s22 [redacted]

From: News
Sent: Friday, 26 September 2025 3:02 PM
To: John Flint
Subject: RE: Media enquiry, re TGA [SEC=OFFICIAL]

Hi John

The Therapeutic Goods Advertising Code applies to therapeutic goods that are advertised to the general public.

The TGA does not comment on individual matters.

Thanks

s22 [redacted]
Media and Events

Australian Government, Department of Health, Disability and Ageing
s22 [redacted] E: news@health.gov.au

From: John Flint
Sent: Friday, 26 September 2025 2:02 AM
To: News
Subject: RE: Media enquiry, re TGA [SEC=OFFICIAL]

Apologies for having to come back to you on a further point, but regarding advertising (final answer below) does this code apply?:

https://www.tga.gov.au/resources/legislation/therapeutic-goods-therapeutic-goods-advertising-code-instrument-2021

If yes, is LifeVac Australia's website and its Facebook site in breach of the code?

Kind regards,

John

From: News <news@health.gov.au>
Sent: Friday, 5 September 2025 8:16 AM
To: John Flint <john.flint@wanews.com.au>; News <news@health.gov.au>
Subject: RE: Media enquiry, re TGA [SEC=OFFICIAL]

Hi John,

Please see further response below.

The Therapeutic Goods Administration (TGA) does not routinely collect supply data for medical devices (ie: information about the purchasers or users). Information is held by sponsors and manufacturers, who are responsible for maintaining distribution records in accordance with regulatory requirements. The TGA may

request supply data to assist post-market reviews or investigations. We do not have access to personal information about specific individuals (ie: users).

In relation to our oversight activities - all medical devices included in the Australian Register of Therapeutic Goods (ARTG) are subject to ongoing monitoring by the TGA following approval. This includes ensuring the device performs as intended and continues to be safe. We take a proactive risk-based approach in how we monitor, including reviewing emerging evidence from clinical and academic research, adverse event reports or complaints, published literature, and alerts from international regulatory counterparts. Where new evidence or potential linkages are identified through this monitoring, the TGA may initiate further investigation or review. During a review, the TGA may also seek expert advice from the Advisory Committee on Medical Devices (ACMD) relating to risks and benefits of these devices. For more information about post-market reviews, please see: https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews/medical-device-post-market-reviews-process.

Patients are strongly encouraged to report any adverse event or near (potential) adverse event to the TGA. Adverse event reporting allows us to monitor medical device use, their performance in the real world and identify trends that may indicate emerging safety and performance issues. For more information about reporting, please see: Incident Reporting and Investigation Scheme (IRIS)

Importantly, advertising should not take advantage of people's concern for their health by using fearmongering in advertisements. Advertisers should avoid words or images that would give the impression that the safety and efficacy of the advertised goods is guaranteed or remarkable.

Kind regards,
s22

Media Unit

Australian Government, Department of Health, Disability and Ageing
s22 E: news@health.gov.au

Unless stated otherwise, this information is provided on a background basis and should not be attributed.

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: John Flint <john.flint@wanews.com.au>
Sent: Wednesday, 3 September 2025 9:42 PM
To: News <news@health.gov.au>
Subject: RE: Media enquiry, re TGA [SEC=OFFICIAL]

OFFICIAL

Hi s22

I just have a couple of follow-up questions for further clarification.

Re: The TGA checks for compliance with selected requirements before including the device on the ARTG and maintains oversight after approval.

Does oversight include checking with users to see if the device works as claimed and is safe? If no, what is overseen?

The company frequently publishes claims on its social media pages that its product has saved “another life”. Has the TGA ever asked the company to put it in touch with these happy customers?

My deadline is Friday lunchtime. Thanks.

Kind regards,

John

OFFICIAL

From: News <news@health.gov.au>
Sent: Friday, 8 August 2025 3:58 PM
To: John Flint <john.flint@wanews.com.au>
Cc: News <news@health.gov.au>
Subject: Media enquiry, re TGA [SEC=OFFICIAL]

Hi John,

The following response is attributable to a spokesperson for the TGA.

Response:
Sponsors are permitted to say that their device is included in the Australian Register of Therapeutic Goods (ARTG) in their advertising, so long as the information is consistent with the indications or intended purposes stated in the ARTG entry for that product.
However an ARTG entry must not be presented as a TGA endorsement of the product. More information about how therapeutic goods can be marketed, and appropriate claims can be found at www.tga.gov.au/how-we-regulate/advertising/applying-advertising-code.

The LifeVac ARTG entry 285082 – see: www.tga.gov.au/resources/artg/285082 includes standard conditions to ensure ongoing compliance. No extra conditions have been applied to this device.

All medical devices must comply with quality, safety and performance requirements. These requirements are outlined on our website at: www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/quality-safety-and-performance-requirements-medical-devices-essential-principles. This includes requirements for electrical safety, mechanical safety, materials used to make the products, quality control of the production, clinical evidence that support the therapeutic claims, and labelling requirements. The TGA takes a risk-based approach to checking medical devices and for class I medical devices such as the LifeVac device (the lowest risk class), the manufacturer is legally responsible for verifying the safety and performance of the device The TGA checks for compliance with selected requirements before including the device on the ARTG and maintains oversight after approval.

***
Thank you

s22 [redacted]
Media and Events, Corporate Communication Branch
Australian Government, Department of Health, Disability and Ageing
s22 [redacted] | E:news@health.gov.au
Unless stated otherwise, this information is provided on a background basis and should not be attributed.

From: John Flint <john.flint@wanews.com.au>
Sent: Thursday, 7 August 2025 2:15 PM
To: News <news@health.gov.au>
Subject: Media enquiry, re TGA

Hi media team,

I researching a commercial anti-choking device, LifeVac, that is listed on the Australian Register of Therapeutic Goods (ARTG).

Does this mean it call be marketed as TGA approved?

Are there any conditions attached to its listing?

Has the TGA determined the product is safe and fit for purpose. If yes, what did the evaluation consist of?

I am working on a story for the weekend.

Thanks in advance for any help on this.

Kind regards,

John

John Flint
Senior Journalist - Investigations | Editorial

T (08) 94829267 **M** 0408902339

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GPO Box D162, Perth WA 6840
john.flint@wanews.com.au

thewest.com.au | perthnow.com.au | 7news.com.au

s22 [redacted]

From: News
Sent: Thursday, 14 August 2025 1:59 PM
To: john.flint@wanews.com.au
Cc: News
Subject: Media enquiry, re TGA [SEC=OFFICIAL]

Follow Up Flag: Follow up
Flag Status: Completed

Hi John,

The following response is attributable to a spokesperson for the TGA.

Response:
Is it true that the TGA conducted a two-year long clinical review of the LifeVac device?

The TGA routinely undertakes post-market reviews. Between 2018-2020, the TGA undertook a number of post-market reviews across a range of device types, including anti-choking devices included in the Australian Register of Therapeutic Goods (ARTG). The LifeVac (ARTG entry 285082) was included in this review period. As part of any post-market review, the TGA considers a range of information to make an informed assessment about the device under review. This information can include clinical evidence, risk management, labelling and design reviews. Additional information regarding the TGA's post-market review work can be found at: https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews

Are the following statement accurate? I note that LifeVac also claims on its website that "it is the only airway clearance device that can be legally sold in Australia."

a. *"Unlike first aid, LifeVac has its effectiveness and safety constantly monitored by regulators under a risk management structure."*

All medical devices included in the Australian Register of Therapeutic Goods (ARTG) are subject to ongoing monitoring by the TGA following approval. The TGA takes a risk-based approach to regulation, and post-market monitoring enables us to assess how medical devices perform in real-world settings to identify emerging safety or performance concerns and undertake regulatory action, if necessary.

b. *"There is only one genuine device that is non-invasive, **proven and reviewed** by the TGA, the LifeVac."*

There are two anti-choking devices included in the Australian Register of Therapeutic Goods:

- LifeVac Anti-Choking Device
- Aero Healthcare - Airway emergency clearance/suction plunger

Did the TGA ever say "it would take an Australian to die before they would even consider regulatory action"?
TGA remains concerned about the health and safety of Australian consumers accessing unregistered, unapproved, or counterfeit therapeutic products.
The TGA has taken action and engaged with digital platforms in relation to Lifevac devices.
The TGA actively monitors digital platforms and social media for unlawful advertising and counterfeit therapeutic goods. We work closely with platforms such as eBay, Meta, and Amazon to deter and remove non-compliant content.
When breaches are identified, platforms are notified and, in many cases, platforms act swiftly in accordance with their user policies when alerted to breaches.
In the 2024–25 financial year, the TGA requested the removal of over 13,700 online advertisements.
The TGA's compliance and enforcement activities are guided by compliance priorities that focus on enhancing public safety and addressing serious breaches of the Therapeutic Goods Act 1989 (the Act) and regulations, or that involve repeated or wilful non-compliance.
We take a strategic approach to prioritising compliance investigations.
All compliance and enforcement actions are undertaken in accordance with the TGA's regulatory compliance framework which ensures consistency, fairness, and proportionality in decision-making.

The TGA's compliance and enforcement activities are guided by compliance priorities that focus on enhancing public safety and addressing serious breaches of the Therapeutic Goods Act 1989 (the Act) and regulations, or that involve repeated or wilful non-compliance.
If we receive signals regarding the safety, quality, or performance of medical devices, we gather information and undertake regulatory action if required.

***
Thank you

s22
Media and Events, Corporate Communication Branch

Australian Government, Department of Health, Disability and Ageing
s22 | E:news@health.gov.au

From: John Flint <john.flint@wanews.com.au>
Sent: Tuesday, August 12, 2025 3:30 PM
To: News <news@health.gov.au>
Subject: RE: Media enquiry, re TGA [SEC=OFFICIAL]

Hi s22

Thanks for your help last week.

I am still working on this story, re: LifeVac.

My follow-up questions regard statements made by LifeVac about the TGA in the following video (using an AI avatar):

https://www.facebook.com/lifevacaustralia/videos/1253252642946905/

Is it true that the TGA conducted a two-year long clinical review of the LifeVac device?

Are the following statement accurate?

"Unlike first aid, LifeVac has its effectiveness and safety constantly monitored by regulators under a risk management structure."

*"There is only one genuine device that is non-invasive, **proven and reviewed** by the TGA, the LifeVac."*

In the video, LifeVac has criticised the TGA for not doing enough to stop counterfeit products. Specifically, it stated:

"Counterfeits have been evaluated in the UK by their regulator, the MHI, and found to be dangerous to public safety due to defective and poor manufacturing and design. Despite this danger, the TGA has been ineffective at stopping Australians from being exposed to the advertising and sale of these dangerous counterfeits. This is despite three years of complaints the TGA has stated that it would take an Australian to die before they would even consider regulatory action. I think you would agree that this is both alarming and appalling."

Did the TGA ever say "it would take an Australian to die before they would even consider regulatory action"?

I note that LifeVac also claims on its website that "it is the only airway clearance device that can be legally sold in Australia." We know that's not true because another such device, Dechoker was registered by the TGA on December 6 last year.

Any further comments or clarification are invited.

My deadline is COB Wednesday.

Thanks again.

Kind regards,

John

From: News <news@health.gov.au>
Sent: Friday, 8 August 2025 3:58 PM
To: John Flint <john.flint@wanews.com.au>
Cc: News <news@health.gov.au>
Subject: Media enquiry, re TGA [SEC=OFFICIAL]

Hi John,

The following response is attributable to a spokesperson for the TGA.

> **Response:**
> Sponsors are permitted to say that their device is included in the Australian Register of Therapeutic Goods (ARTG) in their advertising, so long as the information is consistent with the indications or intended purposes stated in the ARTG entry for that product.
> However an ARTG entry must not be presented as a TGA endorsement of the product. More information about how therapeutic goods can be marketed, and appropriate claims can be found at www.tga.gov.au/how-we-regulate/advertising/applying-advertising-code.
>
> The LifeVac ARTG entry 285082 – see: www.tga.gov.au/resources/artg/285082 includes standard conditions to ensure ongoing compliance. No extra conditions have been applied to this device.
>
> All medical devices must comply with quality, safety and performance requirements. These requirements are outlined on our website at: www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/quality-safety-and-performance-requirements-medical-devices-essential-principles. This includes requirements for electrical safety, mechanical safety, materials used to make the products, quality control of the production, clinical evidence that support the therapeutic claims, and labelling requirements. The TGA takes a risk-based approach to checking medical devices and for class I medical devices such as the LifeVac device (the lowest risk class), the manufacturer is legally responsible for verifying the safety and performance of the device The TGA checks for compliance with selected requirements before including the device on the ARTG and maintains oversight after approval.

***
Thank you

s22 [redacted]
Media and Events, Corporate Communication Branch

Australian Government, Department of Health, Disability and Ageing
s22 [redacted] | E:news@health.gov.au
Unless stated otherwise, this information is provided on a background basis and should not be attributed.

From: John Flint <john.flint@wanews.com.au>
Sent: Thursday, 7 August 2025 2:15 PM

Document 2

To: News <news@health.gov.au>
Subject: Media enquiry, re TGA

Hi media team,

I researching a commercial anti-choking device, LifeVac, that is listed on the Australian Register of Therapeutic Goods (ARTG).

Does this mean it call be marketed as TGA approved?

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Has the TGA determined the product is safe and fit for purpose. If yes, what did the evaluation consist of?

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Thanks in advance for any help on this.

Kind regards,

John

John Flint
Senior Journalist - Investigations | Editorial

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