From: <u>BEDFORD, Chris</u>

Subject: RE: Life Vac [SEC=OFFICIAL]

Date: Thursday, 23 March 2023 7:58:00 PM

Attachments: image001.png

image002.png image003.png image004.png image005.png

Hi s47F

Further to emails below.

Following 511C first complaint, 9 advertisements were removed from online platforms immediately. Our compliance team also started more focused monitoring. Since the first complaint we have facilitated removal of close to 300 advertisements for the product (a photo of the product is below).

While s11C is claiming that the TGA is not doing anything, significant focus is being undertaken to support compliance and a disproportionate amount of resources are currently allocated compared to other identified priorities. All advertisements identified, the TGA have facilitated removal of, plus more through our own monitoring program.

We acknowledge that the eBay platform seems to be the most problematic for unlawful advertisements (under Australian legislation). However eBay are doing all that they can to assist, and in addition to removing the advertisements we've requested, they've removed many more. They designed and implemented a blocking filter just for which has now blocked over 575 advertisements from being listed by other parties. Not only have eBay put in place restrictions on the Australian site but globally.

is the only Australian sponsor with the product on the ARTG, however, as noted, others are advertising the product on eBay Australia. It is often not possible, without carrying out an investigation, for the TGA to identify a legitimate advertisement from an unlawful advertisement. The advertisements not listed by safe on the ARTG with the correct information.

When state wrote to the Minister and approached the media we believe he had not submitted a vero form (verified rights owner form) to eBay to protect his rights and IP. eBay have now confirmed with us that state has since completed this form and eBay have put it in place to further restrict others from advertising this product.

claims that other international regulators have taken action but the TGA has not. A review of American and British eBay shows similar advertising.

In addition to consulting with eBay on a number of occasions we have also consulted with the ACCC who have received similar complaints from significant. They have indicated that the matter is not significant enough for them to action, and it relates to a therapeutic good for which TGA is the appropriate regulator.

If an advertisement is found to be for a counterfeit product or is a scam (i.e. purchased product will not be received) we will escalate action. However we believe that the advertisements are for legitimate product, possibly advertised by Chinese or American 'sponsors'/retailers.

may wish to speak to the manufacturer (his supplier) to discuss why other

Document 1 retailers are not restricted, by them, from promoting the product in Australia when still retailers are not restricted, by them, from promoting the product in Australia when the only Australian sponsor. We have an FOI request that is being processed from s11C seeking our communications with eBay. As always we are happy to discuss. Cheers, Chris **Chris Bedford Acting First Assistant Secretary** Regulatory Practice and Support Division Australian Government Department of Health and Aged Care T: 02 6289 5327 | M: **\$22** | E: chris.bedford@health.gov.au Location: Gulgana Building, Fairbairn, Canberra GPO Box 9848, Canberra ACT 2601, Australia Executive Assistant | \$22 | E: **s22** @health.gov.au The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present. @Health.gov.au> Sent: Thursday, 23 March 2023 5:15 PM @health.gov.au> Cc: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>; DUFFY, Tracey <Tracey.Duffy@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; 522 @Health.gov.au>; \$22 @health.gov.au>; \$22 @Health.gov.au> **Subject:** RE: Life Vac [SEC=OFFICIAL] Hi **S22** Thanks for the update. I don't think a new M response is necessary – by email is fine. From: **\$22** @health.gov.au> Sent: Tuesday, 21 March 2023 4:00 PM @Health.gov.au> Cc: Minister Butler DLO < Minister. Butler. DLO@Health.gov.au >; DUFFY, Tracey

<<u>Tracey.Duffy@health.gov.au</u>>; BEDFORD, Chris <<u>Chris.Bedford@health.gov.au</u>>; SEDFORD, Chris <<u>Chris.Bedford@health.gov.au</u>>; SEDFORD, Chris <<u>Chris.Bedford@health.gov.au</u>>; SEDFORD, Chris.Bedford@health.gov.au @Health.gov.au>; \$22 @health.gov.au>;

@Health.gov.au>

**Subject:** FW: Life Vac [SEC=OFFICIAL]

Hi **S47F** 

Sorry for the slow response.

At the meeting it was agreed that Tracey and Chris would look into it and get back to you. I note that MC23-002877 is the Min Corro referred to in the email below as having been received. The response (attached) was sent on 3 March.

Also for your info – we have receive an FOI request (FOI 4298) from s11C of LifeVac Australia for the following documents:

"Any documents, directives or other communications with eBay Australia and the TGA regarding the LifeVac Airway Clearance Device ARTG Number: 285082.

Given the response we have provided to \$11C (MC23-002877) – do you want a new M response created in PDMS to respond to Pat Conroy? Or would you be happy for an update to be provided by email?

I have copied Tracey and Chris to this email to assist with their follow up.

Thanks

s22

Executive Office Manager to Deputy Secretary John Skerritt

Health Products Regulation Group

(comprising the Therapeutic Goods Administration and the Office of Drug Control)

T: s22 | E: s22 @health.gov.au

Location: Fairbairn Level 2 North - 2.N.461

From: \$47F

Sent: Tuesday, 21 March 2023 11:05 AM

To: \$22

Cc: Minister Butler DLO Minister.Butler.DLO@Health.gov.au

**Subject:** Life Vac [SEC=OFFICIAL]

Hi **s22** 

I remember this being discussed during our meeting last week, but I was driving and having trouble with the GPS (!), so missed significant parts of what John and Tracey said.

Can you send me something?

Thanks

s47F

347F

Office of the Hon Mark Butler MP Minister for Health and Aged Care

m: **\$47** 

e: s47F health.gov.au

From: \$47F Health.gov.au>

**Sent:** Friday, 10 March 2023 4:19 PM

To: \$22 @health.gov.au>; \$22

@health.gov.au>

Subject: FW: Life Vac [SEC=OFFICIAL]

As promised ...

**Thanks** 

From: s47F Health.gov.au>

Sent: Thursday, 9 March 2023 3:01 PM

To: \$47F Health.gov.au>

**Subject:** FW: Life Vac [SEC=OFFICIAL]

Hey **S47F** 

Do you have any advice on this one?

Kind regards,

**S4/**F

s47F

Office of the Hon Mark Butler MP

Minister for Health and Aged Care

Suite MG.50 | PO Box 6022

Parliament House, Canberra ACT 2600



The Office and Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: S47F (P. Conroy, MP) S47F @aph.gov.au>

Sent: Thursday, 9 March 2023 1:59 PM

To: \$47F

Subject: Life Vac

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Ні **S47**F

Thank you so much for getting back to me, it's appreciated in what I imagine is a crazy week in Parliament.

is a constituent and S11C Life Vac, a small distribution company that supplies Life Vac to consumers in Australia. As you can see from the information below we met with prior to receiving the response from the Minister's office. To forwarded the response once he received it this week. I've attached the corro from eBay, ACCC. To from Julie Collins' office is going to liaise with eBay but it may also be helpful if we can have the TGA act. I have pasted the email he sent to us outlining the issues to facing with counterfeit products being sold on online market platforms.

"Life Vac is a local (Belmont) company that is the only registered importer and supplier of the LifeVac Airway Clearance Device in Australia. Our device is the only device of this type listed on the ARTG and been review and assessed by them for safety and compliance. So far, we have saved 671 lives including 402 children all after first aid has failed, including lives in Australia, the most recent a 10½ month old in WA who choked on a sausage and first aid attempts by the mother failed. The device is patented and the name is protected by trademark.

However, since November 2021 we have become aware of various online shopping platforms advertising illegal (no ARTG numbers), counterfeit LifeVac devices (including ebay, Amazon. Fruugo, etc). These breach our trademark by using our name, use our videos and literature/logos to deceive consumers and breach our exclusive worldwide patent on the device of this type. We not have reports lodged with the MHRA in the UK of failures in these fakes causing harm and potential death due to faulty manufacture and design.

In response so far we have, on a weekly (sometimes daily basis) notified the sellers, reported these breaches of the Therapeutic Goods Act to the TGA, reported them to the shopping platform, reported to the ACCC and to Fair Trading.

The outstanding failure in all this has been the TGA and ACCC. The ACCC agreed with everything we told them but informed us that the matter was not sufficiently important for them to get involved. eBay has failed to admit they have any control or responsibility to uphold their own policy on illegal and non-TGA approved products, let alone recognise their obligation under law. The TGA keeps saying that it acknowledges the issue and I can keep reporting if I like and they will "mention" it to ebay at the "next opportunity" but have failed to make any demands or enact any enforcement on their illegal activity. As a result, I have written to the Federal Health Minister

Mark Butler to intervein and act to pressure the TGA to do their job and not only enforce the law but protect the public of Australia from dangerous medical devices. One would have thought that this is their primary function as it is listed as their focus for this year. So far, I have had no response from Mr Butler's office.

Next week 311C on behalf of LifeVac with be appearing on A Current Affair to talk about LifeVac its role in saving lives and the children that have died after first aid fails. This national coverage is expected to generate huge interest in LifeVac, however for the unwary there are still these counterfeit devices being advertised as genuine "LifeVac" that may potentially cause a series of incident of harm or death if relied upon in an emergency and the regulator seems to be powerless against a multi-national to exercise its power in these circumstances.

We are seeking the urgent assistance of Mr Conroy in this matter of public safety that is impacting on a local business."

If you need any further information \$47F feel free to give me a buzz.

Cheers

s 7F

Kind regards

s47F

s47F

Office of Pat Conroy MP

Federal Member for Shortland

Minister for Defence Industry

Minister for International Development and the Pacific

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Postal Address | PO Box 499 | BELMONT NSW 2280

T: **s47F** | M. **s47F** 

All electoral communications authorised by Paul Erickson ALP Canberra