Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Reclassification of medical devices that administer medicines or biologicals by inhalation

Guidance on the transitional arrangements and obligations

Version 1.3, August 2023

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

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

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

Contents

About this guidance

This guidance aims to assist sponsors of **medical devices that administer medicines or biologicals by inhalation** with meeting their obligations and outlines transitional arrangements to help comply with new regulations.

From **25 November 2021** medical devices that administer medicines or biologicals by inhalation will be required to meet regulatory requirements demonstrating the safety and efficacy of the product commensurate with the higher classification (**Class IIa or Class IIb**).

Background

In early 2019 the Therapeutic Goods Administration (TGA) conducted a public consultation seeking feedback on a proposal to reclassify medical devices that administer medicines or biologicals by inhalation. The proposed regulatory changes supported the commitment made in the Australian Government Response to the Review of Medicines and Medical Devices Regulation to align Australian medical device regulations, where possible and appropriate, with the European Union framework.

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

The amendments include the reclassification of medical devices that administer medicines or biologicals by inhalation, effective from 25 November 2021.

Further regulatory refinements were made on 29 October 2021 to provide greater clarity around the regulation of these products.

Requirements for reclassification

The requirements include:

- more detailed assessment of the manufacturer's quality management systems and assessment of technical documentation related to the device
- conformity assessment documents demonstrating procedures appropriate for their classification.

The following guidance aims to assist sponsors of these devices with meeting their obligations and outlines transitional arrangements to help sponsors comply with the new regulations.

Medical devices that administer medicines or biologicals by inhalation

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

Subclause 5.10 of Schedule 2:

If a medical device is intended to be used to administer medicines or biologicals by inhalation:

(a) if the mode of action of the device has an essential impact on the efficacy and safety of the medicines or biologicals—the device is classified as Class IIb; or

(b) if the device is intended to treat a life-threatening condition—the device is classified as Class IIb; or

(c) if paragraphs (a) and (b) do not apply—the device is classified as Class IIa.

Medical devices intended to administer medicines or biologicals by inhalation are widely used for the treatment of respiratory disorders (for example, 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 (for example, diabetes, analgesia, thyroid disorders and genetic disease).

Examples of devices to be reclassified

In considering the appropriate classification of a medical device that is intended to be used to administer medicines or biologicals by inhalation, sponsors may wish to consider the following:

- Does the mode of action (for example, action, mechanism or operation) of the device have an impact on the delivery, dosage, efficacy and safety of the medicine or biological that is being delivered to the person? For example, if a medicine or biological is required to be aerosolised to be efficacious prior to inhalation by a patient and the device failed to aerosolise the medicine or biological, this would have an impact on the efficacy of the medicine or biological. In this instance, the device would be classified as **Class IIb**.
- Is the device intended to administer a medicine or biological by inhalation to treat a life-threatening condition where, if the operation of the device failed it could result in the death of the person? For example, a medical device that is intended to deliver medicines by inhalation to treat a severe asthma attack where if the device failed it could result in the death of the person would be classified as **Class IIb**.

Some examples of medical devices intended for administering medicines or biologicals, and a comparison of the old classification versus the new classification are provided below.

Comparison of old vs new classification

Device	Old classification	New classification
Inhalation 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 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 IIb** - *if the mode of action of the device has an essential impact on the efficacy and safety of the medicine or biological, or if it is intended to treat a life-threatening condition* *Or* **Class IIa** - *if the mode of action of the device does not have an essential impact on the efficacy and safety of the medicine or biological, or if it is not intended to treat a life-threatening condition*

Device	Old classification	New classification
Nebulisers and their accessories • **Mouthpiece, nebulisers cup/container,** Nebulisers are devices that transform solutions or suspensions of medications into aerosols that are better for deposition in the lower airways. This mode of administering medicine is critical for respiratory disorders and may include delivery of antibiotics, bronchodilators, corticosteroids and more. These devices can be used for patients who are not able to use other inhaler devices (for example, too young or too ill). Nebulisers are used with accessories (for example, invasive devices such as mouthpieces/face masks) 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 IIb** - *if the device is intended to treat a life-threatening condition* *Or* **Class IIa** - *if the device is not intended to treat a life-threatening condition*
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 IIb** - *if the device is intended to treat a life-threatening condition* *Or* **Class IIa** - *if the device is not intended to treat a life-threatening condition*
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** *(if the device is intended to treat a life-threatening condition)*

Device	Old classification	New classification
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 (for example, 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 of 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 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** *(if the device is intended to treat a life-threatening condition)*
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 products (for example, 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 keep the airways open by preventing the tongue from covering the epiglottis.	**Class I** or **Class IIa** *(invasive medical device for transient or short-term use)*	**Class IIb** - *if the device is intended to treat a life-threatening condition* *Or* **Class IIa** - *if the device is not intended to treat a life-threatening condition*
Nasopharyngeal airway A nasopharyngeal airway (NPA), also known as a nasal trumpet 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 (for example, oxygen supply) by inhalation. When a person becomes unconscious, the muscles in their jaw relax and the tongue can 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 IIb** - *if the device is intended to treat a life-threatening condition* *Or* **Class IIa** - *if the device is not intended to treat a life-threatening condition*

Device	Old classification	New classification
Refillable inhaler device A refillable handheld device used to deliver aerosolized medication into the mouth of a patient.	**Class I** or **Class IIa** *(invasive medical device for transient or short-term use)*	**Class IIb** - *if the mode of action of the device has an essential impact on the efficacy and safety of the medicine or biological, or if it is intended to treat a life-threatening condition* *Or* **Class IIa** - *if the mode of action of the device does not have an essential impact on the efficacy and safety of the medicine or biological, or if it is not intended to treat a life-threatening condition*

Please note

The examples provided above are for medical devices that are **not intended to 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 Australia.

Devices pre-filled with medicines or biologicals

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

Item 3(c) of the Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010 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 specified in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

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 including:

- **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 product 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 an integrated mouthpiece into which a pressurised metal canister containing the solution or suspension of medicine is placed.

- **Dry powder inhaler, prefilled with the medication**

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.

There is no change to 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** intended exclusively for use in the given combination, and which may be multi-dose, but is not reusable. These devices (such as asthma puffers) will **continue to be declared not to be medical devices.**

What you need to do

If you are the sponsor of medical device that administers medicines or biologicals by inhalation, the action you will need to take to comply with the new regulations will depend on the status of your product:

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

Medical devices included in the ARTG prior to 25 November 2021

If you have a medical device that administers medicines or biologicals by inhalation in the ARTG with a start date before 25 November 2021, there are transitional arrangements in place to ensure that you can continue to supply your device while you apply for it to be included in the ARTG in accordance with the new classification.

If you would like to continue to supply your device you must:

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

Please note

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

If you **notify** the TGA of your devices **before 25 May 2022** but you do not **submit an application** for ARTG inclusion with the correct classification **before the transition deadline**, you must cease supplying your device from the day of the transition deadline and cancel your inclusion.

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

If you have submitted an application for inclusion in the ARTG for a medical device that administers medicines or biologicals by inhalation before 25 November 2021, your device application will be assessed and the device will be included in the ARTG under the old classification rules.

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

- Notify the TGA that you have an ARTG inclusion that will need to be reclassified by whichever is the later date:
    - **Before 25 May 2022**
    - **Within 2 months of the start date of your ARTG entry**
- Submit a reclass application for your device to be included in the ARTG with the correct classification **before the transition deadline**.

Cancelling your ARTG inclusion

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

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

If you **notify** the TGA of your device before the due date, but you **do not submit an application** for the correct classification **before the transition deadline**, you must:

- cease supplying your device from the day of the transition deadline
- cancel your ARTG inclusion.

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

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

For more information refer to the Medical device inclusion process.

Notifying the TGA

To notify the TGA that you have an ARTG inclusion for a device that administers medicines or biologicals by inhalation that needs to be reclassified, you will need to fill in the online form on our Consultation Hub:

https://consultations.health.gov.au/tga/reclass-md-administer-medicines-by-inhalation

The form will be available until 24 May 2022.

The information you will need to provide includes the existing ARTG number, current classification, and new classification.

Application to transition

Timeframes for reclassifying transitional ARTG inclusion

To continue supplying your devices, you must submit your reclassification application for the correct class **before the transition deadline.** In July 2023, the Government agreed that regulatory amendments should be drafted to extend this transition deadline to 1 July 2029. The regulatory amendments are underway and are expected to be in place before December 2023. Once the amendments are made, the transition deadline would be **1 July 2029**. More information about the proposed regulatory amendment can be found at https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/eu-mdr-transition/eu-mdr-transition-extension.

If you have submitted your application before this date, but it has not yet been finalised by the TGA, you are able to continue to supply your devices using your existing ARTG entry until a decision is made about your reclass application.

How to submit a reclassification application

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

3. Select the option to ‘Reclassify an existing register entry’

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

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

Please note

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

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

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

If there is a change of manufacturer, you must submit a new application *(i.e.* select “Create a new inclusion in the register” instead of “Reclassify an existing register entry” in the Step 3 shown above) and provide information about the existing ARTG entry in the application form or in a supporting document attached with the form.

What to include in your application

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

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

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

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

Fees

You will need to pay the relevant application fee.

Please note

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

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

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

If your inclusion application is not successful

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

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

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

When to cease supply using your old ARTG entry

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

When to cease supply using an old ARTG entry

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Authorisation Branch	March 2021
V1.1	Update due to regulatory refinements	Medical Devices Authorisation Branch	November 2021
V1.2	Addition of reclassification instructions	Medical Devices Authorisation Branch	December 2022
V1.3	Update the transition deadline, weblink and some minor edits	Medical Devices Authorisation Branch	August 2023

Therapeutic Goods Administration

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

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