EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

These Regulations reduce regulatory burden for sponsors and manufacturers of medical devices and improve the availability of unapproved prescription medicines for seriously ill patients.

An object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act. Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), principally to reduce regulatory burden for sponsors and manufacturers of medical devices (e.g. by exempting surgical loan kits from the requirement to be included in the Australian Register of Therapeutic Goods (the Register)), and improve access to unapproved medicines for the treatment of seriously ill patients.

In particular, the Regulations:

- better align the regulation of system or procedure packs with the European Union;
- require device sponsors to provide a final report of an adverse event involving their device, 120 days after the initial report was made, to ensure that device safety information is current and accurate;
- provide greater flexibility for device sponsors and manufacturers in how they provide patient information materials for implantable devices;
- avoid the inadvertent up-classification of ancillary devices used in surgery, devices that are composed of substances or combinations of substances and devices that administer medicines or biologicals by inhalation;
- exempt patient-matched devices from the requirement to be included in the Register where less than 5 are made by a manufacturer in a financial year, and provide more time for sponsors of other such devices to notify the TGA of details of their products;
- exempt surgical loan kits supplied to hospitals in Australia for use in surgery from the requirement to be included in the Register, reducing regulatory burden for suppliers;
- improve access to unapproved prescription medicines for seriously ill patients by exempting imported prescription medicines that are needed for supply to such patients in hospitals or other healthcare facilities;
- enable the Secretary to refund fees relating to applications for conformity assessment certificates in respect of certain higher risk devices, for which the kinds of evidence required to support an application for marketing approval was recently broadened;
- improve the flexibility of the current transitional arrangements for devices that are surgical mesh (other than urogynaecological mesh); and

- prescribe a number of medicines that may be accessed under the Authorised Prescriber Scheme without the need for Human Research Ethics Committee approval.

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 be a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after they are registered on the Federal Register of Legislation, except the system or procedure pack and surgical loan kit amendments which commence on 25 November 2021, and the devices reclassification amendments which commence immediately after the commencement of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (i.e. 25 November 2021).

Consultation

The TGA consulted in October 2019 on the regulation of system or procedure packs, and in 2020 invited respondents to that consultation (including members of the Medical Technology Association of Australia (MTAA)) to targeted workshops in February and March 2020 to refine the proposals. There was overall support and these regulations reflect workshop feedback. The TGA consulted in August 2021 on refinements to improve flexibility around patient information materials. 34 submissions were received, including from healthcare professionals, hospitals and device sponsors and manufacturers, with the majority supportive of the proposals. The TGA consulted on a range of measures relating to personalised medical devices between 7 June and 14 July 2021, with 137 submissions from a range of respondents. One theme from submissions was the need for a mechanism to allow low volume personalised devices to be supplied to patients without the need to be included in the Register. These amendments deliver this reform. The TGA consulted on the proposed exemption of surgical loan kits with industry (including members of the MTAA) and hospitals in December 2019, January 2020 and May 2021, with all stakeholders supportive of the proposal. The TGA conducted targeted consultations with a number of stakeholders including Medicines Australia, the Society of Hospital Pharmacists Australia, the Pharmaceutical Society of Australia and State and Territory Chief Pharmacists on proposals to improve access to unapproved prescription medicines for seriously ill patients, with broad support from respondents. The amendments to improve the flexibility of the transitional arrangements relating to the up-classification of surgical mesh medical devices are designed to reflect feedback from sponsors of such devices to the TGA across 2019-21. The TGA also consulted with the National Aboriginal Community Controlled Health Organisation (NACCHO in relation to the addition of nifedipine to the list of unapproved medicines that may be accessed under the TGA's Authorised Prescriber Scheme without Human Research Ethics Committee approval. NACCHO supported the proposal.

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

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021.*

Section 2 – Commencement

This section provides for the Regulations to commence on the day after registration on the Federal Register of Legislation, except Part 1 and Part 7 of Schedule 1 which commence on 25 November 2021 and Part 4 of Schedule 1 which commences immediately after the commencement of the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (i.e. 25 November 2021).

Section 3 – Authority

The Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedules

This section gives legal effect to the amendments in the Schedules.

Schedule 1 – Amendments

Part 1—System or procedure packs

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Paragraph 3.10(3)(aa)
This item repeals and replaces paragraph 3.10(3)(aa) of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), to clarify the kinds of therapeutic goods that may be included in a system or procedure pack that is a medical device used for a special purpose.

Paragraph 3.10(3)(aa) of the MD Regulations provides that where a system or procedure pack contains therapeutic goods that are not medical devices, subregulation 3.10(3) applies where those goods are medicines and biologicals that are included in the Register, or where they are other therapeutic goods that are either included in the Register or tampons, menstrual cups or disinfectants that are exempt from inclusion in the Register. Paragraph 3.10(3)(aa) of the MD Regulations also provides that subregulation 3.10(3) only applies if the packaging of medicines, biologicals or other therapeutic goods included in a system or procedure pack has not been modified and those therapeutic goods have not been modified. If a medicine, biological or other therapeutic good included in a system or procedure pack has been

modified or its packaging has been modified, the system or procedure pack would not be a medical device used for a special purpose.

Item [2] – Paragraphs 3.10(3)(b) and (c)
This item makes a minor editorial amendment to paragraphs 3.10(3)(b) and (c) of the MD Regulations to remove the words 'for use' after the reference to indications.

Item [3] – Subregulation 3.10(4)
This item repeals and replaces subregulation 3.10(4) of the MD Regulations, including the note, to clarify that, if a system or procedure pack that is a medical device used for a special purpose is to be supplied in a sterile state, the production quality assurance procedures must be applied to the device or the manufacturer may choose to apply the full quality assurance procedures.

Items [4] to [7] – Paragraph 7.5(2)(e) of Schedule 3
These items amend paragraph 7.5(2)(e) of Schedule 3 to the MD Regulations to provide that the declaration of conformity for a system or procedure pack must state that the manufacturer has a conformity assessment document, declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) for each medical device in the system or procedure pack (depending on whether a conformity assessment document, declaration or statement is required under the MD Regulations for the particular device). The declaration also has to state that the manufacturer has evidence that each medical device complies with the applicable provisions of the essential principles. This item does not apply where a medical device, or the packaging of a medical device, in a system or procedure pack that is a medical device used for a special purpose has been modified in some way.

Item [8] – Paragraph 7.5(2)(g) of Schedule 3
This item makes a minor editorial amendment to paragraph 7.5(2)(g) of Schedule 3 to the MD Regulations, to clarify that a declaration of conformity for a system or procedure pack that is a medical device used for a special purpose must state that each medicine, biological and other therapeutic good included in a system or procedure pack is intended to be used within the approved indications of the medicine, biological or other therapeutic goods.

Item [9] – Paragraph 7.5(2)(h) of Schedule 3
This item repeals and replaces paragraph 7.5(2)(h) of Schedule 3 to the MD Regulations, to clarify that the declaration of conformity for a system or procedure pack that is a medical device used for a special purpose must state that the mutual compatibility of each therapeutic good and any other goods in the system or procedure pack has been verified in accordance with the instructions for use provided by the manufacturer of each medical device and the approved indications of each medicine, biological and other therapeutic good included in the system or procedure pack. Separately, paragraph 7.5(2)(ha) provides that the declaration of conformity must also state that the system or procedure pack has been manufactured in accordance with such instructions or indications.

Item [10] – After paragraph 7.5(2)(i) of Schedule 3
This item introduces paragraph (ia) in subclause 7.5(2) of Schedule 3 to the MD Regulations, to provide that if a manufacturer of a system or procedure pack has modified the packaging of any medical device included in the system or procedure pack, or modified a medical device included in the system or procedure pack in any way, the declaration of conformity for the system or procedure pack must state the matters in subclause 7.5(2A).

Item [11] – After paragraph 7.5(2)(k) of Schedule 3
This item repeals and replaces paragraph 7.5(2)(k) of Schedule 3 to the MD Regulations to clarify that a declaration of conformity for a system or procedure pack to be supplied in a sterile state must state that the full quality assurance procedures or production quality assurance procedures have been applied, as required by regulation 3.10(4) of the MD Regulations, in accordance with the instructions for use of each medical device provided by the manufacturer of the device, or the approved indications of each medicine, biological or other therapeutic good in the system or procedure pack.

Item [12] – After subclause 7.5(2) of Schedule 3
This item introduces two subclauses in clause 7.5 of Schedule 3 to the MD Regulations. Where a medical device in a system or procedure pack or its packaging has been modified, subclause 7.5(2B) provides that the manufacturer must ensure that the modification does not affect the quality, safety or performance of the medical device and, if the modification is not done in accordance with the instructions for use of the medical device as provided by the manufacturer of the device, the manufacturer must have (as required for the particular device) a conformity assessment document, declaration of conformity or statement of conformity for the medical device as modified. Subclause 7.5(2A) requires that the declaration of conformity for the system or procedure pack reflect compliance with subclause 7.5(2B).

Item [13] – Dictionary
This item introduces a definition of 'approved indications' in the Dictionary to the MD Regulations, to provide that the 'approved indications' of a medicine, biological or other therapeutic goods, means the indications included in the Register in relation to the medicine, biological or other therapeutic goods, or otherwise the indications in relation to the medicine, biological or other therapeutic goods.

Part 2—Reports about adverse events or occurrences for medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

Item [14] – At the end of subregulation 5.7(1)
This item adds a note at the end of subregulation 5.7(1) of the MD Regulations, to refer to new regulation 5.8A.

Item [15] – After regulation 5.8
This item introduces new regulation 5.8A to the MD Regulations, to provide for a statutory condition applying automatically to the inclusion of a medical device in the Register. The condition in regulation 5.8A applies to a person in relation to whom a kind of medical device is included in the Register who gives adverse event information to the Secretary in accordance with subsection 41MP(2) or subsection 41MPA(2) of the Act within the timeframe covered in paragraphs 5.7(1)(a), (b) or (c) of the MD Regulations (the statutory condition does not apply in relation to paragraph 5.7(1)(d) of the MD Regulations).

Pursuant to the condition, such a person is required to give a written report to the Secretary, within 120 days of having provided information to the Secretary in accordance with subsection 41MP(2) or subsection 41MPA(2) of the Act and regulation 5.7 of the MD Regulations, that provides an update to that information, explains any actions by the person

or the manufacturer of the device to investigate the event and alleviate its impact on patients or other users, and any details of similar events in the last 3 years.

The purpose of this condition is to ensure that comprehensive safety information is provided to the Secretary following an adverse event or occurrence associated with a medical device, so that appropriate action can be taken to adequately investigate and address the adverse event or occurrence. This will better inform the management of device safety issues through improved access to complete information about adverse events, which will aid in the assessment of, and planning for, adverse event trends.

Part 3—Patient implant cards and patient information leaflets

Therapeutic Goods (Medical Devices) Regulations 2002

Item [16] – After Division 9.1 of Part 9
This item introduces new Division 9.1A to the MD Regulations to provide for a reduction in the applicable fees for applications to the Secretary under sections 41MA and 41MAA of the Act for consent to import, supply or export a medical device that does not comply with the essential principles (these are set out in Schedule 2 to the MD Regulations) in respect specifically of implantable medical devices that do not comply with Essential Principle 13A regarding patient information materials (i.e. either or both of 13A.2 and 13A.3).

Subregulation 9.1AA(1) applies where such an application is covered by paragraph (a) of item 1.15 of the table in Part 1 of Schedule 5 to the MD Regulations, with the effect that the amount of the fee is not to be worked out in accordance with Part 1 of Schedule 5 but rather that where such an application that relates to a single entry in the Register, or to a medical device that is not included in the Register, the applicable fee is $30.

Subregulation 9.1AA(2) applies where such an application is covered by paragraph (b) of item 1.15 of the table in Part 1 of Schedule 5 to the MD Regulations, with the effect that the amount of the fee is not to be worked out in accordance with Part 1 of Schedule 5 but rather that where such an application relates to more than one entry in the Register, the applicable fee is the number of separate entries in the Register in relation to the entries concerned, multiplied by $30.

Item [17] – Clause 13A of Schedule 1 (heading)
This item repeals and replaces the heading to clause 13A of Schedule 1 to the MD Regulations, to clarify that this essential principle relates to patient information to be made available about implantable medical devices or active implantable medical devices (and is not limited to information in the form of a card or leaflet).

Item [18] – Paragraph 13A.1(b) of Schedule 1
This item amends paragraph 13A.1(b) of Schedule 1 to the MD Regulations to broaden the scope of this paragraph to include similar articles to those already listed. The effect of this is to exclude similar implantable medical devices from the requirements of clause 13A that perform ancillary roles and do not significantly alter the risk profile of the surgery when implanted. As such devices are lower risk, patient information materials are not required, reducing regulatory burden on sponsors of these devices.

Items [19] to [23] – Clause 13A.2 of Schedule 1
These items amend clause 13A.2 of Schedule 1 to the MD Regulations, including the clause heading, the table heading and a table column heading, to provide greater flexibility in the provision of a patient implant card. The effect of the amendments is that the information in the table in clause 13A.2 can either be in the form of a card (i.e. a patient implant card) and available for provision to a patient receiving the device, or be in electronic form and available in a way that is readily accessible by the patient concerned. For either option, clause 13A.4 must be satisfied.

These amendments give sponsors the option to provide the information either in the form of a card that can be handed to a patient who receives the relevant medical device or in electronic form that is easily accessible by a patient who receives the relevant medical device. This flexibility is intended to reduce regulatory burden for sponsors while ensuring that patients are able to receive patient information material about the particular device they have received.

Items [24] to [30] – Clause 13A.3 of Schedule 1
These items amend clause 13A.3 of Schedule 1 to the MD Regulations, including the clause heading, the table heading and a table column heading, to provide greater flexibility in the provision of a patient information leaflets. The effect of the amendments is that the information in clause 13A.3 can either be in the form of a leaflet (i.e. a patient information leaflet) and available for provision to a patient receiving the device, or be in electronic form and available in a way that is readily accessible by the patient concerned. For either option, clause 13A.4 must be satisfied.

These amendments give sponsors the option to provide the information either in the form of a leaflet that can be handed to a patient who receives the relevant medical device or in electronic form that is easily accessible by a patient who receives the relevant medical device. This flexibility is intended to reduce regulatory burden for sponsors while ensuring that patients are able to receive patient information material about the particular device they have received.

Items [31] to [34] – Clause 13A.4 of Schedule 1
These items make minor editorial amendments to clause 13A.4 of Schedule 1 to the MD Regulations, including the heading, to accommodate the amendments made to clauses 13A.2 and 13A.3 of Schedule 1.

Items [35] to [37]– Part 1 of Schedule 5 (table item 1.15, column headed "Matter", paragraph (a) and column headed "Amount ($)")
These items amend item 1.15 in Part 1 of Schedule 5 to the MD Regulations, to clarify that the fee in (a) also applies to medical devices that are not included in the Register and the fees prescribed for item 1.15 are subject to regulation 9.1AA.

Part 4—Reclassification of medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

Item [38] – Subclause 3.1(1) of Schedule 2
This item makes a minor amendment to subclause 3.1(1) of Schedule 2 to the MD Regulations to include a reference to a medical device covered by clause 5.10 or 5.11, which are introduced by the Regulations. The effect of this is the carving out of a medical device covered by clause 5.10 or 5.11 from the classification rule in clause 3.1.

Items [39] and [40] – Subclauses 3.1(2A) and (4) of Schedule 2
These items repeal subclause 3.1(2A) and (4) of Schedule 2 to the MD Regulations, as these subclauses are included in Part 5 of Schedule 2 instead, as clauses 5.10 (without amendment) and 5.11 (with minor clarifications) respectively.

Item [41] – Subclause 3.2(3A) of Schedule 2
This item amends subclause 3.2(3A) of Schedule 2 to the MD Regulations, to clarify that the medical devices classification rule in subclause 3.2(3A) does not apply to a reusable surgical instrument. That is, devices intended by the manufacturer to specifically be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient, that are not a reusable surgical instrument, are Class III medical devices. This amendment is intended to ensure that reusable surgical instruments that are used in surgery and come in contact with the heart, central circulatory system or central nervous system are not inadvertently classified at a higher classification. Examples of such devices include a heart valve sizer, vessel sizer/dilator and vascular scissors. Reusable surgical instruments are classified as Class I medical devices under subclause 3.2(4) of Part 3 of Schedule 2 to the MD Regulations.

Item [42] – Subclause 3.4(4B) of Schedule 2
This item repeals and replaces subclause 3.4(4B) of Schedule 2 to the MD Regulations to clarify that this provision only applies to a device intended by the manufacturer to be a motion-preserving device for the spine (such as a spinal replacement disc), which is classified as a Class III medical device. This classification rule is not intended to capture all devices intended to come in contact with a person's spinal column or exclude devices that are spinal fusion implantable device. The effect of this amendment is to ensure that subclause 3.4(4B) does not unintentionally classify lower-risk devices such as screws, rods and hooks that come in contact with a person's spinal column as Class III medical devices.

Item [43] – At the end of Part 5 of Schedule 2
This item introduces clause 5.10 and 5.11 at the end of Part 2 of Schedule 2 to the MD Regulations. Clause 5.10 replaces subclause 3.1(2A), which is repealed by these Regulations, without amendment. Clause 5.11 replaces subclause 3.1(4) of Schedule 2 to the MD Regulations, to clarify the classification of devices composed of substances, or combinations of substances. For such devices that are introduced into the human body through a body orifice or applied to and absorbed by the skin, the devices would be Class IIa if the device is applied to and absorbed by the skin or introduced into the nasal or oral cavity as far as the pharynx and achieves its intended purpose in those cavities or on the skin, or otherwise Class IIb.

Part 5—Medical devices assembled or adapted at point of care

Therapeutic Goods (Medical Devices) Regulations 2002

Item [44] – At the end of Part 9

This item introduces regulation 9.9 in Division 9.4 to Part 9 of the MD Regulations, to provide a mechanism for the refund or waiver of the fees specified in item 1.6A of the table in Part 1 of Schedule 5 to the MD Regulations and waiver of the fees in item 1.5 of the table in Part 1 of Schedule 5 as applicable.

The refund and waiver powers in regulation 9.9 are only in relation to medical devices covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, which expressly provides that the goods covered by these items are medical devices and, therefore, regulated as therapeutic goods under the Act. The *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021* amended the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* to clarify that the materials or articles that are specified in items 3A, 3B, 3C, 3D and 3E are medical devices when used by a health practitioner or other suitably trained or qualified person acting on the instruction of a health practitioner, being:

- materials or other articles used to obtain dental impressions;
- materials or other articles used in the direct or indirect restoration of teeth including, but not limited to, dental amalgam, crown forms and temporary crown materials;
- materials and other articles used to manufacture non-implantable dental appliances including, but not limited to, denture reline materials and preformed acrylic teeth; and
- materials and other articles used in the manufacture of externally-applied orthopaedic devices including, but not limited to, fibreglass bandages used in the manufacture of splints or orthoses.

If sponsors of such devices wish to apply for revocation of the cancellation of such a device from the Register or apply for inclusion of such a device in the Register, these amendments empower the Secretary to provide a refund of the fees already paid or a waiver of the fees until 31 December 2022.

Subregulation 9.9(1) provides that the Secretary must, on behalf of the Commonwealth, refund the fee in item 1.6A of the table in Part 1 of Schedule 5 for a request for revocation of the cancellation of an entry of a medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, if the request for a refund is made on or after 21 August 2021 and before commencement of this regulation. The effect of this amendment is that, where revocation of the cancellation has already been requested, the Secretary must refund the fee in item 1.6A.

Subregulation 9.9(2) provides that the Secretary must, on behalf of the Commonwealth, waive the fee in item 1.6A of the table in Part 1 of Schedule 5 for a request for revocation of the cancellation of an entry of a medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020,* as in force from time to time, if the request for a waiver is made after the commencement of this regulation and before the end of 31 December 2022. The effect of the amendment is that for future requests for revocation of the cancellation before 31 December 2022, the Secretary must refund the fee in item 1.6A.

Subregulation 9.9(3) provides that the Secretary must, on behalf of the Commonwealth, waive the fee covered by item 1.5 of the table in Part 1 of Schedule 5 for an application for inclusion in the Register of a medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time, if the application is made after commencement of this regulation and before the end of 31 December 2022 and the applicant had made a request for cancellation of that entry in the Register (under paragraph 41GL(d) of the Act) before commencement of this regulation.

Regulation 9.9 incorporates the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* as in force from time to time, in accordance with section 14 of the *Acts Interpretation Act 1901* and subsection 63(4) of the Act, and is available for free from the Federal Register of Legislation (www.legislation.gov.au).

Item [45] – Part 1 of Schedule 4 (after table item 1.3A)
This item introduces item 1.3B in Part 1 of Schedule 4 to the MD Regulations to provide a new exemption from inclusion in the Register for medical devices covered by item 1.3B. Item 1.3B exempts medical devices that are manufactured by a health professional or person acting under the written instructions of a health professional, and manufactured from other medical devices that are included in the Register and covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time. The effect of this new exemption is to clarify that devices manufactured from a medical device in the Register that is covered by item 3A, 3B, 3C, 3D or 3E do not need to separately be included in the Register, reducing regulatory burden for sponsors of such devices.

Item 1.3B incorporates the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* as in force from time to time, in accordance with section 14 of the *Acts Interpretation Act 1901* and subsection 63(4) of the Act, and is available for free from the Federal Register of Legislation (www.legislation.gov.au).

Part 6—Patient-matched medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

Items [46] and [47] – At the end of regulation 7.1 and Part 1 of Schedule 4 (at the end of the table)
These items introduce subregulation 7.1(8) to the MD Regulations and item 1.7 in Part 1 of Schedule 4. The effect of these amendments is that the first five (5) devices of a kind of patient-matched medical device manufactured by a particular manufacturer in a financial year would be exempt from inclusion in the Register. This is to reduce regulatory burden for manufacturers of patient-matched medical devices who produce a small amount of patient-matched medical devices within a year. If a manufacturer produces more than five (5) of one kind of patient-matched medical device within a financial year, they will need to apply for that kind of medical devices to be included on the Register.

Item [48] – Part 2 of Schedule 4 (table item 2.14, column headed "Conditions")
This item amends the condition associated with item 2.14 in Part 2 of Schedule 4 to the MD Regulations, to provide sponsors with an additional year, i.e. until 25 August 2022, to notify the Secretary of each kind of medical device covered by the description in paragraph 11.51(3)(b) that is intended to be supplied on or after 1 November 2024.

Part 7—Surgical loan kits

Therapeutic Goods (Medical Devices) Regulations 2002

Item [49] – Part 2 of Schedule 4 (at the end of the table)
This item introduces item 2.16 in Part 2 of Schedule 4 to the MD Regulations, to provide an exemption from inclusion in the Register for certain medical devices that are surgical loan kits. Item 2.16 provides an exemption for a medical device that is a surgical loan kit where the surgical loan kit is to be supplied to hospitals in Australia for use in a surgical procedure and only contains medical devices that are reusable surgical instruments, implantable medical devices or Class I medical devices included in the Register. This exemption reduces regulatory burden for manufacturers of surgical loan kits, with the risk associated with use mitigated as exempt surgical loan kits must only contain medical devices included in the Register and be used in a hospital setting.

Item 2.16 also only applies where a number of conditions are met, which would manage any safety risks associated with surgical loan kits. The conditions include that the device must comply with the essential principles and the manufacturer must apply appropriate conformity assessment procedures (if any) at all times. Further, the manufacturer must maintain information about the device and provide it to the Secretary or allow an authorised person to enter and inspect manufacturing premises. Importantly, along with the manufacturer keeping records relating to the supply of the device, the manufacturer or sponsor must also keep information about adverse events and provide to the Secretary.

Part 8—Nicotine vaping products

Therapeutic Goods (Medical Devices) Regulations 2002

Items [50] to [53] – Part 1 of Schedule 4 (table item 1.6, column headed "Kinds of medical devices", subparagraphs (a)(iii), (b)(iii), (c)(iii) and (d)(iii))
These items amend the exemption in item 1.6 in Part 1 of Schedule 4 to the MD Regulations to clarify that this exemption also applies where a system or procedure pack contains a nicotine vaping product that is exempt from inclusion in the Register under Schedule 5 or 5A to the TG Regulations. This amendment is intended to cover a potential gap in the exemption in item 1.6 where a nicotine vaping product is exempt from inclusion in the Register, for example, if a nicotine vaping product is extemporaneously compounded for a particularly person for therapeutic application to that person.

Therapeutic Goods Regulations 1990

Item [54] – Schedule 5 (after table item 5)
This item introduces item 5A to the table in Schedule 5 to the TG Regulations to provide an exemption from inclusion in the Register for a kit covered by subsection 7B(1) of the Act that contains one or more nicotine vaping products as the only therapeutic goods in the kit. This exemption is intended to cover a kit where a nicotine vaping product, that is exempt from or included in the Register, is packaged together with a vaping device that is not a medical device, for use as a unit. Such kits are not required to be included in the Register.

Part 9—Access to medicines in emergency situations

Therapeutic Goods Regulations 1990

Item [55] – Schedule 5A (after table item 1A)
This item introduces item 1B to Schedule 5A to the TG Regulations, to provide an exemption from inclusion in the Register for unapproved therapeutic goods that are required urgently in emergency situations. This exemption applies to therapeutic goods imported into Australia that are needed for dispensing as a medicine prescribed for persons who are seriously ill with a condition for which premature death is reasonably likely to occur in the absence of early treatment. A number of conditions need to be met for this exemption to apply, including that the goods are kept in a warehouse or properly secured area under the control of the sponsor or are delivered by or on behalf of the sponsor to a hospital or other healthcare facility to be kept until the medicines are supplied in accordance with a prescription. Further the sponsor must keep records relating to the source and delivery of the goods and give the records to the Secretary if requested.

The purpose of this exemption is to prevent potential delays to patient access to lifesaving medications. This is particularly the case for clinics in remote communities that require unapproved therapeutic goods for emergency use in patients. This exemption does not require the sponsor to maintain direct control of life-saving medicines needed in emergency situations (as is the requirement for item 1 of Schedule 5A) as such medicines may instead be held by a hospital or other healthcare facility after being delivered to the hospital or facility by or on behalf of the sponsor to deal with emergency situations in a timely manner where the goods are supplied on prescription. A hospital or health care facility holding the unapproved therapeutic goods must have appropriate security and storage arrangements for those medicines.

Part 10—Consumer medicine information documents

Therapeutic Goods Regulations 1990

Items [56] to [58] – Subregulation 9A(1) and paragraph 9A(1A)(b)
These items amend subregulations 9A(1) and 9A(1A) of the TG Regulations, to clarify that consumer medicine information is only required for medicines that are included in the Register. By expressly providing that subregulations 9A(1) and 9A(1A) only apply to therapeutic goods included in the Register, this amendment is intended to remove uncertainty around whether consumer medicine information is needed for unapproved therapeutic goods

supplied under a special access pathway or goods exempt from inclusion in the Register. This amendment does not alter existing arrangements for consumer medicine information and gives effect to the intended application of regulation 9A.

Items [59] to [61] – Subregulations 72(2), 72(3) and 72(5)
These items amend the transitional provisions in regulation 72 of the TG Regulations, to accommodate the amendments made to regulation 9A to clarify that consumer medicine information is only required for registered goods. These amendments are intended to remove incorrect and misleading references to unapproved therapeutic goods in the transitional provisions relating to consumer medicine information. The effect of these amendments is to clarify that consumer medicine information is only required for medicines included in the Register and the effect of the transitional arrangements remains unchanged.

Part 11—Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item [62] – Division 9.3 of Part 9 (heading)
This item repeals and replaces the heading of Division 9.3 of the MD Regulations as a consequence of the amendments made by this Part of the Regulations.

Items [63] and [64] – At the end of Division 9.3 of Part 9
These items introduce regulation 9.8 to Division 9.3 in Part 9 of the MD Regulations to provide for the refund of application and assessment fees for applications for a conformity assessment certificate made in relation to a device to which former regulation 4.1 applied, and provide review rights for a decision whether or not to issue a refund. Regulation 4.1 was repealed by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*.

Item 63 introduces regulation 9.8. Subregulation 9.8(1) applies if a person made an application between 1 January 2019 and the commencement of this provision under section 41EB of the Act for a conformity assessment certificate for a device covered by former regulation 4.1 as in force immediately before 28 July 2021, and between 1 January 2019 and 1 December 2021 the person paid all or part of the application or assessment fee associated with the application for a conformity assessment certificate. Further, subregulation 9.8(1) only applies if, between 28 July 2021 and 1 March 2022, the applicant withdraws the application in writing before the Secretary made a decision on the application and requested a refund in writing with accompanying information that satisfies the requirements of subparagraphs 41FDB(2)(d)(i) and (ii) of the Act for that classification of medical device.

If the circumstances in subregulation 9.8(1) are met, the Secretary is required to decide whether or not to refund any of the fee and, if so, decide the amount of the fee to be refunded, taking into account the extent to which the assessment or assessments, or the testing, in connection with the application has been completed at the time the person withdrew their application. As the TGA is a cost recovery agency, the assessment fee for an application for a conformity assessment certificate covers the cost of the assessment. Therefore, only the proportion of the fee for the proportion of the assessment that has not yet been undertaken at the time the application is withdrawn would be refunded.

The Secretary is required to make a decision under subregulation 9.8(1) within the 'applicable period' which is defined in subregulation 9.8(4) as either 20 days from the commencement of this regulation, if the request for refund was made on or after 28 July 2021 and before commencement of this regulation, or 20 days from the request for the refund if the request is made on or after commencement of this regulation.

Item 64 amends subregulation 10.7(1) to provide that the decision of the Secretary in paragraph 9.8(1)(g) or (h) is an initial decision that may be subject to internal review.

Items [65] to [67] – Subregulations 11.29(2), (3) and (4)
These items amend regulation 11.29 of the MD Regulations to extend the transitional period for regulation amendments relating to surgical mesh.

Item 65 makes minor amendments to subregulation 11.29(2) to accommodate the introduction of subregulation 11.29(4A).

Item 66 repeals and replaces subregulation 11.29(3) to remove the requirement for notification to be given to the Secretary. This notification requirement was initially included so the TGA could understand and plan for the quantity of devices that were likely to be transitioning, however this notification is no longer needed since most surgical mesh devices have already transitioned.

Item 67 introduces subregulation 11.29(4A) which provides that the regulation amendments in the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017* relating to surgical mesh, do not apply to a pre-commencement entry before the day applicable under subregulation (4B) if a number of criteria are met. This transitional arrangement only applies if the device covered by the entry is surgical mesh other than urogynaecological mesh, and the person has not made an application for inclusion in the Register referred to in subregulation (3) before 1 December 2021. The regulation amendments also only apply if a person made an application under section 41EB of the Act for a conformity assessment certificate between 1 July 2020 and 1 December 2021, which is not withdrawn before 1 December 2021 and has not lapsed, and the certificate is issued within the 6 months preceding 1 December 2021.

Subregulation 11.29(4B) provides that the regulation amendments only apply to a device that meets the criteria in subregulation 11.29(4A) from the later of 1 December 2021 and the day after the earlier of either: (1) the day the application for the conformity assessment certificate is withdrawn; (2) the day the application lapses under section 41EG of the Act; (3) the day a decision to refuse a conformity assessment certificate becomes final and would not be subject to change; or (4) 6 months after the conformity assessment certificate is issued if an application for inclusion in the Register has not been made yet or, if an application for inclusion in the Register is made, the relevant day specified in subregulation 11.29(4C), which is the earlier of the day the person withdraws, the day the application lapses or the day on which the application is finally determined.

Item [68] – Subregulation 11.29(5)
This item makes a minor amendment to subregulation 11.29(5) to clarify that the meaning of finally determined in this subregulation is only for the purposes of this regulation.

Item [69] – Regulation 11.30
This item repeals regulation 11.30 of the MD Regulations as a consequence of the amendments made by this Part of the Regulations.

Therapeutic Goods Regulations 1990

Item [70] – After paragraph 3(3)(ba)
This item amends subregulation 3(3) of the TG Regulations to declare the *Therapeutic Goods Act 2019* (Qld) and the *Therapeutic Goods Regulation 2021* (Qld) to correspond to the TG Act and TG Regulations, for the purposes of the definition of 'corresponding State law' in section 3(1) of the Act. The *Therapeutic Goods Act 2019* (Qld) and *Therapeutic Goods Regulation 2021* (Qld) commenced on 27 September 2021.

Items [71] to [81] – Subregulation 12B(1B)
These items introduce a number of new items to the table in subregulation 12B(1B) of the TG Regulations, including argipressin, disulfiram, famotidine and nifedipine. The effect of adding these new items to the table in subregulation 12B(1B) is that the Secretary may authorise a medical practitioner under subsection 19(5) of the Act, under the Authorised Prescriber scheme, where the medical practitioner does not have human research ethics committee approval to supply these medicines.

Item [82] – After subregulation 12B(1B)
This item introduces subregulation 12B(1C) to the MD Regulations, for the purpose of subsection 19(6) of the Act, to enable the Secretary to authorise a medical practitioner under subsection 19(5) of the Act (i.e. under the Authorised Prescriber scheme), where the medical practitioner does not have human research ethics committee approval to supply certain medicinal cannabis products. The medicinal cannabis products to which subregulation 12B(1C) applies are those: (1) containing 98% or more cannabidiol and 2% or less other naturally-derived cannabinoids, and no other active ingredients, in liquid or capsule form for oral administration for either the treatment of refractory chronic pain in adult patients or the treatment of refractory anxiety in adult patients; (2) containing 60-98% naturally-derived cannabidiol with the remaining cannabinoid content naturally-derived (e.g. naturally-derived tetrahydrocannabidiol), and no other active ingredients, in liquid or capsule form for oral administration for either the treatment of refractory chronic pain in adult patients or the treatment of refractory anxiety in adult patients; and (3) containing 40% or more naturally-derived cannabidiol with the remaining cannabinoid content naturally-derived (e.g. natural-derived tetrahydrocannabidiol), and no other active ingredients, in liquid or capsule form for oral administration for the treatment of refractory chronic pain in adult patients. The effect of this amendment is that the Secretary may authorise a medical practitioner under subsection 19(5) of the Act, under the Authorised Prescriber scheme, where the medical practitioner does not have human research ethics committee approval to supply these medicines.

Part 12—Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

Items [83] to [85] – Regulation 11.39 (column 1 of items 3 and 4 of the table in the definition of *transitional medical device*) and subregulations 11.40(1), (2), (3) and (5)
These items make consequential amendments to regulations 11.39 and 11.40 of the MD Regulations, to replace references to subclause 3.1(2A) with clause 5.10 and references to subclause 3.1(4) with clause 5.11, and include references to the amendments made by the Regulations in regulation 11.40.

Item [86] – In the appropriate position in Part 11
This item introduces Division 11.13 to the MD Regulations to provide application, saving and transitional provisions relating to the Regulations.

Regulation 11.59 provides that the amendments relating to system or procedure packs apply: (1) from 25 November 2021 for devices included in the Register as a result of an application for inclusion in the Register made on or after 25 November 2021; (2) from 25 November 2025 for a device included in the Register because of an application made before 25 November 2021; and (3) from 25 November 2025 for system or procedure packs that are exempt under Schedule 4 to the MD Regulations and are manufactured on or after 25 November 2025.

Regulation 11.60 provides that the amendments relating to adverse event reporting apply in relation to information in subsection 41MP(2) or 41MPA(2) of the Act given to the Secretary on or after the commencement of Part 1 of Schedule 1 to the Regulations.

Regulation 11.61 provides that the amendments relating to a request for a consent to non-compliance with patient information materials requirements apply in relation to an application for consent made on or after the commencement of Part 3 of Schedule 1 to the Regulations and the amendments to clauses 13A.1 to 14A.4 apply in relation to a medical device that is imported, supplied or exported after the commencement of Part 3 of Schedule 1. Subregulation 11.61(3) also provides that if a person made an application for consent covered by item 1.15 of the table in Part 1 of Schedule 5 to the MD Regulations between 1 January 2021 and the commencement of this regulation and paid the applicable fee, the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable under regulation 9.1AA if the application had been made on the day this regulation commences.

Regulation 11.62 provides that the amendments relating to medical devices assembled or adapted at the point of care apply in relation to a medical device manufactured on or after the commencement of item 1.3B of the table in Part 1 of Schedule 4 to the Regulations.

Regulation 11.63 provides that the amendments relating to patient-matched medical devices apply to patient-matched medical devices manufactured on or after the commencement of item 1.7 of Part 1 of Schedule 4 to the Regulations in the financial year that item 1.7 commences and each financial year after.

Regulation 11.64 provides that the amendments relating to surgical loan kits apply on or after the commencement of Part 7 of Schedule 1 to the Regulations to a surgical loan kit manufactured before, on or after that commencement.

Regulation 11.65 provides that: (1) the amendments to subparagraph (a)(iii) of item 1.6 of the table in Part 1 of Schedule 4 to the MD Regulations apply to a system or procedure pack imported on or after the commencement of Part 8 of Schedule 1 to the Regulations; (2) the amendments to subparagraph (b)(iii) apply to a system or procedure pack manufactured after that commencement; and (3) the amendments to subparagraphs (c)(iii) and (d)(iii) apply to a system or procedure pack supplied on or after that commencement, where imported or manufactured on or after that commencement.

Regulation 11.66 provides that regulations 11.29 and 11.30, as in force immediately before the commencement of Part 11 of Schedule 1 to the Regulations continue to apply on or after that commencement in relation to an application referred to in paragraph 11.29, as if it were in force, that was made before that commencement.

Therapeutic Goods Regulations 1990

Item [87] – In the appropriate position in Part 9
This item introduces Division 16 to the TG Regulations to provide application provisions relating to the Regulations.

Regulation 80 provides that the amendments to introduce item 5A to Schedule 5 to the TG Regulations apply to kits manufactured on or after the commencement of Part 8 of Schedule 1 to the Regulations.

Regulation 81 provides that the amendments to introduce item 1B to Schedule 5A to the TG Regulations apply to therapeutic goods imported into Australia on or after the commencement of Part 9 of Schedule 1 to the Regulations.

Regulation 82 provides that the amendments relating to consumer medicine information apply to supplies of therapeutic goods on or after the commencement of Part 10 of Schedule 1 to the Regulations.

Regulation 83 provides that the amendments to regulation 12B made by Part 11 of Schedule 1 to these Regulations apply in relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Part.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

The *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* (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 Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act).

The purpose of the Regulations is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), principally to reduce regulatory burden for sponsors and manufacturers of medical devices (e.g. by exempting surgical loan kits from the requirement to be included in the Australian Register of Therapeutic Goods (the Register)), and improve access to unapproved medicines for the treatment of seriously ill patients.

In particular, the Regulations:

- better align the regulation of system or procedure packs with the European Union;
- require device sponsors to provide a final report of an adverse event involving their device, 120 days after the initial report was made, to ensure that device safety information is current and accurate;
- provide greater flexibility for device sponsors and manufacturers in how they provide patient information materials for implantable devices;
- avoid the inadvertent up-classification of ancillary devices used in surgery, devices that are composed of substances or combinations of substances and devices that administer medicines or biologicals by inhalation;
- exempt patient-matched devices from the requirement to be included in the Register where less than 5 are made by a manufacturer in a financial year, and provide more time for sponsors of other such devices to notify the TGA of details of their products;
- exempt surgical loan kits supplied to hospitals in Australia for use in surgery from the requirement to be included in the Register, reducing regulatory burden for suppliers;
- improve access to unapproved prescription medicines for seriously ill patients by exempting imported prescription medicines that are needed for supply to such patients in hospitals or other healthcare facilities;
- enable the Secretary to refund fees relating to applications for conformity assessment certificates in respect of certain higher risk devices, for which the kinds of evidence required to support an application for marketing approval was recently broadened;
- improve the flexibility of the current transitional arrangements for devices that are surgical mesh (other than urogynaecological mesh); and
- prescribe a number of medicines that may be accessed under the Authorised Prescriber Scheme without the need for Human Research Ethics Committee approval.

Human rights implications
The Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the 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:

- ensuring timely access to life-saving medicines required urgently for the use of seriously ill patients in hospitals and other healthcare facilities in Australia;
- supporting easier access for patients to a number of medicines through the Authorised Prescriber pathway;
- ensuring that safety information relating to adverse events involving medical devices is up to date and accurate; and
- reducing the regulatory burden for sponsors and manufacturers of a range of kinds of medical devices, to encourage the continued supply of devices in Australia and remove potential impediments to their continued supply.

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 and Aged Care