



Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

ENFORCEABLE UNDERTAKING

Therapeutic Goods Act 1989

Section 42YL

The commitments in this undertaking are offered to the Secretary of the Australian Department of Health given for the purposes of section 42YL of the *Therapeutic Goods Act 1989* (**the Act**) by

Strapit Medical and Sports Supplies Pty Ltd

ACN: 160 082 173

The undertakings are in force for three (3) years from the date of last signature.

Definitions

1. The following definitions are used in this undertaking:
 - a) **the Department** means the Australian Government Department of Health
 - b) **the Act** means the *Therapeutic Goods Act 1989* (Cth)
 - c) **the ARTG** means the Australian Register of Therapeutic Goods
 - d) **the Promisor** means the person giving the undertaking
 - e) **the Regulations** means the *Therapeutic Goods Regulations 1990*
 - f) **the Secretary** means the Secretary of the Australian Department of Health
 - g) **the TGA** means the Therapeutic Goods Administration, part of the Department

Persons giving this undertaking

2. This undertaking is given to the Secretary by Strapit Medical Sports Supplies Pty Ltd, ACN: 160 082 173 (**Strapit**) o _____ VIC 3074 for the purposes of section 42YL of the Act.

Background

TGA's role

3. The TGA is a part of the Department and is responsible for the regulation of therapeutic goods in Australia including medicines, biologicals and medical devices.

4. In Australia, goods used as personal protective equipment (PPE) including face masks and shields, medical gloves and gowns and hand sanitisers are generally regulated as therapeutic goods and are required to be entered on the ARTG) unless excepted from this requirement.
5. The TGA's regulation of therapeutic goods includes ensuring the safety, efficacy, quality and timely availability of therapeutic goods used in Australia, as well as ensuring that the advertising of such goods to Australians meet the relevant requirements in the Act.

Strapit

6. Strapit is an Australian proprietary limited company registered under *Corporations Act 2001* (Cth) which was given Australian Company Number 160 082 173.
7. Strapit has been a sponsor of therapeutic goods and registered with the TGA since 2013. At the time of this undertaking, Strapit is the person in relation to whom fifteen (15) therapeutic goods are entered in the Register.
8. These goods primarily include PPE, hand sanitisers and medical devices such as thermometers.
9. Strapit is responsible for the material which appears on <https://strapit.com.au/> and <https://surgicalmask.com.au/> (the Websites).

Previous compliance and enforcement action taken by the TGA

CC-0EU4NZDF/2020*

10. On 24 July 2020, a delegate of the Secretary gave three (3) infringement notices (notices) to Strapit in relation to alleged unlawful advertising of therapeutic goods. The notices related to alleged contraventions of subsection 42DLB(1), where subsections (2), (6) and (9) of the Act applied.
11. On 18 February 2021, following the final payment of the notices, the matter was resolved, the TGA closed its case and in accordance with section 42YKD of the Act:
 - a) Strapit's liability for the alleged contraventions was discharged;
 - b) Proceedings seeking an order under subsection 42Y(2) of the Act could not be brought by the Secretary in relation to the alleged contraventions; and
 - c) Strapit was not regarded as having admitted liability for the alleged contraventions.
12. The case was published on the TGA's database of Advertising Compliance Investigations Outcomes.¹

CC-JLVP5KYW/2021*

13. In July 2021, the TGA received a report of alleged non-compliant advertising by Strapit on the Websites.
14. The case was subsequently referred to the Advertising and Product Investigations Section within the Regulatory Compliance Branch of the TGA for further consideration.
15. A case was subsequently created and allocated to an Assistant Director to investigate noting the previous compliance and enforcement action taken by the TGA.

Review of the Websites

¹ [Case Preview - Custom Portal \(health.gov.au\)](https://casepreview.health.gov.au)

16. On or about 3 November 2021, the Websites were reviewed, and it was identified that the following advertisements for the specified therapeutic goods allegedly contravened subsection 42DLB(1) of the Act where subsection (6) of the Act applies. This was because in the TGA's view the advertisements contained references which indicated the products, while registered on the ARTG, had been 'approved' by the TGA without approval to make such claims:

<https://surgicalmask.com.au/>

- a) Face Shields - TGA Approved - <https://surgicalmask.com.au/products/face-shield-tga-approved?variant=35660468027543>;
- b) FACE SHIELDS - TGA APPROVED & AUSTRALIAN MADE - <https://surgicalmask.com.au/products/face-shields-tga-approved-australian-made?variant=34664829714583>;
- c) Infrared Forehead Thermometer UFR106 - <https://surgicalmask.com.au/products/infrared-forehead-thermometer-ufr106?variant=34906299465879>;
- d) LEVEL 2 ISOLATION GOWN - Universal - <https://surgicalmask.com.au/products/surgical-isolation-gown-level-2-aami-call-to-order?variant=36241775526039>
- e) LEVEL 3 ISOLATION GOWN - Universal - <https://surgicalmask.com.au/products/surgical-isolation-gown-level-3-aami?variant=36665208373399>
- f) PURIFAS FACESHIELD - TGA APPROVED - <https://surgicalmask.com.au/products/purifas-faceshield-tga-approved?variant=35505970282647>
- g) Reusable Face Shields - TGA Approved - <https://surgicalmask.com.au/products/reusable-face-shields-tga-approved?variant=35684104306839>
- h) Strapit Level 3 Surgical VISOR mask - TieBack model & Antifog - <https://surgicalmask.com.au/products/strapit-level-3-surgical-visor-mask-tieback-model-antifog?variant=37586595971223>
- i) ULTRA FEEL NITRILE GLOVES - MEDICAL BLUE DISPOSABLE POWDER FREE (BOX 100) - <https://surgicalmask.com.au/products/nitrile-gloves-medical-blue-disposable-powder-free-box-100?variant=38237820453015>
- j) KN95 Respirator Mask - <https://surgicalmask.com.au/products/strapit-kn95-particulate-respirator-5-ply-optimal-filtration-box-of-10?variant=33885563650093>

<https://strapit.com.au/>

- k) Ultra Feel Nitrile Gloves (Box of 100) - <https://strapit.com.au/collections/antibacterial-1/products/ultra-feel-nitrile-gloves-box-of-100>
- l) Purifas Face Shield - TGA Approved - <https://strapit.com.au/collections/antibacterial-1/products/purifas-face-shield-tga-approved>
- m) Strapit KN95 Particulate Respirator - 5 Ply OPTIMAL FILTRATION - <https://strapit.com.au/collections/disposable-surgical-masks/products/strapit-kn95-particulate-respirator-5-ply-optimal-filtration>

- n) Face Shield - TGA Approved - <https://strapit.com.au/collections/face-shields/products/face-shield-tga-approved>
- o) Reusable Face Shield - TGA Approved - <https://strapit.com.au/collections/face-shields/products/reusable-face-shield-tga-approved>
- p) Face Shield - TGA Approved and Australian Made - <https://strapit.com.au/collections/face-shields/products/face-shield-tga-approved-and-australian-made>
- q) Ultra Feel Nitrile Gloves (Box of 100) - <https://strapit.com.au/collections/gloves/products/ultra-feel-nitrile-gloves-box-of-100>
- r) Infrared Forehead Thermometer - <https://strapit.com.au/products/infrared-forehead-thermometer>.

(the Advertisements)

- 17. Evidence was captured by way of screen captures of the advertisements referred to above.
- 18. On 19 November 2021, the TGA provided Strapit with an opportunity to comment on the allegations of non-compliance with the Act.
- 19. On 1 December 2021, Strapit, through its legal representatives, responded to the allegations and indicated that while all products were registered on the ARTG it would be willing to provide a written undertaking under section 42YL of the Act.

The Secretary's conclusion as to the contraventions of the Act

- 20. The Secretary has formed the reasonable belief that Strapit has contravened subsection 42DLB(1) of the Act where subsection (6) applied, for advertising, or causing the advertising of therapeutic goods in circumstances where the advertisements contained statements suggesting or implying that the goods had been recommended or approved by or on behalf of a government or government authority, the TGA, and the statements were not:
 - a) statements of the availability of the goods as a pharmaceutical benefit;
 - b) statements authorised or required by a government or government authority; or
 - c) statements prescribed by the Regulations for the purposes of this paragraph.

Acknowledgement of breach

- 21. Strapit acknowledges that the conduct described at paragraph [16] above contravened the Act.

Period of undertaking

- 22. This undertaking comes into effect when both the following are satisfied:
 - a) the undertaking is executed by Strapit; and
 - b) the Secretary accepts the undertaking so executed.
- 23. Upon the commencement of this undertaking, Strapit undertakes to assume the obligations set out in paragraphs [25] to [34] below.

24. This undertaking terminates on the third anniversary of the day on which it comes into effect.

Undertakings

25. Under section 42YL of the Act, Strapit has offered, and the Secretary has agreed to accept the following undertakings:

- a) that Strapit will not, and will ensure that its subsidiaries will not, for the period that this undertaking is in effect, advertise therapeutic goods in any way which is in breach of the regulatory requirements of the Act.
- b) that for the period that this undertaking is in effect Strapit will:
 - i. cease any advertisements on the Websites for therapeutic goods which suggest or imply that the goods have been "listed", "approved" or "registered" by the TGA;
 - ii. review and amend, as necessary, any Uniform Resource Locator that suggests an approval or recommendation of products by the TGA;
 - iii. take steps to rectify any potential harm caused by the alleged breach by publishing a corrective statement on its Websites within 14 days of the date of this undertaking; and
 - iv. remedy the deficiencies in Strapit's compliance systems by providing further training for its staff on therapeutic goods advertising, with a focus on correct representations and statements about products registered on the ARTG.
- c) that for the period that this undertaking is in effect, Strapit will monitor and report on the implementation of this undertaking by:
 - i. nominating and engaging an external qualified compliance professional in the manner specified in paragraphs [26] to [27] below for the first annual review and audit;
 - ii. appointing an internal compliance officer with suitable seniority and relevant experience or training in the regulation of therapeutic goods to conduct the second and third annual reviews and audits; and
 - iii. requiring, for the first annual review and audit, the external qualified compliance professional and, after the first annual review and audit, the internal compliance officer to conduct an annual review and audit to ensure compliance with the undertaking and provide a report of those reviews to the TGA annually, for the duration of this undertaking, in accordance with paragraphs [30] – [32].
- d) that Strapit will pay the costs of its compliance with this enforceable undertaking.
- e) that Strapit will provide all documents and information requested by the Secretary from time to time for the purposes of assessing its compliance with the terms of this enforceable undertaking.

Engagement of an external qualified compliance professional

26. Strapit undertakes, within one month of the date of execution of this undertaking, to, at its own expense, engage an external qualified compliance professional to review the implementation of regulatory procedures to ensure that it does not contravene the Act or the *Therapeutic Goods Advertising Code (No. 2) 2018 (Cth)* (the Code).

27. For the purposes of this undertaking, an external qualified compliance professional is a person, including a legal practitioner, with experience in advising on compliance matters concerning the regulation of therapeutic goods in Australia, who has no financial or other interest in Strapit.

Appointment of internal compliance officer

28. Strapit undertakes, within twelve months of the date of execution of this undertaking, to, at its own expense, engage an internal compliance officer to review the implementation of regulatory procedures to ensure that it does not contravene the Act or the Code.

29. Prior to the engagement of the internal compliance officer, the Undertaking Parties each undertake to inform the TGA of the identity and expertise of one or more persons it proposes to appoint.

Annual written report and interim reports

30. For the period of this undertaking, Strapit undertakes to require, in relation to the first annual review, the external qualified compliance professional (**the Consultant**) and, after the first annual review and audit, the internal compliance officer (**the Compliance Officer**) to provide an annual written report to the TGA regarding:

- its compliance with the Act;
- the compliance of its advertisements with the Code; and
- a review of its compliance education programs.

31. Strapit undertakes to ensure that:

- the first annual review is completed by the Consultant and the written report relating to that review is provided by that person to the TGA by email to [REDACTED]@tga.gov.au prior to 30 November 2022;
- the second annual review is completed by the Compliance Officer and the written report relating to that review is provided by that person to the TGA by email to [REDACTED]@tga.gov.au prior to 30 November 2023; and
- the third annual review is completed by the Compliance Officer and the written report is provided by that person to the TGA by email to [REDACTED]@tga.gov.au one month prior to the expiration of the period of this undertaking.

32. The annual written opinion must address and include the following:

- the Consultant's or Compliance Officer's opinion as to whether all advertisements comply with the Act and the Code;
- copies of Strapit's policies and standard operating procedures for the preparation and review of advertisements for therapeutic goods;
- details of the information gathered and examined during the review;
- the name and relevant experience of the person appointed as the compliance manager;
- actions, if any, recommended by the Consultant or Compliance Officer to ensure compliance with the Act; and
- a signed statement by the Consultant or Compliance Officer that they have seen this undertaking, that they have prepared the annual written opinion and that, notwithstanding their engagement by Strapit, the opinion contains their

impartial and professional opinion regarding Strapit's compliance with the Act and Advertising Code.

Acknowledgements

33. Strapit acknowledges that:
 - a) this undertaking was given voluntarily by Strapit;
 - b) the Secretary may make this undertaking and information about this undertaking publicly available including by publishing it on the TGA's website;
 - c) the Secretary may, from time to time, make public reference to this undertaking including in news media statements and in publications by the TGA or the Department including on various forms of social media;
 - d) this undertaking in no way derogates from the rights and remedies available to the Secretary, the Commonwealth or to any other person arising from the conduct referred to in paragraphs 2 to 6;
 - e) the Secretary's acceptance of this enforceable undertaking does not affect the power of the Secretary to investigate or pursue a criminal prosecution, to seek a pecuniary civil penalty or use any other power available to the Secretary under the Act in relation to any contravention or breach, or possible contravention or possible breach of the Act (not referred to in the Background section of this enforceable undertaking) arising from future conduct; and
 - f) this undertaking has no operative force until accepted by the Secretary.
34. Strapit and the Secretary acknowledge that the date of the enforceable undertaking is the date on which it is accepted by the Secretary.

Executed by

Executed by Strapit Medical and Sports Supplies Pty Ltd ACN 160 082 173 in accordance with Section 127 of the *Corporations Act 2001*

Signature of director
secretary

(Please delete as applicable)

Signature of director/company

Name of director (*print*)
secretary (*print*)

Paul Haas

Name of director/company

Date:

06/05/2022

ACCEPTED BY A DELEGATE OF THE SECRETARY OF THE DEPARTMENT OF HEALTH
UNDER SECTION 42YL OF THE *THERAPEUTIC GOODS ACT 1989*

G. Mitchell

Gillian Mitchell

Delegate of the Secretary

Regulatory Practice and Support Division

Department of Health

31 May 2022