

# **PRESS RELEASE**

19 September 2023

## **TGA APATHY WILL KILL AUSTRALIANS**

LifeVac Australia is the sole importer, and distributor, of the genuine ARTG-listed LifeVac Airway Clearance Device. Even after saving over 1,290 lives including in Australia, it took a two-year battle with the TGA, involving the Health Minister to prove that LifeVac was safe and effective and should remain on the Register of Therapeutic Goods (ARTG).

However, since October 2022 online shopping sites, such as eBay and Amazon as well as various fake sites have been selling counterfeit, untested, and unapproved fake “LifeVac” medical devices in Australia. These sellers have stolen a load of images, videos, and other media from our legitimate sites around the world in order to deceive Australian consumers that they are purchasing a genuine medical device that is safe, effective, and approved.

It is illegal in Australia to sell or advertise counterfeit products, specifically medical devices; they cannot be sold without being listed on the ARTG. Selling these counterfeit devices, manufactured in China, that are poor and unsafe copies of the genuine LifeVac device is a breach of the Therapeutic Goods Act, Australian Consumer Law, and is subject to civil and criminal penalties for perpetrators.

Despite repeatedly reporting these illegal and unsafe (and unabated) practices since October 2022 to the TGA (the Regulator) and the ACCC; no effective action has been taken to eliminate this dangerous practice, which puts Australian consumers at risk and is likely to result in the death or serious harm to anyone who relies on these untested devices in an emergency. Documents obtained under FOI prove that no directive to cease has ever been made, no compliance notice has been issued and no civil or criminal charges have been instigated or even mentioned to these illegal sellers or even any mention of an infringement of the Therapeutic Goods Act.

Specifically, the Branch Head of the Regulatory Compliance Department of the TGA, has repeatedly failed in her duty to protect the safety of the public by deliberately misrepresenting our complaints as merely “trademark issues”; and displayed extreme partiality toward eBay in allowing them to escape regulation and compliance (including civil and criminal prosecution) by allowing them to self-regulate with impunity; provided false and misleading statements to the Health Minister and serious maladministration in refusing to uphold the TGA’s stated purpose i.e.

***“The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods. The ARTG contains therapeutic goods that can be lawfully supplied in Australia.”***

It would seem incomprehensible that a regulatory, legislated authority would be deliberately unwilling to pursue its primary function. It is difficult to see what possible motive the TGA (and its officers) may have for this gross dereliction of duty. The only response from the TGA has been to initiate an “audit” to force LifeVac to reclassify LifeVac kits under the ARTG, at a higher risk category (despite no evidence of harm) and thus subject the genuine LifeVac to yet another level of regulatory evidence and compliance (and cost), while continuing to allow illegal, counterfeit devices to be sold openly without regulation. This action is clearly in retaliation for complaints made concerning TGA's impropriety

Australians should be outraged that a government regulator, with the role, authority, and power to protect them from harm, would choose to not only to ignore a serious threat to the public but deliberately protect the illegal trade in counterfeit goods. The TGA has not provided any justification for its lack of action, based on any policy or legal exemption for these illegal, counterfeit products.

For the sake of the health and well-being of your loved ones, please contact the Health Minister, Hon Mark Butler via the link below and express your feelings on this outrageous situation and the failure of the TGA and its officers to regulate appropriately.

<https://www.health.gov.au/ministers/contact-minister>

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