EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022

The Regulations clarify requirements for medical devices containing nanomaterials, to improve transparency and better ensure that device sponsors and manufacturers are aware of the requirements for such products.

The *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods used in, or exported from, Australia. Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* (the Regulations) principally amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to more clearly identify the safety and quality requirements that apply to medical devices containing nanomaterials, without introducing any new regulatory requirements for such products. The amendments highlight that a device must be designed and produced to ensure that the risks associated with the size and properties of particles which may be released into a patient's or user's body are minimised.

The Regulations also make a small number of other, minor amendments to the MD Regulations, and the *Therapeutic Goods Regulations 1990* (the TG Regulations), including in particular to:

- reduce regulatory burden for medical device sponsors by reducing fees for requests to vary an entry in the Australian Register of Therapeutic Goods (the Register) for a medical device where the request arises as a result of sponsors transitioning their products to comply with new legislation in the EU;
- make it clearer that the current limits on the number of medical devices that may be imported into Australia in reliance on the exemption from inclusion in the Register that underpins the TGA's personal importation scheme apply to in vitro diagnostic (IVD) medical devices;
- reduce regulatory burden for patients and medical practitioners by introducing new unapproved medicines that a medical practitioner may supply to their patients under the TGA's Authorised Prescriber scheme (which allows authorised medical practitioners to supply therapeutic goods such as medicines, medical devices or biologicals that are not included in the Register, to specified classes of patients), without an ethics committee's approval; and
- exempt certain essential medicines that are compounded by hospital pharmacists in anticipation of being needed by patients of the hospital, without (as currently) having to wait until the details of the patient are known – this would reflect the current administrative practice of many hospitals, and reduce the risk of delays to essential treatments.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

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 the day after registration on the Federal Register of Legislation.

Consultation

Public consultation was conducted on a number of options for the regulation of medical devices containing nanomaterials, between February and April 2021. Seven submissions were received, including four from industry stakeholders, one from the Royal Australian College of Surgeons, one from the University of Sydney and one from a private individual. Six submissions supported the option which the Regulations reflect. The other submission did not engage with the proposed options and argued for the prohibition of nanomaterials in Australia.

The TGA undertook targeted consultation in relation to the proposed changes to update the list of medicines in the TG Regulations that may be supplied under the TGA's Authorised Prescriber scheme without an ethics committee's approval. The TGA engaged with sponsors of a small number of medicines that are currently able to be supplied in this way in relation to the possible removal of those products from the list to reflect that the medicines have recently been included in the Register. Through this engagement it was identified that the removal of those medicines may impact their accessibility in Australia, and as a result their inclusion in the list has been preserved.

Public consultation was conducted on the proposal to exempt medicines that are compounded by hospital pharmacists in anticipation of patient need, between December 2021 and February 2022. 29 submissions were received, including from hospitals or health networks, State and Territory health departments, hospital pharmacists and consumers. The majority of submissions were supportive of the proposal.

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

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022.*

Section 2 – Commencement

This section provides for the Regulations to commence the day after registration on the Federal Register of Legislation.

Section 3 – Authority

This section makes it clear 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 this instrument has effect according to its terms.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

Schedule 1 – Amendments relating to medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Subparagraph 9.1AA(3)(b)(iii)
This item makes a minor editorial amendment to subparagraph 9.1AA(3)(b)(iii) of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to accommodate the amendment made by item 2 below.

Items [2] and [3] – At the end of paragraph 9.1AA(3)(b), and paragraph 9.1AA(3)(c)
Under sections 41MA and 41MAA of the Act it may be an offence or civil penalty to import, supply or export a medical device that does not comply with the essential principles (these are minimum benchmarks of safety and performance for medical devices, and are set out in Schedule 1 to the MD Regulations), unless the Secretary has consented to the importation, supply or export of the device.

Section 41MC of the Act makes it clear that the consent of the Secretary under sections 41MA and 41MAA may be given unconditionally or subject to conditions, and in respect of particular medical devices or kinds of medical device.

The current application fee for applications to the Secretary for consent under sections 41MA and 41MAA is set out in item 1.15 of Part 1 of Schedule 5 to the MD Regulations, and is, principally, $513 for an application involving a single entry in the Register or a medical device that is not included in the Register, or $513 for the first entry plus $103 for each additional entry for an application involving more than one entry in the Register, where the way in which the relevant devices do not comply is the same.

Regulation 9.1AA of the MD Regulations provides a mechanism for accessing a reduced fee of $30 per entry in the Register (specified in subregulation 9.1AA(1) and (2)), rather than the amounts specified in item 1.15, if (relevantly) a medical device is affected by the EU transition within the meaning of subregulation 9.1AA(3).

Most medical devices supplied in Australia are manufactured overseas and for many of these the manufacturer's evidence of the adequacy of the device's manufacture has been obtained under the EU regulatory scheme. Medical device manufacturers and sponsors are currently transitioning from the older EU regulations mentioned in paragraph 9.1AA(3)(b) to the newer EU regulations mentioned in paragraph 9.1AA(3)(c). The steps they may need to take as part of that transition may mean that their devices may not comply with some aspects of the Australian essential principles (in particular, in relation to labelling), and as a consequence the TGA is expecting to receive a large number of requests for consent to import, supply or export transitioning medical devices that do not comply with the essential principles.

The reduced fee mechanism in subregulation 9.1AA(1) and (2), which reflects a streamlined process for assessing such applications, is designed to reduce the regulatory burden and cost of these consequential regulatory steps in Australia for the medical device industry, and to minimise the risk of impacts on the availability of transitioning devices here.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

The amendments made by items 2 and 3 introduce two additional circumstances in which the reduced fee mechanism may be accessed for transitioning medical devices, principally in relation to in vitro diagnostic (IVD) medical devices.

The first of these is where a medical device manufacturer or sponsor may be transitioning from manufacturer's evidence obtained against ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*, published by the International Organization for Standardization (ISO 13485), to an overseas regulator conformity assessment document mentioned in paragraph 9.1AA(3)(c).

The second of these is where an overseas regulator conformity assessment document is issued, or is expected to be issued, under the Medical Device Single Audit Program (MDSAP), within the meaning of the *Therapeutic Goods (Overseas Regulators) Determination 2018*.

These circumstances reflect, in particular, that IVD medical devices may be transitioning from ISO 13485 to the EU regulation mentioned in subparagraph 9.1AA(3)(c)(ii) or to manufacturer's evidence obtained under the MDSAP scheme, in relation to the transitional process occurring in the EU.

In relation to incorporation by reference, ISO 13485 is incorporated as in force from time to time, in accordance with subsection 63(4) of the Act, and may be obtained from the International Organization for Standardization website. While unfortunately ISO 13485 is not freely available from the International Organization for Standardization website, an abstract of it is available from that website. It is not anticipated that the fact that ISO 13485 is not freely available would detrimentally impact those most affected by ISO 13485's incorporation – manufacturers and sponsors of IVD medical devices – as they would be expected to have a copy of it (this is particularly likely because many such manufacturers and sponsors have relied on ISO13485 to demonstrate their compliance with regulatory requirements in other jurisdictions, including the EU). A copy of ISO 13485 may also be viewed, by prior written arrangement, at the TGA in Fairbairn, ACT.

The *Therapeutic Goods (Overseas Regulators) Determination 2018* is a notifiable instrument, made under section 41BIB of the Act, and is freely available on the Federal Register of Legislation. It is incorporated as in force at the commencement of the proposed Regulations. This instrument specifies overseas regulators of medical devices (such as the United States Food and Drug Administration) that medical device sponsors and manufacturers may rely on in Australia to certify the suitability of their manufacturing processes. It is incorporated by reference because it contains a description of the MDSAP cooperative program of international therapeutic goods regulators.

Item 3 also corrects an inadvertent error in the title of the EU regulation referred to in subparagraph 9.1AA(3)(c)(ii), by replacing the reference to "765" with the correct reference "746".

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

Item [4] – In the appropriate position in Part 11
This item amends the MD Regulations to introduce new regulation 11.69. Subregulation 11.69(1) makes it clear that the amendments to regulation 9.1AA made by the Regulations apply in relation to an application for consent that is made on or after the commencement of regulation 11.69.

Subregulation 11.69(2) introduces a mechanism requiring the Secretary to refund the difference between the fee under item 1.15 in Part 1 of Schedule 5 to the MD Regulations and the reduced fee in subregulation 9.1AA(2), for relevant applications made on or after 1 January 2022 and before the commencement of regulation 11.69. This principally has the effect that sponsors of IVD medical devices that are able to access the reduced fee as a result of the proposed Regulations (i.e. where they are transitioning from ISO 13485 to one of the overseas regulator conformity assessment documents mentioned in paragraph 9.1AA(3)(c), including such a document issued under MDSAP) will be able to access the refund for applications made since 1 January 2022, consistent with the existing refund mechanism in regulation 11.68.

This item also introduces new regulation 11.70 to the MD Regulations, which makes it clear that the amendments to Schedule 4 to the MD Regulations by item 7 below apply in relation to a medical device that is imported into Australia on or after the commencement of new regulation 11.70.

Items [5] and [8] – After clause 7.6 of Schedule 1, and Dictionary
Item 5 introduces new clause 7.7 to Part 2 of Schedule 1 to the MD Regulations, for the purpose of better highlighting the applicable requirements in the essential principles for medical devices containing nanomaterials.

New subclauses 7.7(1) and (2) make it clear that a medical device must be designed and produced in a way that ensures that any risks associated with the size and the properties of particles which are, or can be, released into a patient's or user's body are minimised, and that particular attention must be given in this regard to the use of nanomaterials.

Existing subclauses 7.1, 7.5 and 7.6 cover similar ground, but do not expressly refer to nanomaterials in the context of the safe design and construction of medical devices. New subclauses 7.7(1) and (2) are therefore designed to clarify the requirements for devices containing nanomaterials, and to more closely align with the EU requirements for such devices.

Consistent with the EU approach, new subclause 7.7(3) makes it clear that subclause 7.7(1) does not apply to particles that only come into contact with intact skin.

Item 8 amends the Dictionary to the MD Regulations to make it clear that nanomaterial has the meaning given by Article 2(18) of Regulation 2017/745 (as in force from time to time) of the European Parliament and the Council of the European Union.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

The manner of incorporation of this EU regulation is as it is in force from time to time, in accordance with subsection 63(4) of the Act, and the EU regulation is freely available from EUR-Lex .

Item [6] – After paragraph 13A.1.(1)(b) of Schedule 1
Clauses 13A.2 to 13A.4 set out requirements relating to the making available of a patient implant card and a patient information leaflet in relation to implantable medical devices and active implantable medical devices. Clause 13A.1 identifies medical devices to which these requirements do not apply, e.g. sutures and staples.

This item amends subclause 13A.1(1) to make it clear that the requirements of clauses 13A.2 to 13A.4 also do not apply to medical devices that are intended by the manufacturer to be for export only.

This reflects that medical devices that are for export only must comply with requirements that apply in their destination markets overseas, and that requiring patient implant cards and patient information leaflets that are designed as components of Australia's regulatory scheme may cause confusion for sponsors and overseas patients and their health practitioners.

Item [7] – Schedule 4 (table item 1.1, column "Kinds of medical devices", paragraph (c))
Item 1.1 in Part 1 of Schedule 4 to the MD Regulations provides the basis for the TGA's personal import scheme as it applies to medical devices. Item 1.1 has the effect of exempting medical devices from the requirement to be included in the Register where they are imported into Australia for use in the treatment of the importer or a member of the importer's immediate family, or for the in vitro examination of a specimen obtained from the importer or immediate family member, if the criteria in paragraphs (a)-(d) of item 1.1 apply.

One of these criteria, in paragraph (c) of item 1.1 is that certain quantity limits apply in the case of a Class 4 IVD medical device, Class III medical device, Class 3 IVD medical device, Class IIb medical device, Class 2 IVD medical device or Class IIb medical device.

These limits are currently specified by reference to the quantity imported in any one importation being not more than the quantity required to provide 3 months treatment using the device according to the treating medical practitioner's directions, and the total quantity imported in any 12-month period being not more than the quantity required to provide 15 months treatment on the same terms.

A need has arisen to update the way in which these quantity limits are expressed, to better reflect that IVD medical devices are principally used to diagnose, rather than to treat, a disease, ailment, defect or injury, and to reflect that the device manufacturer's instructions, and public health directions, may also be relevant to how often a device should be used. This has been illustrated by the use of rapid antigen tests (which are IVD medical devices) during the COVID-19 pandemic.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

This item substitutes paragraph (c) of item 1.1 with a new paragraph (c) that, in particular, adopts the broader term “use” rather than “treatment”, to ensure that the quantity limits specified apply in relation to IVD medical devices., The new paragraph (c) also provides the manufacturer’s instructions or directions, or recommendations or advice by a Commonwealth, State or Territory health authority as alternatives to a treating medical practitioner’s directions as the basis for determining the likely quantity required for the use of a device in a 3 or 12 month period.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

Schedule 2 – Amendments relating to medicines and fees

Therapeutic Goods Regulations 1990

Item [1] – Regulation 2 (definition of IN1 application)
Regulation 2 of the *Therapeutic Goods Regulations 1990* (the TG Regulations) defines a number of categories of application that a person may make to the Secretary under section 26BD of the Act for a variation to the legislative instrument made by the Minister under section 26BB of the Act which specifies ingredients that may be used in listed or assessed listed medicines (these are lower risk medicines that are listed in the Register under section 26A, or section 26AE, of the Act), principally for the approval of a new ingredient for use in such medicines.

The IN1 category of such applications currently refers to an application for a variation that requires an evaluation of the safety and quality of an ingredient based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction.

Concerns have arisen that this does not accommodate the situation in which the variation applied for requires an evaluation of the *safety* of the ingredient based on an evaluation from a competent regulatory authority of a foreign country or foreign jurisdiction, and an evaluation of the *quality* of the ingredient based on a monograph in a default standard (as defined in subsection 3(1) of the Act).

This item substitutes the current IN1 definition in regulation 2 of the TG Regulations with a new definition that provides that flexibility, in paragraph (b) of the new definition, as an alternative to the current definition (which is preserved in paragraph (a) of the new definition).

Item [2] – At the end of regulation 7
Under subsections 42DL(10) and 42DLB(7) of the Act, it is an offence or civil penalty to advertise a substance, or goods containing such substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H to the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or government authority). The substances to which these provisions relate are principally over the counter or prescription substances, or substances that require restrictions in order to reduce abuse, misuse or physical or psychological dependence.

While the advertising of such substances or goods is prohibited under subsections 42DL(10) and 42DLB(7), confusion has arisen as to whether the advertising of such products is similarly prohibited when therapeutic goods that are, or that contain, such substances are compounded for individual patients and are not included in the Register.

This confusion has arisen because such therapeutic goods are currently not prescribed for the purposes of subsections 42DL(12) and 42DLB(9), which specify an offence and civil penalty for an advertisement that refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of those provisions.

Accordingly, to address this confusion and ensure consistency in the regulation of such products, this item amends regulation 7 to prescribe for the purposes of subsections 42DL(12)

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

and 42DLB(9) of the Act therapeutic goods that are, or that contain, a substance that is included in Schedule 3, 4 or 8 to the current Poisons Standard and that is not included in Appendix H to the current Poisons Standard, and that are extemporaneously compounded for a particular person for therapeutic application to that person.

Items [3]-[7] – Subregulation 12B(1B) (table items 4, 4A, 36 and 51)
Under subsection 19(5) of the Act, the Secretary may authorise a medical practitioner to supply specified therapeutic goods, or a specified class of therapeutic goods, for use in the treatment of their patients. Subsection 19(5), and related provisions in section 19, provide the basis for the TGA's Authorised Prescriber scheme for accessing unapproved medicines.

Subsection 19(6) of the Act sets out that an authority under subsection 19(5) may only be given in specified circumstances including, in paragraph 19(6)(aa), to a medical practitioner who has the approval of an ethics committee to supply the goods. However, subsection 19(6) also highlights that paragraph 19(6)(aa) does not apply in circumstances prescribed for the purposes of subsection 19(6).

Subregulation 12B(1B) of the TG Regulations prescribes circumstances, for this purpose, principally being if the supply is of a medicine that contains an active ingredient specified in column 2 of an item in the table under subregulation 12B(1B), in the strength and concentration specified (if any) in column 2, in the dosage form specified in column 3, with the route of administration specified in column 4 for the indication specified in column 5, of that table.

Items 3-7 make a small number of changes to the table in subregulation 12B(1B), principally to introduce 3 new medicines that may be supplied to patients under the authorised prescriber scheme without the needs for ethics committee approval (metolazone, amiloride and ganciclovir), and introduce new indications for 2 existing medicines in the table (Gallium-68 prostate specific membrane antigen and argipressin).

Item [8] – In the appropriate position in Part 9
This item amends the TG Regulations to introduce new Division 20, to set out a small number of application provisions relevant to the Regulations.

New regulation 88 provides that the amendment of item 1 of the table in Schedule 5 to the TG Regulations by item 9 below applies in relation to therapeutic goods that are imported on or after the commencement of new regulation 88.

New subregulation 89(1) provides that the amendment of item 2A of the table in clause 3 of Schedule 9 to the TG Regulations by item 11 below applies in relation to a request to vary an entry in the Register that is made on or after the commencement of new regulation 89.

New subregulation 89(2) introduces a refund mechanism requiring the Secretary to refund a person who, on or after 1 January 2022 and before the commencement of new regulation 89 made a request of a kind covered by paragraph (c) of item 2A of the table in clause 3 of Schedule 9 to the TG Regulations (as item 2A was in force before that commencement) and who paid the fee that applied under item 2A at that time, the difference between the fee paid and the fee that would have applied in relation to the request under paragraph (d) of item 2A (as introduced by item 11 below) if the request had been made on the day on which new regulation 89 commences.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

Item [9] – Schedule 5 (table item 1, column 2, paragraph (b))
Item 1 of Schedule 5 to the TG Regulations provides the basis for the TGA's personal import scheme as it applies to therapeutic goods other than medical devices – in practice, principally medicines and biologicals. Item 1 has the effect of exempting therapeutic goods from the requirement to be included in the Register where they are imported into Australia for use in the treatment of the importer or a member of the importer's immediate family, where the criteria specified in paragraphs (a)-(d) apply.

One of these criteria is, at paragraph (b), that for injections that contain material of human or animal origin, the goods are the subject of an approval under section 19 of the Act, or are insulin preparations.

In practice this means that travellers to Australia are required to contact an Australian medical practitioner to obtain such an approval, prior to their travel. This adds an impost to the traveller and the Australian health system.

The risks posed by such products is now considered to be likely to be quite low, as they will in most instances have been approved by an overseas regulator. This risk assessment aligns with changes to the TGA's approach to Transmissible Spongiform Encephalopathies minimisation, and is supported by the recent removal of the deferral of blood donors in relation to variant Creutzfeldt-Jakob Disease geographical risk.

As such, item 9 amends item 1 of Schedule 5 to repeal paragraph (b).

Item [10] – Schedule 5 (after table item 6)
Item 6 of Schedule 5 to the TG Regulations exempts medicines from the requirement to be registered or listed in the Register if they are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than medicines that are used for gene therapy or that are medicinal cannabis products.

Concerns have arisen that there is a need for hospitals to compound some medicines in anticipation of being needed by patients, and that it would cause delays to treatment if hospital pharmacists could only compound such medicines once the details of a patient are known, with potentially significant risks for patient health and safety.

To address this concern, item 10 amends Schedule 5 to introduce a new exemption (item 6A) which has the effect of exempting medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) that are compounded in a private or public hospital in the circumstances outlined in subparagraphs (a)(i) or (ii) in anticipation of being needed for therapeutic application to patients of the hospital, and that are considered by the relevant hospital's drug and therapeutic committee (however described) as being appropriate for compounding in anticipation of being needed to treat a patient at the hospital.

This brings the TG Regulations into line with the administrative practices of hospitals in relation to this practice, and avoid delays in access to essential treatments for hospital patients.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

Item [11] – Clause 3 of Schedule 9 (table item 2A)
Paragraph (c) of item 2A of the table in clause 3 of Schedule 9 to the TG Regulations specifies that the fee for a request to vary an entry in the Register in relation to a medical device under section 9D of the Act (other than subsection 9D(2C) of the Act) is $482.

Concerns have arisen that this fee may reflect a regulatory burden for sponsors of medical devices that need to vary the entries in the Register for their products to reflect updates associated with transitioning to comply with new regulations in the EU (i.e. as a result of being affected by the EU transition within the meaning of subregulation 9.1AA(3) of the MD Regulations).

As such, this item amends item 2A of the table in clause 3 of Schedule 9 to the TG Regulations to provide, as an alternative to the current fee of $482 for a request to vary an entry in the Register for a medical device in paragraph (c), a fee of $190 per 10 Register entries (or part thereof), where the criteria in new paragraph (d) are satisfied.

These criteria are that:

- the reason for the variation is that the kind of medical device is affected by the EU transition within the meaning of subregulation 9.1AA(3) of the MD Regulations;
- the variation only relates to an update to the manufacturer's evidence for the medical device, as recorded in the entry in the Register; and
- the manufacturer's evidence to which the update relates is the same for each of the entries to which the request relates.

The new fee of $190 for up to 10 Register entries reflects a streamlined process for assessing variation requests that are expected to arise as a result of the EU transition for affected device sponsors, and reflects the effort required for staff of the TGA's Medical Devices Authorisation Branch to process such variations.

Item [12] – Clause 3 of Schedule 9 (table item 9)
This item makes a minor change to item 9 of the table in clause 3 of Schedule 9 to the TG Regulations, to remove an error.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022

The *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* (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 *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to, principally, more clearly identify the safety and quality requirements that apply to medical devices containing nanomaterials, without introducing any new regulatory requirements for such products. The amendments highlight that a device must be designed and produced to ensure that the risks associated with the size and properties of particles which may be released into a patient's or user's body are minimised.

The Regulations also make a small number of other, minor amendments to the MD Regulations, and the *Therapeutic Goods Regulations 1990* (the TG Regulations), including in particular to:

- reduce regulatory burden for medical device sponsors by reducing fees for requests to vary an entry in the Australian Register of Therapeutic Goods (the Register) for a medical device where the request arises as a result of sponsors transitioning their products to comply with new legislation in the EU;
- make it clearer that the current limits on the number of medical devices that may be imported into Australia in reliance on the exemption from inclusion in the Register that underpins the TGA's personal importation scheme apply to in vitro diagnostic (IVD) medical devices;
- reduce regulatory burden for patients and medical practitioners by introducing new unapproved medicines that a medical practitioner may supply to their patients under the TGA's Authorised Prescriber scheme (which allows authorised medical practitioners to supply therapeutic goods such as medicines, medical devices or biologicals that are not included in the Register, to specified classes of patients), without an ethics committee's approval; and
- exempt certain essential medicines that are compounded by hospital pharmacists in anticipation of being needed by patients of the hospital, without (as currently) having to wait until the details of the patient are known – this would reflect the current administrative practice of many hospitals, and reduce the risk of delays to essential treatments.

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687

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 to 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 in a number of ways, including in particular by ensuring that the safety and performance requirements that apply to medical devices containing nanomaterials are clear and unambiguous, enabling new unapproved medicines to be supplied by an authorised medical practitioner to their patients without the need for an ethics committee's approval, and by making it clear that hospital pharmacists may compound essential medicines in anticipation of being needed by patients without the risk that having to delay such preparations until the details of patients are known could delay the provision of critical medical treatment.

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.

Mark Butler, Minister for Health and Aged Care

Authorised Version Explanatory Statement registered 19/12/2022 to F2022L01687