

ENFORCEABLE UNDERTAKING

Therapeutic Goods Act 1989

Section 42YL

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

Your Solution Compounding Pharmacy Pty Ltd

ACN 152 996 551

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

Definitions

1. The following definitions are in use in the undertaking:
 - a) **the Act** means the *Therapeutic Goods Act 1989* (Cth)
 - b) **Covered Websites** means any website that is controlled or operated by YSCP, or that is controlled or operated by persons on behalf of YSCP, and includes:
 - i. the Website, and
 - ii. any websites that may be created after the commencement of this undertaking
 - c) **the Code** means the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*
 - d) **the Department** means the Australian Government Department of Health and Aged Care
 - e) **the Register** means the Australian Register of Therapeutic Goods, as maintained by the Secretary under section 9A(1) of the Act
 - f) **the Regulations** means the *Therapeutic Goods Regulations 1990* (Cth)
 - g) **the Secretary** means the Secretary of the Department
 - h) **the TGA** means the Therapeutic Goods Administration, part of the Department
 - i) **the Website** means the website located at Uniform Resource Locator '<https://www.yoursolutioncompounding.com>'
 - j) **YSCP** means Your Solution Compounding Pharmacy Pty Ltd ACN 152 996 551

Persons giving this undertaking

2. This undertaking is given to the Secretary by Your Solution Compounding Pharmacy Pty Ltd ACN 152 996 551 of 5/264 South Pine Road, Brendale QLD 4500 for the purposes of Section 42YL of the Act.

Background

YSCP

3. YSCP is an Australian proprietary limited company registered under *Corporations Act 2001* (Cth) which was given Australian Company Number 152 996 551.
4. YSCP is a compounding pharmacy and its primary business is compounding of pharmaceutical goods. YSCP also supplies pharmaceutical goods to consumers.
5. These goods primarily include compounded medicines.
6. From at least 23 November 2023 to 20 June 2024, compounded medicines including tirzepatide and semaglutide could be purchased by consumers through the Website.
7. YSCP is responsible for the material which appears on the Website and its subdomains.

TGA Concerns

8. Under the Act it is an offence, and gives rise to a contravention of a civil penalty provision, for an advertisement of therapeutic goods to refer to:
 - a) substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority but not including a foreign government or foreign government authority (sections 42DL(1), 42DL(10), 42DLB(1) and 42DLB(7) of the Act); and
 - b) therapeutic goods that are not entered in the Register and that are prescribed by the Regulations, other than a reference authorised or required by a government or government authority but not including a foreign government or foreign government authority (sections 42DL(1), 42DL(12), 42DLB(1) and 42DLB(9) of the Act and regulation 7 of the Regulations).
9. The TGA is concerned that the Website promoted the use or supply of therapeutic goods from at least 23 November 2023 to 20 June 2024, in that it contained:
 - a) pricing schedules for semaglutide that can be ordered throughout the Website;
 - b) buttons that redirect readers to webpages focused on semaglutide orders; and
 - c) web pages dedicated to initial and repeat orders of semaglutide which have portals to upload prescriptions for semaglutide only (an image of an advertisement is included at Annexure B).
10. The TGA considers that YSCP unlawfully advertised therapeutic goods, including tirzepatide and semaglutide, in contravention of section 42DLB(1) of the Act where subsections 42DLB(7) and (9) applied in circumstances where advertisements on the Website referred to:
 - a) substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard; and
 - b) therapeutic goods that are not entered in the Register and that were prescribed by the Regulations.

Acknowledgement of Breach

11. As a result of the TGA's investigations and in response to the TGA's concerns, YSCP:
- a) acknowledges that the Website likely contravened section 42DLB(1) of the Act where subsections 42DLB(7) and (9) applied; and
 - b) offers this undertaking to the TGA to address the TGA's concerns.

Undertakings

Period of Undertaking

12. This undertaking comes into effect when both of the following are satisfied:
- a) the undertaking is executed by YSCP; and
 - b) the Secretary accepts the undertaking so executed.
13. Upon the commencement of this undertaking, YSCP undertakes to assume the obligations set out in paragraphs 16 to 23 below.
14. This undertaking has effect for 3 years from the day it comes into effect.

Application of the undertaking to all Covered Websites

15. This undertaking applies to the Covered Websites.

Undertakings

16. Under section 42YL of the Act, YSCP has offered, and the Secretary has agreed to accept the following undertakings:
- a) that YSCP will not, for the period that this undertaking is in effect, advertise therapeutic goods including referring to individual prescription-only medicines on the Covered Websites in any way which is in breach of the requirements of the Act.
 - b) YSCP 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.
 - c) YSCP will pay the costs of its compliance with this undertaking.

Engagement of an external qualified compliance professional

17. YSCP undertakes, within one month of this undertaking coming into effect, to engage an external qualified compliance professional (**Consultant**) to advise and assist with the measures specified in paragraph 18 below.
18. YSCP's engagement of the Consultant will include a requirement for the Consultant to, within six months from the engagement of the Consultant, provide a written opinion on the matters listed at Annexure A (**the Consultant's Report**).
19. For the purposes of this undertaking, a Consultant 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, personal or other interest in the business activities of YSCP.

Provision of assistance by YSCP to the Consultant

20. YSCP will provide the Consultant with:

- a) access to any information the Consultant requests; and
 - b) any assistance the Consultant requests,
- for the purposes of preparing the Consultant's Report.

Implementation of the Consultant's recommendations

21. YSCP will implement all recommendations made by the Consultant in the Consultant's Report unless the TGA specifically agrees in writing that any recommendation need not be implemented upon request in writing from YSCP.

Provision of documents to the TGA

22. Within 7 calendar days of YSCP engaging a Consultant, YSCP must provide to the TGA the identity and contact details of the Consultant that YSCP has engaged.
23. Within 7 calendar days of YSCP receiving the Consultant's Report from the Consultant, YSCP must provide to the TGA a copy of the Consultant's Report.

Acknowledgements

24. YSCP acknowledges that:

- a) this undertaking was given voluntarily by YSCP;
- 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; and
- d) this undertaking in no way derogates from the rights and remedies available to the Secretary, the Commonwealth or any other person arising from the conduct referred to in paragraph 9 above.

Executed by

Executed by Your Solution Compounding Pharmacy Pty Ltd ACN152 996 551 in accordance with Section 127 of the *Corporations Act 2001*.



Signature of Director/Secretary



Name of Director/Secretary

(print)

26.03.2025.....

Date:

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



Signature of Delegate of the Secretary



Name of Delegate of the Secretary

(print)

.....4 April 2025.....

Date:

Annexure A

Requirements for the Consultant's Report (see paragraph 18)

25. The Consultant's Report must address and include the following:

- a) the Consultant's opinion as to whether the Covered Websites comply with the Act and the Code;
- b) the Consultant's opinion as to whether YSCP has in place an effective compliance program that ensures the Covered Websites comply with the Act and the Code.
- c) actions, if any, recommended by the Consultant to:
 - i. bring the Covered Websites into compliance with the Act and the Code; and
 - ii. improve YSCP's policies, processes or procedures to ensure ongoing compliance with the Act and the Code;
- d) copies of YSCP's policies, procedures or other similar documentation concerning the preparation and review of content published to the Covered Websites;
- e) details of the information gathered and examined by the Consultant in the course of preparing the Consultant's Report; and
- f) a signed statement by the Consultant that they have seen this undertaking, that they have prepared the written opinion and that, notwithstanding their engagement by YSCP, the opinion contains their impartial and professional opinion regarding YSCP's compliance with the Act and the Code.


Annexure B

Your Solution Order Form

Your Solution Order Form

+

cp.com.au/Semaglutide



Semaglutide Order Form

Due to the Global shortage of Ozempic, we are currently compounding semaglutide.

We can supply patients with up to **4 pre-filled syringes** (not a multi-dose pen) per month that contain the weekly dose prescribed by your practitioner. Our compounded semaglutide injections have a 30-day expiry and are ideally stored between 2-8°C but can be kept at room temperature (below 30°C) if required.

Below are the prices for commonly prescribed doses:

| | | |
|--------|----------|--|
| 0.25mg | \$149.99 | SEMAGLUTIDE 0.25MG (0.187ML) PF SYRINGE 1.34MG/ML INJ SOLN x 4EA |
| 0.5mg | \$159.99 | SEMAGLUTIDE 0.5MG (0.373ML) PF SYRINGE 1.34MG/ML INJ SOLN x 4EA |
| 0.75mg | \$167.99 | SEMAGLUTIDE 0.75MG (0.56ML) PF SYRINGE 1.34MG/ML INJ SOLN x 4EA |
| 1mg | \$175.99 | SEMAGLUTIDE 1MG (0.746ML) PF SYRINGE 1.34MG/ML INJ SOLN x 4EA |
| 1.25mg | \$182.99 | SEMAGLUTIDE 1.25MG (0.933ML) PF SYRINGE 1.34MG/ML INJ SOLN x 4EA |
| 1.5mg | \$192.99 | SEMAGLUTIDE 1.5MG (0.469ML) PF SYRINGE 3.2MG/ML INJ SOLN x 4EA |
| 1.7mg | \$196.99 | SEMAGLUTIDE 1.7MG (0.531ML) PF SYRINGE 3.2MG/ML INJ SOLN x 4EA |
| 1.75mg | \$200.99 | SEMAGLUTIDE 1.75MG (0.547ML) PF SYRINGE 3.2MG/ML INJ SOLN x 4EA |
| 2mg | \$209.99 | SEMAGLUTIDE 2MG (0.625ML) PF SYRINGE 3.2MG/ML INJ SOLN x 4EA |
| 2.4mg | \$229.99 | SEMAGLUTIDE 2.4MG (0.75ML) PF SYRINGE 3.2MG/ML INJ SOLN x 4EA |

To place an order, please fill out the form below and complete your payment. You will be notified when your order is ready to collect or when it has been dispatched to your delivery address. Lead-times are currently around 7-10 business days.

PLEASE NOTE:

- If your order is being delivered, your product will only be dispatched on Monday, Tuesday or Wednesday.
- We **can** accept e-Prescriptions.

Due to a large number of inquiries related to this compound we are currently experiencing delays and wait times can take up to 7-10 business days. We are working diligently to get to your order, and we greatly appreciate your patience.

?

If you have **previously ordered from us**, please use our **REPEAT ORDER FORM** 