

## **EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*  
*Therapeutic Goods (Charges) Act 1989*

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

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia. The *Therapeutic Goods (Charges) Act 1989* (the Charges Act) imposes annual charges on the registration, listing and inclusion of therapeutic goods in the Australian Register of Therapeutic Goods, and on the licensing of therapeutic goods manufacturers. The Therapeutic Goods Administration (TGA), which is part of the Department of Health, is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act. Amongst other matters, the regulations may prescribe fees in respect of matters under the Act or regulations made under it, and provide for the refund, reduction or waiving of such fees. Subsection 5(1) of the Charges Act provides that the Governor-General may make regulations not inconsistent with the Charges Act, prescribing the amounts of charges.

The principal purpose of the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (the Regulations) is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to support the implementation of recommendation 20 of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review). Recommendation 20, agreed to by the Government as part of its Response to the Review, proposed the harmonisation, where possible, of the regulation of medical devices in Australia with that of the European Union (the EU).

The Regulations are designed to do this by reclassifying certain kinds of medical devices (e.g. spinal implantable medical devices like spinal disc replacements), to ensure that the level of pre-market scrutiny applied to applications for marketing approval for such products is commensurate with the risk they may pose to users, consistent with the EU.

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

- better address new and emerging technologies in medical devices that are or that utilise software, and personalised medical devices such as custom-made devices, to ensure such products are subjected to appropriate scrutiny and manufacturing standards;
- introduce a new, tailored regulatory framework for in vitro diagnostic medical devices that are companion diagnostics (these are principally pathology tests for identifying the presence or absence of biological features such as genes in order to determine whether a person is likely to benefit, or be at risk from, a particular medicine or biological);
- introduce a new, tailored regulatory framework for faecal microbiota transplant products (these are biologicals that comprise, contain or are derived from, human stool, and are used to repopulate a person's bowel with benevolent microorganisms, e.g. after use of antibiotics has affected such bacteria);

- introduce a new, more user-friendly format for consumer medicine information documents, to assist consumers to be aware of and understand important information about the safe use of prescription and registered over the counter medicines;
- encourage sponsors of prescription opioids to support their safe use, e.g. by introducing smaller pack sizes and reducing the class of persons for whom such products are suitable;
- a number of minor measures, including for example to exempt certain nappy rash products from the requirement to be entered in the Register.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised. The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on various dates – the reclassification of medical devices, personalised devices and software commence on 25 August 2020, with most other measures commencing on 1 January 2020 or the day after registration.

### **Consultation**

The TGA undertook extensive public and targeted consultation on the above significant measures. In particular, public consultation was held between January and March 2019 on active medical devices for therapy, spinal implantable medical devices and devices that are or that utilise software, and between March and April 2019 on personalised medical devices and the other reclassification matters.

In relation to the reclassification of medical devices, 48 submissions were received, including from industry representative bodies (e.g. the Medical Technology Association of Australia (MTAA) and AusBiotech Ltd), consumer advocacy bodies (e.g. the Consumers Health Forum of Australia (CHF) and Pain Australia) and healthcare professionals (e.g. the Australian Dental Industry Association), with a strong consensus in favour of the proposed alignment. Targeted consultations were held in June 2019 on spinal implantable medical devices and accessories to active implantable medical devices, and feedback incorporated into the proposed Regulations. In relation to software, 41 submissions were received, including from industry representative bodies (e.g. MTAA and the Medical Software Industry Association), sponsors and manufacturers (e.g. ResMed and Medtronic Australasia), CHF and healthcare professionals (e.g. the Australian Medical Association), with a strong consensus in support. Webinars, and two workshops, were held between June and September 2019, and feedback incorporated into the proposed Regulations. In relation to personalised medical devices, 25 submissions were received, with again a strong consensus for the proposed changes.

22 submissions were received between January and March 2019 on the new framework for human faecal microbiota transplant products, with the majority in favour of regulating these products as biologicals. Feedback was incorporated into the proposed Regulations, e.g. to only require higher risk products to be covered by a manufacturing licence. 23 submissions were received between October and December 2018 on the new framework for *in vitro* diagnostic medical devices that are companion diagnostics, with strong support for the proposed changes. 98 submissions were received between January and March 2018 on prescription opioids, with consistent support for the proposed reforms.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*  
Section 5 of the *Therapeutic Goods (Charges) Act 1989*

**Details of the Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019**

**Section 1 – Name**

This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (the Regulations).

**Section 2 – Commencement**

This section provides for the commencement of the Regulations on a number of different dates.

In particular, sections 1-4, Schedules 8 (fee waivers for certain requests relating to prescription opioids) and 10 (application, savings and transitional provisions) and Part 4 of Schedule 9 of the Regulations (other minor measures) commence the day after the Regulations are registered.

Schedules 1-3 (reclassification of medical devices, programmed and programmable medical devices or software that is a medical device and personalised medical devices) commence on 25 August 2020, and Schedule 4 (in vitro diagnostic medical devices that are companion diagnostics) commence on 1 February 2020.

Schedules 5 (faecal microbiota transplant products) and 7 (handling and testing of samples), and Parts 1-3 of Schedule 9 (fee waiver for requests to vary product information for medicine so that it complies with the approved form, clinical trials and nappy rash products) would commence on 1 January 2020, and Schedule 6 (consumer medicine information documents) commence on 1 January 2021.

**Section 3 – Authority**

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

**Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations has effect according to its terms.

## Schedule 1 – Reclassification of medical devices

### **Introduction**

Section 41DB of the Act provides that the regulations may specify classifications, to be known as medical device classifications, applying to medical devices or kinds of medical devices, and matters in relation to such classifications.

Medical device classifications, which are specified in the table in subregulation 3.1(1) of the MD Regulations and determined in accordance with Schedules 2 and 2A to the MD Regulations, signify the risk a device may pose to a user, and are relevant to a number of important elements of the regulatory scheme, e.g. the level of pre-market scrutiny required for an application for marketing approval and minimum procedures (such as implementing a quality management system or implementing design control in an existing quality management system) that must be followed by a manufacturer as part of demonstrating that the device they manufacture conform with the essential principles (these are minimum standards for safety, quality and performance for devices).

The measures in Schedule 1 support the implementation of recommendation 20 of the Review by reclassifying a number of kinds of devices to better align with their classification in the EU under Chapter III of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and Council of Europe of 5 April 2017 (EU Regulation 2017/745) (this EU regulation is available for free at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745#d1e32-140-1>).

This provides greater consistency in relation to the regulation of these devices with a key international market, and ensure the level of pre-market scrutiny applied to applications for marketing approval for such products is commensurate with the risk they may pose to users.

### **Part 1 – Spinal implantable medical devices**

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

##### **Item 1– After paragraph 5.3(1)(b)**

Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) identifies a range of kinds of higher risk medical devices for the purposes of paragraph 41FH(1)(a) of the Act. The effect of inclusion in regulation 5.3 for a kind of device is that the Secretary must select for audit any application for marketing approval involving such a product.

This item amends regulation 5.3 to include a reference to a medical device that is a spinal fusion implantable device.

Examples of spinal fusion implantable devices are screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

Spinal fusion implantable devices are to be excluded from the scope of the new classification rule to be introduced by item 5 below, which classifies medical devices that are motion-preserving devices for the spine or devices that come into contact with a person's spinal column as Class III.

This means that spinal fusion implantable devices will continue to be classified as Class IIb, under the current classification rule in subclause 3.4(2) of Schedule 2 to the MD Regulations (for devices described in paragraph 3.4(1)(b) of Schedule 2).

However, although the classification of such products is not proposed to change, they are still important devices and are used during spinal fusion surgical procedures.

As such, and in order to ensure consistency, this item amends regulation 5.3 to ensure that the Secretary is required to select applications for the inclusion of spinal fusion implantable devices in the Register for audit.

The medical devices that will be the subject of the new classification rule to be introduced by item 5 below will also be required to be selected for audit, on the basis of the existing requirement in paragraph 5.3(1)(i) which refers, principally, to Class III devices.

This item, taken together with the changes that would be introduced by item 5, ensure that all applications for inclusion in the Australian Register of Therapeutic Goods (the Register) for spinal implantable medical devices will be subjected to such an audit.

These measures are to support the risk classification of such products by ensuring that the level of pre-market scrutiny applied to them is commensurate with the risk that they may pose to persons in whom they are implanted.

#### **Items 2, 3 and 4 – Regulation 5.12 (heading and subregulation 5.12(1))**

Regulation 5.12 of the MD Regulations provides that it is a condition of the inclusion of certain kinds of medical devices in the Register that the person in relation to whom the kind of device is included must give the Secretary a written notice if the person intends to import, supply or export such a kind of device but the entry in the Register for the kind of device does not include the product name of the device or information about the manufacturer's intended purpose of the device.

Item 2 makes a minor change to the heading for regulation 5.12, to reflect the amendment that would be introduced by item 3.

Item 3 amends regulation 5.12 of the MD Regulations to include a reference to spinal fusion implantable devices, in order to ensure that this condition would also apply to sponsors of such products.

Item 4 includes a note in regulation 5.12 to highlight that examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

In practice, the condition in regulation 5.12 will only apply if the information in the entry in the Register for such a product is incomplete (this is because paragraph 5.12(2)(b) makes it clear that it only applies when the product name of a device to which regulation 5.12 applies, or information about the manufacturer's intended purpose for such a device, is not already in the Register).

### **Item 5 – Subclause 3.4(2) of Schedule 2**

This item makes a minor amendment to subclause 3.4(2) of Schedule 2 to the MD Regulations, to reflect the amendment to be introduced by item 5 below.

### **Item 6 – After subclause 3.4(4A) of Schedule 2**

Schedule 2 to the MD Regulations sets out the classification rules for medical devices other than in vitro diagnostic (“IVD”) medical devices, for the purposes of subregulation 3.2(1) of the MD Regulations.

Schedule 2 to the MD Regulations does not currently contain a specific classification rule for medical devices that are intended by their manufacturer either to be a motion-preserving device in relation to the spine, or to come into contact with a person’s spinal column.

Such products are principally currently covered by clause 3.4 of Schedule 2, which applies to surgically invasive medical devices that are intended for long-term use and implantable medical devices, with the classification of most such products being Class IIb. An example of such a device would be a spinal disc replacement.

Under rule 8 of Chapter III of Annex VIII of EU Regulation 2017/745, in Europe these kinds of medical devices are classified as Class III, if they are spinal disc replacement implants or are implantable devices that come into contact with the spinal column (with the exception of components such as screws, wedges, plates and instruments).

To align with this approach and to better ensure that the requirements under the regulatory scheme for such products are attuned to the risks they may pose, this item amends clause 3.4 of Schedule 2 to introduce a new classification rule for medical devices (other than spinal fusion implantable devices such as screws, cages, plates, hooks or wedges) that are intended by their manufacturer either to be a motion-preserving device in relation to the spine, or to come into contact with a person’s spinal column.

Under the new rule, such devices will be classified as Class III medical devices.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register as Class IIb medical devices, or that are the subject of an application for marketing approval as a Class IIb device that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

## **Part 2 – Active implantable medical devices**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Items 7 and 8, 13-18 and 20-32**

These items make consequential amendments to regulations 1.6, 1.7, 3.6, 5.3, 5.10, 5.11, 8.1, clauses 1.1, 1.6, 1.9, 3.5, 3.6, 4.7 and 4.8 of Schedule 3, item 1.1 of Schedule 4, item 1.5 of Schedule 5 and a small number of definitions in the Dictionary, of the MD Regulations, to reflect the amendment to be made by items 8 and 18 below.

**Item 9 – Subregulation 3.1(1) (table)**

Under the table in subregulation 3.1(1) of the MD Regulations, the medical device classifications for medical devices other than IVD medical devices are Class I, Class IIa, Class IIb, Class III and Class AIMD.

This item replaces the current table in subregulation 3.1(1) with a new table that, principally, omits the classification of AIMD.

This measure, taken together with the amendment that would be introduced by item 17 below, is designed to better align the classification of medical devices (and in particular of active implantable medical devices, to which the classification of AIMD relates) in Australia with the approach in the EU under EU Regulation 2017/745.

Under EU Regulation 2017/745, medical devices are classified as Class I, Class IIa, Class IIb or Class III, with no Class AIMD.

**Items 10-12 – Paragraphs 3.1(2)(a)-(c)**

These items make minor amendments to paragraphs 3.1(2)(a) and (b) to reflect the introduction of a new table of medical device classifications by item 8 above, and repeal paragraph 3.1(2)(c) to reflect that the new table (as amended) would only contain 5 columns, not 7 as currently.

**Item 19 – Subclause 5.7(1) of Schedule 2**

Currently under subclause 5.7(1) of Schedule 2 to the MD Regulations, an active implantable medical device is classified as Class AIMD.

Active implantable medical devices are higher risk devices defined in the Dictionary to the MD Regulations as an active medical device (other than an implantable medical device) that is intended by its manufacturer to either be introduced wholly or partly into the body of a human being by surgical or medical intervention, or to be introduced into a natural orifice of a human being by medical intervention and to remain in place after the procedure.

Examples of such products include implantable cardiac pacemakers that are intended to restore or establish a normal heart beat when the heart beats too fast, too slow or at an irregular rhythm, and cochlear implants that are designed to stimulate the cochlear nerve.

As outlined above, under EU Regulation 2017/745 the EU does not have an AIMD medical device classification, and under rule 8 in Chapter III of Annex VIII of the EU regulation these kinds of medical devices are classified as Class III.

To align with this approach and to better ensure that the requirements under the regulatory scheme for such products are attuned to the risks they may pose, this item amends subclause 5.7(1) of Schedule 2, to make it clear that the classification of active implantable medical devices is Class III, rather than Class AIMD.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register as Class AIMD medical devices, or that are the subject of an application for marketing approval as a Class AIMD device that has not been finally determined, when these amendments commence, will have the benefit of a

transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

### **Part 3 – Medical devices that administer medicines or biologicals by inhalation**

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

##### **Item 33 – At the end of subclause 3.1(2) of Schedule 2**

Schedule 2 to the MD Regulations does not currently contain a specific classification rule for medical devices that administer medicines or biologicals by inhalation.

Such products are principally currently covered by clause 3.1 of Schedule 2, which applies to invasive medical devices (other than surgically invasive medical devices) intended to be used to penetrate a body orifice of a person, with classifications varying from Class I to Class IIb.

Examples of such products include spacers that are intended to be attached to a metered dose inhaler to facilitate a better delivery of the medicine contained in the spacer, and nasal oxygen cannulas that deliver supplemental oxygen or increased airflow to a person.

Under rule 20 of Chapter III of Annex VIII of EU Regulation 2017/745, in Europe these kinds of medical devices are classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as Class IIb.

To align with this approach and to better ensure that the requirements under the regulatory scheme for such products are attuned to the risks they may pose, this item amends subclause 3.1 of Schedule 2, to introduce a new, specific classification rule for invasive medical devices (other than surgically invasive medical devices) that are intended to be used to penetrate a body orifice of a person and to administer medicines or biologicals by inhalation.

Under this new rule, a device of this kind will be classified as Class IIb if its mode of action has an essential impact on the efficacy and safety of the medicine or biological it administers, or if it is intended to treat a life-threatening condition, and as Class IIa in any other case.

It is important to note that the new classification rule for such products is a separate rule from, and is independent of, the classification rules in existing subclauses 3.1(2) and (3) of Schedule 2 to the MD Regulations, and will apply whether or not a device of the kind covered by the new rule is connected to an active medical device.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register with a different classification to that which would apply under the new rule (e.g. as a Class I medical device), or that are the subject of such an application for marketing approval that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.



## **Part 4 – Medical devices that are substances for introduction into the body**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Items 34, 35 and 38 – Clause 2.4 of Schedule 2, and Dictionary**

Item 34 makes a minor change to the heading of clause 2.4 of Schedule 2 to the MD Regulations, to reflect the change that would be introduced by item 34.

Clause 2.4 of Schedule 2 to the MD Regulations applies to a non-invasive medical device that is intended by its manufacturer to be used in contact with injured skin, and sets out the classifications of such devices in subclauses 2.4(2)-(4).

Under Chapter I of Annex VIII of EU Regulation 2017/745, in Europe injured skin and injured mucous membrane are covered by a single defined term, which relates to an area of skin or mucous membrane that presents a pathological change or a change following a disease or wound.

Item 35 makes a minor change to subclause 2.4(1) to include a reference to mucous membrane alongside the existing reference to injured skin in subclause 2.4(1), for greater consistency with the EU approach.

Item 38 amends the Dictionary to the MD Regulations, to include a definition of ‘injured skin or mucous membrane’ that is intended to be consistent with the definition in Chapter I of Annex VIII of EU Regulation 2017/745.

#### **Item 36 – Subparagraph 3.1(2)(c)(ii) of Schedule 2**

Subclause 3.1 of Schedule 2 to the MD Regulations applies to an invasive medical device (other than a surgically invasive medical device) that is intended by its manufacturer to be used to penetrate a body orifice of a person.

Under subparagraph 3.1(2)(c)(ii) of Schedule 2, the classification of such a medical device is Class IIa if the device is intended to be used in oral cavity as far as the pharynx or in an ear canal up to the ear drum, or if it is intended to be used in a nasal cavity and is not liable to be absorbed by the mucous membrane.

This item makes a minor change to subparagraph 3.1(2)(c)(ii) to include a reference to skin alongside the existing reference to mucous membrane, for greater consistency with the EU approach.

#### **Item 37 – At the end of clause 3.1 of Schedule 2**

Schedule 2 to the MD Regulations does not currently contain a specific classification rule for medical devices that are composed of substances or combinations of substances that are intended by their manufacturer to be introduced into the human body through an orifice or applied to the skin, and absorbed by, or locally dispersed, in the human body after introduction or application.

Such products are principally currently covered by clause 3.1 of Schedule 2, which applies to invasive medical devices (other than surgically invasive medical devices) intended to be used to penetrate a body orifice of a person, with classifications varying from Class I to Class IIb.

Examples of such products include saline nasal solution sprays that are intended to penetrate, clean, clear and sometimes hydrate nasal passages and the sinus cavity, and orally administered weight loss capsules that are intended to facilitate weight loss and treat obesity through appetite control by forming a viscous gel in the stomach or small intestine to increase distention and create the sensation of fullness.

Under rule 21 of Chapter III of Annex VIII of EU Regulation 2017/745, in Europe these kinds of medical devices are classified as:

- Class III if, principally, they or their products of metabolism are systemically absorbed by the human body in order to achieve their intended purpose, or if they achieve their intended their purpose in the stomach or lower gastrointestinal tract and are systemically absorbed by the human body; or
- Class IIa if they are applied to the skin, in the nasal cavity or in the oral cavity as far as the pharynx; or
- Class IIb in any other case.

To align with this approach and to better ensure that the requirements under the regulatory scheme for such products are attuned to the risks they may pose, this item amends clause 3.1 of Schedule 2 to introduce a new, specific classification rule for devices composed of substances, or combinations of substances, that are intended to be introduced into the human body through an orifice or applied to the skin, and to be absorbed by, or locally dispersed, in the human body after introduction or application.

Under this new rule, a device of this kind will be classified as either Class III, Class IIa or Class IIb, consistent with rule 21 of Chapter III of Annex VIII of EU Regulation 2017/745, as outlined above.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register with a different classification to that which would apply under the new rule (e.g. as a Class I medical device), or that are the subject of such an application for marketing approval that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

## **Part 5 – Active medical devices for therapy**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 39 – At the end of clause 4.2 of Schedule 2**

Schedule 2 to the MD Regulations does not currently contain a specific classification rule for active medical devices for therapy that are intended by their manufacturer to have an integrated or incorporated diagnostic function that significantly determines patient management.

Such products are principally currently covered by clauses 4.2 and 4.3 of Schedule 2, which apply to active medical devices for therapy and active medical devices for diagnosis, with classifications of Class IIa or Class IIb depending on circumstances specified in those clauses.

Examples of such products include closed loop systems that are used to continuously monitor a person's biological conditions in real time and adjust a therapy in order to maintain or achieve a particular physiological state, and automated external defibrillators with an integrated diagnostic function. In such products this function is designed to analyse a person's cardiac arrhythmias and automatically or semi-automatically treat the patient by administering a controlled electric shock (defibrillation) to the person in order to re-establish a normal cardiac rhythm.

Under rule 22 of Chapter III of Annex VIII of EU Regulation 2017/745, in Europe these kinds of medical devices are classified as Class III medical devices.

To align with this approach and to better ensure that the requirements under the regulatory scheme for such products are attuned to the risks they may pose, this item amends clause 4.2 to introduce a new, specific classification rule for active medical devices for therapy that include a diagnostic function the purpose of which is to significantly determine patient management by the device.

Under this new rule, these kinds of devices will be classified as Class III.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register with a Class IIa or Class IIb classification, or that are the subject of such an application for marketing approval that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

## **Part 6 – Medical devices in direct contact with the heart etc.**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 40 – Clause 1.1 of Schedule 2**

This item makes a minor change to clause 1.1 of Schedule 2 to the MD Regulations, to reflect the change that would be introduced by item 40 below.

#### **Item 41 – At the end of clause 1.1 of Schedule 2**

Clause 1.1 of Schedule 2 to the MD Regulations sets out what is meant by a number of specified phrases relating to the length of use of a medical device that appear in Schedule 2.

For example, paragraph 1.1(a) explains that a medical device is intended to be “transient use” if its manufacturer intends the device to be used continuously for less than 60 seconds.

Each of these interpretations uses the term “used continuously”, though this term is not defined or explained in the MD Regulations.

This item amends clause 1.1 of Schedule 2 to provide some clarity in this regard by explaining that, for the purposes of determining whether a medical device is intended to be used continuously, any temporary interruption or removal is to be disregarded.

This includes, for example, a temporary interruption or removal in order to clean or disinfect a device or ensure its safe or effective use, or for reasons relating to a person operating a device.

This is designed to ensure greater consistency in relation to the interpretation of this term under paragraph 3.6 of Chapter II of EU Regulation 2017/745, which principally provides for the meaning of that term without regard to such periods.

#### **Item 42 – After subclause 3.2(3) of Schedule 2**

Under subclauses 3.2(3) of Schedule 2 to the MD Regulations, surgically invasive medical devices that are intended by their manufacturer to be for transient use to diagnose, monitor, control or correct a defect of the heart or the central circulatory system through direct contact with those parts of the body, are classified as Class III.

However, under rule 6 of Chapter III of Annex VIII of EU Regulation 2017/745, in Europe a somewhat broader range of these kinds of medical devices are classified as Class III devices than in Australia.

In particular, surgically invasive medical devices that are intended for transient use and that are intended specifically for use in direct contact with the heart or central circulatory system or central nervous system (as distinct from such devices that are intended to be used to diagnose, monitor, control or correct a defect in such parts of the body through direct contact with them) would not appear to be classified as Class III under subclauses 3.2 of Schedule 2, though they would be under rule 6 of the EU Regulation 2017/745.

The effect of this is that under subclause 3.2(2) of Schedule 2, such devices are currently classified as Class IIa in Australia.

To align with the approach under the EU Regulation 2017/745 and to better ensure that the requirements under the regulatory scheme for such products are attuned to the risks they may pose, this item amends clause 3.2 of Schedule 2 to introduce a new classification rule for surgically invasive medical devices for transient use that are intended by the manufacturer to be used in direct contact with the heart, circulatory system or central nervous system.

Under this new rule, these devices will be classified as Class III.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register with a Class IIa classification, or that are the subject of such an application for marketing approval that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

#### **Item 43 – Paragraph 3.3(4)(b) of Schedule 2**

This item substitutes a new paragraph 3.3(4)(b) of Schedule 2 to the MD Regulations, with the effect of making it clear that a surgically invasive medical device that is intended for short term use and to be used in direct contact with the heart, central circulatory system or central nervous system of a person, is classified as Class III.

The current paragraph 3.3(4)(b) only identifies such devices as being Class III if they are intended to be used in direct contact with the central nervous system of a person, i.e. it does not make provision for such devices where they are intended specifically for use in direct contact with the heart or central circulatory system.

The effect of this is that under subclause 3.3(2) of Schedule 2, such devices are currently classified as Class IIa.

The application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register with a Class IIa classification, or that are the subject of such an application for marketing approval that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

## **Part 7 – Amendments relating to charges**

### ***Therapeutic Goods (Charges) Regulations 2018***

#### **Items 44 and 45 – Paragraph 7(4)(d) and at the end of the instrument**

This Part sets out a small number of changes to the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations), in relation to active implantable medical devices, in relation to the reclassification of such products from Class AIMD to Class III.

Item 43 removes the reference to the annual charge for a Class AIMD medical device in paragraph 7(4)(d) in the Charges Regulations.

In order to ensure that such products are not subject to 2 sets of annual charges in the same financial year as a result of the amendments, item 44 introduces a new Division and new regulation 10 to the Charges Regulations.

This new regulation 10 makes it clear that if, at any time during a charge year, the same device is included in the Register as a Class AIMD and a Class III medical device, the charge in respect of the inclusion of the device in the Register as a Class III device for the charge year is nil.

## Schedule 2 – Programmed or programmable medical device or software that is a medical device

### **Introduction**

While some medical device software existed in 2002 when the Act was amended to introduce a specific framework for the regulation of medical devices (Chapter 4 refers) and the MD Regulations were made, in recent years rapid advances in computing technology and software production have led to significant increases, in particular in the number of medical devices that consist of software that operate on their own (i.e. rather than being accessories to, or incorporated into, physical devices), and to changes in the risk profiles for such products.

Some examples of such products include smart phone apps that detect skin cancer, X-ray image processing software that can screen for various conditions, software that interacts with a patient to deliver behaviour-based therapy and software that uses information about a person to make a diagnosis. Any or all of these types of products may include artificial intelligence features in their data processing algorithms.

The current regulatory framework considers harm that can directly be caused by a physical interaction with a medical device; however, it does not adequately address the risk of patient harm where information is the source of harm. Software that processes data to provide information to be used in treating a person, for example - a diagnosis of a disease, or the specification of a therapy to be delivered, can cause harm when the information is incorrect. Most medical devices that consist of software are currently classified as Class I medical devices, the lowest risk classification of device (under the classification rule in clause 4.1 of Part 4 of Schedule 2), while devices that can cause harm through physical interaction are classified at higher levels according to the harm they may cause.

In addition, the International Medical Device Regulators Forum (IMDRF), of which Australia is a founding member, has developed guidance for the regulation of software to address such concerns, and the EU has recently moved to reform its regulation of software devices in harmony with the IMDRF guidance.

The amendments in this Schedule are designed to update important elements of the regulatory scheme for programmed or programmable medical devices and software that is a medical device, to better address the range of emerging technologies in this field, and to align with the IMDRF and EU approach (this means these measures also support the implementation of Review recommendation 20).

### **Part 1 – Classification rules**

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

##### **Item 1 – Schedule 2 (note to Schedule heading)**

Schedule 2 to the MD Regulations sets out the classification rules for medical devices other than IVD medical devices.

The wording in parenthesis below the heading for Schedule 2 refers to regulation 2 of the MD Regulations, to signpost that Schedule 2 does so for the purposes of regulation 3.2 of the MD Regulations.

This item replaces the wording in parenthesis with a new note that makes that clearer, and that also signposts that regulation 3.3 of the MD Regulations sets out principles for applying the classification rules in Schedule 2. This is designed to aid understanding of the classification rules and principles, for industry and consumers.

### **Item 2 – At the end of Part 4 of Schedule 2**

This item amends Part 4 of Schedule 2 to the MD Regulations, to introduce a number of new classification rules (4.5–4.8) that have been specifically designed for programmed or programmable medical devices or software that is a medical device).

The phrase ‘programmed or programmable medical devices’ is intended to capture hardware medical devices incorporating software or any other form of software-type instruction set (such as field programmable gate arrays) that have the same sort of function as software. These types of medical devices may include software functions for either or both of enabling the functionality of a hardware medical device, or of providing information to be used for a therapeutic purpose. The rules for programmed or programmable medical devices including software that is a medical device, are relevant for hardware programmed or programmable medical devices, when they include the latter function.

Note that the new medical device classification rules for programmed, programmable, and software medical devices include reference to ‘public health risk’. In this context, the term ‘risk’ should take the everyday meaning, such as the one defined in the Macquarie Dictionary:

*Exposure to the chance of injury or loss; a hazard or dangerous chance.*

The term ‘risk’ in this context *should not* be taken to be that as currently defined in many international standards, i.e., that risk is severity of harm combined with the likelihood of occurrence.

#### *4.5 – Programmed or programmable medical device or software that is a medical device for use in relation to diagnosing or screening for a disease or condition*

New classification rule 4.5(1) applies to a programmed or programmable medical device, or software that is a medical device, intended by its manufacturer to be used to process data or information in order to provide a diagnosis of a disease or condition or to screen for a disease or condition.

The information provided by the medical device, in the form of a diagnosis or a screening result, is provided to a ‘user’ which could include but is not limited to: a lay-person, a care-giver, a patient, a healthcare professional. A key point is that the diagnosis is provided *directly* to a user without any intermediate oversight by, or involvement of, a relevant health professional (which is the case for 4.5(2)). The 4.5(1) rule could also apply to a relevant health professional as a user but the difference is that the diagnosis or screening decision is actually being undertaken by the device—not the relevant health professional based on information being provided to the health professional by the device (which is the case for 4.5(2)).

If such products are intended to provide a diagnosis of, or to screen for, a disease or condition that may lead to the death of a person or to a severe deterioration of a person’s health without

urgent treatment, or that may pose a high risk to public health, they are classified as Class III under new paragraph 4.5(1)(c).

If such products are intended to provide a diagnosis of, or to screen for, a serious disease or serious condition or a disease or condition which may pose a moderate risk to public health (and where paragraph 4.5(1)(c) does not apply), they are classified as Class IIb under new paragraph 4.5(1)(d).

Such products in any other case are classified as Class IIa under new subclause 4.5(1).

New classification rule 4.5(2) applies to a programmed or programmable medical device, or software that is a medical device, intended by its manufacturer to be used to provide information to a relevant health professional for the purposes of assisting or enabling the health professional to make a diagnosis of a disease or condition.

The inclusion of the term ‘relevant’ to describe the health professional is intended to emphasise the role of the health professional in making the diagnosis with the provided information; that is, the information provided by a medical device under this classification rule is not to be solely relied upon for the diagnosis. For example, a relevant health professional for diagnosing certain forms of cancer would be an oncologist, whereas a general practitioner would not be considered to be a relevant health professional in that case. However, a general practitioner could be a relevant health professional for diagnosing other sorts of diseases and conditions.

If such products are intended to provide information to a relevant healthcare professional in relation to a disease or condition that may lead to the death of a person or to a severe deterioration of a person’s health without urgent treatment, or that may pose a high risk to public health, they are classified as Class IIb under new paragraph 4.5(2)(a).

If such products are intended to do so in relation to a serious disease or condition or a disease or condition which may pose a moderate risk to public health (and where paragraph 4.5(2)(a) would not apply), they are classified as Class IIa under new paragraph 4.5(2)(b).

Such products in any other case are classified as Class I under new paragraph 4.5(2)(c).

The lower risk classifications under subclause 4.5(2) compared with subclause 4.5(1) principally reflects the involvement of a relevant health professional in the process of diagnosing a disease or condition, with this mitigating to an extent the risk that such products may pose in comparison with the situations covered by subclause 4.5(1).

#### *4.6 – Programmed or programmable medical device or software that is a medical device for use for monitoring the state or progression of a disease or condition*

New classification rule 4.6 applies to a programmed or programmable medical device, or software that is a medical device, intended by its manufacturer to be used to provide information that is to be used to monitor the state or progression of a disease or condition of a person, or to monitor parameters in relation to a person.

Medical devices covered under this rule process data in order to provide an output in the form of information about the state of a disease or condition, or about patient parameters. The data



that are used as an input to such a device may include multiple or single sources and could consist of, for example, data provided by physiologic sensors such as heart rate monitors, data from environmental sensors such as those that measure radiation absorbed by a person in a given environment, data from other medical devices such as those used in an intensive care unit, periodic data manually input by a patient such as dietary intake, or data mined from a patient's medical records such as symptoms or test results.

The output of these devices is information as to the state or progression of a disease or condition that has already been diagnosed, or information in relation to the state of patient parameters. The form of the output information is not limited and may include text-based or graphic-based information, or may include other visual or audio formats such as alarms.

If such products are intended to provide information for this purpose in relation to a person and the information could indicate that the person, or another person, may be in immediate danger or that there may be a high risk to public health, they are classified as Class IIb under new paragraph 4.6(a).

If such products are intended to provide information for this purpose in relation to a person and the information could indicate that the person, or another person, may be in another form of danger (i.e. in danger but not immediate danger) or that there may be a moderate risk to public health, they are classified as Class IIa under new paragraph 4.6(b).

Such products in any other case are classified as Class I under new paragraph 4.6(c).

#### *4.7 – Programmed or programmable medical device or software that is a medical device for use in specifying or recommending a treatment or intervention*

New classification rule 4.7(1) applies to a programmed or programmable medical device, or software that is a medical device, intended by its manufacturer to be used to process data or information in order to specify or recommend a treatment or intervention.

The information provided by the medical device, in the form of a specified treatment or intervention, is provided to a 'user' which could include but is not limited to: a lay-person, a care-giver, a patient, a healthcare professional. A key point is that the treatment or intervention is specified *directly* to a user without any intermediate oversight by, or involvement of, a relevant health professional (which is the case for 4.7(2)). The 4.7(1) rule could also apply to a relevant health professional as a user but the difference is that the decision regarding therapy or intervention is actually being undertaken by the device—not the relevant health professional based on information being provided to the health professional by the device (which is the case for 4.7(2)).

If such products are intended to specify or recommend a treatment or intervention in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may lead to the death of a person or to a severe deterioration of a person's health or may pose a high risk to public health, they are classified as Class III under new paragraph 4.7(1)(a).

If such products are intended to specify or recommend a treatment or intervention in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may otherwise be harmful to a person or may pose

a moderate risk to public health, they are classified as Class IIb under new paragraph 4.7(1)(b).

Such products in any other case are classified as Class IIa under new paragraph 4.7(1)(c).

New classification rule 4.7(2) applies to a programmed or programmable medical device, or software that is a medical device, intended by its manufacturers to be used to recommend a treatment or intervention to a relevant health professional for the purposes of assisting or enabling the health professional to make a decision about the treatment or intervention.

The inclusion of the term ‘relevant’ to describe the health professional is intended to emphasise the role of the health professional in making a decision, about the treatment or intervention to be applied, with the provided information; that is, the information provided by a medical device under this classification rule is not to be solely relied upon for specifying a treatment or intervention. For example, a relevant health professional for treating certain forms of glaucoma would be an ophthalmologist, whereas a general practitioner would not be considered to be a relevant health professional in that case. However, a general practitioner could be a relevant health professional for treating other sorts of diseases and conditions.

If such products are intended to recommend a treatment or intervention to a relevant health professional in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may lead to the death of a person or to a severe deterioration of a person’s health or may pose a high risk to public health, they are classified as Class IIb under new paragraph 4.7(2)(a).

If such products are intended to recommend a treatment or intervention in circumstances where the absence of the treatment or intervention (e.g. a failure to apply it), or where the treatment or intervention itself, may otherwise be harmful to a person or may pose a moderate risk to public health, they are classified as Class IIa under new paragraph 4.7(2)(b).

Such products in any other case are classified as Class I under new paragraph 4.7(2)(c).

The lower risk classifications under subclause 4.7(2) compared with subclause 4.7(1) principally reflects the involvement of a relevant health professional in the use of software to which subclause 4.5(2) relates and the process of diagnosing a disease or condition, with this mitigating to an extent the risk that such products may pose in comparison with the situations covered by subclause 4.7(1).

#### *4.8 – Programmed or programmable medical device or software that is a medical device that is to provide therapy to a person through the provision of information*

New classification rule 4.8 applies to a programmed or programmable medical device, or software that is a medical device, intended by its manufacturer to provide therapy to a person, through the provision of information to the person. The provision of information to a person may take the form of instructions to the person, for example, instructions for performing physical movements or mental exercises; and there may be an exchange of information with the person, for example, the person may be asked for information about their symptoms.

If such products are intended to provide therapy to a person in relation to therapy that may result in the death or a severe deterioration of a person’s health, they are classified as Class III under new paragraph 4.8(1)(a).

If such products are intended to do so in relation to therapy that may cause serious harm to the person and where paragraph 4.8(1)(a) does not apply, they are classified as Class IIb under new paragraph 4.8(1)(b).

If such products are intended to do so in relation to therapy that may still cause harm to the person but in circumstances where neither paragraph 4.8(1)(a) or (b) apply, they are classified as Class IIa under new paragraph 4.8(1)(c).

In any other case such products are classified as Class I under new paragraph 4.8(1)(d).

As most existing medical devices that would be covered by the new classification rules, and that are already included in the Register are currently classified as Class I devices (under clause 4.1 of Part 4 of Schedule 2 to the MD Regulations), the application provisions in Schedule 10 of the Regulations are designed to ensure that such devices that are already included in the Register with a Class I classification, or that are the subject of such an application for marketing approval that has not been finally determined, when these amendments commence, will have the benefit of a transitional period (principally, until 1 November 2024) before the new rule begins to apply to them.

### **Item 3 – Schedule 2A (note to Schedule heading)**

This item amends Schedule 2A to the MD Regulations, which sets out the classification rules for IVD medical devices, to introduce clearer notes about regulations 3.2 and 3.3 of the MD Regulations, consistent with item 1A above.

### **Item 4 – Dictionary (at the end of the definition of ‘active medical device’)**

This item amends one existing definition in the Dictionary to the MD Regulations, and introduce two new defined terms to the Dictionary.

#### *Amendment to definition of ‘Active medical device’*

An ‘active medical device’ is defined in the Dictionary to the MD Regulations as, principally, a medical device that is intended by its manufacturer to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity), and to act by converting this energy.

This item amends this definition to make it clear that software that is a medical device is an active medical device. This reflects and clarifies that such products have long been regarded as active medical devices in Australia, and would also align with the EU approach in relation to such products.

#### *‘Inclusion day’*

This item also introduces 2 definitions that are common to both existing transitional arrangements that are already included in the MD Regulations, and to the transitional arrangements to be introduced by the Regulations.

‘Inclusion day’ is defined, for an entry of a kind of medical device in the Register, as meaning the day on which the inclusion of that kind of device in the Register commences.

#### *‘Finally determined’*

‘finally determined’ is defined, for an application, as the first time both of the following conditions are met:

- a decision has been made as to whether or not to grant the application; and
- there is no longer any possibility of a change in the outcome of the decision.

## **Part 2 – Essential Principles**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 5 – Clause 12.1 of Schedule 1**

The essential principles, which are set out in Schedule 1 to the MD Regulations, represent minimum benchmarks of safety, quality and performance of medical devices.

Clause 12 of Schedule 1 is designed for medical devices that are connected to or equipped with an energy source, and current clause 12.1 provides that where such a medical device incorporates an electronic programmable system (in particular, this covers both medical devices that consist of software and those that consist of a physical device that is driven by or that includes software) it must be designed and produced in a way that ensures that the performance, reliability and repeatability of the system are appropriate for the intended purpose of the device, and that any consequent risks associated with a single fault condition in the system are minimised.

This represents a very broad set of requirements, without providing clarity in relation to all of the elements of what would be involved in complying with these overarching requirements.

To provide greater clarity in this regard, and to better identify these elements for sponsors and manufacturers of such medical devices (in particular, software), this item replaces the current subclause 12.1 with a more detailed and up to date list of requirements.

The updated list of safety and performance requirements relevant to software was informed by the new EU Medical Device Regulation and recently published guidance from the IMDRF. The updated 12.1 includes six subclauses of which each broadly covers a particular area of concern. Subclause (1) covers design and production considerations, Subclause (2) reinforces the idea that for these kinds of devices the state of the art (as referred to in Schedule 1 Clause 2) should be applied, Subclause (3) refers to considerations for computing platforms and external factors, Subclause (4) refers to requirements for operation, Subclause (5) includes considerations for cyber security and Subclause (6) was added to address concerns regarding the use of data and is of particular importance for devices that include artificial intelligence features.

These new requirements include, for example, that a programmed or programmable medical device, or software that is a medical device, that is intended to make use of data or information be designed and produced in a way that ensures the matters listed in new paragraphs 12.1(1)(a)-(g). These include, for example, the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate given its intended purpose, and that any consequent risks or impairment of performance associated with one or more fault conditions of the device are eliminated or appropriately reduced. Also for example, new subclause 12.1(2) requires that such products must be developed, produced and maintained having regard to the generally acknowledged state of the art

(including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution), and new subclause 12.1(3) requires that if such products are intended to be used in combination with computing platforms, they must be designed and developed in such a manner that takes into account the capability, resources and configuration of those platforms and the external factors (including information technology environment) related to the use of the platforms.

#### **Item 6 – Subclause 13.2(3) of Schedule 1**

Clause 13.2 of Schedule 1 to the MD Regulations sets out essential principles that relate to the location of information that is required under clause 13 of Schedule 1 to be provided with a medical device (e.g. information identifying the manufacturer of a device).

Subclauses 13.2(1) and (2) require that, principally, such information must be provided on the device itself or, if this is not practicable, on the packaging of the device or (where devices are packaged together) on the outer packaging used for such devices.

Current subclause 13.2(3) of Schedule 1 provides that if it is not practicable to comply with subclause 13.2(1) or (2) in relation specifically to the information identified in subregulation 10.2(1) of the MD Regulations or in clause 13.3 of Schedule 1, the information must be provided on a leaflet supplied with the device.

The information concerned relates to the name and address of the sponsor of the device (subregulation 10.2(1)) and a range of information about the safe use of a medical device including, for example, sufficient information to enable a user to identify the device and any warnings, restrictions or precautions that should be taken in relation to the device's use.

This item replaces the current subclause 13.2(3) of Schedule 1 to the MD Regulations with a new subclause 13.2(3), with the main effect of making it clear that for a medical device that is software, this information may be provided electronically as an alternative to providing it on a leaflet. This is in order to reflect the way in which many users obtain and access software.

#### **Item 7 – After clause 13A.4 of Schedule 1**

This item introduces a new clause 13B to Schedule 1 to the MD Regulations, which requires that for a medical device that is software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the software, and must be in English (though they may also be in any other language).

The current version and build number is important information for users of software to be aware of, so that they are able to verify that they are using the most up to date version and build of the software, particularly if updates have been made to the version and build of software to eliminate bugs or other problems that may affect its performance.

This information is also important from a post-market monitoring perspective and in ensuring that adverse events and threats to cybersecurity involving such products are able to be identified and responded to in a timely fashion.

## Schedule 3 – Personalised medical devices

### **Introduction**

Over the past two decades, rapid advances in materials science and computing technology have driven exponential change in medical imaging technology, manufacturing technology and (as a result) medical device technology.

Advances in areas such as 3D printing have allowed more complex and, in some cases, higher risk, medical devices to be manufactured, including devices that are designed for the use of individual patients, such as custom-made medical devices.

The current requirements in the MD Regulations for custom-made medical devices were developed when such products principally comprised low-risk products such as glass eyes, prosthetic limbs and prescription lenses.

The amendments in this Schedule are designed to amend the requirements in the MD Regulations to better address the evolution of these kinds of medical devices, principally in relation to the scope of the current exemption for custom-made medical devices from the requirement to be included in the Register, but also importantly in relation to the applicable conformity assessment procedures and reporting requirements for such products.

### **Part 1 – Definitions**

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

##### **Item 1 – At the end of Part 1**

This item introduces a new item 1.8 to the MD Regulations that, for the purposes of subsection 41BG(4) of the Act, makes it clear that the class of persons described in new item 1.8 are not manufacturers of a medical device.

Subsection 41BG(4) of the Act provides that a person is not the manufacturer of a medical device if the person is included in a class of persons prescribed by the regulations for the purposes of that subsection.

The class of persons who are identified by new item 1.8 for this purpose as not being manufacturers of medical devices are health professionals, or suitably qualified persons within a healthcare facility, who produce a medical device using a medical device production system that is included in the Register.

An example of this is a dentist who uses such a medical device production system to produce crowns or other dental products that are medical devices for the dentist's patients. The effect of new item 1.8 is that the dentist would not be the manufacturer of the crowns or other dental products produced by the system.

##### **Items 2-4 – Dictionary**

These items introduce a number of new definitions to the Dictionary to the MD Regulations, and would replace the current definition of 'custom made medical device' with a new definition for that term.

### *Custom-made medical device*

Custom-made medical devices are currently defined in the Dictionary to the MD Regulations as, principally, medical devices that are made in accordance with a request by a health professional specifying the design characteristics or construction of the device, and that are intended to be used only in relation to a particular individual or by a health professional to meet special needs arising in the course of the health professional's practice.

Item 2 replaces this definition with a more up to date definition of such products, that in particular emphasises that this term relates to medical devices:

- that are intended by the manufacturer to be for the sole use of a particular patient or particular health professional;
- that are manufactured in accordance with a written request from, and particular design characteristics specified by, a health professional (even if the design is developed in consultation with the manufacturer); and
- in circumstances where those design characteristics are intended to address either or both of the anatomical or physiological features, or pathological condition of the intended recipient patient or health professional.

The new definition also makes it clear that the meaning of custom-made medical device does not include a patient-matched device, and does not include a mass-produced device such as an adaptable medical device.

These are new terms for which definitions are also introduced by these items.

Examples of custom-made medical devices include:

- an artificial cervical disc replacement, requested by a spinal surgeon, for the reconstruction of a person's cervical disc following cervical discectomy to treat cervical radiculopathy, where the dimensions of the person's cervical spine are such that conventional artificial cervical discs would not address the person's needs; and
- an endoscope with a modified steering mechanism requested by a gastroenterologist to address a loss in the gastroenterologist's manual dexterity as a result of a disability that they suffer, where either the gastroenterologist themselves, or their health professional, requests the endoscope manufacturer to produce a modified product designed specifically to overcome the gastroenterologist's loss of dexterity.

### *Adaptable medical device*

Item 1 introduces a definition of 'adaptable medical device', with that term covering in particular a mass-produced medical device that is intended by the manufacturer to be able to be assembled or adapted after it has been supplied for the purpose of addressing an individual's anatomical or physiological features or pathological condition, or to otherwise perform as intended by the manufacturer.

So adaptable medical devices are one example of a mass-produced medical device, and while an adaptable medical device may be assembled or adapted by an individual in order to suit their particular needs, the manufacturer of such a product will have manufactured the device in order to ensure that the device is able to be so assembled or adapted, but will not have designed it for the individual's actual needs.

An example of an adaptable medical device is a mass-produced polymer surgical implant for cranial reconstruction that is supplied in a sterile state and that is intended to be

thermoformed during the cranial reconstruction surgical procedure, where the manufacturer's instructions provide details for the surgeons on how to heat and shape the polymer to suit the patient's anatomy.

It should be noted that an adaptable medical device is one type of personalised medical device; however, personalising a medical device is not the only reason that a medical device might be adaptable. There are already medical devices in common use that are required to be adapted according to the manufacturers' instructions, such as through assembly or adjustment, prior to their use. This is often, though not necessarily, related to their installation.

#### *Mass-produced medical device*

Item 3 defines a mass-produced medical device as a device that is manufactured according to standardised dimensions or designs, is not designed for a particular individual and that is manufactured in a continuous production process or in a homogenous batch.

#### *Patient-matched medical device*

Item 3 also defines a patient-matched device (noting in particular that the new definition of custom-made medical device identifies that such products are not within the meaning of the new definition for that term).

A patient-matched medical device is defined as a medical device that, in particular, is manufactured within a specified design envelope, to match an individual's anatomical or physiological features or pathological condition, is designed by the manufacturer (even if the design is developed in consultation with a health professional) and is manufactured using production processes that are able to be validated or verified, and reproduced.

#### *Specified design envelope*

'Specified design envelope' is also defined for the purposes of the reference to that term in the new definition of patient-matched medical device, as minimum and maximum dimensions, performance limits or other relevant factors that characterise a medical device's design for production purposes. These may be based on a standard device template.

Performance limits could include (but not be limited to) such things as power, torque, speed, energy output, or computational power.

'Other relevant factors' could include (but not be limited to) such things as allowable environmental limits for operation; specifications for materials and their properties; or other factors that determine limits or boundaries of design for transfer to production.

An example of such patient-matched medical devices is an externally worn orthosis (helmet) to shape the skull of an infant to prevent plagiocephaly (flat head syndrome), based on 3D images of the infant's head, provided by a prosthetist to the manufacturer, where the manufacturer produces the orthosis within validated parameters.

#### *Medical device production system*

It is important to note that item 3 also introduces a definition for a medical device production system. Principally, these are systems that consist of raw materials and main production equipment that are intended by their manufacturer to be used together by a health professional or other suitably qualified person within a healthcare facility, to produce a



particular medical device for the use of a patient of the health professional or healthcare facility (i.e. at the point of care).

In some instances, the use of such systems may require or involve the use of ancillary equipment, such as common tools, or inputs such as patient image data, but these would not form part of the system itself.

An example of such a system would be a 3D printer, together with the raw materials to be used by the printer, to generate a medical device, such as dentures or a crown for a tooth, using patient image files loaded into the system by a dentist.

## **Part 2 – Reports**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 5 – After regulation 10.3**

Under subregulation 10.3(1) of the MD Regulations, the manufacturer of a custom-made medical device that is manufactured in Australia must, within 2 months after the device is first manufactured in Australia, inform the Secretary of the manufacturer's name and business address and provide a description of the kinds of such devices they are manufacturing.

Under subregulation 10.3(2) of the MD Regulations, a sponsor who imports custom-made medical devices must comply with equivalent requirements within 2 months of first importing such a device.

In each instance, a failure to do so is an offence, and may result in a maximum penalty of 10 penalty units.

As custom-made medical devices are exempt from inclusion in the Register, these requirements are designed to support post-market monitoring of such products to ensure their safety and performance, by alerting the TGA to their manufacture and importation.

However, these reports only relate to the first instance of manufacture or importation of such products, and do not provide a complete picture of how many such products are being made or imported, or of where the same such devices are manufactured or imported.

To better support post-market monitoring and the development of an informed understanding of trends involved for such products across the TGA, industry, health professionals and consumers, this item augments these existing requirements by introducing new regulation 10.3A.

New subregulation 10.3A(1) requires Australian manufacturers of custom-made medical devices to provide a written report to the Secretary (using the form approved by the Secretary for that purpose under new subregulation 10.3A(3) of all of the custom-made medical devices they have manufactured in a financial year, by 1 October in the following financial year (e.g. by 1 October 2022 for financial year 2021-22).

New subregulation 10.3A(2) sets out similar requirements for sponsors, in relation to the details of custom-made medical devices that they have imported for a financial year.

In each instance, a failure to do so would be an offence, that may result in a maximum penalty of 10 penalty units.

The proposed new offences do not involve any possible imprisonment, would not be offences of strict or absolute liability and would reflect a maximum penalty level consistent with the similar existing offences in regulation 10.3 (consistent with the *Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*, September 2011, published by the Attorney-General's Department and available on [www.ag.gov.au](http://www.ag.gov.au)).

### **Part 3 – Conformity assessment procedures**

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

##### **Item 6 – Paragraph 7.1(a) of Schedule 3**

Schedule 3 to the MD Regulations sets out the conformity assessment procedures (these are requirements for manufacturers of medical devices) that must be applied to medical devices used for a special purpose, for the purposes of subregulation 3.10(2) of the MD Regulations.

Under subregulation 3.10(1) of the MD Regulations, the description “medical devices used for a special purpose includes exempt devices – i.e. devices which are set out in Schedule 4 to the MD Regulations as being exempt from the requirement to be included in the Register - such as custom-made medical devices.

This item makes a minor amendment to clause 7.1 of Schedule 3, to reflect the changes to be introduced by item 18 below.

##### **Item 7 – Subclause 7.2(1) of Schedule 3 (note)**

This item makes a minor amendment to subclause 7.2(1) of Schedule 3 to the MD Regulations to repeal the note under that subclause. This note relates to the first 2 years after the commencement of the MD Regulations in 2002, and is no longer needed.

##### **Items 8-10 – Paragraphs 7.2(2)(c), (e) and (f) of Schedule 3**

Clause 7.2 of Schedule 3 to the MD Regulations sets out conformity assessment procedures that apply specifically to custom-made medical devices.

Subclause 7.2(2) of Schedule 3 requires a manufacturer of such a product to prepare a written statement that includes the elements set out in paragraphs 7.2(2)(a)-(g).

These items make minor amendments to paragraphs 7.2(2)(c), (e) and (f) of Schedule 3, to ensure that those paragraphs are consistent with the proposed new definition of a custom-made medical device to be introduced by item 2 above.

##### **Item 11 – After subclause 7.2(3) of Schedule 3**

Under the current clause 7.2 of Schedule 3 to the MD Regulations, the written statement that is required to be prepared by a manufacturer of a custom-made medical device under

subclause 7.2(2) must be signed by a person authorised by the manufacturer to do so and must set out the name and position of that person and when the person signed the statement.

However, clause 7.2 does not require the manufacturer to provide a copy of the statement with such a device.

This item therefore amends clause 7.2 to introduce a new subclause 7.2(3A) which would require a manufacturer to do so.

This measure is designed to assist health professionals and patients to be better informed about their custom-made medical device, and about its safe use – for example, the information set out in subclause 7.2(2) includes sufficient information to enable the user to identify the device, and a statement explaining that the device complies with the essential principles or, if it does not, a statement explaining which provisions of the essential principles that it does not comply with and the reasons why.

#### **Item 12 – Subclause 7.6(2) of Schedule 3**

Clause 7.6 of Schedule 3 to the MD Regulations requires a manufacturer to which clauses 7.2 or 7.5 of Schedule apply to keep the statement and documentation required under those clauses.

Subclause 7.6(2) requires such a manufacturer to keep the statement and documentation for at least 5 years after the manufacture of the last medical device to which the statement and documentation relates.

This item substitutes a new subclause 7.6(2), which would preserve this requirement but would make it clear that if the device in question is an implantable medical device, the manufacturer must keep the required statement and documentation for at least 15 years after the manufacture of the medical device to which the statement and documentation relates.

### **Part 4 - Exemptions**

#### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Items 13 and 16-22**

These items make minor amendments to regulation 1.6 and paragraphs 4.3F(e) and 4A.31(h) of the MD Regulations, and to subparagraphs 1.8(2)(c)(i), 3.5(2)(c)(i), 5.7(2)(c)(i), 6.6(2)(c)(i) and 6B(2)(c)(i) of Schedule 3 to the MD Regulations, to reflect the introduction of a definition of ‘unique product identifier’ by item 32 below.

#### **Item 14 – Paragraph 3.11(2)(a)**

This item makes a minor amendment to regulation 3.11 of the MD Regulations, to reflect the change to be introduced by item 29B below.

#### **Item 15 – At the end of regulation 3.11**

Subregulation 3.11(1) of the MD Regulations has the effect that in addition to the conformity assessment procedures that apply to medical devices used for a special purpose (including custom-made medical devices) under subregulation 3.10(2) of the MD Regulations, the clinical evaluation procedures in Part 8 of Schedule 3 to the MD Regulations must also be

applied to such devices, for the purpose of demonstrating that they comply with the applicable provisions of the essential principles (in particular, clauses 1, 3 and 6 of Schedule 1 to the MD Regulations).

This item makes a minor, consequential change to regulation 3.11 to reflect the change to be introduced by items 29B and 30 below, and to make it clearer that custom-made medical devices are subject to subregulation 3.11(1), and are not covered by the description of certain devices used for a special purpose that are exempted from subregulation 3.11(1) by subregulation 3.11(2).

#### **Item 23 – Part 1 of Schedule 4 (table item 1.5)**

Item 1.5 of Part 1 of Schedule 4 to the MD Regulations exempts custom-made medical devices from the requirement to be included in the Register.

This item repeals item 1.5 from Part 1 of Schedule 4, to reflect the proposed introduction of a new exemption for custom-made medical devices in Part 2 of Schedule 4, by item 24 below.

#### **Item 24 – At the end of Part 2 of Schedule 4**

This item amends Part 2 of Schedule 4 to the MD Regulations, to introduce new exemptions from the requirement to be included in the Register for custom-made medical devices, and a specified exemption from this requirement for patient-matched medical devices.

#### *Exemptions for Custom-made medical devices*

Item 24 moves the current exemption for custom-made medical devices that is in Part 1 of Schedule 4 to the MD Regulations, to Part 2 of Schedule 4. This item adds two new items to this Schedule: item 2.12 in relation to custom-made medical devices that are manufactured in Australia, and item 2.13 in relation to custom-made devices that are manufactured outside Australia.

These principally reflect the need to include conditions applying to the exemptions, in order to support the safety and quality of these devices.

The conditions that apply to the exemption of custom-made medical devices manufactured in Australia under the new item 2.12 in Part 2 of Schedule 4 are similar to the conditions of exemption that apply to Class 1 – 3 in-house IVD medical devices, in item 2.10 of Part 2 of Schedule 4.

In particular, the proposed conditions require the manufacturer of such a device to:

- have available at all times evidence to substantiate the application of the conformity assessment procedures to their devices;
- allow an authorised person to enter, at any reasonable time, any premises (including premises outside Australia) where the manufacturer or any other person deals with the device (this includes, for example premises where the device is designed or manufactured) and to undertake a number of specified actions including, for example, to inspect those premises and any thing on those premises that relates to the device and to examine, take measures of, conduct tests on, require tests to be conducted or take samples of any such thing; and
- if asked to do so by an authorised person, product to the authorised person any documents relating to the device that the authorised person requires, and allow the authorised person to copy those documents.

These conditions are designed to ensure that appropriate post-market monitoring powers are in place to allow the TGA to verify the safety of the manufacturing process for these products.

New item 2.13 in Part 2 of Schedule 4 also requires the sponsor of a custom-made medical device that is manufactured outside Australia to comply with equivalent conditions.

*Exemption for Patient-matched medical devices*

It is important to note that this item also amends Part 2 of Schedule 4 to introduce a new, specific exemption for patient-matched medical devices.

This is designed to minimise the impact of the introduction of the new definition of custom-made medical device on those devices that meet the current definition of that term in the Dictionary to the MD Regulations but that will be patient-matched medical devices rather than custom-made devices under the new definitions to be introduced by items 2 and 3 above.

The new exemption (item 2.14 of Part 2 of Schedule 4) includes a small number of conditions that would, principally, require the sponsor of such a device to, before 25 February 2021, notify the Secretary in writing of each kind of such device that they intend to supply in Australia on or after 1 November 2024, providing the unique product identifier given to each device of that kind as well as a small amount of other information, such as the name and address of the sponsor and manufacturer of such devices.

The application provisions in Schedule 10 to the Regulations (subregulation 11.51(3)) make it clear that this exemption only applies in relation to a patient-matched medical device that is manufactured on or after 25 August 2020 and before 1 November 2024. This is intended to reflect that this exemption is principally designed to minimise the impact of the introduction of the new definition of custom-made medical devices for these products and to provide a transitional period to prepare to apply to include such products in the Register.

**Item 25 - Dictionary**

This item amends the Dictionary to the MD Regulations to include a definition for ‘unique product identifier’, a term used in these amendments and in a number of existing parts of the MD Regulations.

The definition does not introduce any new elements of the meaning of that term as reflected in the existing references to it in the MD Regulations, but rather brings those elements together in a single definition. This definition makes it clear that this term means the unique product identifier (for example, the product name or model number) given to a medical device by its manufacturer to identify the device and any variants.

## **Part 5 – Classification rules**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 26 – After subregulation 3.3(5)**

Regulation 3.3 of the MD Regulations sets out a number of important principles in relation to applying the classification rules that are set out in Schedule 2 to the MD Regulations for medical devices other than IVD medical devices, and in Schedule 2A to the MD Regulations for medical devices that are IVD medical devices.

This item amends regulation 3.3 to introduce a new principle for applying the classification rules, in relation to medical device production systems (these are systems that consist of main production equipment and raw materials that are manufactured by a manufacturer for health professionals to use to produce medical devices, such as crowns or dentures).

The new principle (new subregulation 3.3(5A)) makes it clear that a medical device production system has the same classification as the medical device the system is intended to produce. For example, if such a system is intended by its manufacturer to produce dental products that are Class I medical devices, under the new principle the system itself will also be classified as a Class I device.

**Item 27 – Clause 5.4 of Schedule 2** Clause 5.4 of Schedule 2 to the MD Regulations currently provides that a non-active medical device that is intended by its manufacturer to be used to record X-ray diagnostic images is classified as Class IIa.

This item substitutes a new clause 5.4 for this rule, principally in order to update it to better address the range of emerging technologies other than just X-rays that may now be used to generate diagnostic images, and to address anatomical models (including physical anatomical models that may be made for example by 3D printers, and virtual anatomical models that for example a surgeon may use to explore a person's anatomy before a surgical procedure) that are used for diagnostic or other purposes.

Under new subclause 5.4(1), a medical device that is intended by the manufacturer to be used to record patient images will be classified as Class IIa if the images are to be used for either or both of the diagnosis or monitoring of a disease, injury or disability or the investigation of a physiological process, and if the images are acquired through a method that relies on energy outside the visible spectrum (for example, ultrasounds and magnetic resonance imaging are examples of methods that rely on energy that is outside the visible spectrum).

Under new subclause 5.4(2), a medical device that is an anatomical model (whether physical or virtual) that intended by the manufacturer to be used for either or both of the diagnosis or monitoring of a disease, injury or disability or the investigation of a physiological process, will also be Class IIa.

Under new subclause 5.4(3), a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the diagnosis or monitoring of a disease, injury or disability or the investigation of a physiological process, will also be Class IIa.

## **Part 6 – Essential principles**

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **28 – Subclause 13.4(3) of Schedule 1 (at the end of the table)**

Clause 13.4 of Schedule 1 to the MD Regulations sets out requirements for instructions for use for medical devices.

Under subclause 13.4(3) of Schedule 1, instructions for the use of a medical device must include information mentioned in the table under subclause 13.4(3) that is applicable to the device.

These include, for example, the intended purpose of the device, the intended user of the device and the kind of patient on whom the device is intended to be used.

This item amends this table to add the following additional information that will be required to be included in instructions for use for medical devices that are, respectively, adaptable medical devices or medical device production systems:

- for an adaptable medical device – instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles; and
- for a medical device production system – instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles.

## Schedule 4 – IVD companion diagnostics

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Introduction**

IVD companion diagnostics are IVD medical devices that are pathology tests designed to identify the presence or absence of specific biomarkers (principally, these are features such as molecules, genes or other characteristics that can be used to identify or measure a pathological or physiological processes such as a disease) in a person.

The purpose of detecting the presence or absence of the biomarker through the use of an IVD companion diagnostic is to identify whether a person is likely to benefit from the use of a particular medicine or biological, or also whether they may be at particular risk from such a product.

As such, both the medicine or biological, and the IVD companion diagnostic, are designed to be used together for this purpose.

IVD companion diagnostics are particularly important in relation to the safe use of precision medicines that are intended to be based on unique patient health and disease information, including cell-based therapies, immunotherapies and targeted therapies.

As such, the reliability of IVD companion diagnostics, and the need for a set of appropriate, tailored regulatory requirements to ensure their safety, quality and performance, is very important.

Regulators in the United States and the EU have moved to bring in such specific regulatory requirements for IVD companion diagnostics, and this Schedule accordingly amends the MD Regulations to introduce similar requirements for Australia.

#### **Item 1 – At the end of regulation 1.6**

Section 41BE of the Act provides that a medical device is taken to be of the same kind as another medical device if they have the same sponsor, same manufacturer, same device nomenclature code and if they are the same in relation to any other characteristics prescribed in the regulations.

Regulation 1.6 of the MD Regulations identifies that the unique product identifier of a medical device (as defined by item 32 of Schedule 3 above) is such a characteristic for the purposes of section 41BE, for the medical devices identified in regulation 1.6 (e.g. Class III medical devices).

This item amends regulation 1.6, with the effect that unique product identifier will also be such a characteristic for a medical device that is an IVD companion diagnostic.

#### **Item 2 – Paragraphs 4.3F(e) and 4A.31(h)**

This item makes minor amendments to each of paragraphs 4.3F(e) and 4A.31(h) of the MD Regulations, to reflect the changes to be introduced by item 1 above.



### **Item 3 – At the end of paragraph 5.3(1)(j)**

Paragraph 5.3(1)(j) of the MD Regulations identifies IVD medical devices for which the Secretary must select an application for marketing approval for audit – e.g. an IVD medical device that is intended for self-testing.

This item amends paragraph 5.3(1)(j) to add new subparagraph 5.3(1)(j)(x) for IVD companion diagnostics. This is designed to ensure that applications for marketing approval for such products will be subjected to an application audit, in order to ensure that the level of pre-market scrutiny applied to such products is commensurate with the level of risk they may pose if they do not function as intended.

### **Item 4 – After paragraph 1.3(f) of Schedule 2A**

Schedule 2A to the MD Regulations set out classification rules for medical devices that are IVD medical devices.

Under current paragraph 1.3(f)(i) of Schedule 2A to the MD Regulations, an IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended to be for use in the selection of patients for selective therapy or management.

This classification rule is intended to include IVD companion diagnostics. However, there has been some confusion as to whether it does so, and this has led in some instances to some sponsors of IVD companion diagnostics applying to include their products in the Register with a lower classification, as a Class 2 IVD.

To clarify the applicable medical device classification for IVD companion diagnostics, this item amends clause 1.3 of Schedule 2A to introduce a new paragraph 1.3(fa) that would make it clear that an IVD medical device or an IVD in-house IVD medical device that is intended by its manufacturer to be used as an IVD companion diagnostic is classified as a Class 3 IVD medical device or Class 3 in-house IVD medical device.

### **Item 5 – Clause 1.3 of Schedule 2A (note)**

The note at the end of clause 1.3 of Schedule 2A provides that for paragraph (f) of clause 1.3, an IVD medical device would fall into Class 2 under clause 1.7 if a therapy decision would usually be made only after further investigation, or if the device is used for monitoring.

This item amends this note to make it clear that it does not apply to an IVD companion diagnostic.

### **Item 6 - Dictionary**

This item amends the Dictionary to the MD Regulations to introduce a definition of IVD companion diagnostic.

The proposed new definition makes it clear that an IVD companion diagnostic is an IVD medical device that is intended by its manufacturer to be used for the examination of a specimen from the body of an individual, to:

- identify whether the individual would be likely to benefit from the use of a particular medicine or biological; or
- identify whether the individual is likely to be at a particular risk from the use of a particular medicine or biological; or

- monitor the individual's response to the use of a particular medicine or biological.

Importantly, the definition also requires that to be an IVD companion diagnostic, the IVD medical device must be mentioned in product information for the medicine or biological as being essential for the medicine's or biological's safe and effective use.

Paragraph (c) of the proposed new definition highlights that if the medicine or biological concerned comprises blood, a blood component, cells, tissues or an organ from a (human) donor other than the individual, and the IVD medical device is intended by the manufacturer to be used for the examination of the specimen merely to determine whether the medicine or biological is compatible with the individual, then the IVD is not an IVD companion diagnostic.

## Schedule 5 – Faecal microbiota transplant products

### ***Therapeutic Goods Regulations 1990***

#### **Introduction**

Faecal microbiota transplant (FMT) products are principally donated faecal matter, and therapeutic materials produced through the processing of such matter. FMT products may include in particular fresh or banked human faecal matter that may be introduced to a recipient's bowel by a range of methods including for example a colonoscopy or a rectal enema, or through oral ingestion of such matter that has been filtered, centrifuged, cultured and encapsulated or otherwise prepared appropriately to allow for oral ingestion.

In particular, FMT products may be effective in repopulating healthy bacteria in a recipient's bowel with benevolent microorganisms, in particular to treat recurrent *Clostridioides difficile* infection (a bacterial infection) and ulcerative colitis (a chronic, relapsing-remitting mucosal inflammatory bowel disease).

When used and presented as being for use in relation to the prevention, curing or alleviating of such diseases, FMT products are considered to be therapeutic goods for the purposes of the Act, and FMT products that contain human cells (colonocytes) – even where the presence of these cells is incidental to the mechanism of action of the product in treating the relevant disease or condition - are considered to be biologicals for the purposes of section 32A of the Act and to therefore be subject to regulation as biologicals under Part 3-2A of the Act.

However, as FMT products are a very new and emerging spectrum of products they have not, until now, been regulated under the therapeutic goods regulatory scheme.

The amendments in this Schedule are therefore designed to amend the *Therapeutic Goods Regulations 1990* (“the TG Regulations”) to do so by providing a regulatory framework that has been tailored specifically for FMT products, in order to ensure the safety, quality and efficacy of such products for Australian patients.

These measures will also be enhanced with the commencement of a standard, to be made by the Minister under section 10 of the Act, which will set out important requirements relating to, in particular, the screening and testing of such products before they are used in a recipient.

#### **Item 1 – Regulation 2**

This item amends regulation 2 of the TG Regulations to introduce a definition of ‘faecal microbiota transplant product’. This definition defines such products as a thing that comprises, contains or is derived from human stool, and that is for introduction into a person for a therapeutic use.

#### **Item 2 – Before clause 1 of Schedule 16**

As part of the new regulatory framework for FMT products, it is intended that where such products are principally manufactured, tested and provided to a patient in a hospital setting under the supervision or direction of a medical practitioner, such products will be Class 1 biologicals.

In particular, identifying such FMT products as Class 1 biologicals means that hospitals will not be required to obtain a manufacturing licence under Part 3-3 of the Act for the

manufacture of such products, as Class 1 biologicals are exempt from the operation of Part 3-3 under section 33B of the Act.

This measure is part of ensuring that the new framework for FMT products strikes the correct balance between appropriate regulation and ensuring access for Australian patients and avoiding constraints that may inhibit innovation without meaningfully enhancing safety.

Class 1 biologicals are defined in regulation 2 of the TG Regulations as those biologicals identified as being Class biologicals in Schedule 16 to the TG Regulations.

This item amends Schedule 16 to the TG Regulations to provide that for the purposes of the definition in regulation 2, a biological will be a Class 1 biological if it is an FMT product that meets specified criteria, including in particular that it:

- is not advertised to consumers;
- is to be collected under the supervision or direction, or in accordance with the requirements, of a registered medical practitioner;
- in circumstances where each later step in the manufacture of such products is to be carried out in a hospital by, or under the supervision or direction of, the practitioner (unless the step relates to the storage or testing of the biological, in which case it may instead be carried out by a person under a contract with the hospital in a State or internal Territory); and
- is for use in a recipient who is a patient of the hospital and under the clinical care of the practitioner.

## Schedule 6 – Consumer medicine information documents

### ***Therapeutic Goods Regulations 1990***

#### **Introduction**

There are several thousand prescription and over the counter medicines supplied in Australia that are required to be accompanied with a patient information document (perhaps better known as consumer medicine information documents (CMI)).

Concerns have arisen about the complexity and readability of these documents, and the TGA has been consulting with consumer, health professional and industry representatives to develop improved templates for CMI documents.

The new templates (one for prescription medicines, and one for over the counter medicines) have been designed with such concerns in mind, and developed in conjunction with medicine sponsors, health practitioner groups, consumers and other stakeholders to better provide consumers with reliable and easy to understand information about the safe and effective use of such products (including through the use of a summary at the start of the templates).

The amendments in this Schedule will complement this work by requiring such medicines to be supplied with CMI documents that are in line with the new templates, while also providing transitional arrangements for medicines that are being supplied in Australia when the new measures commence.

#### **Item 1 – Subregulations 9A(1) and (1A)**

Subregulation 9A(1) of the TG Regulations makes it clear that the sponsor of therapeutic goods that are specified in Part 1 of Schedule 10 to the TG Regulations (principally, these are prescription medicines) must not supply the goods if the sponsor does not also supply with the goods written information about them that meets the requirements for a patient information document set out in Schedule 12 to the TG Regulations (in practice, a sponsor may do so by ensuring that such information is available or accessible for patients).

It is an offence for a sponsor to not comply with this requirement, with a maximum penalty level of 10 penalty units.

Subregulation 9(1A) of the TG Regulations sets out an equivalent offence in relation to over the counter medicines, in respect of the requirements for a patient information document for such products set out in Schedule 13 to the TG Regulations.

This item makes a minor amendment to each of subregulations 9A(1) and (1A) of the TG Regulations, to replace the reference to “patient information document” with a reference to “consumer medicine information document”, to improve clarity and reflect the broader use and better understanding of “consumer medicine information document”.

#### **Item 2 – Paragraph 9B(3)(a)**

This item makes a consequential amendment to paragraph 9B(3)(a) of the TG Regulations, to also replace a reference to “patient information document” with “consumer medicine information document”.

### **Item 3 – Schedule 12**

As part of measures to improve the clarity and usefulness of CMI, this item would repeal this schedule and introduce a new Schedule 12.

The new Schedule 12 continues to require, as the current Schedule 12 does, that such documents be written in English, be clearly legible, written in language that will be easily understood by patients and be consistent with the relevant product information.

In addition, the new Schedule 12 also requires that CMI documents for prescription medicines must set out all the information required by the “TGA Consumer Medicine Information (Prescription Medicine) Template”, published by the TGA (for free) on its website ([www.tga.gov.au](http://www.tga.gov.au)) (“the Prescription Medicine Template”), and must do so in the same order as the template. Further, if a consumer information document is supplied electronically, it must be in the form of a PDF or HTML file.

It is important to note that the intention is to adopt the template as it is at the commencement of this Schedule, and not to purport to adopt it as in force from time to time.

It is also important to note that, under heading 2 of the new Schedule 12, if the CMI document for a prescription medicine is enclosed within, or set out on or affixed to a surface of, the packaging for such a medicine, it would not be required to be in the same order as the Prescription Medicine Template, or to include the summary that forms part of that template.

This reflects that in such circumstances the CMI document is less flexible and less able to accommodate the summary component of the Prescription Medicine Template.

### **Item 4 – Schedule 13**

This item sets out equivalent amendments to Schedule 13 to the TG Regulations, in relation to over the counter medicines and the TGA’s new TGA Consumer Medicine Information (Non-prescription Medicine) Template (“the Non-prescription Medicine Template”) (also available for free from the TGA’s website [www.tga.gov.au](http://www.tga.gov.au)), to those that are introduced for prescription medicines by item 3 above.

The main difference for over the counter medicines, in comparison with prescription medicines, in relation to CMI documents, is that under the Non-prescription Medicine Template the use of the summary component of that document will be optional, whereas the use of the summary is a required component of the Prescription Medicine Template.

This principally reflects that such documents would generally contain less information for over the counter medicines in comparison with prescription medicines, as over the counter medicines are more likely to be associated with a longer history of established safe use.

## Schedule 7 – Handling and testing of samples

### **Introduction**

Part 5 of the TG Regulations sets out requirements and arrangements relating to the handling and testing of samples of therapeutic goods by analysts at the TGA, including in particular samples of therapeutic goods that are provided by sponsors in compliance with statutory conditions of the entry of their goods in the Register to make such samples available.

These requirements and arrangements are principally designed to ensure the integrity of test results of samples tested by the TGA for the purpose of identifying whether the goods are safe for use and are complying with important elements of the regulatory scheme, such as applicable standards.

The provisions of Part 5 have not been updated for quite some time, and there is now a need to update them, in particular to improve clarity and remove duplication and inconsistencies.

### **Item 1 – Regulation 2 (definition of *official analyst*)**

This item makes a minor amendment to regulation 2 of the TG Regulations, to reflect the change that is introduced by item 2 below.

### **Item 2 – Subregulation 23(1)**

This item amends subregulation 23(1) of the TG Regulations to introduce a small number of new definitions for the purposes of Part 5 of the TG Regulations – for ‘analyst’, ‘appropriately fastened and sealed’ and ‘official analyst’.

The definition of ‘official analyst’ is to be moved from regulation 2 to subregulation 23(1) by items 1 and 2, taken together.

The introduction of a definition of ‘analyst’ reflects that as part of the modernisation and streamlining of Part 5, the Secretary will have the power to appoint persons with appropriate qualifications and experience as analysts or official analysts to test samples of therapeutic goods.

### **Item 3 – Subregulation 23(1) (definition of *relevant test*)**

This item amends subregulation 23(1) of the TG Regulations to repeal the definition of ‘relevant test’ from that subregulation, as this term would not be needed as a result of the amendments proposed to improve the clarity of regulation 28 below.

### **Item 4 – Subregulation 23(1) (definition of *responsible analyst*)**

This item amends subregulation 23(1) of the TG Regulations to make it clear that the definition of ‘responsible analyst’ in that subregulation means an analyst or an official analyst who is nominated as a responsible analyst under paragraph 25(3)(c) of the TG Regulations.

### **Item 5 – Subregulation 25(2)**

Subregulation 25(2) of the TG Regulations currently provides that, for Part 5 of the TG Regulations, a sample of therapeutic goods is appropriately fastened and sealed if it is fastened and sealed in a vessel or package that is marked with the name and address of the sponsor of the goods or the person from whom it was taken, and in such a manner as to prevent the opening of the vessel or package or the removal of the name and address without breaking the seal.

Some of this terminology is outdated, particularly the reference to “vessel” and the requirement for the name and address of the sponsor or person from whom the sample was taken to, in all instances, be identified.

This item therefore repeals and substitute a new subregulation 25(2) to update these requirements.

The new subregulation 25(2) makes it clear that a sample of therapeutic goods is appropriately fastened and sealed if it is fastened and sealed in a container or package that is marked with a unique identification number, or with the name and address of the sponsor or the person from whom the sample was taken, and in such a manner as to prevent the opening of the container or package or the removal of the unique identification number or name and address without breaking the seal.

This will allow authorised officers, when taking samples, or sponsors when providing samples of their goods to the Secretary in accordance with paragraphs 28(5)(h) or 41FN(2) of the Act, to mark such samples with a unique identification number rather than with relevant name and address details.

The new subregulation 25(2) also reflects that ‘container’ is a defined term in the Act.

#### **Item 6 – Regulation 25 (heading)**

This item makes a minor change to introduce a broader heading for regulation 25, to reflect the amendments that are made by items 7 and 9 below.

#### **Item 7 – Subregulation 25(1)**

Subregulation 25(1) of the TG Regulations currently provides that the Secretary may, in writing, appoint a person who has appropriate qualifications and experience to be an official analyst for the purposes of the TG Regulations.

To improve the efficiency of the TGA’s handling and testing of samples of therapeutic goods, this item would amend subregulation 25(1) of the TG Regulations, to allow the Secretary to appoint a person with the appropriate qualifications and experience to be an official analyst or an analyst for the purposes of the TG Regulations.

This will allow a greater number of persons with the appropriate qualifications and experience to be available to examine and test samples of therapeutic goods, and in so doing would support the TGA’s post-market monitoring of the safety and quality or performance of therapeutic goods.

#### **Item 8 – Subregulation 25(2)**

Currently under subregulation 25(2) of the TG Regulations, the Secretary is to maintain a register of the names of official analysts, and is to cause those names to be published in the *Gazette* or on the Department’s website from time to time.

However, this register is not considered necessary, and the requirement has led to concerns about the risk of inappropriate contacting or cyber-bullying of APS employees whose details may be included in such a register. The publication of the register could also lead to an increased risk of the generation of fraudulent certificates, using the names of published analysts.



As such, this item amends regulation 25 to repeal subregulation 25(2), as part of appropriate measures to protect the health and safety of employees.

#### **Item 9 – Paragraph 25(3)(c)**

Currently under paragraph 25(3)(c) of the TG Regulations, an official analyst may nominate another official analyst to be the responsible analyst for a sample of therapeutic goods (i.e. to be responsible for the examination and testing of the sample).

To improve the efficiency of the TGA’s handling and testing of samples of therapeutic goods, this item would, taken together with the changes to be introduced by item 8 above, allow an official analyst to nominate an analyst (i.e. a person with the appropriate qualifications and experience to analyse therapeutic goods, but who is not an official analyst) to be the responsible analyst for a sample of therapeutic goods.

This will allow a greater number of persons with appropriate qualifications and experience to undertake the examination and testing of samples of therapeutic goods, and in so doing would support the TGA’s post-market monitoring of the safety and quality or performance of therapeutic goods.

#### **Item 10 – At the end of regulation 25**

Under paragraph 25(3)(b) of the TG Regulations, an official analyst may determine the tests that are to be performed on a sample of therapeutic goods taken by an authorised officer or provided by a sponsor in compliance with their conditions of entry in the Register.

This item amends regulation 25 to introduce new subregulations 25(4) and (5) to the TG Regulations, to make clearer the relationship between the official analyst’s power in paragraph 25(3)(b) and the tests identified in regulation 28 of the TG Regulations.

New subregulation 25(4) makes it clear that if an official analyst determines a test under paragraph 25(3)(b) for the purpose of identifying whether particular goods comply with an applicable standard (for goods other than medical devices) or comply with the essential principles (for medical devices), the test must be a test covered by regulation 28.

New subregulation 25(5) also makes it clear that if an official analyst determines a test under paragraph 25(3)(b) for another purpose, the test is to be a test that the official analyst considers appropriate.

#### **Item 11 – Paragraph 26(2)(a)**

Currently under paragraph 26(2)(a) of the TG Regulations, an authorised officer who takes a sample of therapeutic goods must ensure that the sample is appropriately packaged, fastened and sealed.

To ensure greater consistency across Part 5 of the TG Regulations in relation to the handling requirements for samples of therapeutic goods, this item amends paragraph 26(2)(a) to remove the reference to “packaged”, so that the requirement in that paragraph will mirror the terms of new subregulation 23(2) (item 5 above refers).

### **Items 12 - 14 – Paragraph 26A(1)(a), subparagraphs 26A(1)(b)(i) and (ii) and paragraphs 27(1)(a) and (b)**

These items make equivalent amendments to paragraph 26A(1)(a), subparagraphs 26A(1)(b)(i) and (ii) and paragraphs 27(1)(a) and (b) of the TG Regulations, to remove the current reference in those paragraphs and subparagraphs to “packaged”.

### **Item 15 – Paragraph 27(2)(a)**

Regulation 27 of the TG Regulations sets out obligations for samples officers who receive samples of therapeutic goods from authorised officers or sponsors, and obligations for responsible analysts (i.e. analysts or official analysts nominated under paragraph 25(3)(c)) who collect such samples from the samples officer.

Paragraph 27(2)(a) of the TG Regulations currently requires that the responsible analyst must, as soon as practicable, collect the sample from the samples officer and arrange for an analysis of the sample by relevant tests to the extent the responsible analyst considers necessary to establish the matters mentioned in subparagraphs 27(2)(a)(i) and (ii).

To improve clarity, and to avoid confusion over whose responsibility it is to determine the tests that are to be performed on a sample, this item replaces the reference to “relevant tests to the extent the [responsible] analyst considers necessary” in paragraph 27(2)(a) with a clearer reference that identifies that the tests to which this requirement relates are the tests determined by the official analyst under paragraph 25(3)(b) of the TG Regulations to be the tests that are to be performed on the sample.

### **Item 16 – At the end of paragraph 27(2)(a)**

This item introduces a new subparagraph 27(2)(a)(iii) to the TG Regulations, with the effect that one of the matters that the responsible analyst must arrange for the testing of a sample to establish is whether, for a listed or assessed listed medicine, the medicine contains an ingredient that is not permitted for use in such a medicine under paragraph 26BB(1)(a) of the Act, or whether a requirement relating to the use of such an ingredient under paragraph 26BB(1)(b) of the Act has been contravened.

### **Item 17 – Regulation 28 (heading)**

This item introduces a new heading for regulation 28 of the TG Regulations, to make it clearer that the purpose of regulation 28 is to set out the tests that an official analyst may determine to be performed on a sample of therapeutic goods in order to identify whether the goods comply with an applicable standard (for goods other than medical devices) or the essential principles (for medical devices).

### **Item 18 – Subregulation 28(1)**

This item makes a minor amendment to subregulation 28(1) of the TG Regulations to remove the reference to “relevant” tests in that subregulation, as part of improving the clarity of the provisions in Part 5.

### **Item 19 – Paragraph 28(1)(b)**

Currently under paragraph 28(1)(b) of the TG Regulations, one of the tests that may be determined by an official analyst for the purpose of identifying whether a sample of therapeutic goods (other than a medical device) complies with an applicable standard is a test specified in a monograph in the British Pharmacopeia.

This item amends paragraph 28(1)(b) of the TG Regulations to also include a test specified in a monograph in the European Pharmacopoeia or the United States Pharmacopoeia-National Formulary.

This reflects that these pharmacopoeias are also standards under the definition of that term in subsection 3(1) of the Act.

**Item 20 – Paragraph 28(1)(c)**

Paragraph 28(1)(c) of the TG Regulations has the effect that one of the tests that may be determined by an official analyst for the purpose of identifying whether a sample of therapeutic goods (other than a medical device) complies with an applicable standard is a test specified in a monograph in the British Pharmacopoeia (Veterinary) in relation to that standard if, principally, the goods are for veterinary use.

This item repeals paragraph 28(1)(c), to reflect that the Act no longer provides for the regulation of goods that are for veterinary use.

**Item 21 – Subregulation 28(2)**

This item makes a minor amendment to subregulation 28(2) of the TG Regulations to remove the reference to “relevant” tests in that subregulation, to improve clarity (consistent with changes that are introduced by items 15 and 18 above).

**Item 22 – Regulation 29 (heading)**

This item introduces a new heading for regulation 29, to better reflect that, under regulation 29, it is the responsible analyst who must send copies of the certificate setting out the results of the testing of a sample of therapeutic goods.

**Item 23 – Subregulation 29(1)**

Subregulation 29(1) of the TG Regulations currently requires the responsible analyst to send a signed certificate to the sponsor of the goods that the responsible analyst has arranged for the testing of, setting out the results of the examination and analysis.

This item amends subregulation 29(1), principally to update this regulation by removing the requirement for the certificate to be signed and to make it clearer that it is the responsible analyst that must issue the certificate.

**Item 24 – Subregulations 29(2) and (3)**

Subregulation 29(2) of the TG Regulations currently requires the responsible analyst to send a copy of the certificate setting out the results of the examination and analysis of a sample of therapeutic goods to the Secretary and (if the sample was taken under subregulation 25(3)) the person from whom the sample was taken, if that person was not the sponsor.

Subregulation 29(3) of the TG Regulations currently requires the responsible analyst to do so (and to send the certificate to the sponsor under subregulation 29(1)) within a reasonable time after completing the testing.

In particular, the requirement for the responsible analyst to send a copy of the certificate to the Secretary is unnecessary, as the responsible analyst would be a person with appropriate qualifications and experience within the TGA.

This item repeals subregulations 29(2) and (3) and introduces a new subregulation 29(2) to replace those subregulations, principally to remove this unnecessary requirement.

**Item 25 – Subregulation 29(4)**

This item makes a minor amendment to subregulation 29(4) of the TG Regulations, to reflect the changes to be introduced by item 24 above.

**Item 26 – Paragraph 29(4A)(a)**

This item makes a minor amendment to subregulation 29(4A) of the TG Regulations, to reflect the changes to be introduced by item 24 above.

**Items 27 - 30 – Subregulations 29(5) and (6)**

These items make minor amendments to subregulations 29(5) and paragraph 29(6)(a) of the TG Regulations, principally to reflect the changes to be introduced by item 23 above.

**Item 31 – Regulation 30 (heading)**

This item introduces a new heading for regulation 30 of the TG Regulations, to make it clearer that regulation 30 sets out the arrangements in relation to where a person asks for a review of the results of the analysis undertaken in relation to their goods.

**Items 32 and 33 – Paragraph 30(1)(a) and subregulation 30(2)**

These items make minor amendments to introduce a new paragraph 30(1)(a) and to amend subregulation 30(2) of the TG Regulations, to reflect the changes to be introduced by item 24 above.

**Items 34 and 35 – Subregulation 30(4)**

Subregulation 30(4) of the TG Regulations currently provides that a person is not to be regarded as having sent the Secretary evidence establishing that their goods comply with a particular standard or requirement or the essential principles unless the person has sent the Secretary a certificate of an analyst with appropriate qualifications and experience that sets out that the analyst has tested a part of the same sample of the goods as that tested by the responsible analyst and the results of that analysis and the tests used in the analysis.

These items amends subregulation 30(4) to make it clearer that the analyst referred to in subregulation 30(4) is a third party – i.e. is an analyst from outside the TGA, whose analysis is arranged by the sponsor or other person from whom the sample was taken.

**Item 36 – Subregulation 30(5)**

This item makes a minor amendment to subregulation 30(5) of the TG Regulations, to reflect the changes to be introduced by items 7 and 9 above.

**Items 37 – 41 – Subregulation 30(6)**

These items make a number of minor amendments to improve the clarity of subregulation 30(6) of the TG Regulations.

Under subregulation 30(5) of the TG Regulations, subregulation 30(6) applies where a sponsor or other person from whom a sample of therapeutic goods is taken has asked for a review of the results of the analysis of their goods and has sent the Secretary evidence that their goods do comply with the relevant applicable standard or other requirement or essential

principles, based on an analysis by a third party analyst (arranged by the sponsor or person) of a part of the same sample of the goods as tested by the responsible analyst.

In such circumstances, subregulation 30(6) requires the Secretary, at the request of the sponsor, to direct that the steps set out in paragraphs 30(6)(a) or (b) of the TG Regulations be taken, in order to verify the results of the third party analyst.

The only exception to this is where the results of the third party analyst shows a lack of homogeneity in the sample.

The steps in paragraphs 30(6)(a) or (b) involve directing the official analyst to send so much of the sample as remains unimpaired or (if no part of the sample remains unimpaired) a new sample to be taken from the same batch as the original sample, to an analyst agreed upon by the sponsor or person or (in the absence of such an agreement) an analyst nominated by the Secretary (in practice in most instances this would involve agreeing upon an independent analyst unrelated to the TGA or the sponsor or person).

Item 37 amends subregulation 30(6) to remove the reference to “at the request of the sponsor” in relation to the requirement for the Secretary to direct that the steps in (a) or (b) be undertaken, to make it clear that the Secretary must take such action in order to verify the results obtained by the sponsor or person, and that the sponsor’s request is not a condition precedent for such action.

Item 38 amends subregulation 30(6) to both reflect the changes to be introduced by items 7 and 9 above, and to make it clear that the Secretary could direct any official analyst to take the step mentioned in paragraph 30(6)(a), and that this would not be limited to the official analyst who determined the tests to be performed on the sample under paragraph 30(5)(b) of the TG Regulations.

Items 39 and 41 make minor amendments to subregulation 30(6), principally to reflect the changes to be introduced by items 7 and 9 above and to avoid confusion by using “person” rather than “analyst” to describe the person whom the Secretary must direct that a part of a sample or new sample must be sent under subregulation 30(6).

Item 40 makes a minor amendment to subregulation 30(6) to reflect the changes to be introduced by item 36 above.

#### **Items 42 - 45 – Subregulation 30(7)**

Items 42, 44 and 45 make minor amendments to improve the clarity of subregulation 30(7) of the TG Regulations, by making it clearer that subregulation 30(7) applies if a sample of therapeutic goods is sent to a person (in most instances, an independent analyst) mentioned in subregulation 30(6).

Item 43 makes a minor amendment to paragraph 30(7)(a) of the TG Regulations, to reflect the changes to be introduced by items 7 and 9 above.

#### **Items 46 and 47 – Subregulation 30(9)**

These items make minor amendments to subregulation 30(9) of the TG Regulations, principally to reflect that it is the responsible analyst, rather than the official analyst, whose findings would be reflected in a certificate issued under subregulation 29(1).

**Items 48 - 51 – Subregulations 30(10) and (11)**

These items make minor amendments to improve the clarity and readability of subregulations 30(10) and (11) of the TG Regulations and to reflect the changes to be introduced to subregulation 30(6) of the TG Regulations by item 39 above.

## **Schedule 8 – Fee waivers for certain requests relating to prescription opioids**

### ***Therapeutic Goods Regulations 1990***

#### **Introduction**

Concerns have arisen in recent years over the safe use of prescription medicines that are pharmaceutical opioids.

These products are now responsible for more deaths and poisoning hospitalisations in Australia than illegal opioids such as heroin. Every day in Australia nearly 150 hospitalisations and 14 emergency department admissions involve opioid harm, and 3 people die from drug-induced deaths involving opioid use.

These figures are too high, and the Australian Government has asked the TGA to play a role in tackling the problem. To help reduce the harm, the TGA conducted a public consultation on prescription opioids in 2018, for which a total of 98 submissions were received, with feedback indicating strong and consistent support from all stakeholders for a regulatory response.

Following that consultation, the TGA established the Opioid Regulatory Advisory Group (ORAG), which included representatives from a range of health professional and consumer organisations, to provide independent, expert advice on this issue.

Through the above consultation and the support of ORAG, a number of actions have been identified to help address the problems associated with prescription opioids.

These include the use of smaller pack sizes for the treatment of acute pain following injury or surgery to avoid or reduce the risk of addiction and reduce the number of unused opioids that may be circulating in the community, and the use of relevant warning statements, including a boxed warning at the start of the Product Information (PI) and CMI for such products, alerting consumers and health professionals to the potential for harmful and hazardous use of these products.

The amendments introduced by this Schedule support such measures, principally by providing that where sponsors of prescription opioids request that the Secretary vary the entry for their goods in the Register to introduce a smaller pack size or to add a boxed warning and other warning or precaution statements about the goods to the PI and CMI, the Secretary must waive the fee that would otherwise apply in relation to such requests.

#### **Item 1 – After subregulation 45(6)**

Regulation 45 of the TG Regulations provides for the waiver or reduction of fees in Schedules 9 or 9A to the TG Regulations in a range of specified circumstances.

This item introduces new subregulations 45(7) – (9) to introduce a fee waiver mechanism for certain kinds of requests by sponsors to vary the entry in the Register for their prescription opioid medicines.

New subregulation 45(7) makes it clear that the Secretary must waive a fee prescribed in Schedule 9 in relation to a request by a sponsor of a prescription opioid under subsections 9D(2) or (3) of the Act to vary the entry in the Register for their medicine if:

- the request is made in the period beginning on the commencement of new subregulation 45(7) (on the day after the registration of the Regulations) and ending at the end of 31 December 2020; and
- the request is made solely for an opioid reform purpose, as described in proposed new subregulation 45(8), or for an opioid reform purpose and an associated variation of product information purpose as described in proposed new subregulation 45(9).

New subregulation 45(8) sets out that a request for a variation to an entry in the Register for a prescription opioid will be for an opioid reform purpose if it is made:

- under subsection 9D(2) of the Act, to either add a warning or precaution in relation to the goods that does not include any comparison of the goods with any other therapeutic goods by reference to qualify, safety or efficacy, or to reduce the class of persons for whom the goods are suitable; or
- under subsection 9D(3) of the Act, to introduce a smaller pack size in relation to the goods.

New subregulation 45(9) sets out that an opioid reform request will be for an associated variation of product information request if it is made:

- under subsection 9D(3) of the Act; and
- paragraphs 9D(3)(b)-(c) are satisfied in relation to the request; and
- the request is made for the purpose of varying product information in relation to the prescription opioid, so that the product information is in the form approved under section 7D of the Act in relation to that product.

These measures are designed to encourage sponsors of prescription opioids to submit requests to vary the entries the Register for their products to introduce smaller pack sizes or to add appropriate warning statements or reduce the class of persons for whom their products are suitable, and to do so in a timely manner before the end of 2020.

In so doing, it is intended that these measures will contribute to the safer and more effective use of these high risk medicines.



## **Schedule 9 – Other amendments**

### **Introduction**

This Schedule contains a small number of more minor amendments to the TG Regulations, including in relation to fee waiver for certain requests to vary an entry in the Register for a registered medicine to update product information and to provide for a power for authorised officers to inspect the premises of certain kinds clinical trials.

### **Part 1 – Fee waiver for requests to vary product information for medicine**

#### ***Therapeutic Goods Regulations 1990***

##### **Item 1 – At the end of regulation 45**

Prescription medicines, and some registered over the counter medicines, have product information – defined in subsection 3(1) of the Act as information relating to the safe and effective use of therapeutic goods, including information regarding the usefulness and limitations of the goods.

Under section 7D of the Act, the Secretary may approve a form of product information in relation to medicine (and may approve different forms for different medicines or different classes of medicine).

In 2018, the approved form for product information for prescription medicines was updated, under section 7D.

As part of this update, sponsors of prescription medicine are to be provided with a period of time (1 January – 31 December 2020) in which requests to vary the entry in the Register for their medicine to update their product information so that it complies with the new approved form will not attract a fee.

This is designed to assist any sponsors who have not already sought a variation to their entry in the Register to update their product information to do so by the end of 2020.

Accordingly, this item amends regulation 45 of the TG Regulations to require the Secretary to waive a fee prescribed in Schedule 9 for requests to vary an entry in the Register for a registered medicine, if:

- the requirements of paragraphs 9D(3)(b)-(c) of the Act are satisfied in relation to the request; and
- the request is made solely for the purpose of varying the product information for the medicine so that it is in the form approved under section 7D of the Act in relation to the medicine; and
- the request is made in the period beginning on 1 January 2020 and ending at the end of 31 December 2020.

## **Part 2 – Clinical trials**

### ***Therapeutic Goods Regulations 1990***

#### **Item 2 – Regulation 2**

This item introduces a definition of ‘Practice Guideline’ to regulation 2 of the TG Regulations, which makes it clear that this term has the meaning given by paragraph 12AB(2)(a) of the TG Regulations.

#### **Item 3 – Regulation 2 (Definition of Practice Guidelines)**

This item repeals the current definition of ‘Practice Guidelines’ in regulation 2 of the TG Regulations, as this definition is no longer needed in light of the introduction of a definition for ‘Practice Guideline’ by item 2 above.

#### **Items 4 and 5 – Paragraph 12AB(2)(a)**

This item makes minor amendments to paragraph 12AB(2)(a) of the TG Regulations, to reflect that the correct title of the document mentioned in that paragraph is the “Guideline for Good Clinical Practice”, rather than the “Guidelines for Good Clinical Practice”, and to correct the name of the organisation responsible for the publication of that document.

#### **Item 6 – Subregulation 12AC(1)**

Regulation 12AC of the TG Regulations set out the powers of an authorised officer in relation to a clinical trial mentioned in regulation 12AB of the TG Regulations (these are clinical trials approved by the Secretary under subsections 19(1)(b) of the Act (for medicines) or 32CK(1)(e) of the Act (for biologicals).

This item amends subregulation 12AC(1) of the TG Regulations, to make it clear that authorised officers also have the powers set out in paragraphs 12AC(1)(a) – (f) of the TG Regulations in relation to a clinical trial mentioned in item 3 of Schedule 5A to the TG Regulations.

#### **Item 7 – Paragraph 12AD(a)**

This item makes a minor amendment to paragraph 12AD(a) of the TG Regulations, to reflect the changes to be introduced by items 2 and 4 above.

#### **Item 8 – Schedule 5A (at the end of the cell at table item 3, column 3)**

Under item 3 of Schedule 5A to the TG Regulations, therapeutic goods used solely for experimental purposes in humans (i.e. clinical trials) are exempt from the requirement to be included in the Register (under section 18 of the Act and subregulations 12(2) and (3) of the TG Regulations), subject to the conditions set out in column 3 for that item.

These conditions include, for example, that before starting to use the goods the sponsor of the goods must notify the Secretary (using the approved form) that the sponsor intends to sponsor the trial.

This item amends item 3 to introduce 3 new such conditions. Principally, these new conditions make it clear that:

- the sponsor must comply with requests by an authorised officer, whether made before or after the start of the trial, to provide information about the conduct of the trial (whether

the sponsor is themselves conducting the trial or another body or organisation is doing so for the sponsor);

- if a body or organisation is conducting the trial for the sponsor, the body or organisation must comply with requests by an authorised officer, whether before or after the start of the trial, to provide information about the trial; and
- the sponsor (if the sponsor is conducting the trial themselves) or the body or organisation conducting the trial for the sponsor must allow an authorised officer to do the things mentioned in regulation 12AC (these include, for example, entering the site of a clinical trial and inspecting, examining, taking measurements of or conducting tests on any thing on the site that relates to the trial).

This measure is designed to address concerns that arisen in recent years that, while there are powers for authorised officers to enter and inspect the site of a clinical trial approved by the Secretary under the Act, there is currently no equivalent power for clinical trials that are authorised by item 3 of Schedule 5A.

These amendments will therefore place both kinds of clinical trials on an equal footing in this regard, and support the safe use of therapeutic goods in the latter kind of trial. This is an important safety initiative for clinical trial participants in particular.

### **Part 3 – Nappy rash products**

#### ***Therapeutic Goods Regulations 1990***

##### **Item 9 – Schedule 5 (after table item 8A)**

This item amends Schedule 5 to the TG Regulations, to introduce a new exemption from the requirement to be included in the Register for certain nappy rash products.

The products that are the subject of the new exemption are unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action).

It is important to note that this exemption only applies for topical products that are for protecting against or providing relief from nappy rash in the manner noted above, and is exclusive of products that are intended to protect against or provide relief from any other skin condition (including where such products are also for protecting against, or providing relief from, nappy rash).

##### **Item 10 – Schedule 7 (after table item 11)**

Schedule 7 to the TG Regulations lists therapeutic goods that are exempt from the requirement to be covered by a manufacturing licence issued under Part 3-3 of the Act.

This item amends Schedule 7 to exempt the same nappy rash products identified in item 9 above from the requirement to be covered by a manufacturing licence (raising the same matter in relation to the scope of this exemption as noted above for the exemption introduced by item 9).

## **Part 4 – Other amendments**

### ***Therapeutic Goods Regulations 1990***

#### **Item 11 – Regulation 2 (note 2 to the definition of *Australian Approved Names List*)**

This item makes a minor amendment to note 2 under the definition of ‘Australian Approved Names List’ in regulation 2 of the TG Regulations, to reflect a recent change to the name of the TGA document referred to in that note.

#### **Items 12 and 13 – Subparagraphs 16M(1)(b)(i) and (ii)**

These items make very minor amendments to each of subparagraphs 16M(1)(b)(i) and (ii) of the TG Regulations to correct inadvertent typographical errors in those subparagraphs.

## Schedule 10 – Application, saving and transitional provisions

### ***Therapeutic Goods (Medical Devices) Regulations 2002***

#### **Item 1 – in the appropriate position in Part 11**

This item introduces a new Division 11.10 to the MD Regulations, which sets out application and transitional provisions relating to the following measures in the Regulations:

- the reclassification of medical devices (Subdivision B of the new Division);
- programmed or programmable medical devices or software that is a medical device (Subdivision C of the new Division);
- personalised medical devices (Subdivision D of the new Division); and
- IVD companion diagnostics (Subdivision E of the new Division).

#### **Subdivision A – Definitions**

##### **Regulation 11.38 - Definitions**

This regulation sets out definitions for a small number of terms that are common to all of the application, saving and transitional provisions in new Division 11.10, for:

- ‘amending regulations’ – meaning these Regulations;
- ‘finally determined’ – meaning, for an application, the first time both of the following conditions are met:
  - a decision has been made as to whether or not to grant the application; and
  - there is no longer any possibility of a change in the outcome of the decision;
- ‘unique product identifier’ – meaning, in relation to a medical device, the unique product identifier given to the device by its manufacturer to identify the device and any variants.

#### **Subdivision B – Reclassification of medical devices**

##### **Regulation 11.39 - Definitions**

This regulation sets out definitions for a small number of terms that are common to only the measures in Subdivision B of new Division 11.10, in relation to the reclassification of medical devices, for:

- ‘inclusion day’ – meaning, for an entry of a kind of transitional medical device in the Register, the day on which the inclusion of that kind of device in the Register commences;
- ‘pre-commencement entry’ – meaning an entry of a kind of transitional medical device in the Register if that kind of medical device is included in the Register because of an application made before 25 August 2020 (whether the inclusion day for the entry occurred before, on or after 25 August 2020);
- ‘transitional AIMD device’ – meaning a transitional medical device of a kind mentioned in column 1 of item 2 of the table in the definition of ‘transitional medical device’; and
- ‘transitional medical device’ – meaning a medical device of a kind mentioned in column 1 of an item in the table under this definition if the medical device is, immediately before 25 August 2020, included in the Register with the classification mentioned in column 2 of that table or if, on 25 August 2020, the device was the subject of an application for inclusion in the Register with the classification mentioned in column 2 and the application had not been finally determined.

This table identifies the current classification levels for all of the kinds of devices which would be reclassified as a result of the amendments in Parts 1-6 of Schedule 1 to the Regulations.

**Regulation 11.40 – Transitional medical devices – application of amendments**

Parts 1-6 of Schedule 1 of the Regulations amends the MD Regulations to reclassify (and in most instances up-classify) the kinds of medical devices to which those Parts relate.

Under paragraph 41GN(1)(f) of the Act, a kind of medical device may be cancelled from the Register if the Secretary is satisfied that a certification made by the device sponsor when applying for inclusion in the Register is (relevantly) no longer correct – including the certification that would have been made by the sponsor under paragraph 41FD(c) of the Act about the correct classification for their device.

For new applications for inclusion in the Register made on or after 25 August 2020, subregulation 11.40(1) makes it clear that the new classification rules introduced by Parts 1-6 of Schedule 1 would apply from that date.

However, to avoid transitional medical devices being liable to be cancelled following the commencement of Schedule 1 on 25 August 2020, and to allow sponsors and manufacturers of transitional medical devices time to prepare for the new requirements, new regulation 11.40 in this Part sets out transitional arrangements for affected products.

The transitional provisions in subregulations 11.40(2)-(5) apply if, immediately before the commencement of Parts 1-6 on 25 August 2020, an affected kind of device is a transitional medical device (as defined by regulation 11.39).

The transitional provisions provide a period of time – principally, until 1 November 2024 – for sponsors of transitional devices to re-apply for marketing approval for their kind of device under the new classification, and to prepare for the new requirements.

If they do so before then, the new rules would not apply to their kind of device until that application is finally determined or it lapses under section 41FK of the Act or is withdrawn.

However, it is important to note that this is dependent on sponsors of transitional devices providing the Secretary with the notification required under new regulation 11.41, to be introduced by this Subdivision.

**Regulation 11.41 – Transitional medical devices – Secretary must be notified of unique product identifiers of devices supplied under pre-commencement entries**

New regulation 11.41 introduces, for the purposes of subsection 41FN(5A) of the Act, a statutory condition applying to the inclusion of a transitional device in the Register, under which a sponsor of such a product must notify the Secretary, before the later of 25 February 2021 and the day 2 months after the kind of device is included in the Register, of:

- the unique device number assigned to that kind of device by the Secretary under section 41FL of the Act; and
- the unique product identifier given to each such device by its manufacturer, that the sponsor is supplying in Australia.

If a sponsor of a transitional device does not provide the required notification, then the new rules will apply to their kind of device on and after the later of 25 February 2021 and the day 2 months after the kind of device is included in the Register.

### **Regulations 11.42 and 11.43 – Transitional medical devices – selecting applications for auditing, and waiver of certain application fees**

Separately, new regulations 11.42 and 11.43 respectively ensure that any transitional medical devices that are active implantable medical devices that have been re-classified from Class AIMD to Class III devices by the amendments in Part 2 will not be subject to an application audit under regulation 5.3 of the MD Regulations, and that the Secretary must waive the application fee for such an application that would otherwise apply under paragraph (b) of item 1.5 of Schedule 5 to the MD Regulations (this waiver requirement would apply until 24 August 2021).

This reflects that these products have, or will have, previously been subject to such an audit as part of their application for inclusion in the Register under the current AIMD medical device classification and will, in relation to the fee waiver mechanism, provide an incentive for sponsors to apply early in the transitional period to apply to include their products in the Register as Class III devices.

### **Subdivision C – Programmed or programmable medical device or software that is a medical device**

#### **Regulation 11.44 - Definitions**

New regulation 11.44 sets out definitions for a small number of terms that are common to only the measures in Subdivision C of new Division 11.10, in relation to programmed or programmable medical devices, or software that is a medical device, for:

- ‘inclusion day’ – meaning, for an entry of a kind of medical device in the Register, the day on which the inclusion of that kind of device in the Register commences;
- ‘transitional kind of medical device’ – meaning a kind of medical device included in the Register because of an application made before 25 August 2020 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

#### **Regulation 11.45 Programmed or programmable medical device or software that is a medical device – classification rules**

Part 1 of this Schedule introduces amendments that reclassify (and in most instances up-classify) the medical device classification of a range of medical devices that are programmed or programmable medical devices, or software that is a medical device.

Under paragraph 41GN(1)(f) of the Act, a kind of medical device may be cancelled from the Register if the Secretary is satisfied that a certification made by the device sponsor when applying for inclusion in the Register is (relevantly) no longer correct – including the certification that would have been made by the sponsor under paragraph 41FD(c) of the Act about the correct classification for their device.

For new applications for inclusion in the Register made on or after 25 August 2020, new subregulation 11.45(1) makes it clear that the new classification rules would apply from that date.

However, to avoid transitional kinds of medical devices being liable to be cancelled when the changes to device classifications for such products commence on 25 August 2020, and to

allow sponsors and manufacturers of transitional kinds of medical devices time to prepare for the new requirements, new regulation 11.45 sets out transitional arrangements for affected products.

The transitional provisions in new subregulations 11.45(2)-(5) apply if, immediately before the commencement of Parts 1-6 on 25 August 2020, an affected software device is a transitional kind of medical device (as defined in regulation 11.44).

The transitional provisions provide a period of time – principally, until 1 November 2024 – for sponsors of transitional devices to re-apply for marketing approval for their kind of device under the new classification, and to prepare for the new requirements.

If they do so before then, the new rules will not apply to their device until that application is finally determined or it lapses under section 41FK of the Act or is withdrawn.

However, it is important to note that this is dependent on sponsors of transitional devices providing the Secretary with the notification required under new regulation 11.46, to be introduced by this Subdivision.

#### **Regulation 11.46 – Secretary must be notified in relation to a transitional kind of medical device**

New regulation 11.46 introduces, for the purposes of subsection 41FN(5A) of the Act, a statutory condition applying to the inclusion of a transitional kind of medical device in the Register that is a programmed or programmable medical device or software that is a medical device.

Under this condition, a sponsor of such a product must notify the Secretary, before the later of 25 February 2021 and the day 2 months after the kind of device is included in the Register, of:

- the unique device number assigned to that kind of device by the Secretary under section 41FL of the Act; and
- the unique product identifier given to each such device by its manufacturer, that the sponsor is supplying in Australia.

If a sponsor of a transitional kind of medical device does not provide the required notification, then the new rules will apply to their kind of device on and after the later of 25 February 2021 and the day 2 months after the kind of device is included in the Register.

#### **Regulation 11.47 – Programmed or programmable medical device, or software that is a medical device – essential principles**

Subregulation 11.47(1) makes it clear that new clause 13B of Schedule 1 to the MD Regulations, as introduced by Schedule 2 of these Regulations (in relation to requiring the current version number and current build number of software to be accessible and identifiable for users), applies on and after 25 August 2020 for new devices for which inclusion in the Register is sought from that date.

Subregulation 11.47(2) makes it clear that for software that is a transitional kind of medical device (as defined in regulation 11.44), new clause 13B will apply on and after 1 November 2024.



## **Subdivision D – Personalised medical devices**

### **Regulation 11.48 – Definitions**

New regulation sets out definitions for a small number of terms that are common to only the measures in Subdivision D of new Division 11.10, in relation to personalised medical devices, for:

- ‘inclusion day’ – meaning, for an entry of a kind of medical device in the Register, means the day on which the inclusion of that kind of device in the Register commences; and
- ‘transitional kind of medical device’ – meaning a kind of medical device included in the Register because of an application made before 25 August 2020 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

### **Regulation 11.49 – Personalised medical devices – reports**

New regulation 11.49 makes it clear that new subregulation 10.3A(1) and (2) would only apply to custom-made medical devices that are, respectively, manufactured in, or imported into, Australia, on or after 25 August 2020.

### **Regulation 11.50 – Personalised medical devices – conformity assessment procedures**

New regulation 11.50 makes it clear that the amendments of clause 7.2, and the repeal and substitution of subclause 7.6(2), of Schedule 3 to the MD Regulations made by Schedule 3 to these Regulations applies in relation to a medical device that is manufactured on or after 25 August 2020.

### **Regulation 11.51 – Personalised medical devices - exemptions**

New regulation 11.51 sets out saving and application provisions in relation to the amendments that would be made in relation to the exemption of custom-made medical devices and patient-matched medical devices in Part 4 of Schedule 3 of the Regulations.

Subregulation 11.51(1) saves the current exemption for custom-made medical devices – in item 1.5 of Part 1 of Schedule 4 to the MD Regulations - by providing that it continues to apply to a custom-made medical device (within the meaning of that term immediately before the commencement of these amendments on 25 August 2020) that is manufactured before that day, or that is manufactured on or after that day if the request from the health professional to manufacture it was made before that day.

Subregulation 11.51(2) makes it clear that the new exemption for custom-made medical devices – new item 2.12 of Part 2 of Schedule 4 – applies in relation to a custom-made medical device that is manufactured on or after 25 August 2020, where the request from the health professional for its manufacture is made on or after that day.

Subregulation 11.51(3) makes it clear that the new exemption for patient-matched medical devices – new item 2.13 of Part 2 of Schedule 4 – applies in relation to a patient-matched medical device if:

- it is manufactured on or after 25 August 2020 and before 1 November 2024; and
- before 25 August 2020, information about the device is given to the Secretary in accordance with regulation 10.3 of the MD Regulations (principally, regulation 10.3 requires a manufacturer or sponsor of a custom-made medical device to notify the Secretary of the manufacturer’s or sponsor’s name and address, and description of such devices being custom-made by the manufacturer).

### **Regulation 11.52 – Personalised medical devices – classification rules**

New regulation 11.52 sets out transitional arrangements in relation to the amendments that are to be made in relation to the classification of personalised medical devices by Part 5 of Schedule 3 to the Regulations.

Most of the medical devices that are not covered by the current clause 5.4 classification rule but that are covered by the new clause 5.4 (e.g. anatomical models) are currently classified as Class I medical devices, principally under the classification rule in clause 2.1 of Schedule 2 to the MD Regulations (which provides that a non-invasive medical device is classified as Class I, unless the device is classified at a higher level under another clause in Parts 2, 4 or 5 of Schedule 2).

Under paragraph 41GN(1)(f) of the Act, a kind of medical device may be cancelled from the Register if the Secretary is satisfied that a certification made by the device sponsor when applying for inclusion in the Register is (relevantly) no longer correct – including the certification that would have been made by the sponsor under paragraph 41FD(c) of the Act about the correct classification for their device.

Subregulation 11.52(1) makes it clear that the new clause 5.4, as substituted by Schedule 3 of the Regulations, would apply on and after 25 August 2020 in relation to an application for a kind of medical device to be included in the Register that is made on or after 25 August 2020, and to a kind of medical device that is included in the Register as a result of such an application.

However, to avoid transitional kinds of medical devices being liable to be cancelled when the changes to device classifications commence on 25 August 2020, new regulation 11.52 sets out transitional arrangements for affected products.

The transitional provisions in subregulations 11.52(2)-(5) apply if, immediately before the commencement of new clause 5.4 on 25 August 2020, an affected kind of device is a transitional kind of medical device (as defined in new regulation 11.48).

The transitional provisions provide a period of time – principally, until 1 November 2024 – for sponsors of transitional kinds of medical devices to re-apply for marketing approval for their kind of device under the new classification, and to prepare for the new requirements.

If they do so before then, the new rules would not apply to their device until that application is finally determined or it lapses under section 41FK of the Act or is withdrawn.

However, it is important to note that this is dependent on sponsors of transitional devices providing the Secretary with the notification required under new regulation 11.53, to be introduced by this Part.

### **Regulation 11.53 – Secretary must be notified in relation to a transitional kind of medical device**

New regulation 11.53 introduces for the purposes of subsection 41FN(5A) of the Act, a statutory condition applying to the inclusion of a transitional kind of medical device in the Register that is a personalised medical device of a kind that would be covered by the classification rules in Part 5 of Schedule 3 (e.g. anatomical models).

Under this condition, a sponsor of such a product must notify the Secretary, before the later of 25 February 2021 and the day 2 months after the kind of device is included in the Register, of:

- the unique device number assigned to that kind of device by the Secretary under section 41FL of the Act; and
- the unique product identifier given to each such device by its manufacturer, that the sponsor is supplying in Australia.

If a sponsor of a transitional kind of medical device does not provide the required notification, then the new rules will apply to their kind of device on and after the later of 25 February 2021 and the day 2 months after the kind of device is included in the Register.

### **Subdivision E – IVD Companion diagnostics**

#### **Regulation 11.54 – IVD companion diagnostics**

New subregulation 11.54(1) makes it clear that the amendment of paragraph 5.3(1)(j) by Schedule 4 of the Regulations (in relation to the selection of applications for inclusion in the Register for audit involving IVD companion diagnostics) applies to applications for inclusion in the Register that are made on or after 1 February 2020.

New subregulations 11.54(2)-(5) have the effect that the amendments made by Schedule 4 of the Regulations in relation to the classification of IVD companion diagnostics, and the circumstances in which a medical device is taken to be of the same kind as another, will not apply until 1 July 2022 for an IVD companion diagnostic that, immediately before 1 February 2020:

- was either a Class 4 in-house IVD medical device or an IVD medical device other than an in-house IVD medical device that was included in the Register or was the subject of an application for inclusion in the Register that had not been finally determined; or
- was either a Class 4 in-house IVD medical device or an IVD medical device other than an in-house IVD medical device that was not included in the Register but was covered by a conformity assessment certificate (issued by the Secretary under section 41EC of the Act) that was in effect, or was proposed to be covered by a conformity assessment certificate for which an application had been made that had not been finally determined; or
- was a Class 1, Class 2 or Class 3 in-house IVD medical device (under item 2.10 of Schedule 4 to the MD Regulations, these IVD medical devices are exempt from the requirement to be included in the Register).

New subregulation 11.54(6) makes it clear that these provisions do not preclude a person from applying to include an IVD companion diagnostic in the Register in accordance with the MD Regulations - as amended by Schedule 4 of the Regulations - before 1 July 2022 if they wish to do so.

Importantly also, subregulation 11.54(7) has the effect that the application fee in paragraph (h) of item 1.5 of Schedule 5 to the MD Regulations for applications to include an IVD medical device in the Register, will not apply to such applications made on and after 1 February 2020 and before 1 July 2022.

This is designed to encourage sponsors of such products to apply for marketing approval and to engage with the proposed new requirements at an early stage, and in order to support the availability of these important products for Australian consumers.

### ***Therapeutic Goods Regulations 1990***

#### **Item 2 – In the appropriate position in Part 9**

This item introduces a new Division 12 to the TG Regulations, which sets out application and transitional provisions relating to the following measures in the Regulations:

- faecal microbiota transplant products (Subdivision B of the new Division);
- consumer information documents (Subdivision C of the new Division);
- handling and testing of samples (Subdivision D of the new Division);
- fee waivers and refunds for certain requests relating to prescription opioids (Subdivision E of the new Division); and
- clinical trials (Subdivision F of the new Division).

#### **Subdivision A - Definitions**

##### **Regulation 69 - Definitions**

This regulation sets out definitions for 2 terms that are common to all of the application, saving and transitional provisions in new Division 12, for:

- ‘amending regulations’ – meaning these Regulations; and
- ‘finally determined’ - meaning, for an application, the first time both of the following conditions are met:
  - a decision has been made as to whether or not to grant the application; and
  - there is no longer any possibility of a change in the outcome of the decision.

#### **Subdivision B – Faecal microbiota transplant products**

##### **Regulation 70 – Faecal microbiota transplant products – Division 4 of Part 3-2A of the Act**

New regulation 70 principally exempts FMT products from the requirement to be included in the Register until 1 January 2021.

If a person applies by 31 December 2020 to include an FMT product in the Register, the exemption will continue in place on and after 1 January 2021, until the application is finally determined, lapses or is withdrawn.

This measure is designed to provide a period of time for sponsors of FMT products to transition to full regulation under the therapeutic goods regulatory scheme, and in particular to prepare applications to include their products in the Register.

It is important to note that the exemption is subject to the condition that if a sponsor of an FMT product knows of information relating to an event or occurrence that indicates that the product may have an unintended harmful effect, the sponsor must provide that information to the Secretary within the period specified in regulation 16AB of the TG Regulations.

##### **Regulation 71 - Faecal microbiota transplant products – Part 3-3 of the Act**

New regulation 71 exempts FMT products that are biologicals (other than those that are Class 1 biologicals) from the requirement to be covered by a manufacturing licence issued under Part 3-3 of the Act, until 1 January 2021.

If a manufacturer of such a product applies for a licence by 31 December 2020, the exemption will continue in place until the application is finally determined or withdrawn.

This measure is also intended to assist manufacturers of these higher risk biologicals to transition to full registration under the therapeutic goods regulatory scheme.

The exemption does not cover FMT products that are Class 1 biologicals because, under section 33B of the Act, Part 3-3 of the Act (and in particular the requirement for a manufacturing licence) does not apply to a Class 1 biological.

### **Subdivision C – Consumer medicine information documents**

#### **Regulation 72 – Consumer medicine information documents**

New subregulation 72(1) provides that, subject to the rest of regulation 72, the amendments made to regulations 9A and 9B of, and Schedules 12 and 13 to, the TG Regulations by Schedule 6 of the Regulations, will apply to prescription or over the counter medicines that are supplied in Australia on and after the commencement of Schedule 6 on 1 January 2021.

However, under subregulations 72(2) and (3), these amendments will not apply to prescription or over the counter medicines until 1 January 2026 for medicines that, immediately before 1 January 2021 are registered in the Register or covered by one of the pathways for the lawful supply of unapproved therapeutic goods.

These pathways are that the goods were an exempt good under sections 18 or 18A of the Act, or that they were the subject of an approval or authority under section 19 of the Act or the subject of an approval under section 19A of the Act.

Subregulations 72(4) and (5) also sets out transitional arrangements for prescription and over the counter medicines that, immediately before 1 January 2021, are the subject of an application for registration in the Register that has not been finally determined.

Under these arrangements, if a medicine is included in the Register as a result of such an application then, principally, the amendments made to regulations 9A and 9B of, and Schedules 12 and 13 to, the TG Regulations, will not apply to them until 1 January 2026.

### **Subdivision D – Handling and test of samples**

#### **Regulation 73 – Handling and testing of samples**

New regulation 73 makes it clear that the repeal and substitution of subregulation 23(2) of the TG Regulations by Schedule 7 to the Regulations, the amendment of paragraph 25(3)(c) by that Schedule, subregulations 25(4) and (5) as added by that Schedule and the amendments of paragraph 27(2)(a) and regulations 28, 29 and 30 by that Schedule, will apply in relation to samples of therapeutic goods that are taken or delivered on or after 1 January 2020.

### **Subdivision E – Fee waivers and refunds for certain requests relating to prescription opioids**

### **Regulation 74 – Fee waivers and refunds for certain requests relating to prescription opioids**

New subregulation 74(1) provides that the introduction of subregulations 45(7) – (9) to the TG Regulations by Schedule 8 of the Regulations applies in relation to requests to vary an entry in the Register that are made on or after the commencement of those subregulations (on the day after the registration of the Regulations).

However, new subregulation 74(2) makes it clear that if, on or after 31 August 2019 and before the commencement of Schedule 8, a person makes such a request in relation to a prescription opioid and the request is solely for an opioid reform purpose or an opioid reform purpose and an associated variation of product information purpose (as outlined above), and the person paid the applicable fee for the request, the Secretary must refund the fee to the person.

This is designed to particularly encourage the timely making of these kinds of requests by prescription opioid sponsors, so that smaller pack sizes and appropriate warnings are able to be put in place as soon as possible to help combat the risks associated with these products.

### **Subdivision F – Clinical trials**

#### **Regulation 75 – Clinical trials**

New subregulation (1) makes it clear that the amendments in Part 2 of Schedule 9 to these Regulations in relation to clinical trials have effect as if a written assurance given before 1 January 2020 under paragraph 12AB(2)(a) of the TG Regulations that a clinical trial would be conducted in accordance with the Practice Guidelines were, on and after 1 January 2020, a written assurance that the trial would be conducted in accordance with the Practice Guideline.

New subregulations 75(2) and (3) make it clear that the amendments to subregulation 12AC(1) and paragraph 12AD(a) of the TG Regulations by Part 2 of Schedule 9 apply in relation to things done on or after, or uses on or after, 1 January 2020 in relation to a clinical trial that began before, on or after 1 January 2020.

Subregulation 75(4) makes it clear that the amendment of Schedule 5A to the TG Regulations by Part 2 of Schedule 9 applies in relation to requests made on or after 1 January 2020 to provide information acquired before, on or after that date, and to things mentioned in regulation 12AC of the TG Regulations done on or after 1 January 2020, in relation to a clinical trial that began before, on or after 1 January 2020.

## Statement of Compatibility with Human Rights

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

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

The *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (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) and subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989*.

The principal purpose of the Regulations is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to support the implementation of recommendation 20 of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review). Recommendation 20, agreed to by the Government as part of its Response to the Review, proposed the harmonisation, where possible, of the regulation of medical devices in Australia with that of the European Union (the EU).

The Regulations are designed to do this by reclassifying certain kinds of medical devices (e.g. spinal implantable medical devices like spinal disc replacements), to ensure that the level of pre-market scrutiny applied to applications for marketing approval for such products is commensurate with the risk they may pose to users, consistent with the EU.

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

- better address new and emerging technologies in medical devices that are or that utilise software, and personalised medical devices such as custom-made devices, to ensure such products are subjected to appropriate scrutiny and manufacturing standards;
- introduce a new, tailored regulatory framework for in vitro diagnostic medical devices that are companion diagnostics (these are principally pathology tests for identifying the presence or absence of biological features such as genes in order to determine whether a person is likely to benefit, or be at risk from, a particular medicine or biological);
- introduce a new, tailored regulatory framework for faecal microbiota transplant products (these are biologicals that comprise, contain or are derived from, human stool, and are used to repopulate a person's bowel with benevolent microorganisms, e.g. after use of antibiotics has affected such bacteria);
- introduce a new, more user-friendly format for consumer medicine information documents, to assist consumers to be aware of and understand important information about the safe use of prescription and registered over the counter medicines;
- encourage sponsors of prescription opioids to support their safe use, e.g. by introducing smaller pack sizes and reducing the class of persons for whom such products are suitable;
- a number of minor measures, including for example to exempt certain nappy rash products from the requirement to be entered in the Register.

### **Human rights implications**

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

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

The Regulations take positive steps to promote the right to health by ensuring that the applicable regulatory requirements for medical devices that are or that utilise software, and for personalised medical devices such as custom-made devices, adequately reflect the risks that such products may pose to users, and by introducing appropriate regulatory oversight of faecal microbiota transplant products and a tailored regime of regulatory requirements that addresses the risks that may be posed to users of IVD companion diagnostics.

The Regulations also take positive steps to promote the right to health by supporting reforms to improve the safe use of prescription opioids, and by introducing the use of improved consumer medicine information documents for prescription and over the counter medicines.

### **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**