

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021

Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Department of Health.

Subsection 3(1) of the Act defines ‘therapeutic goods’ as goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use, and includes biologicals and medical devices. Sections 7, 7AA, 32A and 41BD of the Act provide mechanisms to determine or clarify whether particular goods are or are not therapeutic goods, biologicals or medical devices, and therefore subject to the national system of controls established by the Act, including the requirement for those goods to be included in the Australian Register of Therapeutic Goods (“the Register”).

Relevantly, section 7AA of the Act provides that the Minister may determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3) of the Act, and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

The matters that the Minister must have regard to before making a determination under subsection 7AA(3) of the Act are:

- (a) whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act;
- (b) whether it is appropriate in all the circumstances to apply the national system of controls established by the Act to regulate the specified goods; and
- (c) whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

Section 41BD of the Act provides the definition of ‘medical device’. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i) to (v), including for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection 41BD(2B), is also a medical device.

Instruments made under section 7AA and subsection 41BD(2B) of the Act are disallowable legislative instruments within the meaning of subsection 8(4) of the *Legislation Act 2003* (“the Legislation Act”).

Purpose of amendments

The *Therapeutic Goods (Excluded Goods) Determination 2018* (“the Principal Determination”) is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act.

The *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* (“the Principal Instrument”) is made under subsection 41BD(2B) of the Act. The Principal Instrument specifies that particular classes of instruments, apparatus, appliances, materials or other articles are medical devices for the purposes of the Act.

The *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021* (“the Amendment Determination”) is made under section 7AA of the Act and amends the Principal Determination. The *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021* (“the Amendment Instrument”) is made under subsection 41BD(2B) of the Act and amends the Principal Instrument.

The purpose of the Amendment Determination is to address concerns relating to the level, and impact, of regulation under the Act of certain lower risk personalised medical devices. The Amendment Determination amends the Principal Determination to specify certain kinds of lower risk devices, such as spectacle frames and medicament trays, as excluded goods for the purposes of the Act, with the effect that these devices are not subject to regulation as therapeutic goods in Australia.

The purpose of the Amendment Instrument is to complement the Amendment Determination by clarifying that other specified kinds of personalised medical devices, around which there has been some confusion, are medical devices and, as such, are regulated as therapeutic goods under the Act.

Together, the Amendment Determination and Amendment Instrument are designed to provide greater clarity with respect to the regulation of personalised medical devices in Australia, and to ensure that the focus of the regulation of these products under the Act and *Therapeutic Goods (Medical Devices) Regulations 2002* (“the Medical Devices Regulations”) remains on devices with a risk profile that warrants regulation under the scheme to ensure their safety and performance.

Specifically, the Amendment Determination amends the Principal Determination to insert the following new items:

- anatomical models that are intended by the manufacturer to be used for educational or record-keeping purposes;
- cosmetic finishing components for orthoses and prostheses;
- craniofacial prostheses that are spectacle-retained or adhesive-retained;
- dental impression trays;
- ear moulds intended to anchor hearing aids;
- medicament trays intended to hold medicaments;
- mouthguards intended to be used to protect teeth from external forces, such as mouthguards used in contact sports;
- ocular prostheses intended to be used for cosmetic purposes;
- physical impressions of a patient’s anatomy, and models cast from such impressions; and
- spectacle frames.

The Amendment Instrument amends the Principal Instrument to clarify that the following materials or articles are medical devices, when intended by the person under whose name those articles are or are to be supplied, to be used by a health practitioner, or other person suitably trained or qualified who is acting on the instruction (or at the request) of a health practitioner:

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

Background

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. To better address the evolution of these kinds of medical devices, the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (“the 2019 Amendment Regulations”) amended the Medical Devices Regulations to introduce a new, tailored regulatory framework for personalised medical devices.

However, the focus of the reforms leading to the 2019 Amendment Regulations was particularly on higher risk personalised medical devices, and concerns have arisen that the level of regulation involved under the Act and the Medical Devices Regulations does not reflect the risk profile of a number of much lower risk devices, such as spectacle-retained and adhesive-retained craniofacial prostheses that are principally cosmetic, medicament trays designed to hold medicaments and ear moulds intended to anchor hearing aids.

In addition to being low risk, these kinds of devices are principally used by health practitioners registered under a law of a state or territory. These practitioners are subject to appropriate oversight by the Australian Health Practitioner Regulation Agency in their respective professions. As such, the Amendment Determination reduces regulatory burden for manufacturers and reflects that these products are more appropriately subject to regulation under other schemes, including under the Australian Consumer Law.

Separately, concerns have also arisen over a need for greater clarity around the regulatory status of a number of materials and other articles that are, in practice, regulated as medical devices in Australia but for which there is some confusion as to their regulatory status. These are principally:

- materials and other articles intended, by the person under whose name the articles are or are to be supplied to be used, to obtain dental impressions, or in the direct or indirect restoration of teeth; and
- materials and other articles that are used in the manufacture of personalised medical devices including, but not limited to, thermoplastics that are intended for use in the manufacture of non-implantable dental appliances.

In practice these materials and other articles have been regulated as medical devices in Australia and included in the Register on that basis. As such, the Amendment Instrument reflects the administrative practice and aligns Australia’s approach in relation to the regulation of such products as medical devices with that of other jurisdictions, such as the European Union and Canada.

This approach is designed to assist industry in understanding their regulatory requirements and responsibilities including, where relevant, the need for inclusion of certain products in the Register. It also provides patients with a degree of assurance as to the nature and effectiveness of such products.

Consultation

The TGA undertook extensive public consultation between March and April 2019 on personalised medical devices reforms. Twenty-five submissions were received, with a strong consensus for the proposed changes that were principally implemented through the 2019 Regulation Amendments.

Following the commencement of the new regulatory framework for personalised medical devices on 25 February 2021, the TGA received feedback indicating that there were impacts on certain sectors of the devices industry, and concerns about over-regulation associated with the reforms. In light of that feedback, the TGA conducted further public consultation between June and July 2021 on potential refinements to the framework to better target its main elements and moderate the impact of the reforms.

The TGA received a total of 137 submissions from a variety of stakeholders including public and private hospitals, state governments, industry representative bodies, health practitioners and suppliers. The submissions reflected a range of areas of medical practice including audiology, dental, obstetrics, osteopathy, prosthetics, allied healthcare, nursing, occupational therapy, physiotherapy, rehabilitation and podiatry.

The majority of respondents supported the proposals, including the proposed exclusions of the lower risk personalised medical devices specified in the Amendment Determination, and the clarification of the regulatory status of the kinds of devices specified in the Amendment Instrument.

The consultation also identified a number of other issues and suggestions for further refinements of the personalised medical devices reforms, and the TGA will continue to engage with stakeholders on these matters.

The Office of Best Practice advised that a Regulation Impact Statement was not required in relation to these measures (OBPR ID 24680).

Details of the Amendment Determination and Amendment Instrument are set out in **Attachment A** and **Attachment B**, respectively.

The Amendment Determination and Amendment Instrument are compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment C**.

The Amendment Determination and Amendment Instrument are disallowable legislative instruments for the purposes of the Legislation Act and commence on the day after the instruments are registered on the Federal Register of Legislation.

This explanatory statement has been prepared in relation to the Amendment Determination and Amendment Instrument in accordance with subsection 15J(4) of the Legislation Act.

Details of the *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021* (“the Amendment Determination”).

Section 2 – Commencement

This section provides that the Amendment Determination commences the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is section 7AA of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that provision.

Section 4 – Schedules

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

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Excluded Goods) Determination 2018* (“the Principal Determination”).

Item 1 makes a minor amendment to correct a typographical error in a definition.

Item 2 inserts new table item 1A in Schedule 1 to the Principal Determination to exclude anatomical models that are intended by the manufacturer to be used for educational or record-keeping purposes from the scope of the Act.

Item 3 inserts new table items 2B and 2C in Schedule 1 to the Principal Determination to exclude cosmetic finishing components for orthoses and prostheses, and craniofacial prostheses that are spectacle-retained or adhesive-retained, from the scope of the Act.

Item 4 inserts new table item 3AA in Schedule 1 to the Principal Determination to exclude dental impression trays from the scope of the Act.

Item 5 inserts new table item 7AA in Schedule 1 to the Principal Determination to exclude ear moulds that are intended by the manufacturer to anchor hearing aids from the scope of the Act.

Item 6 inserts new table item 10A in Schedule 1 to the Principal Determination to exclude medicament trays that are intended by the manufacturer to hold medicaments from the scope of the Act.

Item 7 inserts new table items 11A, 11B and 11C in Schedule 1 to the Principal Determination to exclude, principally, mouthguards intended by the manufacturer to be used to protect teeth from external forces (such as mouthguards for use in contact sports), ocular prostheses intended by the manufacturer to be used for cosmetic purposes, and physical impressions of a patient's anatomy, and models cast from such impressions, from the scope of the Act.

Item 8 inserts new table item 12A in Schedule 1 to the Principal Determination to exclude spectacle frames from the scope of the Act.

Details of the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021* (“the Amendment Instrument”).

Section 2 – Commencement

This section provides that the Amendment Instrument commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument is subsection 41BD(2B) of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that provision.

Section 4 – Schedules

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

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* (“the Principal Instrument”).

Item 1 makes a minor consequential amendment to section 4 of the Principal Instrument to add the words ‘health practitioner’ and ‘manufacturer’, to reflect that both of these terms are defined in the Act and are referred to in the Amendment Instrument in accordance with those definitions.

Item 2 amends section 4 of the Principal Instrument to add a new definition for ‘relevant practitioner’.

Item 3 inserts new table items 3A to 3E in Schedule 1 to the Principal Instrument, to clarify that the following products are medical devices:

- materials and other articles that are intended by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner to obtain dental impressions;
- materials and other articles intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner in the direct or indirect restoration of teeth including, but not limited, to dental amalgam, crown forms and temporary crown materials;
- materials and other articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner in the manufacture of non-

implantable dental appliances including, but not limited to, denture repair and relining materials; and

- materials and other articles that are intended, by the person under whose name the articles are or are to be supplied, to be used by a relevant practitioner in the manufacture of externally-applied orthopaedic devices including, but not limited to, fibreglass bandages used in the manufacture of splints or orthoses.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021

Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021

These disallowable legislative instruments 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 legislative instruments

The *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021* (“the amendment determination”) and the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021* (“the amendment instrument”), are respectively made under section 7AA and subsection 41BD(2B) of the *Therapeutic Goods Act 1989* (“the Act”).

Section 7AA of the Act provides that the Minister may determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3) of the Act, and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

Section 41BD of the Act provides the definition of ‘medical device’. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i)–(v), including, for example, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection 41BD(2B), is also a medical device.

The amendment determination amends the *Therapeutic Goods (Excluded Goods) Determination 2018*, and the amendment instrument amends the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

Purpose

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. To better address the evolution of these kinds

of medical devices, the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (“the 2019 Amendment Regulations”) amended the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the Medical Devices Regulations”) to introduce a new, tailored regulatory framework for personalised medical devices.

However, the focus of the reforms leading to the 2019 Amendment Regulations was particularly on higher risk personalised medical devices, and concerns have arisen that the level of regulation involved under the Act and the Medical Devices Regulations does not reflect the risk profile of a number of much lower risk such devices, for example, spectacle-retained and adhesive-retained craniofacial prostheses that are principally cosmetic, medicament trays designed to hold medicaments and ear moulds used to anchor hearing aids.

Separately, concerns have also arisen over a need for greater clarity around the regulatory status of a number of materials and other articles that are, in practice, regulated as medical devices in Australia but for which there is some confusion as to their regulatory status.

The principal purpose of the amendment determination is to address concerns relating to the level, and impact, of regulation for certain lower risk devices, such as spectacle frames and medicament trays, by specifying such devices to be excluded goods for the purposes of the Act, with the effect that these devices are not subject to regulation as therapeutic goods in Australia.

The principal purpose of the amendment instrument is to complement the amendment determination by clarifying that other specified kinds of personalised medical devices, around which there has been some confusion, are medical devices and, as such, are regulated as therapeutic goods under the Act.

Human rights implications

The amendment determination and amendment instrument engage the right to health in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

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

The amendment determination promotes and supports the right to health by reducing unnecessary regulatory burden for manufacturers of lower risk devices, such as ear moulds for anchoring hearing aids, and medicament trays, for which regulation under the Act is not commensurate with the risk profile of such products; and thereby supporting access to such products by consumers.

In contrast, the amendment instrument promotes and supports the right to health by reducing the risk of confusion, and providing greater certainty, for both industry and consumers around the regulatory status of certain products that are regulated in practice as medical devices in Australia. This is designed to assist industry in understanding their regulatory requirements and responsibilities, and provides the public with a level of assurance as to the safety and performance of such devices.

Conclusion

The amendment determination and amendment instrument are compatible with human rights because they promote the right to health in Article 12 of the ICESCR and otherwise do not raise any other human rights issues.