

From: [REDACTED]
Sent: Thu, 7 Aug 2025 10:56:26 +0000
To: [REDACTED]
Cc: [REDACTED]
Subject: TGA email to UK MHRA - Lowenstein medical CPAP [SEC=OFFICIAL]

Hi [REDACTED]

I hope all is well with you.

We have received the e-mail below from TGA.

Please can you draft a response and send this to the signal mailbox?

Thank you.

Kind regards,
[REDACTED]

From: [REDACTED]
Sent: Thursday, August 7, 2025 5:50 AM
To: [REDACTED]
Cc: [REDACTED]
Subject: TGA email to UK MHRA - Lowenstein medical CPAP [SEC=OFFICIAL]

Dear [REDACTED] and MHRA team,

I hope this message finds you well.

I, as delegate of the Secretary for the purposes of section 61 of the Act, approve under subsection 61(5) of the Act, the release to the UK MHRA of therapeutic goods information set out below in accordance with Memorandum of Understanding (MoU).

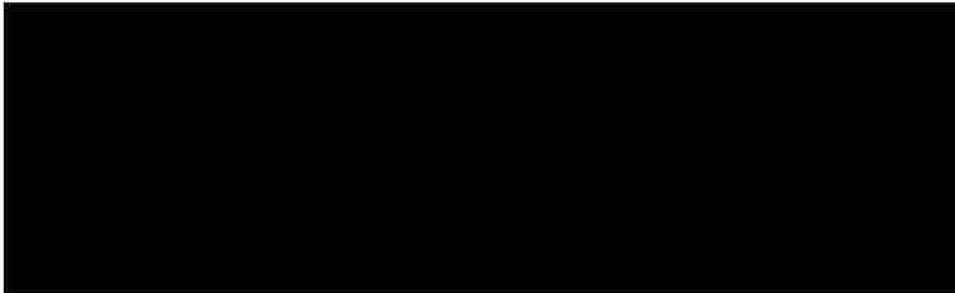
As you may be aware, the Therapeutic Goods Administration (TGA) is undertaking a post-market review of ventilator, CPAP and BiPAP devices included in the Australian Register of Therapeutic Goods (ARTG).

We have received an enquiry regarding an incident impacting a WM090TD CPAP ventilator supplied by Lowenstein Medical. As the device was supplied within the UK, and the patient was under the care of a UK healthcare provider, we understand that MHRA may be the appropriate regulatory authority for oversight and follow-up in this jurisdiction. As such, in our response to the person, we have provided some information about our post-market review (<https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews/post-market-review-ventilators-cpap-and-bipap-devices>) and advised the enquiry is outside of our remit as the incidents did not occur in Australia.

If there are any updates regarding regulatory activity with respect to these devices, we would welcome the opportunity to be informed on the outcome of your review, as this device is also under review in our jurisdiction.

Please do not hesitate to reach out if there are any updates or if further input is needed from our side.

Warm regards,



This email comes to you from Ngunnawal Country
PO Box 100, Woden ACT 2606
www.tga.gov.au



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.

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