Australian Government

Department of Health

Therapeutic Goods Administration

Refinements to the Personalised Medical Device Framework

Version 1.0, August 2021

TGA Health Safety Regulation

Contents

Overview

In July 2021, we undertook a public consultation on *Proposed refinements to the personalised medical devices framework*.

The following refinements have now been agreed:

1. Exclusion of specified products
2. Declaration of some products to be medical devices

Exclusion of specified products

The public consultation indicated the importance of the TGA's role as the regulator of medical devices, affirming that in the majority of cases medical devices should not be excluded even where the risks associated with them are considered to be very low risk.

Products proposed for exclusion are therefore limited to the following:

- Products that are already excluded or that do not meet the definition of a medical device but where clarification of the product's regulatory status would be of benefit.
- Accessories to medical devices for which regulation under the therapeutic goods regulatory framework is not commensurate with the risk that such products would pose to a user.
- Products that meet the definition of a medical device where the primary purpose is cosmetic.
- Anatomical models that are manufactured using a cast taken from a direct physical impression from a patient's anatomy.

The *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021* is a legislative instrument designed to exclude the following products:

- 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
  - adhesive-retained
- dental impression trays
- ear moulds that are intended by the manufacturer to anchor hearing aids
- medicament trays that are intended by the manufacturer to hold medicaments
- mouthguards intended by the manufacturer to be used to protect teeth from external forces including, but not limited to, mouthguards used in contact sports
- ocular prostheses intended by the manufacturer to be used for cosmetic purposes
- physical impressions of anatomy, and models cast from such impressions
- spectacle frames

What is the impact of this instrument?

An exclusion means that the specified products are not subject to regulation by the TGA including, in this instance, where they are advertised or supplied in a specified manner for a particular purpose. Excluded products are not required to meet any of the Australian regulatory requirements for medical devices. This means they are not required to be assessed in any way by the TGA before they are supplied and are not able to be included in the Australian Register of Therapeutic Goods (ARTG). Suppliers of excluded products are also not required to report adverse events to the TGA.

These products will still be subject other regulatory requirements, such as consumer protection laws administered by the Australian Competition and Consumer Commission (ACCC) as well as state or territory consumer protection laws.

Note

If you manufacture or supply a product that has been included in the excluded goods determination, **you do not need to register for transition or include the device in the ARTG**.

If you have already registered a product that has been included in the excluded goods determination you are **not required to take any further action**.

Declaration of some products to be medical devices

Feedback received from the consultation indicated:

- the manufacture of a medical device is a key component of clinical practice in many sectors;
- the risks associated with devices manufactured by healthcare practitioners or technicians/laboratories working to their instruction/direction are managed in a profoundly different way to mass-produced devices; and
- without the benefit of the custom-made medical device exemption and/or the inclusion of the materials/components used in these devices in the ARTG, it will be difficult if not impossible for some healthcare practitioners to continue supplying medical devices.

Furthermore, in some sectors (the dental sector, in particular), including the materials and components that are used to make these devices in the ARTG is a well-established practice that:

- aligns with other jurisdictions, including the EU, where the manufacture of some medical devices is regulated as a component of clinical practice;
- manages the risks associated with the device at two key stages – when the material/component is formed and when the materials/components are used to make a device; and
- aligns with the treatment of the device's final assembly by a healthcare practitioner (or a laboratory or technician working to instructions or directions provided by a healthcare practitioner) as a facet of clinical practice regulated by the Australian Health Practitioner Regulation Agency (Ahpra) and professional governing bodies.

Stakeholders indicated that an alternative pathway is required to appropriately manage the risks associated with medical devices manufactured under these circumstances without placing undue regulatory burden on healthcare practitioners or the technicians and laboratories that service them.

The *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical Devices) Instrument 2021* declares certain products, including materials and components used in the manufacture of some medical devices (predominantly in the dental sector) to be a medical device. There are two main groups of products/devices that have been included in this instrument:

1. Products that already meet the definition of a medical device where clarification of the product's regulatory status would be of benefit to healthcare practitioners and members of industry.

2. Products that are materials or components used in the manufacture of a medical device by a healthcare professional or to the directions/instructions issued by a healthcare professional.

The instrument specifies the following products to be 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 for the direct restoration of teeth, including but not limited to:

  (a) amalgam;
  (b) composite resins and respective bonding systems;
  (c) core build-up materials;
  (d) crown forms;
  (e) fibre or metal preformed posts;
  (f) fibre reinforcement materials;
  (g) fissure sealants;
  (h) glass ionomers;
  (i) liners and bases;
  (j) resin-modified glass ionomers;
  (k) temporary crown or bridge materials

- materials and 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 for the indirect restoration of teeth, including but not limited to:

  (a) ceramic;
  (b) crown forms;
  (c) metal alloy;
  (d) temporary crown or bridge 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 externally-applied orthopaedic devices, including but not limited to:

  (a) fibreglass bandages used in the manufacture of splints or orthoses;
  (b) software;
  (c) thermoplastic sheeting used in the manufacture of splints or orthoses

- 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 manufacture non-implantable dental appliances, including but not limited to:

  (a) acrylic;
  (b) denture repair or reline materials;

(c) metal alloy used in casting;

(d) orthodontic components (such as bands, brackets, chains, elastics, ligature ties, separators and wire);

(e) palate expanders;

(f) preformed acrylic teeth;

(g) preformed clasps;

(h) software;

(i) thermoplastic;

(j) wrought wire used in the manufacture of clasps or retainers

- 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

What is the impact of this instrument?

There is no change to the regulation of devices that are supplied to a dental healthcare practitioner for the direct restoration of teeth such as amalgam. These products remain an adaptable medical device that should be included in the ARTG by the Australian-based sponsor before they are supplied to the practitioner for use, and practitioners who use them have no regulatory obligations with the TGA.

For all other devices named in the instrument, where a device is:

- manufactured by a healthcare professional or a technician/laboratory at the instruction, or to directions supplied by, a healthcare professional
- using a material or component named in the instrument
- that has been included in the ARTG

the resultant device will not need to be included in the ARTG.

The person assembling the device, including if they are a healthcare practitioner, will still need to meet all other regulatory requirements for medical devices including:

- ensuring the device(s) meet all relevant Essential Principles, including supplying the devices with adequate labelling and instructions for use;
- reporting adverse events to the TGA; and
- meeting the advertising requirements for therapeutic goods under the TGA legislation including the Therapeutic Goods Advertising Code.

Note

If you are a:

- healthcare practitioner who manufactures a specific device as a component of your clinical practice; or
- an entity who manufactures specific devices for a healthcare practitioner as a component of their clinical practice,

you **will not be required** to register your devices for transition or include them in the ARTG if you are making them from an ARTG-included material or component (s).

If you have already registered your devices for transition you are **not required to take any further action**.

If you are directly importing a material, component(s) or finished medical devices for use in your practice, you will need to **include these products in the ARTG**.

Next steps

While this instrument focuses predominantly on materials and components used in the dental sector, feedback from peak professional bodies and Ahpra indicates this approach to regulation may be appropriate for materials and components, and the devices made from them, in other sectors. We will continue to engage with these sectors, both directly and through peak professional and industry bodies, to identify further products that would be more appropriately regulated in this manner.

Further outcomes from the public consultation will be progressed and communicated as they develop.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Emerging Technology and Diagnostics	August 2021

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