Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reclassification of medical devices that are substances to be introduced into the body or applied to and absorbed by the skin

Guidance on the transitional arrangements and obligations

Version 1.3, December 2022

The purpose of this guidance is to help sponsors and manufacturers comply with the requirements of the therapeutic goods legislation.

This is a guide only, and sponsors and manufacturers are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor and/or manufacturer to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

About this guidance

This guidance aims to assist sponsors of **medical devices that are substances for introduction into the body** with meeting their obligations and outlines transitional arrangements to help comply with new regulations.

From **25 November 2021,** medical devices that are substances for introduction into the body will be required to meet regulatory requirements demonstrating the safety and performance for **Class IIa (low-medium risk) or Class IIb (medium-high risk) devices.**

Background

In early 2019 Therapeutic Goods Administration (TGA) conducted a public consultation seeking feedback on a proposal to introduce new classification rules for medical devices composed of substances that are intended to be introduced into the human body through a body orifice, or applied to skin, that are absorbed or dispersed. The proposed regulatory changes supported the commitment made in the Australian Government Response to the Review of Medicines and Medical Devices Regulation to align Australian medical device regulations, where possible and appropriate, with the European Union framework.

Stakeholders who responded to the public consultation were broadly supportive of the proposed changes and the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* was made on 12 December 2019.

The amendments include the introduction of new classification rules for medical devices composed of substances that are intended to be introduced into the human body through a body orifice or applied to skin, to classify these devices as Class IIa (low-medium risk) or Class IIb (medium-high risk) effective from 25 November 2021.

A further consultation was undertaken in July 2021, with regulatory refinements made on 29 October 2021 to provide greater clarity around the regulation of these products.

Requirements for reclassification

The requirements include:

- conformity assessment documents demonstrating procedures appropriate for a Class IIa or Class IIb medical device.
- more detailed assessment of the manufacturer's quality management systems and assessment of technical documentation related to each device.

Medical devices that are substances for introduction into the body

Medical devices that are composed of substances, or combinations of substances, that are introduced into the human body through a body orifice, or applied to and absorbed by the skin, may include the following products, depending on how it exerts its effect within the body:

- saline solution nasal sprays
- lozenges that only exert their effect in the mouth cavity
- dentifrices for sensitive teeth

- resin-based dental materials applied to the tooth surface
- some wart removers
- gels for vaginal discomfort (not including anti-fungal or antimicrobial chemicals)
- wound protection gels and creams to treat or prevent minor skin irritations
- products for topical use such as creams, gels, or ophthalmic solutions
- weight loss capsules that expand in the stomach to create a feeling of satiety and are not intended to achieve their action in the body by pharmacological, immunological or metabolic means.

Please note

Only those products composed of substances or of combinations of substances that **meet the definition of a medical device are regulated as medical devices.**

Some products **may also fall under the definition of a medicine.** These products are so called **borderline products** (when it is not clear whether a given product is a medical device or a medicine). Many products that have been represented as medical devices in other jurisdictions are considered to be medicines in Australia, as their mechanism, including a chemical effect in or on the human body can be characterised as pharmacological, metabolic or immunological and is therefore inconsistent with the definition of a medical device.

The regulatory pathway (medical device or medicine) for such products is determined based on the product's primary mode of action, intended use and the manufacturer's claims made regarding the product's performance, based on the analysis and scientific evidence. The impact or effect the product may have or any other secondary intended purpose and dose administered should also be taken into account.

From 25 November 2021, the following classification rules will apply:

Subclause 5.11 of Schedule 2 - Medical devices that are substances to be introduced into the body or applied to and absorbed by the skin

If a medical device is composed of substances, or combinations of substances, that are intended to be:

a. introduced into the human body through a body orifice; or

b. applied to and absorbed by the skin;

the device is classified as follows:

c. if the device is introduced into the nasal or oral cavity as far as the pharynx, or is applied to and absorbed by the skin, and achieves its intended purpose in that cavity or on the skin—Class IIa;

d. in any other case—Class IIb.

Please note

As per subclause 5.1 of Schedule 2, **medical devices that incorporates**, or is intended to incorporate, as an integral part, a substance that if used separately, would be a **medicine**; and is liable to act on a patient's body with action ancillary to that of the device, is regulated as a **Class III medical device**.

Examples of devices to be reclassified

In considering the appropriate classification for medical devices composed of substances that are introduced into the human body through a body orifice or the skin, sponsors should consider the following:

- **How is the substance introduced into the human body?** For example, through a body orifice, the surface of the eyeball, or the surface of the skin.
- **For substances applied to the skin, is it absorbed by the body?** For example, some products may not be absorbed via the skin whilst others may be absorbed. If the product is not *intended* to be absorbed by the skin, you may be required to provide evidence that the product is not absorbed. Products that are metabolised in the liver and excreted from the body would be considered a medicine.

Products which are absorbed may present a higher level of risk as its effects may not be easily reversed or ceased if they do not perform as intended. It is important that these factors are considered when evaluating the safety and performance of these products. The level of invasiveness of devices introduced into the human body should also be considered when applying the relevant classification rule.

Some examples and explanations of products that may (sometimes erroneously) have been considered medical devices that may be substances, or combinations of substances, and a comparison of the old classification versus the new classification and clarification of appropriate regulatory pathways are provided below.

Examples of products (where subclause 5.1 of Schedule 2 does not apply)

Medical device	Old classification	New classification	Regulatory pathway
Throat lozenge An orally-administered tablet designed to be dissolved in the mouth to coat irritated mucous membranes of the throat with a protective mucoadhesive hydrogel complex intended to help reduce irritation and associated symptoms.	**Class I** *(transient use invasive medical device not intended to be connected to an active medical device)*	**Class IIa** *(applied in the oral cavity as far as the pharynx and achieve their intended purpose on that cavity)*	**Medical device** – if it is just a barrier for the throat (but must be able to substantiate that it acts as such) and only make claims consistent with the mechanism i.e. moisturise. **Medicine** – if the action is to reduce irritation and symptoms. **Not a therapeutic good** – if the action is consistent with normal expectations of food products.
Saline nasal solution sprays Saline nasal solution sprays are intended to penetrate, clear, clean, and sometimes hydrate the nasal passages and sinus cavity for preventive or symptomatic nasal care.	**Class I** *(transient use invasive medical device not intended to be connected to an active medical device)*	**Class IIa** *(applied in the nasal cavity and achieve their intended purpose on that cavity)*	**Medical device** – if it is just composed of isotonic saline whose mechanism is to irrigate the nasal cavity. **Medicine** – if it is hypertonic saline that has an osmotic effect in the nasal cavity; or contains another substance with an antimicrobial, decongestant, or anti-inflammatory effect.

Medical device	Old classification	New classification	Regulatory pathway
Anti-snoring device A substance in the form of a dissolvable lozenge, dissolvable oral strip, throat spray or rinse that typically contains natural ingredients such as eucalyptus oil, glycerol, menthol or peppermint oil intended to lubricate and tone the mucosa in the back of throat to reduce sound vibration and thereby prevent snoring.	**Class I** *(short-term use invasive medical device not intended to be connected to an active medical device)*	**Class IIa** *(applied in the oral cavity as far as the pharynx and achieve their intended purpose on that cavity)*	Depends on the intended purpose and mode of action; typically, it would not be considered plausible to achieve the desired therapeutic benefit without pharmacological effect.
Skin moisturiser/barrier dressing A substance (for example, cream, paste, ointment, gel, foam, or aerosol) intended to be applied to the skin/external mucosa such as the lips to provide a protective moisture barrier to the external environment and/or to soften and sooth the skin. It is typically used for conditions such as dry, itchy, flaky, cracked, denuded, irritated or sun-damaged skin, cheilitis, and/or herpetic skin lesions. It may be intended for sensitive areas such as the areolar, perianal, lips and ears, dry skin and/or deep fissures such as on the feet. It may include a disposable applicator.	**Class I** *(non-invasive medical device in contact with injured skin and not absorbed by the skin)*	**Class IIa** *(applied to the skin and is absorbed after application)*	**Medical device** – if it is purely a barrier to keep moisture in or out. **Medicine** – if it is used to treat skin irritations or lesions and contains an active ingredient for this purpose.
Vaginal gel to maintain pH balance, treat bacterial vaginosis or treat discomfort (where it meets the definition of a medical device)	**Class IIa** *(short-term use invasive medical device not intended to be connected to an active medical device)*	**Class IIb**	**Medicine** – if this effect within the human body affects the flora. **Medical Device** – where the therapeutic effect is comfort through lubrication or similar.

Medical device	Old classification	New classification	Regulatory pathway
Weight loss capsules that expand in the stomach An orally-administered device intended to facilitate weight loss and treat obesity through appetite control. It is designed to be swallowed before meals to form a viscous gel in the stomach and/or small intestine to increase distention, creating the sensation of fullness and causing the user to eat less. It may additionally slow down intestinal glucose absorption to improve glycaemic control. It typically includes natural or modified fibre which expands after absorbing water.	**Class IIa** *(short-term use invasive medical device not intended to be connected to an active medical device)*	**Class IIb**	**Medical device** – if it only expands to create feeling of satiety. **Medicine** – if it affects absorption in the gastrointestinal system. **Not a therapeutic good** – if the product is composed of food substances and its mechanism is consistent with that of energy-poor food in the alimentary tract.

Exceptions

Sterile saline eye irrigation solutions intended to act on the surface of the eye to flush the eye of irritating particulates/chemicals will remain classified as **Class I sterile** medical devices.

Topical nail treatment solutions designed to treat infected nails (for example, in the case of onychomycosis) and nail-growth disorders (onychodystrophy) by creating a barrier to microorganisms will remain classified as **Class IIa** medical devices; products containing ingredients with antibacterial and/or antifungal action are not medical devices and are regulated as medicines.

Dentifrices which are intended for cleaning the surfaces of teeth and which do not contain any substances included in Schedules 2, 3, 4 or 8 of the Poisons Standard, are not regulated as medical devices. Further details are available at Therapeutic Goods (Excluded Goods) Determination 2018.

Products that are medicines

Chemical substances that are introduced into the human body through a body orifice or the skin, will typically have a pharmacological or metabolic effect on the body. By definition, such products are not medical devices and are characterised as medicines.

Examples of products

Product	Regulatory pathway
Salivation stimulation lozenge An orally-administered tablet intended to increase the secretion of saliva by stimulating the taste receptors of the tongue via the gustatory-salivary reflex and to alleviate the dry mouth symptom (xerostomia) associated with a medical condition or treatment.	**Medicine** – if the lozenge is treating a medical condition. **Not a therapeutic good** – if the action is consistent with normal expectations of food products.
Sodium alginate based products for reflux Sodium alginate is the sodium salt of alginic acid and can be used to relieve symptoms of reflux.	**Medicine** – if the action is achieved through a chemical reaction in the stomach.
Gastrointestinal gas suppressant An orally-administered substance intended to treat disorders of the gastrointestinal (GI) tract caused by gas (for example, swelling of the stomach (aerophagy) and intestine (meteorism) and associated pains/discomforts (cramps, irritable bowel, burping, flatulence). It may also be used to treat functional dyspeptic symptomatology and to prepare for diagnostic abdominal tests (for example, endoscopy, ultrasound scanning). It typically contains simethicone to inhibit the formation of gas bubbles and reduces their surface tension so that they burst; it is available in the form of a non-prescription over-the-counter (OTC) powder, liquid or dissolvable film. After application, this device cannot be reused.	**Medicine** – if the action is achieved through a chemical reaction in the stomach.
Mineral-based gastrointestinal detoxifier An orally-administered substance principally comprised of a mineral such as zeolite, intended to absorb, adsorb, and/or chelate and remove harmful exogenous and/or autologous toxins/substances (for example, heavy metals, ammonium, microbial toxins, pesticides, histamine, serotonin, alcohol, and/or bile acids) from some or most of the gastrointestinal (GI) tract. It may also function as an antioxidant. It is provided in various forms (for example, powder, capsule, liquid) and is normally available non-prescription over-the-counter (OTC) for use in the home or health care facility. This is a single-use device.	**Medicine** – if the action is achieved through a chemical reaction in the stomach.

What you need to do

If you are the sponsor of a medical device composed of substances that are intended to be introduced into the human body through a body orifice or applied to skin, the actions you will need to take to comply with the new regulations will depend on the status of your product:

- Medical devices included in the ARTG prior to 25 November 2021
- Applications to include a medical device in the ARTG lodged before 25 November 2021
- Applications to include a new medical device in the ARTG on or after 25 November 2021

Medical devices included in the ARTG prior to 25 November 2021

If you have a medical device composed of substances that are intended to be introduced into the human body through a body orifice or applied to skin in the ARTG with a start date before 25 November 2021, transitional arrangements are in place to ensure that you can continue to supply your device while you apply for it to be included in the ARTG in accordance with the new classification.

To continue to supply your device you must:

- Notify the TGA **before 25 May 2022** that you have an ARTG inclusion that will need to be reclassified.
- Submit an application for your device to be included in the ARTG under the correct classification **before 1 November 2024.**

Please note

If you do not intend to continue supplying the device, you should cancel your inclusion **before 25 May 2022**.

If you **notify** the TGA of your devices **before 25 May 2022** but you do not **submit an application** for inclusion of your device in the ARTG with the correct classification **before 1 November 2024**, you must cease supply of your device from 1 November 2024 and cancel your ARTG inclusion.

Applications to include a medical device in the ARTG lodged before 25 November 2021

If you have submitted an application for inclusion in the ARTG for a medical device composed of substances that are intended to be introduced into the human body through a body orifice or applied to skin before 25 November 2021, your device application will be assessed and the device will be included in the ARTG under the old classification rules.

To be eligible for the transitional arrangements to reclassify your device under the new classification rules, you must:

- Notify the TGA that you have an ARTG inclusion that will need to be reclassified by whichever is the later date:
  - **Before 25 May 2022**

  - **Within 2 months of the start date of your ARTG entry**

- Submit an application for your device to be included in the ARTG with the correct classification **before 1 November 2024**.

Cancelling your ARTG inclusion

If you **do not notify** the TGA before 25 May 2022 or within two months of the start date for your ARTG entry (whichever is the later date) of your intention to apply for the device to be included in the ARTG under the new classification rules for your device, you will no longer be eligible for the transitional arrangements. You should:

- cease supply of your device from 25 May 2022
- cancel your ARTG inclusion.

If you notify the TGA of your device before the due date, but you **do not submit an application** to include your device in the ARTG for the correct classification **before 1 November 2024**, you must:

- cease supply of your device from 1 November 2024
- cancel your ARTG inclusion.

Applications to include a new medical device in the ARTG on or after 25 November 2021

Any application for inclusion of a new device that is not yet included in the ARTG, submitted to the TGA **on or after 25 November 2021** must be submitted using the correct classification under the new classification rules.

For more information refer to the Medical device inclusion process.

Application to transition

In order to continue supplying your devices, you must submit your application for inclusion in the ARTG for the correct device classification under the new classification rules **before 1 November 2024**. If you have submitted your application before this date, but it has not yet been finalised by the TGA, you are able to continue to supply your devices using your existing ARTG entry until a decision is made about your inclusion application.

Please note

You must submit an application electronically through TGA Business Services using a Class IIa or Class IIb device application form, depending on the classification of your device. If you submit your application using any other form (for example, another classification form) your application will fail and your application fee will not be refunded

Class IIa and Class IIb devices of the same kind

Class IIa and Class IIb devices are considered to be of the same 'kind' and can be included in one ARTG entry when they have the same:

- sponsor
- manufacturer
- classification
- Global Medical Device Nomenclature (GMDN) System Code.

For more information refer to the Medical device inclusion process.

What to include in your application

Applications for ARTG inclusion must be accompanied by appropriate conformity assessment documentation in order to pass preliminary assessment.

The specific documents that you are required to attach are outlined in the final column "Documentation to be provided with the application (Evidence of product assessment)" of Table 2 in the Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs). This information must be provided in addition to the manufacturer evidence.

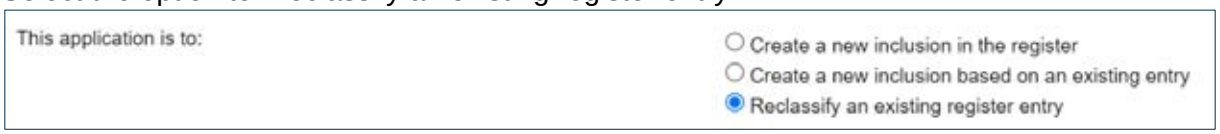
Please ensure you allow sufficient time to obtain your conformity assessment documentation in order to submit your documents with your application.

If you do **not pass preliminary assessment**, your application **will be refused** and you will **not be able to transition** your device to the new classification.

How to submit a reclassification application

1. Create a 'New Device Application' from the menu in the eBS Portal
2. Select "Medical Device - Included" from the first drop down list provided

3. Select the option to 'Reclassify an existing register entry'



4. Search for the ARTG Number to be reclassified: eg. 130099 (example only)

5. Select the "Clone" button.
6. Allow the system to clone the information associated with the ARTG entry into the application
7. Select the new classification from the drop down provided for the "Reclassification" question.

Please note

If the GMDN code in the existing entry has been made obsolete or has been updated, the sponsor is responsible for selecting the most appropriate and current code available in the GMDN agency database.

If you are required to select a new GMDN code that is different to the cloned ARTG entry, you will not be able to validate and submit the application.

Please save the draft application and email TGA Devices info line at devices@tga.gov.au for assistance.

If there is a change of manufacturer, you must submit a new application.

Fees

You will need to pay the relevant application fee.

Please note

Reclassification applications for Class IIa or IIb ARTG inclusions will not be subject to a mandatory audit.

However, TGA will select applications for non-mandatory audit if there are any concerns with the application (e.g. post market signals) or if there are minor changes in the submitted reclassification application. For example, if the information in the new application is not consistent with the information in the current ARTG entry (such as a rewording of the intended purpose).

Advertising to consumers

Advertisements for medical devices that are directed to consumers are required to comply with requirements under the legislation. Guidance about the regulation of therapeutic goods advertising is available on the TGA advertising hub.

If your inclusion application is not successful

If your inclusion application to transition your device to the new classification is not successful, you will be notified of the decision in writing and you will be provided the reasons for the decision.

If you are not satisfied with this decision, you may request reconsideration of this initial decision under section 60 of the *Therapeutic Goods Act 1989* within **90 days** of the decision.

If you are not satisfied with the reconsideration (reviewable decision), you may apply to the Administrative Appeals Tribunal or the court.

When to cease supply using your old ARTG entry

If you do not meet your obligations under the transitional arrangements, you will need to cease supply of your device. The following table outlines the circumstances and timeframes:

When to cease supply of your device using an old ARTG entry

Circumstance	What to do
You have **not notified** the TGA that your device needs to be reclassified before 25 May 2022, or within two months of inclusion of your device under the old classification rules (whichever is the later date).	**Cease supply** of your devices **from 25 May 2022** or the date that is **2 months after the start date of your ARTG entry (whichever is the later date)**.
You have **not submitted an application for inclusion** in the ARTG to transition your device to the correct classification **before 1 November 2024**.	**Cease supply** of your devices **from 1 November 2024.**
Your application for inclusion of your device with the correct classification is unsuccessful.	**Cease supply** of your device from the time that you are **notified of the outcome** of your application.

Version history

Version	Description of change	Author	Effective date
V1.0	Draft	Medical Devices Authorisation Branch	October 2021
V1.1	Update for regulatory refinements	Medical Devices Authorisation Branch	November 2021
V1.2	Updated for clarification	Medical Devices Authorisation Branch	September 2022
V1.3	Updated to include reclassification application steps and for clarification	Medical Devices Authorisation Branch	December 2022

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication D22-5904802