Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Proposed refinements to the regulation of medical devices that are substances introduced into the human body via a body orifice or applied to the skin

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TGA Health Safety Regulation

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Background

In early 2019, the 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, and are absorbed or dispersed. The proposed regulatory changes supported the commitment made 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 introduced 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, effective from 25 November 2021, as set out below.

Classification rule

Subclause 3.1(4) of Schedule 2:

(4) If a device is composed of substances, or combinations of substances, that are:
(a) intended to be:
(i) introduced into the human body through a body orifice; or
(ii) applied to the skin; and
(b) absorbed by, or locally dispersed, in the human body after introduction or application;
the device is classified as follows:
(c) if the device, or its products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose – Class III;
(d) if the device achieves its intended purpose in the stomach or lower gastrointestinal tract and the device, or its products of metabolism, are systemically absorbed by the human body – Class III;
(e) if the device is applied to the skin, or in the nasal or oral cavity as far as the pharynx, and achieves its intended purpose on those cavities – Class IIa;
(f) in any other case – Class IIb.

This new classification rule aligns with EU Regulation 2017/745, rule 21 of Chapter III of Annex VIII.

It is noted that the new classification rule may result in a number of products meeting the definition of both a medical device and a medicine, which creates regulatory inconsistencies due to the different frameworks that might be applied to a given product.

Definitions

The *Therapeutic Goods Act 1989* (the Act) provides definitions for medicines and medical devices.

Under definitions in the Act***, medicine*** *means therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human*.

S41BD of the Act defines a medical device.

(1) A medical device is:

(a) any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

> *(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;*
>
> *(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;*
>
> *(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;*
>
> *(iv) control or support of conception;*
>
> *(v) in vitro examination of a specimen derived from the human body for a specific medical purpose;*

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means[1].

Proposed amendments

While the new classification rule does align with the EU, the recommendation was to align where possible and appropriate. In this case, alignment with the EU may not be appropriate given the overlap in the medicine and medical device regulatory frameworks in Australia for some products.

Therefore, it is proposed that the new classification rule be amended to remove references to products that are systemically absorbed by the body, as these products meet the definition of a medicine.

The proposed amendment is set out below.

[1] Full definition s41BD of the Act

Subclause 3.1(4) of Schedule 2:

(4) If a device is composed of substances, or combinations of substances, that are:

(a) intended to be:

(i) introduced into the human body through a body orifice; or

(ii) applied to the skin; and

(b) absorbed by, or locally dispersed, in the human body after introduction or application; the device is classified as follows:

~~(c) if the device, or its products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose – Class III;~~

~~(d) if the device achieves its intended purpose in the stomach or lower gastrointestinal tract and the device, or its products of metabolism, are systemically absorbed by the human body – Class III;~~

(e) if the device is applied to the skin, or in the nasal or oral cavity as far as the pharynx, and achieves its intended purpose on those cavities – Class IIa;

(f) in any other case – Class IIb.

Refining this rule will provide clarification and will also help further define the correct regulatory pathway for certain products in Australia.

Examples of devices, comparisons of old and new classifications, and clarification of regulatory pathways

Medical device	Current classification	New classification from 25 November 2021	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.	**Class I** *Invasive medical device for transient use, not intended to be connected to an active medical device.*	**Class IIa** *Applied in the oral cavity as far as the pharynx and achieves its intended purpose on that cavity.*	**Medicine** – if the lozenge is treating a medical condition. **Not a therapeutic good** – if the action is consistent with normal expectations of food products.

Medical device	Current classification	New classification from 25 November 2021	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** *Invasive medical device for transient use, not intended to be connected to an active medical device.*	**Class IIa** *Applied in the oral cavity as far as the pharynx and achieves its 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). **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 spray 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** *Invasive medical device for transient use, not intended to be connected to an active medical device.*	**Class IIa** *Applied in the nasal cavity and achieves its intended purpose on that cavity.*	**Medical device** – if it is just 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 effect.
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, and is intended to lubricate and tone the mucosa in the back of the throat to reduce sound vibration and thereby prevent snoring.	**Class I** *Invasive medical device for short-term use, not intended to be connected to an active medical device.*	**Class IIa** *Applied in the oral cavity as far as the pharynx and achieves its intended purpose on that cavity.*	Depends on the intended purpose and mode of action.

Medical device	Current classification	New classification from 25 November 2021	Regulatory pathway
Skin moisturiser or barrier dressing A substance (such as a cream, paste, ointment, gel, foam or aerosol) intended to be applied to the skin or 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 are often found on the feet. It may include a disposable applicator.	**Class I** *Non-invasive medical device in contact with injured skin.*	**Class IIa** *Applied to the skin and absorbed or locally dispersed 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 or treat bacterial vaginosis (where it meets the definition of a medical device) Some vaginal gels intended to be applied in the vagina, for the purpose of maintaining pH balance or treating bacterial vaginosis, may be considered a medical device in some instances. These products typically work as a physical barrier to inhibit the ability of bacteria to bind to the vaginal lining, and by lowering pH levels in the microenvironment, thereby inhibiting bacterial growth.	**Class IIa** *Invasive medical device for short-term use, not intended to be connected to an active medical device.*		**Medicine** – if this is a chemical effect within the human body.

Medical device	Current classification	New classification from 25 November 2021	Regulatory pathway
Weight loss capsule that expands 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** *Invasive medical device for short-term use, not intended to be connected to an active medical device.*	**Class IIb**	**Medical device** – if it just expands to make you feel full. **Medicine** – if it affects absorption. **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.
Sodium alginate–based product for reflux (where it meets the definition of a medical device) Sodium alginate is the sodium salt of alginic acid and can be used to relieve symptoms of reflux. The alginate reacts with the acid in the stomach to produce a 'raft' on the stomach that acts as a physical barrier to reflux.	**Class IIa** *Invasive medical device for short-term use, not intended to be connected to an active medical device.*		**Medicine** – if the action is achieved through a chemical reaction in the stomach.

Medical device	Current classification	New classification from 25 November 2021	Regulatory pathway
Gastrointestinal gas suppressant (where it meets the definition of a medical device) An orally-administered substance intended to treat disorders of the gastrointestinal (GI) tract caused by gas, such as swelling of the stomach (aerophagy) or intestine (meteorism) and associated pain or discomfort (such as cramps, irritable bowel, burping or flatulence). It may also be used to treat functional dyspeptic symptomatology and to prepare for diagnostic abdominal tests, such as endoscopy or ultrasound scanning. It typically contains simethicone to inhibit the formation of gas bubbles and reduce 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 (where it meets the definition of a medical device) An orally-administered substance principally comprised of a mineral such as zeolite that is intended to absorb, adsorb and/or chelate and remove harmful exogenous and/or autologous toxins or substances – such as heavy metals, ammonium, microbial toxins, pesticides, histamine, serotonin, alcohol 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, including powder, capsule and 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.

Medicine and medical device regulatory pathways

The products listed in the above table as medicines would typically be regulated as over-the-counter (OTC) medicines (that is, not as prescription-only medicines). Each OTC medicine is evaluated for safety, efficacy and quality; and the manufacturers are required to have a Good Manufacturing Practice (GMP) licence or clearance (if an overseas manufacturer).

The target evaluation timeframes for these types of OTC medicines range from 150 to 210 working days and the fees range from $11,800 to $28,150. The annual charge for a registered OTC medicine is $1,520.

The target evaluation timeframe for a Class III medical device is 60 working days. Class III medical devices are evaluated for safety and performance and are expected to have overseas conformity assessment certifications and product review, or TGA conformity assessment certification. Application and audit fees can be approximately $8,600 for products that do not require TGA conformity assessment. The annual charge for a Class III medical device is $1,200. The evaluation timeframe for TGA conformity assessment certification is 120 working days and fees range from $24,000 to $60,000+.

Your feedback

Your feedback on this proposed amendment will help us identify any issues that may arise should the Therapeutic Goods Regulations be changed. Feedback will also enable us to tailor our stakeholder education program in relation to these products.

We invite you to provide comment on:

1) Amending the classification rule to remove clauses around products of metabolism and systemic absorption, as below.

Subclause 3.1(4) of Schedule 2:

(4) If a device is composed of substances, or combinations of substances, that are:
(a) intended to be:
(i) introduced into the human body through a body orifice; or
(ii) applied to the skin; and
(b) absorbed by, or locally dispersed, in the human body after introduction or application; the device is classified as follows:
~~*(c) if the device, or its products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose – Class III;*~~
~~*(d) if the device achieves its intended purpose in the stomach or lower gastrointestinal tract and the device, or its products of metabolism, are systemically absorbed by the human body – Class III;*~~
(e) if the device is applied to the skin, or in the nasal or oral cavity as far as the pharynx, and achieves its intended purpose on those cavities – Class IIa;
(f) in any other case – Class IIb.

For the purposes of this survey, we would like your feedback on the following questions:

Amending the new classification rule:

1) **What are the regulatory implications of the proposed changes to the classification rule?**
2) **Do you agree that the proposed amendment to the classification rule – to remove references to products that are systemically absorbed – will clarify the regulation of products that are systemically absorbed by the body?**
3) **Can you think of any other impacts or issues if the classification rule is amended?**

How to submit your feedback

Your input and feedback will help inform any changes to the Regulations in relation to medical devices that are substances introduced into the human body via a body orifice or applied to the skin. In addition to the scope of this consultation, we welcome other feedback on the regulation of medical devices that are substances introduced into the human body via a body orifice or applied to the skin, as well as feedback on our consultation process.

You can submit your feedback using our **online survey tool:**
https://consultations.health.gov.au/tga/proposed-refinements-to-the-regulation-of-medical

Please direct any queries via email to devicereforms@tga.gov.au.

This survey closes at 5pm Friday 13 August 2021

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	DAS	July, 2021

Therapeutic Goods Administration

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