#### s22

From: Therapeutic Goods Administration (TGA) <tga.no-reply@govcms.gov.au> on behalf

of tga.no-reply@govcms.gov.au

Sent: Thursday, 7 August 2025 1:00 AM

**To:** ADR Reports

**Subject:** Medicine or vaccine defect report

**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.

Medicine defect report form

Submitted online on Thursday, August 7, 2025 - 00:59

## **Contact details**

Name: s22

Address: s22

Email address: s22

Telephone number: \$22

Fax number:

Release consent: Yes

# **About the product (general)**

Full name of product: Mounjaro KwikPen

Dosage form: 2,5

Active ingredients: Tirzepatide

Dosage strength: 4.17mg/ml

Product AUST L or AUST R number: 93223829004945

Company name: Eli Lilly

## **About the product (specific)**

Batch or Lot number:

Expiry date: 08 /2026

Where was the product purchased or dispensed: chemist warehouse \$22

What date was it purchased or dispensed: 2025-06-29

Was the product in original packaging: Yes

Description of non-original packaging (if relevant):

Where and how has the product been stored: The pen stopped working after the second injection, but I managed to give myself the third dose. However, when it came to the fourth (and final) injection, the pen wouldn't turn at all. At the pharmacy where I bought the medication, they told me the pen was empty. But I took a photo showing that there was still one full dose left inside. I extracted that dose using a different syringe, and I have a photo as proof.

The fact that the pen malfunctioned is already bad enough — but what's worse is that the pharmacy tried to make me look like I didn't know what I was talking about. That was really upsetting.

Is any of the product available for testing: No

## **About the defect**

Description of the problem: ChatGPT said:

The pen stopped twisting back, so I couldn't press the plunger to inject.

Date defect was discovered: 2025-08-04

Who had the problem with the product: Me

If 'someone else', what is your relationship to that person:

I am that person's

Has the company been contacted: Yes

If Yes: What was the company's response: The pharmacist told me that the pen was empty, even though there was still one dose left. She also said that I must have forgotten how many injections I had done. But I took photos of everything.

Other comments:



From: TGA Info <info@tga.gov.au>
Sent: Thursday, 7 August 2025 11:55 AM

**To:** Advertising Enquiries

**Subject:** FW: TGA Website | Form submission | Get in touch [SEC=OFFICIAL] CCEMS:06500002184

#### **Dear Team**

Please find the below email correspondence for your action from: \$22 . If your area has received this incorrectly, please let us know.

Kindly ensure that any internal correspondence, including this forwarding email, is deleted prior to sending the response.

If you are responding directly to an external enquiry, you are responsible for ensuring that the <u>TGA customer service</u> <u>standards</u> are met.

If your area does not have access to a generic email address, the TCC can send approved responses on your behalf from <a href="mailto:info@tga.gov.au">info@tga.gov.au</a>, provided there is sufficient time for the service standards to be met.

If you have any questions about this email, please contact us.

Kind regards,



#### **TGA Contact Centre**

Regulatory Assistance Section Regulatory Engagement Branch

Phone: 1800 020 653 | Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health, Disability and Ageing
PO Box 100
Woden ACT 2606

www.tga.gov.au





This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

**Important:** This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

| <br>Original | Message |  |
|--------------|---------|--|
|              |         |  |

Submitted on Wed, 2025-08-06 17:16

Submitted by: Anonymous

Submitted values are:

#### Name



#### **Email address**



#### **Enquiry type**

General enquiries

#### Message

To whom it may concern I am looking at advertising restrictions in Australian pharmaceutical space and have come across the below excerpt from Chat-GPT, I am unable to verify this writing seemingly from the TGA or find the original document. Could you please ascertain if the following is accurate and if possible provide the original piece of legislation it is from:

Therapeutic Goods Advertising Code (TGAC) 2021

Section 15 – Inducements

15 Inducements to use or purchase therapeutic goods

A person must not advertise a therapeutic good to consumers in a way that offers any inducement to encourage the use or purchase of the good, unless:

- (a) the inducement is permitted by this Code; or
- (b) the advertisement or the offering of the inducement is authorised or permitted under the Act.

Without limiting subsection (1), an inducement is permitted if it is:

- (a) a price reduction for the purchase of the therapeutic good; or
- (b) the offer of additional quantity of the same therapeutic good at no extra charge; or



From: Advertising Enquiries <Advertising.Enquiries@tga.gov.au>

**Sent:** <u>Monday, 18 August 2025 4</u>:24 PM

To: \$22

- Chat GPT Advertising Code guidance - Response email - AC-000000055711

[SEC=OFFICIAL]



Thank you for your enquiry (our reference AC-000000055711) to the Therapeutic Goods Administration (TGA) regarding Chat GPT Advertising Code guidance. A copy has been included at the bottom of this email for ease of reference. Please accept our sincere apologies for the delay to respond to your enquiry.

The TGA regulates the advertising of therapeutic goods through the administration of the <u>Therapeutic Goods Act 1989</u> (the Act), the <u>Therapeutic Goods Regulations 1990</u> (the Regulations) and the <u>Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021</u> (the Code).

We were unable to locate your below mentioned exert that Chat GPT has written, however you may wish to refer to our <u>Applying the Advertising Code</u> page which provides information to advertisers about their obligations in relation to advertising therapeutic goods.

The information in this email is intended as guidance and is not legally binding on the TGA. To obtain advice specific to your circumstances you may wish to seek independent legal advice or the assistance of a regulatory affairs consultant.

Please note, these consultants are not endorsed by the TGA.

For future reference, please ensure you have considered the information on the <u>TGA Advertising Hub</u> before submitting an enquiry.

Yours sincerely,

# Advertising Enquiries Team Advertising and Compliance Education and Policy Section (ACEPS)

Regulatory Compliance Branch | Regulatory Practice and Support Division Australian Government, Department of Health, Disability and Ageing

Location: Fairbairn Office, Canberra, ACT PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges 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.

----- Original Message -----

Submitted on Wed, 2025-08-06 17:16

Submitted by: Anonymous

Submitted values are:

Name



**Email address** 



#### **Enquiry type**

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