Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Proposed new classification rule for medical devices that administer medicines or biologicals by inhalation

March 2019

TGA Health Safety Regulation

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Contents

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 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 reviews, 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 classification rule for invasive medical devices that administer medicines or biologicals by inhalation.

[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 the potential risks associated with the 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, 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 classification rule, which is appropriately tailored for the Australian regulatory context for invasive medical devices intended to administer medicines and biologicals by inhalation.

In the EU MD Regulation these are referred to as: *"All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation."*

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 20 (Annex VIII, Chapter III) of the EU Medical Devices Regulation.

Effect

All invasive medical devices intended to administer medicines or biologicals by inhalation would be classified as Class IIa unless their mode of action has an essential impact on the efficacy and safety of the administered therapeutic good or they are intended to treat life-threatening conditions, in which case they are classified as Class IIb.

Your feedback

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

[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

We seek your views on the potential amendments and implementation strategy. Your input will assist us to address any unintended consequences and inform the proposal and the regulatory amendment process.

On page 17 there is a list of questions to help you address the proposal in your feedback.

Please refer to page 17 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 the classification and definition of invasive medical devices that administer medicines or biologicals by inhalation?

EU

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

Rule 20[3] prescribes the classification of a particular group of invasive medical devices intended to administer medicinal products by inhalation:

> *All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life- threatening conditions, in which case they are classified as class IIb.*

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

Australia

The classification rules for invasive medical devices are prescribed in Part 3, Schedule 2 of the Australian MD Regulations.[5]

There are currently no specific classification rules in the Australian MD Regulations for medical devices intended to administer medicines or biologicals by inhalation.

[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, 7.7 Rule 20 (OJ L 117, 5.5.2017, p. 145). See also Chapter V, Section 1, Article 51.1 – Classification of Devices, (OJ L 117, 5.5.2017, p. 49).

[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.

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 14 of this paper).

EU and Australian definitions, other classification rules and provisions related to invasive medical devices

Both the EU MD Regulation and the Australian MD Regulations provide definitions of *'invasive device'* and *'body orifice'*.[6]

'Invasive medical device' means a medical device intended by the manufacturer to be used, in whole or in part, to penetrate the body of a human being through a body orifice or through the surface of the body. TGA is consulting separately on the possible alignment with the EU of the definition for *'invasive device'*.[7]

'Body orifice' is also defined in both the EU MD Regulation and Australian MD Regulations as a natural opening or a permanent artificial opening in a human being's body, and includes the external surface of a human eyeball.

Neither the EU MD Regulation nor Australian MD Regulations, define the terms *'essential impact'* or *'life-threatening conditions'*. The 'plain-English' meaning of ***'life-threatening'*** is a very serious condition or disease that can cause death.[8] [9]

The EU MD Regulation refers to ***'invasive medical devices intended to administer medicinal products*** (i.e. products that are not regulated as medical devices)[10] ***by inhalation'***. The *Therapeutic Goods Act 1989* does not provide a description of 'medicinal product', but rather uses the terms therapeutic good, medicine and biological. For the purpose of this consultation paper, the term medicinal product encompasses the meaning ***therapeutic good, such as a medicine or a biological***.

Please note

A substance used for the purpose of treatment may meet the definition of a medical device and may be regulated as a medical device if it achieves its principal intended action by chemical means (i.e. the substance does not achieve its principle intended action by pharmacological, immunological or metabolic means).

Consideration could be given to whether a **medical device intended to administer another medical device by inhalation** should be classified in the same way as an invasive medical device intended to administer medicines or biologicals by inhalation.

[6] OJ L 117, 5.5.2017, pp. 15, 140.

[7] See Consultation: Changes to a number of definitions and scope of the medical device regulatory framework in Australia, Appendix A, Table A2, p.15.

[8] Cambridge Dictionary, https://dictionary.cambridge.org/dictionary/english/life-threatening.

[9] Pallipedia: '**Life threatening condition** is a condition for which curative treatment may be feasible but can fail. A life-threatening condition is usually of short duration with an acute or unexpected onset and may or may not occur in the context of a pre-existing life-limiting condition', http://pallipedia.org/life-threatening-condition/.

[10] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
p.2, paragraph (7) – '*The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as … medicinal products, …*'
p.14, Chapter 1, Article 1 *Subject matter and scope*, paragraph 6(b) – '*medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product.*'

Appendix A – Definitions and other classification rules related to invasive medical devices intended to administer medicines or biologicals by inhalation (on page 19) has been included as a reference tool. It provides an overview and comparison of the relevant definitions, classification rules, and other provisions applicable to invasive medical devices in the EU and Australian MD Regulations.

Appendix A may help you in providing your feedback.

Devices pre-filled with medicines or biologicals

There are a number of different groups of products intended to be used for administering medicines or biologicals by inhalation. However, not all of these products are regulated as medical devices.

The EU MD Regulation provides that products are **regulated as medicinal products rather than medical devices** if:

- The device is intended to administer a medicinal product
- The device and medicinal product is placed on the market in such a way that it forms a **single integral product, and**
- The device is intended **exclusively for use in the given combination** and which is not reusable.[11]

The EU MD Regulation also provides that the relevant General Safety and Performance Requirements are to be fulfilled for such devices.

In Australia, Item 3(c) of the Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010[12] in principle covers similar groups of products and declares that the following articles are declared not to be medical devices: *an article that is intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and which is not reusable (may be multi-dose)*. Currently there are no requirements for manufacturers of device components of such products to comply with requirements of the Australian MD Regulations.

Please note

It is not proposed to change the regulatory pathway for devices intended to administer a medicine in such a way that the medicine and the device form a single integral product which is intended exclusively for use in the given combination and which is not reusable (may be multi-dose). These devices (such as asthma puffers prefilled with medicine) will continue to be declared not to be medical devices.

It is proposed that manufacturers of the device component of such products mentioned above (i.e. devices prefilled with the medicine) should have evidence to demonstrate compliance of the device with the relevant essential principles/General Safety and Performance Requirements.

[11] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Chapter 1, Article 1 (9) (OJ L 117/14, 5.5.207, p14).
[12] Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010 - Item 3(c)

Examples of products declared not to be medical devices include certain pressurised metered dose inhalers (pMDIs) and multi-dose dry powder inhalers (DPIs) prefilled with the medications. Examples include:

- **Metered dose inhaler, such as asthma puffers prefilled with the medication**

  A metered dose inhaler (also known as an aerosol inhaler or puffer) is a hand-held device designed to administer a pre-measured dose of aerosolised medication directly into the mouth of a patient. It typically consists of a shaped plastic holder with integrated mouthpiece into which a pressurised metal canister containing the solution or suspension of medicine is placed.

- **Dry powder inhaler**

  A dry powder inhaler is a hand-held device designed to administer powdered medicine through the mouth and into the bronchial airways. It is a breath-actuated device and requires adequate patient inspiratory flow rate for medicine delivery as it does not include a propellant to aid medicine delivery. This form of medicine administration is an alternative to aerosol inhalation and may induce the patient to greater inhalational effort. This is a reusable device intended for single-patient use.

Medical devices subject to EU MD Regulation Rule 20

EU MD Regulation Rule 20 classifies invasive medical devices intended to administer medicines or biologicals by inhalation.

What are invasive medical devices intended to administer medicines or biologicals by inhalation?

Invasive medical devices intended to administer medicines or biologicals via inhalation (such as aerosols) are widely used for treatment of respiratory disorders (e.g. asthma, obstructive lung disorder, cystic fibrosis, pulmonary arterial hypertension and infectious pulmonary disease). More recently, the use of aerosols has expanded to non-respiratory conditions (e.g. diabetes, analgesia, thyroid disorders and genetic disease).[13] The advantages of using aerosol for administering medicines or biologicals include faster pharmacological action due to the medicine or biological being converted into aerosol and delivered to the site where it is needed.

Some examples of medical devices intended to administer medicines or biologicals include: metered dose inhalers, dry powder inhalers, nebulisers and spacers. Further examples include nasal cannulas, endotracheal tubes, laryngeal masks airway/laryngeal masks, oropharyngeal airways and nasopharyngeal airways.

These devices do not form a single integral product with the medicine or biological that they are intended to deliver. Instead, these devices are typically supplied separately from the medicine or biological they are intended to administer and are regulated as medical devices in both Europe and Australia.

In general, these devices can be broadly categorised into the following groups:

- Non-active devices that are not intended to be connected with an active medical device;
- Devices that are connected to an active medical device; and

[13] Medscape: Use of Metered Dose Inhalers, Spacers, and Nebulizers: Overview, Preparation, Technique, 9 Dec 2015, Praveen Buddiga.

- Active medical devices that depend for its 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]

Accessories to such medical devices are also regulated as medical devices.

Currently, **invasive medical devices intended to be used by penetration of a body orifice** (such as the oral cavity), which **are not active devices 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**.

Examples

Some examples and explanations of invasive medical devices intended for administering medicines or biologicals and a comparison of the current classification versus the proposed classification are provided below.

Device	Current classification	Proposed classification
Inhalation accessory devices • **Spacer/valved holding chambers/face masks** A spacer is a device intended to be used by attaching it to metered dose inhalers to facilitate a **better delivery of a medicine**. For example, it may be used by small children to enable the slow inhalation of the medicine. Face masks can also be used with the spacer. Valved holding chambers allow for a fine cloud of medication to stay in the spacer until the patient breathes it in through a one-way valve, drawing the dose of medicine into the lungs.	**Class I** *(transient use invasive medical device not intended to be connected to an active medical device)*	**Class IIa, or** **Class IIb** *(if the device's mode of action has an essential impact on the efficacy and safety of the administered medicine or biological, or they are intended to treat life- threatening conditions)*

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

Device	Current classification	Proposed classification
Accessories to nebulisers • **Mouthpiece, nebulisers cup/container, tubing** Nebulisers are devices that **transform solutions or suspensions of medications into aerosols** that are optimal for deposition in the lower airways. This mode of administering medicine is critical for respiratory disorders and may include delivery of antibiotics, bronchodilators, corticosteroids, etc. These devices can be used for patients who are not able to use other inhaler devices (e.g. too young or too ill). Nebulisers are used with **accessories** (e.g. **invasive devices such as mouthpiece/face mask**) that are connected to the air compressor via tubing and enable transfer of aerosol to the patient.	**Class I** *(mouthpiece/face mask – short-term use in the oral cavity or nasal cavity)*	**Class IIa, or** **Class IIb** *(if the manufacturer specifically intends the device to be used for treatment of life-threatening conditions)*
Nasal oxygen cannula A nasal cannula (NC) (with tube or without tube) is a device that delivers supplemental oxygen or increased airflow to a patient or person in need of respiratory help. This device is a non-sterile, semi-rigid lightweight tube which on one end splits into two prongs which are placed in the nostrils and from which **a mixture of air and oxygen flows**. It is commonly known as 'nasal prongs'. The other end of the tube is connected to an oxygen supply such as a portable oxygen generator or a wall connection in a hospital via a flowmeter. The NC is generally attached to the patient by way of the tube hooking around the patient's ears or by elastic head band. ***Note**: Oxygen is regulated as a medicine in accordance with the Australian therapeutic goods legislation.*	**Class I** *(short-term use in a nasal cavity)* or **Class IIa** *(if it is intended to be connected to an active medical device via the tube)*	**Class IIa, or** **Class IIb** *(if the manufacturer specifically intends the device to be used for treatment of life-threatening conditions)*

Device	Current classification	Proposed classification
Endotracheal tube (reusable or single-use) An endotracheal tube is a hollow cylinder inserted orally (orotracheal) or nasally (nasotracheal) into the trachea to provide an unobstructed airway. It is typically connected to a ventilator that **delivers oxygen** to the lungs and can convey other gases and vapours to and from the lungs during anaesthesia, resuscitation and other situations where the patient is not properly ventilated. It is typically made of plastic or rubber and is available in various diameters and lengths for adult and paediatric patients.	**Class IIa** *(short-term use invasive medical device)*	**Class IIb** *(intended to be used to treat life-threatening conditions)*
Laryngeal mask airway/laryngeal mask A laryngeal mask airway (LMA, also known as laryngeal mask) is a medical device that keeps a patient's airway open during anaesthesia or unconsciousness. It can be considered a medical device that is used to **deliver medicinal products** (e.g. oxygen supply) by inhalation. It is composed of an airway tube that connects to an elliptical mask with a cuff which is inserted through the patient's mouth and down the windpipe. Once deployed, it forms an airtight seal on top the glottis (unlike tracheal tubes which pass through the glottis) allowing a secure airway to be managed by a health care provider. LMA are most commonly used by anaesthetists to channel oxygen or anaesthesia gas to a patient's lungs during surgery and in the pre-hospital setting (for instance by paramedics and emergency medical technicians) for unconscious patients.	**Class IIa** *(short-term use invasive medical device)*	**Class IIb** *(intended to be used to treat life-threatening conditions)*
Oropharyngeal airway An oropharyngeal airway (OPA, also known as an oral airway, or Guedel pattern airway) is a medical device airway adjunct used to maintain or open a patient's airway and can also be used to **deliver medicinal product**s (e.g. oxygen supply) by inhalation. When a person becomes unconscious, the muscles in their jaw relax and the tongue can obstruct the airway. An OPA is designed to prevent the tongue from covering the epiglottis and keeping the airways open.	**Class I or Class IIa** *(invasive medical device for transient or short-term use)*	**Class IIa**

Device	Current classification	Proposed classification
Nasopharyngeal airway A nasopharyngeal airway (NPA, also known as a nasal trumpet (because of its flared end) or nose hose) is a type of airway adjunct and is designed to be inserted into the nasal passageway to secure an open airway. NPA can also be used to **deliver medicinal products** (e.g. oxygen supply) by inhalation. When a patient becomes unconscious, airway management is necessary as the muscles in the jaw commonly relax and can allow the tongue to slide back and obstruct the airway. NPA is one of the available tools to allow airway management. The purpose of the flared end is to prevent the device from becoming lost inside the patient's nose.	**Class I or Class IIa** *(invasive medical device for transient or short-term use)*	**Class IIa**

Why do we need a specific classification rule for invasive medical devices intended to administer medicines or biologicals by inhalation?

Medical devices intended to be used to administer medicines or biologicals via inhalation to treat acute and chronic life-threatening conditions (such as life-threatening asthma attacks, acute respiratory failure requiring oxygen delivery or mechanical ventilation etc.) are associated with high risks and consequences if they do not perform as intended. It is essential that they operate safely and effectively to ensure that the medicines are appropriately delivered to be able to achieve the desired therapeutic effect.

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 and/or whether or not the device is connected to an active medical device. As the Australian MD Regulations do not currently provide a specific classification rule for these devices, the general classification rules do not adequately consider risks and consequences specific to these devices if they do not perform as intended.

Some problems with invasive medical devices intended to administer medicines or biologicals by inhalation include:

- ***Inhalation accessory devices*** – while there are some advantages associated with the use of these devices (e.g. enhanced medication delivery, compensation for poor technique/coordination with metered dose inhaler, reduced oropharyngeal deposition), there are potential problems, including:
  - Large size and volume of device
  - Possibility of bacterial contamination, especially if the device is not properly cleaned by the user, and
  - Electrostatic charges may reduce the dose of the medicine delivered to the lungs.
- ***Endotracheal tubes*** have been recalled due to the ends of electrode wires at the distal end of the tube extruding through the wall of the tube, entering the cuff and/or puncturing through the cuff and becoming exposed. Some complaints involved serious injuries, including: an extruded/protruding electrode wire penetrated the tracheal wall or a vocal cord and cuff deflation requiring re-intubation of the patient.

- ***Laryngeal mask airways*** have been recalled due to a manufacturing fault in the tube, resulting in a review of customer complaints. This fault may have resulted in partial or total occlusion of the airway tube when the cuff was inflated and partial or total restriction of air delivery to and/or from the patient.

Current classification that may apply to these devices in Australia

There are currently no specific classification rules for invasive medical devices intended to administer medicines or biologicals by inhalation.

The classification rules that currently apply to these devices are set out in Schedule 2, Part 3 and Part 4 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.*

Rule 4.4 Active medical devices intended to administer or remove medicines, etc from a patient's body

(1) Subject to subclause (2), an active medical device that is intended by the manufacturer to be used to administer medicine, body liquids or other substances to a patient, or to remove medicine, body liquids or other substances from a patient, is classified as Class IIa.

(2) *If the device is of a kind such that the administration or removal of the medicine, body liquids or other substances is potentially hazardous to the patient, having regard to the nature of the substances involved, the part of the patient's body concerned, and the characteristics of the device, the device is classified as Class IIb.*

Proposed reclassification

The current Australian MD Regulations classify invasive medical devices intended to be used by penetration of body orifices which are intended to administer medicines or biologicals by inhalation as Class I, unless the device is intended for long-term use or intended to be connected to an active medical device that is classified as Class IIa or higher, in which case the device is classified as Class IIa.

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*[15] 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, any invasive devices intended to administer medicines or biologicals by inhalation will be reclassified to **Class IIa** or to **Class IIb** (if their mode of action has an essential impact on the efficacy and safety of the administered medicine or biological, or device is intended to treat life-threatening condition) respectively.

Sponsors of reclassified medical devices will be required to include their devices in the Australian Register of Therapeutic Goods (ARTG) with the correct classification. Also, manufacturers of any devices with a higher classification than Class I will be required to have the *conformity assessment documents* verifying compliance of the manufacturer's quality management systems with the regulatory requirements appropriate for medical devices of that classification. Sponsors will be required to obtain manufacturer's *conformity assessment documents* and provide copies of these documents to the TGA to demonstrate procedures appropriate for their device when submitting applications for inclusion of the medical device in the ARTG.

Proposed action

It is proposed that a **new classification rule** be included in Schedule 2 in the Australian MD Regulations, to align with EU MD Regulation Rule 20:

> *All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicines or biologicals by inhalation are classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicine or they are intended to treat life-threatening conditions, in which case they are classified as Class IIb.*

What will change for sponsors?

Sponsors who supply, or plan to supply, in Australia medical devices to which Rule 20 applies will be required to provide manufacturer's *conformity assessment documents* appropriate to devices of this classification.[16]

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

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

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

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[17] 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.

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 invasive medical devices intended to administer medicine or biological by inhalation to the TGA on or after the date when the amended regulations take effect must be made in accordance with the new classification rules (consistent with Rule 20) 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 (i.e. by February 2021). 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.

[17] 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.

Fees and charges

The usual application fees will apply for applications for inclusion of the device in the ARTG.

ARTG inclusion applications for invasive medical devices intended to administer medicines or biologicals by inhalation are not currently subject to the mandatory audit assessment requirement, i.e. there will be no audit 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 and Class IIb entries in the ARTG following reclassification.

Engagement

Wherever practicable, the TGA will:

- Liaise with medical device sponsors and manufacturers, the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal, and
- 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 invasive medical devices intended to administer medicines or biologicals by inhalation are very important to us.

When considering the proposed measures, assume that the EU MD Regulation definitions and terminology and Rule 20 apply to invasive medical devices intended to administer medicines or biologicals by inhalation in the context of the Australian MD Regulations.

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

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 unintended—do you anticipate the proposed 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?
- Should the proposed classification rule refer specifically to *medicines* and *biologicals*, or should it refer to any *therapeutic good*?
- Do you have any comments/views regarding the meaning of the terms *essential impact* or *life-threatening conditions*? Should these terms be clarified in our guidance or defined in the Australian MD Regulations? If yes, what definitions do you propose for the meaning of these terms?
- Do you have any comments/views on whether manufacturers of invasive medical devices that are intended to administer a medicine in such a way that the medicine and the device form a single integral product which is intended exclusively for use in the given combination and which is not reusable (may be multi-dose) should have evidence to demonstrate compliance of the device with the relevant essential principles/General Safety and Performance Requirements?
- 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 and other classification rules related to invasive medical devices

EU MD Regulation	Australian MD Regulations	Proposed amendments
CHAPTER I - SCOPE AND DEFINITIONS ***Article 1* - Subject matter and scope**	**Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010** **Articles declared not to be medical devices**	
9. Any device which is intended to administer a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC shall be governed by this Regulation, without prejudice to the provisions of that Directive and of Regulation (EC) No 726/2004 with regard to the medicinal product.	N/A	N/A
However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned.	3(c) an article that is intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and which is not reusable (may be multi-dose);	**No change is proposed**

EU MD Regulation	Australian MD Regulations	Proposed amendments
***ANNEX VIII* - CLASSIFICATION RULES**		
CHAPTER I - DEFINITIONS SPECIFIC TO CLASSIFICATION RULES 2. INVASIVE AND ACTIVE DEVICES ***2.1 'Body orifice'*** means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.	**Dictionary** (regulation 1.3) ***body orifice***: a) means a natural opening, or a permanent artificial opening, in a human being's body; and b) includes the external surface of a human being's eyeball.	The EU definition is consistent with the interpretation of this term in Australia. **No change is proposed**
CHAPTER III - CLASSIFICATION RULES **5. INVASIVE DEVICES** **5.1. Rule 5** All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: • class I if they are intended for transient use; • class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and • class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity	**Schedule 2—Classification rules for medical devices other than IVD medical devices** **Part 3—Rules for invasive medical devices and implantable medical devices** **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:	The EU classification rule is consistent with the respective rule in Australia. **No change is proposed**

EU MD Regulation	Australian MD Regulations	Proposed amendments
and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.	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.	
All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.	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.	**No change is proposed**
CHAPTER III - CLASSIFICATION RULES **6. ACTIVE DEVICES** **6.4 Rule 12** All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of	**Rule 4.4 Active medical devices intended to administer or remove medicines, etc. from a patient's body** (1) Subject to subclause (2), an active medical device that is intended by the manufacturer to be used to administer medicine, body liquids or other substances to a patient, or to remove medicine, body liquids or other substances from a patient, is classified as Class	The EU classification rule is consistent with the respective rule in Australia. **No change is proposed**

EU MD Regulation	Australian MD Regulations	Proposed amendments
the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.	IIa. (2) If the device is of a kind such that the administration or removal of the medicine, body liquids or other substances is potentially hazardous to the patient, having regard to the nature of the substances involved, the part of the patient's body concerned, and the characteristics of the device, the device is classified as Class IIb.	
7. SPECIAL RULES **7.7. Rule 20** All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as class IIb.	No equivalent classification rule	**This classification rule is subject of this consultation paper.**

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, Therapeutic Goods Administration	March 2019

Therapeutic Goods Administration

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