



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Boundary and combination products Consultation on legislating regulatory categories

Version 1.0, June 2024

Copyright

© Commonwealth of Australia 2024

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

About	4
Background	4
Previous consultation and outcomes	4
Consultation	5
Proposal 1: Legislating regulatory categories	5
Proposal 2: Other products	9

About

The Australian Government is undertaking significant reforms to improve the regulation of therapeutic goods in Australia.

The Therapeutic Goods Administration (TGA) is the government authority responsible for evaluating, assessing, and monitoring products that are defined as therapeutic goods including medicines, medical devices, and biologicals.

This consultation seeks feedback on legislating some of the boundary and combination products to provide further clarity on regulatory pathway, and the transitional arrangements required for the affected products to comply with the changes.

Background

Products that meet the legislative definition of a therapeutic good under the [Therapeutic Goods Act 1989](#) (the Act) are regulated by the TGA and need to be included in the [Australian Register of Therapeutic Goods](#) (ARTG) before they can be imported, exported or supplied.

Therapeutic goods are regulated as one of the following categories:

- Medicines as defined under Section 3 of the Act,
- Biologicals as defined under Section 32A of the Act,
- Medical devices as defined under Section 41BD of the Act, and
- Other therapeutic goods (OTGs) which include goods like tampons and disinfectants.

Products that fall under these categories have different regulatory pathways and requirements.

Some products may have attributes of two or more categories and the appropriate regulatory pathway is not immediately obvious. These are referred to as **'boundary products'**.

Some products contain more than one type of therapeutic good with more than one therapeutic action or effect. These are referred to as **'combination products'**.

The regulatory category of these products is determined by a few factors, including the principal therapeutic effect of the product, therapeutic claims and intended use.

See [Guidance on Boundary and Combination Products](#).

Previous consultation and outcomes

In October 2022, we undertook a public consultation on the draft guidance for 'Boundary and combination products - medicines, medical devices, and biologicals.'

The draft guidance also included an example list of boundary and combination products (the List) along with their regulatory category.

From this consultation, several respondents noted that further clarification of the product category, mode of action, and rationale for the product category designation are needed.

Several responses also noted that there were products supplied in Australia that were not aligned with the definition and product category mentioned, including products for lice on the head and body, oral care toothpastes, and compounded and uncompounded emollient and moisturising preparations for therapeutic use.

Suggestions for improvement included the need for greater clarification on how we regulate and categorise boundary and combination products.

Further changes to the list such as clarifying or adding products and their categories, adding an additional column to the list that explains the rationale for why products are categorised as a medicine, medical device, biological or other therapeutic good, and clarifying boundary and combination products through legislation were also suggested.

In response to the feedback provided, we updated the guidance and the List on [boundary and combination products](#).

Consultation

Feedback received in the previous consultation indicated the need for additional clarity and transparency on the appropriate regulatory pathways for some boundary and combination products.

In this consultation, we are seeking feedback on whether:

- legislating some products where possible to formally declare their regulatory category (e.g., medical device, not a medical device or OTG), will provide additional clarity for stakeholders.
- a transitional period of five years is sufficient for sponsors of affected ARTG entries.

The consultation is being hosted on the TGA Consultation Hub and is open for feedback from 24 June to 06 August 2024.

Proposal 1: Legislating regulatory categories

Tabled below are the regulatory categories for some of the products.

1. Review the information
2. Respond to proposal questions related to these products.

Product	Mode of action	Regulatory category
Head and body lice products for humans	Products that achieve the principal intended action primarily through pharmacological or chemical means such as products causing neurotoxicity to the lice.	Medicine
	Products that achieve the principal intended action primarily through physical means such as lice combs, lubricants, and electrocution of the lice.	Medical Device (Exempt)
	Products that achieve the principal intended action through both pharmacological or chemical, and physical means. The action through physical means is considered ancillary.	Medicine
Moisturisers and emollients	Products that incorporate active ingredient(s) and the principal intended action is primarily achieved through pharmacological or metabolic means.	Medicine
	Products that achieve the principal intended action primarily through physical means such as creating a barrier to retain moisture.	Medical Device (Exempt)

Product	Mode of action	Regulatory category
	Products that achieve the principal intended action through both pharmacological or metabolic, and physical means, noting that the purpose of creating a barrier through physical means is considered ancillary.	Medicine
Toothpastes (dentifrices)	Products that incorporate active ingredient(s), and the principal intended action is primarily achieved through pharmacological or chemical means.	Medicine
	Products that achieve the principal intended action primarily through physical means such as providing a protective barrier and blocking dentine pore.	Medical Device (Exempt)
	Products that achieve the principal intended action through both the incorporated active ingredient and physical means, noting that the purpose of creating a barrier through physical means is considered ancillary.	Medicine
Products generated by ozone generators	Products that are used for: <ul style="list-style-type: none"> sanitising or disinfecting a medical device or equipment, or clinical treatment in dentistry 	Medical Device
	Products that are hospital grade or household/commercial grade disinfectant that <u>do not make specific claims</u> *, and are: <ul style="list-style-type: none"> <u>not intended</u> for use internally or on skin, <u>not intended</u> for use on medical device, and <u>intended</u> for use on hard and soft surfaces. 	Exempt Disinfectant
	Products that are hospital grade or household/commercial grade disinfectant that <u>make specific claims</u> *, and are: <ul style="list-style-type: none"> <u>not intended</u> for use internally or on skin, <u>not intended</u> for use on medical device, and <u>intended</u> for use on hard and soft surfaces. 	Listed Disinfectant
	Products for sanitation, environmental control and environmental detoxification.	Excluded Goods
Weight loss treatment - ingested	Products such as capsules that expand in the stomach to create a feeling of satiety by occupying space.	Medical Device

Product	Mode of action	Regulatory category
	Products that affect absorption of calories in the gastrointestinal system by metabolic means.	Medicine

* Virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity are known as "specific claims". See [Disinfectant Claim Guide](#).

Proposal 1a

1.1 Would legislating the products, wherever possible, to be declared as per the regulatory categories mentioned in the table above provide additional clarity on the regulatory pathway for these products?

- Yes/No
- Explain why?

1.2 If your product would need to change regulatory category as per the table above, would a transitional period of five years be sufficient for you to transition your impacted product to the correct regulatory category?

- Yes/No
- Explain why?



Tabled below are the appropriate regulatory categories and classifications for vascular access products and flush syringes.

Review the information and respond to the proposal questions related to these products.

Product	Mode of action	Regulatory category	Classification
Vascular Access Device (VAD) locking solutions	The principal intended action is primarily achieved through physically maintaining the patency of the lumen of a catheter. These may contain substances such as antibiotics or anticoagulants to prevent thrombus or fibrin formation in the catheter. The locking solutions are typically intended to be aspirated out from the VAD, rather than being used as a flushing solution into the patient.	Medical Device	Class IIa – VAD locking solution <u>without</u> ancillary substances such as antibiotics or anticoagulants, as per Clause 3.3 (2) Schedule 2 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> (the Regulations). Regulation 5.1 Schedule 2 of the Regulations does not apply because this product is not intended to come into contact within the systemic circulation of the human body.
			Class IIa - VAD locking solution <u>with</u> ancillary substances such as antibiotics or anticoagulants, as per Clause 3.3 (2) Schedule 2 of the Regulations

Product	Mode of action	Regulatory category	Classification
Pre-filled saline flush syringes	The principal intended action is primarily achieved through physical flushing. These may contain active substances such as antibiotics or anticoagulants and their function is considered ancillary.	Medical Device	Class IIa – pre-filled saline flush syringe, as per Clause 3.3(2) Schedule 2 of the Regulations
			Class III – pre-filled saline flush syringe with active substance such as antibiotics or anticoagulants. As per Regulation 5.1 Schedule 2 of the Regulations

Proposal 1b

1.3 Would legislating the products to be declared as per the regulatory categories and classification mentioned in the table above provide additional clarity on the regulation of these products?

- Yes/No
- Explain why?

1.4 If your product would need to change regulatory category and/or classification as per the table above, would a transitional period of five years be sufficient for you to transition your impacted product to the correct regulatory category?

- Yes/No
- Explain why?



Proposal 2: Other products

The TGA has recently published [updated guidance on boundary and combination products](#).

1. Review the [example list of boundary and combination products](#)
2. Respond to the questions below.



Proposal 2

2.1 Are there any other products that should have their regulatory category clarified through legislation?

- Yes/No
- If yes, list other products that should have their regulatory category legislated for additional clarity and explain why.

Consent to publish your response

Please review the consultation paper and provide your response through the [TGA Consultation Hub](#). If you are unable to use the link and choose to provide a response through Outlook, then please indicate your publishing preferences for your submission.

Select one option from below.



1. I consent to my submission being published, including both my name and my organisation's name.
2. I consent to my submission being published, without my name but including my organisation's name.
3. I consent to my submission being published anonymously (without my name or my organisation's name).
4. I do NOT consent to my submission being published.

If you consent to your submission being published, are there parts that you do not want published? (Please specify which part(s))

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Reforms Taskforce	June 2024

Therapeutic Goods Administration

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

Reference/Publication #