Form 34
Rule 16.33

Reply to Defence

No. VID 715 of 2025

Federal Court of Australia

District Registry: Victoria

Division: General

Regeneron Pharmaceuticals, Inc. and others

Applicants

Sandoz Pty Ltd (ACN 075 449 553)

Respondent

The defined terms in this Defence adopt the definitions used in the Defence to Amended Statement of Claim dated 26 June 2025 (**Defence**).

With the exception of the admissions in the Defence, the Applicants join issue with the Defence and otherwise reply as follows:

1. In relation to paragraph 31 of the Defence, the Applicants say:

   (a) Sandoz has an obligation to prepare and upload the current approved Sandoz Product Information to the Therapeutic Goods Administration (**TGA**) website within two weeks of its approval, to allow consumers and health professionals to access that document at any time.

Particulars

i. Guidance published by the TGA entitled "Understanding requirements for providing a Product Information (PI) document (previously ARGPM Appendix 8: Product Information)", available at https://www.tga.gov.au/resources/guidance/understandi

Filed on behalf of (name & role of party)	The Applicants
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ng-requirements-providing-product-information-pi-document

ii. *Therapeutic Goods Act 1989* (Cth), section. 25AA

(b) Further or alternatively, Sandoz makes product information for its products available to the public, and will, if not restrained, make product information (**Sandoz Product Information**) available for the Sandoz Aflibercept Products.

Particulars

Webpage from Sandoz's website entitled "Consumer Medicine Information and Product Information", available at https://www.sandoz.com.au/our-products/consumer-medicine-information-and-product-information/, a copy of which is included in **Annexure A**.

(c) Further or alternatively, Sandoz has an obligation to make a consumer medicine information document for the Sandoz Aflibercept Products (**Sandoz CMI**) that is consistent with the Sandoz Product Information available to consumers, either in the packaging for the Sandoz Aflibercept Products or in another manner "to enable the information to reach the people who are to receive the medicine".

Particulars

i. Guidance published by the TGA entitled "Consumer Medicine Information (CMI)", available at https://www.tga.gov.au/products/australian-register-therapeutic-goods-artg/consumer-medicines-information-cmi

ii. *Therapeutic Goods Regulations 1990* (Cth), regulation. 9A; Schedule 12, section 1 (d).

(d) Further or alternatively, Sandoz makes consumer medicine information for its products "available in electronic format to ensure the most up to date consumer medicine information is available at all times" and will, if not restrained, make the Sandoz CMI available to the public electronically and/or in its packaging for the Sandoz Aflibercept Products.

Particulars

Webpage from Sandoz' website included in **Annexure A**.

(e) By reason of the matters referred to in paragraph 1 (c) and (d) above, Sandoz will give the Sandoz Product Information to consumers via the Sandoz CMI.

(f) By reason of the matters referred to in paragraph 1 (a), (b), (c), (d) and/or (e) above, the Sandoz Product Information, and further or alternatively, the Sandoz CMI, comprise instructions and/or inducements to use the Sandoz Aflibercept Products:

(i) that are "given" by Sandoz within the meaning of section 117 (2) (c) of the Act; and

(ii) further or alternatively, that are contained in an advertisement published by or with the authority of Sandoz within the meaning of section 117 (2) (c) of the Act.

(g) By reason of the matters referred to in paragraph 1(f) above and in paragraph 32 of the Applicants' Amended Statement of Claim dated 18 June 2025, Sandoz has:

(i) threatened to infringe each of the Asserted Claims pursuant to sections 117(1) and (2)(c) of the Act;

(ii) further or in the alternative, threatened to authorise a person to infringe each of the Asserted Claims; and

(iii) further or in the alternative, threatened to procure or induce the infringement of each of the Asserted Claims.

Date: 4 July 2025

Signed by Grant Fisher
Lawyer for the First Applicant

Signed by Aaron Yates
Lawyer for the Second & Third Applicants

This pleading was prepared by Davies Collison Cave Law Pty Ltd and Corrs Chambers Westgarth and settled by Neil Murray SC, Kate Beattie SC, Clare Cunliffe and Megan Evetts of counsel.

Certificate of lawyer

I, Grant Fisher, certify to the Court that, in relation to the reply filed on behalf of the Applicants, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 4 July 2025

Signed by Grant Fisher
Corrs Chambers Westgarth
Lawyers for the First Applicant

Certificate of lawyer

I, Aaron Yates, certify to the Court that, in relation to the reply filed on behalf of the Applicants, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 4 July 2025

Signed by Aaron Yates
Davies Collison Cave Law Pty Ltd
Lawyers for the Second and Third Applicants

ANNEXURE A

Consumer Medicine Information and Product Information

Related Links

Packaging

Stay Up-To-Date

Corporate Responsibility

Feb 14, 2023

What is consumer medicine information (CMI)?

CMI will tell you:

- What the medicine is used for
- How it works
- How to use it
- Its ingredients
- Its known side effects
- Whether it has any interaction with other medicines

For more information, please contact your doctor or pharmacist.

Consumer Medicine Information, or CMI, provides clear, easy-to-understand information to consumers and their carers about how to use their medicines. Importantly, this information is intended for use in Australia only and does not replace advice from a healthcare professional. Please discuss any concerns or questions you may have with your healthcare professional.

In Australia, Sandoz makes CMIs available in electronic format to ensure the most up to date consumer medicine information is available at all times. You can obtain a printed copy of a product's CMI either from your pharmacist when filling your prescription or by accessing this information from the TGA website.

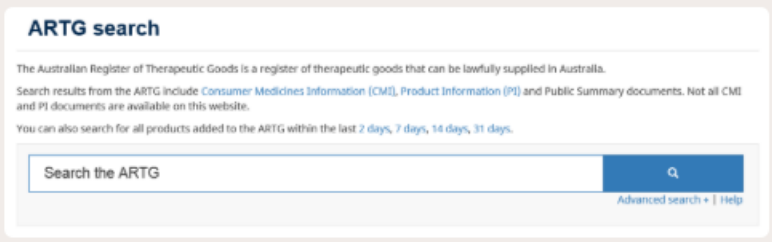
How to search for Consumer Medicine Information

Please access the CMI for your Sandoz medicine from the TGA website by searching for the product.

Step 1: Click on the below link

TGA website

Step 2: Type in the full name of the product (i.e. Clopidogrel Sandoz) and click the search button.



Additionally, you can download the **MedSearch™** app to access the information on your phone.

MedSearch™ is designed to help you find, view and save Consumer Medicine Information (CMI) and Product Information (PI) documents for registered prescription medicines approved by the TGA, included on the Australian Register of Therapeutic Goods.

MedSearch™ is available on

GET IT ON Google Play

Download on the App Store

Product Information

Product Information (PI) for Sandoz products in Australia is intended to assist healthcare professionals make decisions about treatment options and provide advice on the appropriate use of medicines to patients.

This information only applies to Sandoz products available in Australia and does not apply to Sandoz products in other countries. If you are not a healthcare professional please access the Consumer Medicine Information (CMI) as described above.

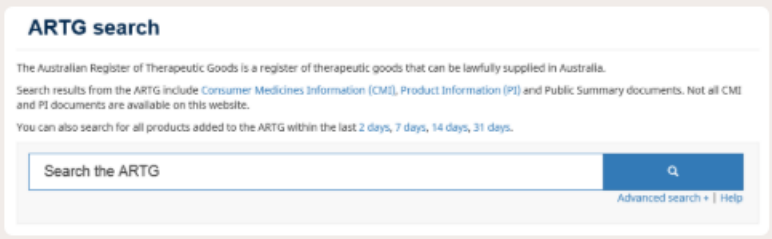
How to search for Product Information (PI)

Please access the PI for your Sandoz medicine from the TGA website by searching for the product.

Step 1: Click on the below link

TGA website

Step 2: Type in the full name of the product (i.e. Clopidogrel Sandoz) and click the search button.



Please ensure you disable pop-up blocking on your browser to view the PDF documents on this page

Sandoz Medical Information: 1800 726 369

Please access Data Sheet and CMIs for Sandoz products in **New Zealand** from the Medsafe website