation 5.7 of the MD Regulations provides the timeframes for giving information of a kind mentioned in subsection 41MP(2) of the Act. All the timeframes relate to the giving of information about adverse events and there is currently no timeframe for providing information about the restriction, suspension, revocation or cancellation of an overseas conformity assessment document, or any other information listed in subsection 41MP(2).

It is important that this information be provided to the Secretary in a timely manner, so that the Secretary can consider this information and its implications for the safety and performance of the relevant medical devices and, if needed, take action to address such matters.

Item 3 – After regulation 10.4
This item introduces new regulation 10.4AA to the MD Regulations. Regulation 10.4AA provides that, for the purposes of paragraph 41MPA(1)(c) of the Act, the period for giving information of a kind mentioned in subsection 41MPA(2) of the Act is the relevant period

specified in regulation 5.7. This provision is comparable to existing regulation 10.4 of the MD Regulations, which provides the same in relation to paragraph 41MP(2)(c) of the Act.

Sections 41MP and 41MPA of the Act set out, respectively, criminal offences and a civil penalty provision for the same actions in relation to not notifying the Secretary of specified kinds of information relating to adverse events associated with medical devices, of which a person knows.

Items 4 to 9 – Subclauses 1.4(3), 3.4(2), 4.4(3), 5.4(3), 6.5(2) and 7.5(4) of Schedule 3 (notes)

These items amend the notes to subclauses 1.4(3), 3.4(2), 4.4(3), 5.4(3), 6.5(2) and 7.5(4) of Schedule 3 of the MD Regulations to include a reference to section 41MPA of the Act alongside existing references to section 41MP of the Act.

Schedule 4 – Approving supply of therapeutic goods under authorised prescriber scheme

Summary
The Amendment Act included amendments to the Act to provide greater flexibility in relation to the circumstances in which medical practitioners may be authorised to supply unapproved therapeutic goods to their patients, reduce the burden on medical practitioners who seek to do so and improve access to unapproved therapeutic goods for Australian consumers.

This Schedule amends the TG Regulations for this purpose, by identifying circumstances in which a medical practitioner may supply unapproved medicines to their patients, without the need for an ethics committee's approval.

The TGA consulted with the Australian Medical Association (the AMA) and the Royal Australian College of General Practitioners (the RACGP) in June 2020 in relation to the inclusion of circumstances relating to where a medicine contains the active ingredient nicotine in solution, salt or base form, with a specified dosage form, route of administration and indication (smoking cessation), with support for the proposal.

Therapeutic Goods Regulations 1990

Item 1 – After subregulation 12B(1A)
This item introduces new subregulation 12B(1B) to the TG Regulations. Subregulation 12B(1B) provides that the requirement in paragraph 19(6)(aa) of the Act, that an authorisation under subsection 19(5) may only be given to a medical practitioner who has the approval of an ethics committee to supply the specified therapeutic goods or the specified class of such goods, does not apply if the supply is of a medicine that falls within the scope of an item in the table in subregulation 12B(1B).

This would have the effect that an ethics committee approval will not be needed for the supply of a medicine that:
- contains an active ingredient at the strength and concentration (if any) specified in column 2 of an item in the table in new subregulation 12B(1B);
- is in the dosage form specified in column 3 for that item of the table; and
- is to be administered by the route specified in column 4 for that item of the table; and
- has the indication specified in column 5 for that item of the table.

The medicines that are covered by the table in subregulation 12B(1B) generally, but not exclusively, reflect the medicines available through the Special Access Scheme Category C (SAS C) pathway provided for in relation to the legislative instrument that may be made under subsection 19(7A) of the Act (and with the inclusion of a small number of medicines that are expected to be added to that pathway in July 2020).

These medicines are considered to have a long-standing history of safe use overseas, and their availability for patients under the authorised prescriber pathway through new subregulation 12(1B) is designed to improve flexibility for prescribers and patients in relation to accessing unapproved therapeutic goods, particularly in remote and rural Australia, as medical practitioners will not need an ethics committee approval to supply these medicines and will be able to supply these medicines without the requirement to notify the Secretary

within 28 days of having supplied them to their patients under the SAS C pathway (subsection 19(7C) of the Act refers).

Schedule 5 – Scientific advice about quality of medicine

Summary
The Amendment Act included amendments to the Act to enable the Secretary to provide early, scientific advice to a person (in practice, this is likely to be medicines sponsors) about prescribed aspects of the safety, quality or efficacy of a registrable medicine (these are higher risk, mostly prescription and over the counter medicines).

To register a new medicine in the Register, a person must submit an application for registration to the Secretary with sufficient supporting information that demonstrates that the medicine meets appropriate standards of quality, safety and efficacy. The TGA has a number of publicly available guidance documents to assist sponsors to understand what accompanying information is likely to be needed to support a successful application for registration.

However, the diversity of products that may be the subject of an application for registration can mean that in some instances, sufficient guidance on complex products may not be available, and guidance may not cover every possible scenario. Currently, precise targeted regulatory advice on whether requirements have been met cannot be provided until the details of products and their supporting evidence are known, after an application has been submitted. Uncertainties about the level and nature of supporting information may risk sponsors investing considerable time and resources into developing supporting evidence that is not required, or missing data that is needed. In either instance, this may delay access to new medicines for consumers.

The measure in the Amendment Act was designed to address such concerns by establishing a process for potential applicants for the registration of a new medicine to be able to seek advice from the Secretary about particular aspects of the safety, quality or efficacy of their medicine before they apply for marketing approval.

The amendments in this Schedule support this reform by prescribing a particular aspect in relation to which the Secretary may provide such advice, noting that other such aspects may be prescribed in the future as experience is built around the new advice mechanism.

The TGA consulted publicly between February and March 2019 on the proposal to allow the Secretary to provide scientific advice to prospective prescription medicine sponsors, with a focus on particular bioequivalence aspects. 23 submissions were received, including from industry representative bodies (e.g. the Generic and Biosimilar Medicines Association (GBMA)), sponsors (e.g. GlaxoSmithKline), CHF, the Pharmacy Guild and RANZCO, with strong support for the measure. Targeted consultation in August 2019, with parties who provided a submission to the earlier consultation, again indicated support.

Therapeutic Goods Regulations 1990

Item 1 – After Part 2D
This item amends the TG Regulations to introduce new Part 2E, including new regulation 10M, after Part 2D of the TG Regulations. Regulation 10M provides that for the purposes of subsection 22G(1) of the Act, a prescribed aspect of the quality of a medicine for oral ingestion is in vitro bioequivalence.

Section 22G(1) of the Act was introduced by the Amendment Act and provides that a person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the quality of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established. Section 22G(2) provides that each request must relate only to one aspect of the quality of the medicine.

Regulation 10M prescribes that an aspect of quality in relation to which scientific advice may be requested from the Secretary is in vitro bioequivalence of a medicine for oral ingestion.

That is, a request for scientific advice about a medicine for oral ingestion has to relate to in vitro bioequivalence. In practice, this would include advice on the validity of in vitro data used to either establish that a medicine is bioequivalent to an overseas reference product, establish bioequivalence across different strengths of the same medicine, or justify that the Biopharmaceutical Classification System (a framework for classifying how easily an oral medicinal product can get into the blood stream) applies to a medicine such that bioequivalence can be established with in vitro data and without in vivo data.

Item 2 – Clause 3 of Schedule 9 (after table item 1AB)
This item introduces new item 1ABA in the table in Part 2 of Schedule 9 to the TG Regulations, to provide a fee of $8570.00 for requests under section 22G of the Act for early scientific advice, for the purposes of paragraph 22G(8)(b) of the Act. As each request under section 22G must relate to only one aspect of quality, safety or efficacy, if a person seeks advice on more than one aspect, they need to submit a separate form for each request and pay the prescribed fee for each request.

This fee has been calculated on the basis of the time and effort that is expected to be required for officers of the Department to provide advice of this nature.

Schedule 6 – Preliminary assessment of applications for variation of permissible ingredients determination

Summary
This Schedule amends the TG Regulations to reflect amendments, made by the Amendment Act to the Act, which introduce preliminary assessment requirements for applications for a recommendation of the Secretary in relation to the approval of new ingredients for use in listed and assessed listed medicines (or other variations to the determination made under section 26BB of the Act). This Schedule also includes amendments to the TG Regulations to address the situation where more than one person applies for the same such recommendation (in practice, principally in relation to seeking the approval of the same ingredient).

The TGA consulted on the issue of timeframes for new ingredient applications for listed and assessed listed medicines at the October 2019 and May 2020 meetings of the TGA-industry working group, the Complementary Medicines Regulatory and Technical Forum. Forum members agreed a transparent approach to managing multiple applications for the same ingredient was needed, and industry representative bodies Complementary Medicines Australia and the Consumer Healthcare Products Australia supported the proposed approach.

Therapeutic Goods Regulations 1990

Items 1 to 4 – Regulation 2 (definition of *IN1 application*, *IN2 application*, *IN3 application* and *IN4 application*)
These items amends a number of definitions in regulation 2 of the TG Regulations to replace references to subsection 26BE(1) of the Act with references to 26BD(1) of the Act, to reflect amendments made to the Act by the Amendment Act to introduce preliminary assessment requirements for new ingredient applications and other applications to vary the section 26BB determination. As a result of these amendments, applications to vary the determination made by the Minister under section 26BB of the Act will be made under section 26BD of the Act rather than section 26BE, and will undergo a process of preliminary assessment provided by new section 26BD of the Act. The amendments to the definition categories of IN1 application, IN2 application, IN3 application and IN4 application are also consequential in this regard, to reflect that applications to vary the section 26BB determination are now to be made under section 26BD of the Act.

Item 5 – Regulation 16GI (heading)
This item repeals and replaces the heading of regulation 16GI of the TG Regulations to reflect the preliminary assessment procedures introduced by the Amendment Act.

Item 6 – Paragraph 16GI(1)(a)
This item amends the terms of paragraph 16GI(1)(a) of the TG Regulations to reflect the preliminary assessment procedures introduced in section 26BD of the Act by the Amendment Act.

Item 7 – Paragraph 16GI(1)(b)
This item amends the terms of paragraph 16GI(1)(b) of the TG Regulations to reflect the preliminary assessment procedures introduced in section 26BD of the Act by the Amendment Act.

This item also amends paragraph 16GI(1)(b) of the TG Regulations to provide that the timeframes in the table in subregulation 16GI(1) are subject to subregulation 16GI(1A), which is introduced by item 9 of this Schedule below.

Item 8 – Subregulation 16GI(1) (table)
The table in subregulation 16GI(1) of the TG Regulations currently sets out the periods within which the Secretary must notify an applicant for the approval of a new ingredient for use in listed and assessed listed medicines that their application has been accepted or rejected, and within which the Secretary must (for an application that has been accepted) make a decision on whether or not to make the requested recommendation.

Items 5-7 amend regulation 16GI to reflect the introduction of preliminary assessment requirements for such applications by the Amendment Act.

This item amends the terms of the table in subregulation 16GI to also reflect the introduction of preliminary assessment procedures, by replacing the references to notification of an application having been accepted or rejected with references to notification of preliminary assessment. The timeframes for evaluation of a section 26BD application remain the same; however, the period of evaluation commences when the application has passed preliminary assessment and the evaluation fee has been paid. Once the application passes preliminary assessment, the period for completing the evaluation would not commence until the evaluation fee has been paid.

Item 9 – After subregulation 16GI(1)
This item introduces subregulation 16GI(1A) to the TG Regulations, to address the situation where more than one section 26BD application is received in relation to the inclusion of the same ingredient in the section 26BB determination, where there is no determination in force under subsection 26BB(1) of the Act in relation to that ingredient.

The Expert Panel Review of Medicines and Medical Devices Regulation (Review) recommended a range of reforms for Government to consider to incentivise innovation and improve the competitiveness of the Australian complementary medicines industry (Recommendation 50). In March 2018, the Government introduced a market exclusivity measure whereby an applicant can request a 2-year period of exclusive use for a new ingredient – this was to reward the applicant's investment in gathering and preparing the data to support the use of the new ingredient in listed medicines.

Only the first applicant to submit a complete application, which goes on to be evaluated and approved, is rewarded with the option of a two-year period of exclusive use. Exclusive use is limited to one applicant in a similar manner to a patent, unless the exclusivity holder permits other parties to use the ingredient.

The provision of exclusivity in relation to the use of new ingredients in this regard is effected through the inclusion of requirements that apply in relation to the use of such ingredients for the 2 year period, as part of the section 26BB determination. However, where more than one applicant submits an application for the same new ingredient to be included in that determination, there is a lack of clarity regarding which applicant is considered to be 'first in line' to be afforded market exclusivity for the ingredient.

Accordingly, this amendment is intended to provide a transparent process to deal with applications for the same ingredient, under which the applicant that submits an application first, if the application passes preliminary assessment and a recommendation is made in relation to that application, is to be granted market exclusivity for the ingredient. This process only applies in the limited situation where more than one applicant submits an application relating to the same ingredient and the ingredient is not already included in a determination made under section 26BB of the Act.

The intention of this process is to place subsequent applications received for the same ingredient that pass preliminary assessment in a queue based on the order in which the applications are received (i.e. the first application would not be in the queue but would be the "frontrunner" that would be evaluated without delay, while subsequent applications would be placed in the queue).

The subsequent applications would then be evaluated in that order, and the applicant of the first successful application would receive market exclusivity if that applicant requested market exclusivity.

New subregulation 16GI(1A) identifies those subsequent applications that would comprise such a queue. Under the new subregulation, it applies where a number of circumstances exist – being where:

- an application is made under subsection 26BD(1) of the Act, passes preliminary assessment and relates to an ingredient that is not included in a determination under section 26BB; and
- at the time the applicant receives notice that their application has passed preliminary assessment, there are one or more other applications under section 26BD that relate to the same ingredient and that have also passed preliminary assessment but have not yet been finally determined.

Subregulation 16GI(1A) provides that the evaluation of that application commences on the later of the start day and the day the evaluation fee is paid. The *current application* is each application received for the same new ingredient except the first application (to which subregulation 16GI(1) applies, rather than new subregulation 16GI(1A)) and the *related application* refers to all applications under section 26BD that have been received prior to receipt of the current application.

If the ingredient has not been included in a determination under subsection 26BB(1), the start day is the day after all the related applications have been finally determined. If the ingredient has been included in the determination, the start day is the day the determination commences.

An application would be considered to be 'finally determined' for this purpose once the application, or applications for review or appeal in relation to the application, have been finally determined or otherwise disposed of. Where the Secretary refuses to make a recommendation, internal review of the decision may be sought under section 60 of the Act.

For example, a situation may arise where three applications relating to the same ingredient (being an ingredient which is not included in the section 26BB determination) are received in consecutive order – Application 1 is received first, then Application 2 and later Application 3. If all 3 applications pass preliminary assessment, the applicants would receive notice of this under subsection 26BD(5) of the Act.

Application 1 would not meet the requirement in paragraph 16GI(1A)(d) because at the time the Secretary gives notice that the application has passed preliminary assessment, there would be no other applications that have been made in relation to that ingredient under section 26BD and that have passed preliminary assessment (this reflects that the first or "frontrunner" application is made first in time and would, in most instances, pass preliminary assessment first). Accordingly, subregulation 16GI(1) would apply to Application 1, not subregulation 16GI(1A).

Application 2 would be a current application as it would meet all the requirements in paragraphs 16GI(1A)(a) to (d), and Application 1 would be a *related application* in relation to Application 2.

Application 3 would be a current application as it would meet all the requirements in paragraphs 16GI(1A)(a) to (d), and Applications 1 and 2 would be *related applications* in relation to Application 3.

In this scenario, if the Secretary makes a recommendation in relation to Application 1 (within the timeframes set out in subregulation 16GI(1) as relevant to the application type) and the ingredient is included in the section 26BB determination, the period of evaluation for Application 2 and Application 3 would commence on the later of the start day (under new paragraph 16GI(1B)(b), this would be the day on which the determination commences), and the day the evaluation fee for each of Application 2 and Application 3 is paid.

In these circumstances, once Application 1 has been finally determined, the queue for evaluation would no longer be maintained - i.e. Applications 2 and 3 could then be evaluated once the relevant evaluation fee for each respective application is paid.

Noting that the ingredient has been included in the section 26BB determination already, if Applications 2 and 3 are seeking the same requirements of use in relation to the ingredient reflected in the 26BB determination, the applicants for Applications 2 and 3 may wish to withdraw their application before paying their evaluation fee. However, if Applications 2 or 3 are seeking different such requirements, they may wish to continue with the process and have their applications evaluated so that, if successful, the section 26BB determination can be varied in accordance with Applications 2 or 3 as necessary once the period of market exclusivity has ended.

Conversely, in this same scenario, if the Secretary refuses to make a recommendation under section 26BE in relation to Application 1, the evaluation period for Application 2 will only commence once Application 1 has been finally determined (i.e. when all avenues of review and appeal have been exhausted), as provided in new paragraph 16GI(1B)(a), and the evaluation fee has been paid. The evaluation period for Application 3 would subsequently only commence when Application 2 has been finally determined and the evaluation fee is paid, or a Determination commences in relation to the ingredient and the evaluation fee is paid.

Another example may be where three applications are received in consecutive order – Applications 1, 2 and 3 – but Application 1 does not pass preliminary assessment. In such circumstances, the Secretary would not, under subsection 26BE(3) of the Act, be required to evaluate Application 1, and it would not be covered by the requirements of either

subregulation 16GI(1) or (1A). Rather, Application 2 would then be evaluated first (i.e. it would become the "frontrunner"), in accordance with the timeframes in subregulation 16GI(1), and Application 3 would be covered by subregulation 16GI(1A) and the timeframes in that subregulation.

Item 10 – Subregulation 16GI(2)
This item makes a minor amendment to subregulation 16GI(2) of the TG Regulations to clarify that the period for evaluation of an application under section 26BD of the Act is provided for in both the table in subregulation 16GI(1) and in subregulation 16GI(1A).

Item 11 – Clause 5 of Schedule 9 (table items 28, 30, 32 and 34)
This item amends a number of fee items in Schedule 9 of the TG Regulations to refer to section 26BD instead of section 26BE of the Act. Following the commencement of the preliminary assessment procedures in the Amending Act, applications that were previously made under section 26BE of the Act are made under section 26BD of the Act. The fee amounts remain unchanged and it is just the reference to the provision that is updated.

Schedule 7 – In-house IVD medical devices

Summary
This Schedule, in particular, introduces an exemption from the requirement to be included in the Register for Class 4 in-house IVD medical devices that are used in the testing of samples of stool, blood or other specimens from the human body for the purpose of assessing the suitability of the person to be a donor of human stool for use in the manufacture of faecal microbiota transplant products (FMT products). Pursuant to the classification rules for IVD medical devices in Schedule 2A to the MD Regulations, such devices are a Class 4 in-house IVD medical device (clause 1.1 of Schedule 2A refers) and would, but for the exemption, be required to be included in the Register to be lawfully supplied (unless one of the pathways for the supply of unapproved medical devices provided for in the Act applies).

This exemption is intended to be in place for a limited time (perhaps up to 4 years) to allow laboratories that manufacture such devices time to work with the TGA towards the validation of these tests so they may in time be included in the Register. This Schedule also includes a small number of amendments to the existing conformity assessment procedures for such devices to include a notification requirement to ensure that the Secretary is able to be aware of what such devices are being used.

The TGA consulted in June 2020 with FMT manufacturers, the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia in relation to the exemption of Class 4 in-house IVDs for the testing of samples to support donor screening in relation to FMT products. These stakeholders supported this proposal.

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – at the end of clause 6B.1 of Schedule 3
This item amends clause 6B.1 of Schedule 3 to the MD Regulations to introduce a new paragraph which references the notification requirements introduced by this Schedule.

Item 2 – At the end of Part 6B of Schedule 3
This item introduces new clause 6B.8 to Part 6B of Schedule 3 to the MD Regulations, which provides that the manufacturer of a kind of Class 4 in-house IVD medical device that the manufacturer intends to be used to test transmissible agents in blood, stool or other specimens from a person's body to assess that person's suitability to be a donor of human stool for the manufacture of FMT products must notify the Secretary about the kind of device. The notification must be in a form approved in writing by the Secretary and contain the information required by the form.

The effect of the new notification requirement is that such a manufacturer would not have to commence notifying the Secretary until after 1 July 2021. The amendment requires that, for a device that is manufactured any time after the commencement of this amendment and before 1 July 2021, the manufacturer must notify the Secretary no later than 20 working days after 1 July 2021. For a device that is manufactured after 1 July 2021, the amendments require the manufacturer to notify the Secretary of the device no later than 20 working days after the manufacture.

Only one such notification is required for each kind of Class 4 in-house IVD medical device manufactured by a manufacturer. If, for example, the manufacturer of the devices changes the device to test for a different or additional transmissible agent, or changes the methodology of the test, the device would be a different kind of Class 4 in-house IVD medical device, so another notification would need to be given to the Secretary in accordance with this new provision.

Item 3 – Part 2 of Schedule 4 (table item 2.10, column headed "Conditions", paragraph (c))

This item repeals paragraph (c) of the conditions in item 2.10 in Part 2 of Schedule 4 to the MD Regulations to reflect that, given the nature of in-house IVD medical devices, a sample could not be taken of the device.

Item 4 – Part 2 of Schedule 4 (table item 2.10, column headed "Conditions", subparagraph (e)(ii))

This item removes the reference to 'the product range', in the condition in subparagraph (e)(ii) of item 2.10 in Part 2 of Schedule 4 to the MD Regulations to reflect that in-house IVD medical devices do not have a 'product range' given the particular nature of in-house IVD medical devices.

Item 5 – Part 2 of Schedule 4 (table item 2.10, column headed "Conditions", subparagraph (f)(ii))

This item amends subparagraph (e)(ii) of item 2.10 in Part 2 of Schedule 4 to the MD Regulations to remove the reference to samples. Given the nature of in-house IVD medical devices, it would not be possible to take a sample of such devices.

Item 6 – Part 2 of Schedule 4 (after table item 2.10)

This item introduces an exemption, new item 2.10A, in the table in Part 2 of Schedule 4 from the requirement to be included in the Register. The exemption applies to a medical device that is a Class 4 in-house IVD medical device intended by its manufacturer to be used to detect the presence of, or exposure to, transmissible agents in blood, stool or other specimens from a person's body in order to assess the suitability of the person to be a donor of human stool for use in the manufacture of a FMT product. Accordingly, the exemption only applies to a quite specific kind of Class 4 in-house IVD medical device.

The conditions that apply in relation to this exemption are comparable to the conditions for the existing exemption for Class 1, 2 or 3 in-house IVD medical devices in existing item 2.10 of Part 2 of Schedule 4 to the MD Regulations. These conditions generally require that the device must comply with the essential principles, the appropriate conformity assessment procedures must be applied at all times, the manufacturer must provide requested information, the manufacturer must have available at all times certain information, the manufacturer must allow an authorised person to carry out an inspection and the Secretary must not have directed that supply cease because the supply compromises public health and safety.

Item 7 – Dictionary

This item introduces a definition of 'faecal microbiota transplant product' in the Dictionary in the MD Regulations. This definition is the same as the definition of such products in the TG Regulations.

Schedule 8 – Changed commencement for reforms in the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulation 2019

Summary

This Schedule amends the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019*, MD Regulations and TG Regulations to reflect the impact of the public health emergency caused by the outbreak of the disease known as coronavirus disease 2019 (COVID-19) by delaying the commencement or effect of reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) 2019* in relation to medical devices that are or that utilise software, personalised medical devices such as custom-made devices, the reclassification of certain kinds of devices and FMT products.

The TGA discussed and received representations in 2020 from MTAA and device sponsors in relation to the commencement of medical device reforms on software, personalised medical devices and reclassification, both in light of COVID-19 and (for reclassification) the EU Parliament's announcement on 16 April 2020 of the delay of EU reforms on which those measures were based. The impact of COVID-19 has included that some Australian device manufacturers have diverted resources to produce products such as face shields, as well as impacts on supply chains, production and domestic travel. The amendments address such concerns.

Part 1 – Main changes

Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

Item 1 – Subsection 2(1) (table item 2)

This item amends the commencement dates for Schedules 1, 2 and 3 of the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*. These Schedules contain amendments that change Australia's medical device regulations to either align with EU medical device regulation (MDR) reforms or to reflect guidance issued by the International Medical Device Regulators Forum. The regulatory changes were to:

- reclassify a number of types of devices such as spinal implants, active implantable devices and devices used in direct contact with the heart, central circulatory system or central nervous system (either to higher risk classifications or different classifications of the same risk level);
- modernise and clarify the requirements for custom-made devices and adopt a number of new definitions for personalised medical devices, including 3D printed devices; and
- modernise and clarify the existing requirements including improvements to classifying software as a medical device.

Following the making of the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*, the COVID-19 crisis has significantly impacted the readiness of many medical device sponsors to comply with the new regulations, particularly for the parts of the medical device sector providing products related to COVID-19 management. Other parts of the industry, including some domestic manufacturers, have diverted their efforts to new or increased production of face shields and 3D printed swabs needed for front line health workers. Companies that develop software have assisted by delivering a broad range of online or downloadable apps that support health services, pharmacy, clinical and other

services to be offered remotely. The period of lock down and limits to travel have also impacted on device supply chains and production.

On 16 April 2020, the EU Parliament approved postponing the commencement date of changes to the EU MDR by one year to 26 May 2021. The EU's rationale was to prevent medical shortages or delays in relation to key medical devices, by not implementing major reforms during COVID-19.

To minimise the disruption and potential regulatory burden that might occur if Australia was to not change its current implementation timeframe for these reforms, the purpose of this amendment is to delay the commencement of the reclassification, software and personalised medical device reforms set out in Schedules 1 to 3 respectively.

This item delays the commencement of the medical device reforms in the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* from 25 August 2020 to 25 November 2021 for reclassification for certain devices; 25 February 2021 for medical device software; and 25 February 2021 for personalised medical devices (including 3D printed devices).

Therapeutic Goods (Medical Devices) Regulations 2002

Items 2 and 3 – Regulation 11.39 (definition of *pre-commencement entry* and paragraphs (a) and (b) of the definition of *transitional medical device*)
This item amends the definitions of pre-commencement entry and transitional medical device in regulation 11.39 of the MD Regulations to change references to 25 August 2020 to 25 November 2021 in these transitional provisions for the reclassification of certain kinds of medical devices. This reflects the delay to the commencement of the reclassification reforms set out in Schedule 1 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Items 4 and 5 – Subregulation 11.40(1) and Subparagraph 11.40(3)(a)(ii)
These items amend subregulation 11.40(1) and subparagraph 11.40(3)(a)(ii) of the MD Regulations to change references to 25 August 2020 to 25 November 2021 in these transitional provisions for reclassification, to reflect the delay to the commencement of the reclassification reforms set out in Schedule 1 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Items 6 and 7 – Subparagraph 11.40(5)(b)(i) and Subparagraph 11.41(2)(c)(i)
These items amend subparagraph 11.40(5)(b)(i) and subparagraph 11.41(2)(c)(i) of the MD Regulations, the transitional provisions for reclassification in relation to the obligation for sponsors of transitional medical devices to notify the Secretary of the unique device number and the unique product identifiers for each of their pre-commencement entry products that they are supplying in Australia in order to qualify for the transitional arrangements, to replace references to 25 February 2021 with 25 May 2022. This is to reflect the delay to the commencement of the reclassification reforms set out in Schedule 1 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Item 8 – subregulation 11.43(3)
This item amends subregulation 11.43(3) of the MD Regulations, the transitional provisions for reclassification relating to the waiver of certain application fees in relation to Class AIMD devices, to replace the reference to 24 August 2021 with 24 November 2022. This is to reflect the delay to the commencement of the reclassification reforms set out in Schedule 1 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Items 9 to 11 and 14 – Regulation 11.44 (definition of *transitional kind of medical device*), subregulation 11.45(1), subparagraph 11.45(3)(a)(ii) and subregulation 11.47(1)
These items amend regulation 11.44 (definition of *transitional kind of medical device*), subregulation 11.45(1), subparagraph 11.45(3)(a)(ii) and subregulation 11.47(1), being the transitional provisions for programmed or programmable medical devices of software that is a medical device in Subdivision C of Division 11.10 of the MD Regulations, to replace references to 25 August 2020 with 25 February 2021. This is to reflect the delay to the commencement of the reclassification, software and personalised medical device reforms set out in Schedules 1 to 3 (respectively) to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Items 12 and 13 – Subparagraph 11.45(5)(b)(i) and Subparagraph 11.46(2)(c)(i)
These items amend subparagraph 11.45(5)(b)(i) and subparagraph 11.46(2)(c)(i) of the MD Regulations, being the transitional provision for programmed or programmable medical devices of software that is a medical device relating to the obligation for sponsors of transitional medical devices to notify the Secretary of the unique product identifier for each of their pre-commencement entry products that they are supplying in Australia in order to qualify for the transitional arrangements, to replace references to 25 February 2021 with 25 August 2021. This is to reflect the delay to the commencement of the reclassification, software and personalised medical device reforms set out in Schedules 1 to 3 (respectively) to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Items 15 to 21 – Regulation 11.48 (definition of *transitional kind of medical device*), subregulations 11.49(1) and (2), subregulations 11.50(1) and (2), 11.51(1) and (2), paragraphs 11.51(3)(a) and (b), subregulation 11.52(1) and subparagraph 11.52(3)(a)(ii)
These items amend regulations 11.48 (definition of *transitional kind of medical device*), 11.49, 11.50, 11.51 and 11.52, being the transitional provisions for personalised medical devices in Subdivision D of Division 11.10 of the MD Regulations, to replace references to 25 August 2020 with 25 February 2021. This is to reflect the delay to the commencement of the reclassification, software and personalised medical device reforms set out in Schedules 1 to 3 (respectively) to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Items 22 and 23 – Subparagraphs 11.52(5)(b)(i) and 11.52(5)(c)(i)
These items amend subparagraphs 11.52(5)(b)(i) and 11.52(5)(c)(i), being the transitional provisions for personalised medical devices relating to the obligation for sponsors of transitional medical devices to notify the Secretary of the unique product identifier for each of their pre-commencement entry products that they are supplying in Australia in order to qualify for the transitional arrangements, to replace references to 25 February 2021 with 25 August 2021. This is to reflect the delay to the commencement of the reclassification, software and personalised medical device reforms set out in Schedules 1 to 3 (respectively) to

the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* given effect by this Part.

Therapeutic Goods Regulations 1990

Items 24 to 31 – Subregulations 70(3), 70(4), 70(5), 71(3) and 71(4)
These items amend subregulations 70(3), 70(4), 70(5), 71(3) and 71(4) of the TG Regulations to extend the exemption for faecal microbiota transplant (FMT) products by 6 months, i.e. extending the end date of the current exemptions for FMT products from the requirement to be included in the Register and the requirement to be manufactured under a licence issued under Part 3-3 of the Act. The transition period for the regulation of FMT products in regulations 70 and 71 of the TG Regulations is currently 12 months commencing 1 January 2021. However, due to delays within the sector caused by the COVID-19 crisis, this amendment extends the period of the exemption by 6 months until 1 July 2021.

Part 2 – Other changes

Therapeutic Goods (Medical Device) Regulations 2002

Item 32 – At the end of regulation 5.11
This item amends regulation 5.11 of the MD Regulations to introduce subregulation 5.11(5) to clarify the reporting requirements for medical devices that change classification.

Regulation 5.11 sets out a statutory condition for the purposes of subsection 41FN(5A) of the Act for medical devices of the kinds mentioned in paragraphs 5.11(1)(a)-(d) to provide certain reports to the Secretary for their devices for the reporting period described in subregulation 5.11(4) (essentially the balance of the financial year in which their kind of device is first included in the Register, and the next 2 financial years). This condition will apply to a number of the kinds of devices covered by the reclassification reforms in Schedule 1 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

The purpose of this amendment is to ensure that the condition will not apply for such devices subject to reclassification reforms, to the extent that sponsors have already complied with the condition for the reporting period in subregulation 5.11(4) in relation to their devices when they were entered in the Register with their previous classification. The condition, conversely, applies to such devices for the balance of that period. This is to avoid duplicating the reporting requirements in regulation 5.11 for transitional kinds of medical devices in relation to reclassification.

The amendment is designed to ensure that any period of previous reporting compliance for the previous entry counts towards the reporting period for the new entry in the Register.

By way of example, for a Class IIb implantable medical device or a Class AIMD medical device that was included in the Register prior to 25 November 2021, a Class III inclusion application would be submitted to the TGA on 30 November 2021 (to transition a Class IIb implantable medical device or a Class AIMD medical device that was included in the Register on 1 January 2020 to a Class III medical device). A decision would be made to

include the device as a Class III medical device on 30 March 2022 so paragraph 5.11 (5)(a) applies. Immediately before 30 March 2022 (i.e. on 29 March 2022), the device was a Class IIb implantable medical device or a Class AIMD medical device (in accordance with paragraph 5.11(1)(c) or 5.11(1)(a) respectively), therefore paragraph 5.11(5)(b) applies.

In this scenario, the reporting period for the Class III medical device is the period beginning on the day when the previous Class IIb implantable medical device or Class AIMD medical device was included in the ARTG (i.e. beginning 1 January 2020). The first annual report would have been provided before 1 October 2020 and the second annual report would have been provided before 1 October 2021. The final report would be due before 1 October 2022 in relation to the Class III Register entry (even if the previous Class IIb implantable medical device or Class AIMD medical device Register entry has been cancelled from the Register).

Schedule 9 – Other amendments

Summary
This Schedule sets out a number of more minor, unrelated amendments including, for example, to remove spent and redundant references to the category of therapeutic goods known as therapeutic devices.

Therapeutic Goods Regulations 1990

Items 1 to 18, 20 and 25 to 29 – Removal of references to therapeutic devices, and related amendments
These items amend a number of regulations to remove references to therapeutic devices (or listed or registered devices) or repeal provisions that relate to therapeutic devices (or listed or registered devices), and also repeal Schedule 6 to the TG Regulations as the only entries in that schedule relate to therapeutic devices. These references are spent and redundant as 'therapeutic devices' is a superseded product category following the introduction of Chapter 4 to the Act. Therapeutic devices that were previously regulated under Part 3-2 of the Act are instead now regulated under Chapter 4 of the Act. Item 26 inserts a fee of $470 for disinfectants to correct an error, as the previous fee for listed therapeutic devices was removed in the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020* but instead should have been retained with the reference to listed therapeutic devices replaced with a reference to disinfectants.

Item 19 – Schedule 7 (cell at table item 2, column 2, paragraph (b))
This item replaces the reference to licensed manufacturers to specifically refer to a licensed manufacturer. This minor correction is intended to ensure the exemption reflects the application of the item since its inception. The reference to "licensed manufacturers" is a reference to licensed manufacturers collectively and therefore not specific enough to import a precise manufacturing intention of a particular licensed manufacturer in relation to the sole therapeutic use of herbs, bulk hamamelis water or oils extracted from herbs. This is problematic because the sole therapeutic use of starting materials of this nature that are used in the manufacture of therapeutic goods is determined in the ordinary course of inspections from the manufacturing intention of the licensed manufacturer in question. The purpose of this amendment is to ensure clarity and precision in the interpretation and application of the exemption.

Items 21 to 24– Schedule 7 (amendments to items 22 and 23)
These items amend items 22 and 23 of the table in Schedule 7 to the TG Regulations to amend the terms of the exemption for radiopharmaceuticals and radiopharmaceutical active ingredient to reflect other items in that table. Paragraphs (a) and (b) in items 22 and 23 are not conditions of the exemption but, rather, describe the nature of the goods that are exempt under those items.

Schedule 10 – Application and transitional provisions

Summary
This Schedule sets out application and transitional arrangements relating to the effect of the amendments in a number of Schedules to the Regulations.

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – In the appropriate position in Part 11
This item inserts a new Division 11.11 in Part 11 of the MD Regulations, which includes application provisions in relation to system or procedure packs, the notification requirement for medical devices and the exemption for certain Class 4 in-house IVD medical devices.

New regulation 11.55 provides that Part 2 of Schedule 1 to these Regulations applies in relation to a system or procedure pack that is manufactured on or after the commencement of that Part.

New regulation 11.56 provides that Schedule 3 to these Regulations applies in relation to information that a person becomes aware of on or after the commencement of that Schedule.

New regulation 11.57 provides that item 2.10A of the table in Part 2 of Schedule 4 applies in relation to a Class 4 in-house IVD medical device manufactured on or after the commencement of this regulation and such a device manufactured before the commence but is intended to be used on or after the commencement.

Therapeutic Goods Regulations 1990

Item 2 – In the appropriate position in Part 9
This item inserts a new Division 13 in Part 9 of the TG Regulations, which includes an application provisions in relation to the authorised prescriber scheme amendments and preliminary assessment for applications to vary the permissible ingredient determination.

New regulation 76 provides that subregulation 12B(1B), inserted by Schedule 4 to these Regulations applies in relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Schedule.

New regulation 77 provides that the amendments to regulation 16GI and the fees associated with applications for variation of the permissible ingredients determination apply in relation to an application made under subsection 26BD(1) on or after the commencement of those amendments in Schedule 6 to these Regulations.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020

The *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* (the Regulations) are 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 principal purpose of the *Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2020* (the MD Regulations) to support measures recently introduced into the *Therapeutic Goods Act 1989* (the Act) by the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020* (the Amendment Act).

The object of 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, 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 Regulations update a number of medical device definitions to more closely align with European Union terminology, and identify matters in relation to which the Secretary may provide scientific advice about a prescription medicine to assist sponsors to better understand the information needed to support a successful application for marketing approval (focussing on the in vitro bioequivalence of such medicines for oral ingestion). The Regulations also support the Amendment Act by identifying circumstances in which a medical practitioner may supply unapproved therapeutic goods to their patients under the authorised prescriber pathway without the need for an ethics committee approval, and by reflecting the introduction of preliminary assessment procedures for applications for the approval of new ingredients for use in listed and assessed listed medicines.

The Regulations make a number of other amendments, to:

- reflect the impact of the public health emergency caused by the outbreak of the disease known as coronavirus disease (COVID-19) by delaying the commencement or effect of reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No .1) Regulations 2019* in relation to medical devices that are or that utilise software, personalised medical devices such as custom-made devices, the reclassification of certain kinds of devices and faecal microbiota transplant products (FMT products);
- amend the timeframes within which the Secretary must decide to make a recommendation to the Minister in relation to an application for the approval of a new ingredient for use in listed or assessed listed medicines, to address the situation in which more than one person applies for approval of the same ingredient;

- exempt oxygen hoods used in hyperbaric chambers for hyperbaric oxygen therapy, and Class 4 in-house in vitro diagnostic (IVD) medical devices used to detect transmissible agents in blood, stool or other specimens from a person's body to assess a person's suitability to donate human stool for use in the manufacture of an FMT product, from the requirement to be included in the Australian Register of Therapeutic Goods; and
- make a number of other, more minor changes and corrections, such as to introduce a timeframe within which a medical device sponsor must notify the Secretary that an overseas-issued certificate or other document they are relying on to demonstrate their device's compliance with the essential principles or conformity assessment procedures has been restricted, suspended or revoked, correct a fee item in relation to disinfectants and to remove spent and redundant references to therapeutic devices.

Human rights implications

The Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Regulations take positive steps to support the right to health by the introduction, in particular, of measures designed to reduce delay for Australian consumers to access new therapeutic goods, by:

- enabling the Secretary to provide scientific advice on the in vitro bioequivalence of medicines for oral ingestion, to assist sponsors to better understand the information needed to support a successful application for marketing approval; and
- improving access to unapproved therapeutic goods for patients that need such goods by identifying circumstances in which a medical practitioner may supply unapproved therapeutic goods to their patients under the authorised prescriber pathway without the need for an ethics committee approval (the circumstances are, generally, where there is a history of safe use of the medicine overseas).

The Regulations, therefore, take positive steps to support the right to health, in particular in relation to the availability and quality of therapeutic goods. Enabling the Secretary to provide early scientific advice to sponsors of medicines for oral ingestion on the in vitro bioequivalence of such medicines is designed to assist them to avoid delays and rejections in connection with applications for marketing approval for such products, allowing these medicines to be more readily available for Australian consumers.

Conclusion

The Regulations are compatible with human rights because they maintain and support the right to health in Article 12 of the ICESCR as outlined above, and do not raise any other human rights issues.

Greg Hunt, Minister for Health