Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

March 2019

TGA Health Safety Regulation

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Introduction

The Australian Government endorsed a significant program of reform to further strengthen the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

In 2015, the Report of the *Expert Panel Review of Medicines and Medical Devices Regulation* (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty[1] which addressed matters within the remit of the TGA. This Recommendation provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure our assessments and decisions are made based on the balance between the benefits and the risks.

The risk classifications of medical devices take into account factors such as potential harm, level of invasiveness, reliance on power, where in the human body the device is used, terms of use, the end user (consumers or a person with appropriate knowledge and expertise), etc.

The TGA periodically reviews classification rules for medical devices to ensure they continue to be appropriate. When undertaking such assessments, the TGA has regard among other things, to the international best regulatory practice and any emerging issues.

This ensures sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, and timeliness of access to medical devices.

This consultation

The focus of this paper is to obtain feedback on a proposal to introduce a new specific classification rule for medical devices composed of substances that are intended to be introduced into the human body via a body orifice or applied to skin that are absorbed or dispersed.

[1] Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, p. 10.

The EU Regulation on medical devices (2017/745)[2] (EU MD Regulation) introduced several amendments to the classification rules effectively reclassifying some categories of medical devices to higher risk classes.

The EU MD Regulation explains that the new requirements increase the robustness of the assessment process, and that the classification rules take into account potential risks associated with technical design and manufacture of the devices. The rules also take into account the level of invasiveness and potential toxicity of certain devices introduced into the human body as well as the place where the device performs its action in or on the human body.

The Australian Government's reforms aim to improve the scope, clarity and appropriateness and operation of regulations governing medical devices. This consultation paper considers the EU regulatory framework as an input into the review and reform of the Australian regulatory requirements for medical devices classification. While the new classification rule in the EU more appropriately reflects the intended use and the risk of medical devices, this paper considers the extent to which a similar approach will be appropriate in the Australian regulatory context, to further our aim of enhancing the smooth functioning of the medical devices market while also achieving high standards of quality, safety and performance.

Potential changes: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, consider introducing a new medical device classification rule, which is appropriately tailored for the Australian regulatory context for substances introduced into the human body via a body orifice or applied to the skin.

In the EU MD Regulation these devices are referred to as: "Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body".

Proposals

It is proposed that a **new classification rule** be included in the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australian MD Regulations), to align with Rule 21 (Annex VIII, Chapter III) of the EU MD Regulation.

Effect

All devices that are composed of substances (or combination of substances) that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body would be classified as Class IIa, Class IIb or Class III, depending on the location in the body where the device achieves its intended purpose.

[2] The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Your feedback

Are you a consumer, industry stakeholder, healthcare provider, patient, industry representative body, consumer advocacy group or other interested party?

We seek your views on the proposed implementation measures. Your input will assist us to address any unintended consequences so as to inform the proposal and the regulatory amendment process.

On page 16 is a list of questions to help you address the proposal in your feedback.

Please refer to page 16 on How to submit your feedback to the TGA.

Please note

This consultation closes on **29 April 2019**.

Before providing feedback, it is important to read the explanatory material that follows.

Where do I find classification rule and definition of devices composed of substances or of combinations of substances intended to be introduced into the human body via a body orifice or applied to the skin?

EU

Regulation (EU) 2017/745 (the EU MD Regulation) specifies the rules that govern the classification of a medical device.

Rule 21[3] prescribes the classification of medical devices composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin:

> *Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:*
>
> - *class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;*
> - *class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;*

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Annex VIII, Chapter III – Classification Rules, 7.8 Rule 21 (OJ L 117/145, 5.5.2017, p. 145). See also Chapter V, Section 1, Article 51 – Classification of Devices, (1) (p. 49)

- *class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and*
- *class IIb in all other cases.*

Article 2 and Annex VIII of the EU MD Regulation provide definitions and other classification rules related to invasive medical devices.[4]

Australia

The classification rules for medical devices are prescribed in Schedule 2 of the Australian MD Regulations.[5]

There are currently no specific classification rules in the Australian MD Regulations for medical devices composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin.

The classification rules that currently may apply to these devices under the Australian MD Regulations are outlined in Current classification that may apply to these devices in Australia (page 12 of this paper).

EU and Australian definitions and provisions related to these medical devices

Both the EU MD Regulation and the Australian MD Regulations provide definitions of ***'invasive device'*** and ***'body orifice'***.[6] The TGA is consulting separately on the possible alignment with the EU of these definitions.[7] [8]

The EU MD Regulation provides a definition of '***injured skin or mucous membrane***' that is not defined in the Australian MD Regulations. It is proposed to incorporate this definition for clarity and consistency purposes.

Neither the EU MD Regulation nor the Australian MD Regulations, define the term ***systemically absorbed*** (or ***systematic absorption***), referred to in classification rule 21.

Appendix A – Definitions, classification rules and other provisions (on page 18) has been included as a reference tool. It provides an overview and comparison in the EU MD Regulation and the Australian MD Regulations of the relevant definitions, classification rules, and other provisions applicable to medical devices composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin.

Table A in Appendix A may help you in providing your feedback.

[4] OJ L 117, 5.5.2017, pp. 15, 140.
[5] Classification rules for IVD medical devices are prescribed in Schedule 2A; see also *Therapeutic Goods Act 1989*, s.41DB and *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 3, Div. 3.1.
[6] OJ L 117, 5.5.2017, pp. 15, 140.
[7] Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia, Appendix A, Table A2, p.15
[8] Consultation: Proposed new classification for medical devices that administer medicines or biologicals by inhalation, Appendix A

Medical devices subject to EU MD Regulation Rule 21

EU MD Regulation Rule 21 classifies devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body.

The EU MD Regulation provides context/principles about the introduction of this classification rule. Specifically the EU MD Regulation explains that the previous classification rules applied to invasive devices did not sufficiently take account of the level of invasiveness and potential toxicity of certain devices which are introduced into the human body. In order to obtain a suitable risk-based classification of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, it is necessary to introduce a classification rule that should take into account the place where the device performs its action in or on the human body, where it is introduced or applied, and whether a systemic absorption of the substances of which the device is composed, or of the products of metabolism in the human body of those substances, occurs.[9]

What products are considered in this paper?

In Australia, products are regulated as **medical devices** if they are intended to be used for humans, for one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological process; or
- control of conception;

and the product **does not achieve its principal intended action by pharmacological, immunological or metabolic means**.

An accessory to a medical device is also regulated as a medical device.[10]

The **purpose for which the product is intended to be used** and mechanism of action are to be ascertained from the **information provided by the manufacturer with the products**, including: labelling, instructions for use, any advertising material, and/or technical documentation related to the product.

This is in principle consistent with the respective requirements in EU; the TGA is consulting on further possible alignment of the definitions of a *medical device, accessory, intended purpose* in a separate consultation paper.[11]

Consequently products that achieve their principal intended action by chemical means (including products that are composed of substances or of combinations of substances), and that are intended for one or more of the medical purposes stated above, may be regulated as medical devices.

[9] OJ L 117/8, 5.5.2017, (59), p 8

[10] *Therapeutic Goods Act 1989*, s.41BD

[11] Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia, Appendix A, Table A1, p.13, Closed 18 February 2019

Some of these products may also fall under the definition of a medicine,[12] i.e. these products are so called *borderline products* (i.e. it is not clear whether a given product is a medical device or a medicine).

Some examples of such products are: saline solution nasal sprays; lozenges that only exert their effect in the mouth cavity; dentifrices for sensitive teeth; some wart removers; gels for vaginal discomfort; wound protection gels creams to treat or prevent minor skin irritations; products for topical use such as creams, gels, or ophthalmic solutions; and some weight loss products that are not intended to achieve their action in the body by pharmacological, immunological or metabolic means.

These products are substance-based medical devices, however, due to their presentations, some of these products may be perceived to be medicines.

The regulatory pathways for such products are determined based on the product's primary modes of action, their intended uses and manufacturer's claims made regarding product's performance, based on the analysis and scientific evidence.

Please note

When this consultation paper refers to products composed of substances or of combinations of substances, it only refers to **products that meet the definition and consequently are regulated as medical devices**.

If any of substances, or a component in the combination of substances, if used separately, is a medicine, or it is of animal or microbial origin, such devices are already Class III[13], and therefore amendments proposed in this consultation paper are not applicable to these devices.

Examples of medical devices composed of substances or a combination of substances

Currently, **invasive medical devices intended to be used by penetration of a body orifice** (such as the oral cavity), or through the surface of the skin, which **are not active devices** (active medical devices depend for their 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)[14] and **are not connected to an active medical device** are classified as:

- **Class I medical devices** if they are: **intended for transient use**; or intended for **short term use** and **used in the oral cavity as far as the pharynx**.
- **Other invasive medical devices** are classified as **Class IIa** or **Class IIb**.

Some examples and explanations of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, along with a comparison of the current classification versus the proposed classification are provided below.

[12] *Therapeutic Goods Act 1989*, s.3

[13] Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 2, Part 5 Special rules for particular kinds of medical devices

[14] Therapeutic Goods (Medical Devices) Regulations 2002, Dictionary (reg. 1.3)

Device	Current classification	Proposed classification
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)*
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, to alleviate the dry mouth symptom (xerostomia) associated with a medical condition or treatment.	**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)*
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 the 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)*
Dentifrice A substance or combination of substances that typically includes mild abrasives, detergents, flavouring agents and other products, specially prepared for cleaning the accessible surfaces of teeth.	**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)*
Eye irrigation solution A sterile solution intended to be used to flush the eye of irritating particulates/chemicals; it may also be used to flush particulates from soft contact lenses during wear. Otherwise known as eyewash, it typically consists of an aqueous solution of sodium chloride sometimes with dyes or preservatives.	**Class I sterile** *(transient use invasive medical device not intended to be connected to an active medical device)*	**Class IIb** *(introduced into the human body via the surface of the eyeball and are absorbed by the human body)*

Device	Current classification	Proposed classification
Vaginal gel to maintain pH balance or treat bacterial vaginosis Some vaginal gels intended to be applied into the vagina for the purpose of maintaining pH balance or treat 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 vaginal lining, and by lowering pH levels in the microenvironment, thereby inhibiting bacterial growth.	**Class IIa** *(short-term use invasive medical device not intended to be connected to an active medical device)*	**Class III** *(if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose)* or **Class IIb** *(in all other cases)*
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 III** *(if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body)* or **Class IIb** *(in all other cases)*
Sodium alginate based-products for reflux 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** *(short-term use invasive medical device not intended to be connected to an active medical device)*	**Class III** *(if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body)* or **Class IIb** *(in all other cases)*

Why we need a specific classification rule for these medical devices?

Medical devices that contain substances or combinations of substances that are introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body potentially present a higher level of risk, as once the device is absorbed or dispersed in the body, its effects may not be easily reversed or ceased if these devices do not perform as intended. It is important that these considerations are addressed when evaluating the performance and safety of such devices.

Currently, these devices are classified as low risk (Class I) or low-medium risk (Class IIa) depending on the duration of use of the device. The Australian MD Regulations do not currently provide a specific classification rule for these devices and as such, the general classification rules do not adequately consider the risks and consequences specific to these devices if they do not perform as intended.

The quality and safety of such devices may be, for example, impacted by the rate of absorption, toxicity, metabolism, interaction with other devices, medicines, other substances in the body, etc.

The proposed classification for these devices considers the level of risks and potential impact of use of these devices. It recognises that the development and advancement of substance-based medical devices is emerging and that these devices have varying levels of risks that need to be considered in the context of patient safety.

Current classification of these devices in Australia

There are currently no specific classification rules for these devices.

The classification rules that currently apply to the devices described above are set out in Schedule 2, Part 3 of the Australian MD Regulations as follows:

Rule 3.1- Invasive medical devices intended to be used by penetration of body orifices

(1) This clause applies to an invasive medical device (other than a surgically invasive medical device) that is intended by the manufacturer to be used to penetrate a body orifice of a patient.

(2) If the device is not intended to be connected to an active medical device, the following rules apply:

(a) if the device is intended for transient use, the device is classified as Class I;

(b) if the device is intended for short-term use:

(i) the device is classified as Class IIa; or

(ii) if the device is intended to be used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum, or in a nasal cavity—the device is classified as Class I;

(c) if the device is intended for long-term use:

(i) the device is classified as Class IIb; or

(ii) if the device is intended to be used in the oral cavity as far as the pharynx or

in an ear canal up to the ear drum, or the device is intended to be used in a nasal cavity and the device is not liable to be absorbed by the mucous membrane—the device is classified as Class IIa.

(3) If the device is intended to be connected to an active medical device that is classified as Class IIa or higher, the device is classified as Class IIa.

Proposed reclassification

The current Australian MD Regulations classify some of the devices composed of substances (or combination of substances) that are intended to be introduced into the human body via a body orifice or applied to the skin as Class I, unless the device is intended for long-term use, in which case the device is classified as Class IIa.[15]

Manufacturers of all medical devices must apply conformity assessment procedures and have appropriate technical documentation demonstrating compliance of the device with the relevant regulatory requirements. Further, manufacturers of all devices (except Class I (low-risk) medical devices) must be assessed by the TGA or an acceptable independent assessment body/overseas regulator, and have a *conformity assessment document*[16] issued by that assessment body/regulator demonstrating that the manufacturer has applied appropriate conformity assessment procedures or requirements, comparable to the conformity assessment procedures, to the device. Manufacturers of Class I medical devices self-declare compliance.

If the proposed reclassification takes effect, it will mean that devices that are composed of substances (or combination of substances) that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body will be reclassified to Class IIa, or to Class IIb or to Class III, depending on the location in the body where the devices achieves its intended purpose.

Sponsors of reclassified medical devices will be required to include their devices in the Australian Register of Therapeutic Goods (ARTG) with the correct classification.[17] Sponsors of Class III medical devices will be required to include each device in the ARTG separately, with an individual unique product identifier (UPI) to improve their traceability.

Also manufacturers of any device higher than Class I are required to have the *conformity assessment documents* verifying compliance of the manufacturer's quality management systems with the regulatory requirements appropriate for medical device of that classification. High-risk Class III medical devices require in addition to the most stringent assessment of manufacturer's quality management systems, assessment of technical documentation related to each device, rather than that of a representative device from a group of similar devices.

Sponsors will be required to obtain manufacturer's *conformity assessment documents* and provide them to the TGA to demonstrate procedures appropriate for their device when submitting applications for inclusion of the medical device in the ARTG.

Strengthened assessments are intended to drive the design and manufacture of better quality, reliable medical devices that are fit for purpose.

[15] Devices containing medicines, or substances that are of animal or microbial origin, are not considered in this consultation paper, as these devices are already Class III

[16] *Therapeutic Goods Act 1989*, s.3

[17] *Therapeutic Goods (Medical Devices) Regulations 2002*, reg. 3.6, 3.7, 3.8, and Schedule 3 – Conformity assessment procedures

Proposed action

It is proposed that a **new classification rule** be included in Schedule 2 of the Australian MD Regulations, to align with the EU MD Regulation Rule 21:

Medical device that is composed of a substance or of a combination of substances that is intended to be introduced into the human body via a body orifice or applied to the skin and that is absorbed by or locally dispersed in the human body is classified as:

- Class III if the device, or its products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- Class III 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 IIa 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; and
- Class IIb in all other cases.

What will change for sponsors?

Sponsors who supply, or plan to supply, in Australia medical devices to which EU MD Regulation Rule 21 applies will be required to provide manufacturer's *conformity assessment documents* appropriate to devices of this classification.[18]

After the regulatory changes take effect, sponsors of these devices will be required to apply for inclusion of their medical devices in the ARTG as either Class IIa, or Class IIb, or Class III (whatever is applicable).

Transitional arrangements

In Europe, under the transitional arrangements, medical devices lawfully placed on the market that have pre-market authorisation in the form of a valid EC Certificate[19] can remain on the market until the expiry date of that EC Certificate or until 27 May 2024 (when these certificates become void), whichever is the earliest. Devices lawfully placed on the market may continue to be made available on the market or put into service until 27 May 2025.

The TGA proposes that the new classification for **new medical devices in Australia** – that is, a device included in the ARTG following successful completion of applications submitted to the TGA on or after the commencement date of the amended regulations – would start from August 2020.

[18] Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410)

[19] EC certificates issued in accordance with EU Directive 93/42/EEC and which comply with the requirements in para. (2) of Article 120 of the EU MD Regulation.

If the application for ARTG inclusion for a medical device is **submitted to the TGA before the date the proposed amendment takes effect**, the device will be subject to the transitional arrangements and will have four (4) years to transition until August 2024.

Applications

At the date that the proposed amendment takes effect:

- **All new applications for marketing approval** (ARTG inclusion) for devices that are composed of substances (or combination of substances) that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, submitted to the TGA on or after the date when amended regulations take effect must be made in accordance with the new classification rules (consistent with Rule 21) that will be provided in Schedule 2 of the Australian MD Regulations.
- **Sponsors of devices already included in the ARTG**, or those for which applications have been submitted before regulatory amendments take effect, must apply to have their device/s re-entered in ARTG with the correct classification. All applications to reclassify devices must be submitted to the TGA by the end of the four year transition period. Where an application to reclassify has been submitted to the TGA but has not been determined (i.e. is still under assessment), the device can continue to be supplied under the existing ARTG entry until the correct classification is finalised (including applications not finalised at the end of the transition period).
- For those **devices for which transitional provisions apply**, sponsors must notify the TGA of all such devices presently supplied under the existing ARTG entry within six (6) months of the amended regulations taking effect. These devices can continue to be supplied for the duration of the four year transition period. If the sponsor has not notified the TGA within this period, they will no longer be eligible for the transitional arrangements.
- If any **application for ARTG inclusion for a device with the current classification is in progress** on the date the regulations come into effect, it may continue. If the application is successful, the device will be included with the current classification. The sponsor must then reapply to include their device in ARTG with the correct classification, as per requirements set out under the transitional arrangements.

Fees and charges

The usual application and audit assessment fees (where applicable) will apply for applications for inclusion in the ARTG.

Class III ARTG inclusion applications are subject to the mandatory audit assessment requirement. ARTG inclusion applications for invasive medical devices for Class IIa and Class IIb are not currently subject to the mandatory audit assessment requirement, i.e. there will be no audit assessment fees associated with these applications.

The TGA however may on its own discretion select any of these applications for audit if there are concerns about the device or information provided with the application.

The usual annual charges will apply for Class IIa, Class IIb and Class III entries in the ARTG (whatever is applicable) following reclassification.

Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal
- provide relevant material on the TGA website.

Feedback notes

It is important to note that while we intend to take the European medical device framework into account the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. We acknowledge that legislation cannot always be successfully replicated across jurisdictions. Therefore, your views on the impacts of the proposed regulatory changes related to medical devices composed of substances introduced into the human body via a body orifice or applied to the skin are very important to us.

When considering the proposed measures, assume that the EU MD Regulation definitions and terminology, Rule 21, and other provisions apply to the medical device as defined in the Australian MD Regulations. You may also wish to consider the possible impact of the proposed alignment by referring to descriptions of relevant devices and their functionality.

Please also keep in mind that current and future technological developments may potentially bring more categories of medical devices under this classification rule.

What we invite you to do

In your submission, we ask you to consider the questions below and provide comments related to any other matter outlined in this consultation paper.

Questions

- What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?
- Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?
- Do you have any comments/views regarding defining the scope of medical devices that should be covered by the proposed new classification rule?
- Do you have any comments/views regarding defining the terms *injured skin or mucous membrane* in the Australian MD Regulations?
- Do you have any comments/views regarding the meaning of the term *systemically absorbed* (or *systematic absorption*)? Should this term be clarified in our guidance or defined in the Australian MD Regulations? If yes, what definition do you propose for the meaning of this term?
- Do you have any comments regarding the transitional arrangements proposed in this paper?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, please ensure your submission is accompanied by a cover sheet.

This consultation closes on 29 April 2019.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

Appendix A - Definitions, classification rules and other provisions

Definitions relating to medical devices are found in the Dictionary (r. 1.3) of the Therapeutic Goods (Medical Devices) Regulations 2002.

There are differences in provisions in EU MD Regulation and Australian MD Regulations. Table A below is a comparison of respective provisions by jurisdiction.

Table A – Definitions and other medical device legislative provisions related to substances intended to be introduced into the human body via a body orifice or applied to the skin

EU MD Regulation	Australian MD Regulations	Proposed amendments
ANNEX VIII - CLASSIFICATION RULES **CHAPTER I - DEFINITIONS SPECIFIC TO CLASSIFICATION RULES** 2. INVASIVE AND ACTIVE DEVICES 2.8 '**Injured skin or mucous membrane**' means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.	**Dictionary** (regulation 1.3) No equivalent definition.	For clarity and consistency purposes we propose to incorporate this EU definition **in the Australian legislation.** Because, in principle, the intent of this definition in the EU MD Regulation is consistent with our interpretation of this term we do not anticipate any impact (rather than greater clarity and consistency) on the regulation of medical devices in Australia.

EU MD Regulation	Australian MD Regulations	Proposed amendments
ANNEX VIII - CLASSIFICATION RULES **CHAPTER III - CLASSIFICATION RULES** 7. SPECIAL RULES 7.8. Rule 21 Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as: - class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose; - class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body; - class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and - class IIb in all other cases.	**Schedule 2—Classification rules for medical devices other than IVD medical devices** No equivalent classification rule	**This classification rule is subject of this consultation paper.**

Version history

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