

ENFORCEABLE UNDERTAKING

Therapeutic Goods Act 1989 Section 42YL

The commitments in this undertaking are given to the Secretary of the Australian Department of Health, Disability and Ageing for the purposes of section 42YL of the
Therapeutic Goods Act 1989 (Cth) by
Midnight Health Pty Ltd ACN 647 966 738

1. Definitions

1.1 The following definitions are used in this undertaking:

- (a) **Act** means the *Therapeutic Goods Act 1989* (Cth).
- (b) **Code** means the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (Cth).
- (c) **Consultant** means external qualified compliance professional.
- (d) **Covered Websites** means any website that is controlled or operated by Midnight Health, or that is controlled or operated by persons on behalf of Midnight Health, and includes:
 - (i) the Websites; and
 - (ii) any websites that may be created after the commencement of this undertaking.
- (e) **Department** means the Australian Government Department of Health, Disability and Ageing.
- (f) **Legal Consultant** means a person, being 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 Midnight Health.
- (g) **Legal Consultant Report** means a written opinion from the Legal Consultant addressing the issues identified at paragraph 5.11 below.
- (h) **Midnight Health** means Midnight Health Pty Ltd ACN 647 966 738.
- (i) **Products** means prescription-only weight loss medicines, including medicines containing tirzepatide and semaglutide.
- (j) **Root Cause Analysis Report** means a written opinion on the outcomes of a root cause analysis into the underlying factors and causes that contributed to the issues identified by the TGA in its correspondence with Midnight Health dated 17 January 2025 and 29 May 2025.
- (k) **Secretary** means the Secretary of the Department.
- (l) **TGA** means the Therapeutic Goods Administration, part of the Department.
- (m) **Websites** mean the websites located at uniform resource locators:

- (i) <https://hub.health/>,
- (ii) <https://stagger.com.au/>, and
- (iii) <https://youly.com.au/>

2. Persons Giving this Undertaking

- 2.1 This undertaking is given to the Secretary by Midnight Health Pty Ltd ACN 647 966 738 of [REDACTED] Queensland, 4006 for the purposes of section 42YL of the Act.

3. Background

Midnight Health

- 3.1 Midnight Health is an Australian proprietary limited company registered under *Corporations Act 2001* (Cth) which was given Australian Company Number 647 966 738.
- 3.2 Midnight Health is a patient-centred digital healthcare provider and digital platform developer.
- 3.3 Midnight Health is responsible for the material which appears on the Websites and its subdomains.
- 3.4 From at least 2 June 2024 to 17 January 2025 Midnight Health advertised Products on the Websites.
- 3.5 Since 17 January 2025, Midnight Health has taken steps to remove from the Websites advertisements for the Products and prevent further advertisements for the Products on the Covered Websites in the future.

TGA Concerns

- 3.6 Under the Act it is an offence, and a contravention of a civil penalty provision, for a person to advertise, or cause the advertising, of therapeutic goods where:
- (a) the advertisement contains a prohibited representation about the goods (whether in express terms or by necessary implication) and there is no permission under section 42DK of the Act in force in relation to the prohibited representation (see: subsections 42DL(1), 42DL(5), 42DLB(1) and 42DLB(2) of the Act);
 - (b) the advertisement contains a restricted representation (whether in express terms or by necessary implication) and neither an approval under section 42DF nor a permission under section 42DK of Act is in force in relation to the restricted representation (see: subsections 42DL(1), 42DL(7), 42DLB(1) and 42DLB(4) of the Act); and
 - (c) substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standards but not in Appendix H of the current Poisons Standards, other than a reference authorised or required by a government or government authority but not

including a foreign government authority (see: subsections 42DL(1), 42DL(10), 42DLB(1) and 42DLB(7) of the Act).

- 3.7 The TGA is concerned that Midnight Health advertised, or caused the advertising of Products, on the Websites in circumstances where:
- (a) the advertisements contained prohibited representations, including that the Products could be used as a treatment for anxiety and depression;
 - (b) the advertisements contained restricted representations, including that the Products could be used to minimise the risk of diabetes or stroke; and
 - (c) the advertisements referred to substances in schedules 4 of the Poisons Standard, namely tirzepatide and semaglutide.
- 3.8 The TGA considers Midnight Health unlawfully advertised Products, including in contravention of section 42DLB(1) of the Act where subsections 42DLB(2), (4) and (7) applied.

4. Acknowledgement of Breach

- 4.1 As a result of the TGA's investigations and in response to the TGA's concerns, Midnight Health:
- (a) acknowledges that the Websites likely contravened sections 42DLB(1) where subsections 42DLB(2), (4) and (7) of the Act applied; and
 - (b) offers this undertaking to the TGA to address the TGA's concerns.

5. Undertakings

Period of Undertaking

- 5.1 This undertaking comes into effect when both the following are satisfied:
- (a) the undertaking is executed by Midnight Health; and
 - (b) the Secretary accepts the undertaking so executed.
- 5.2 Upon the commencement of the undertaking, Midnight Health undertakes to assume the obligations set out in paragraphs 5.5 to 5.13 below.
- 5.3 This undertaking has effect for 12 months from the day it comes into effect.

Application of the undertaking to all Covered Websites

- 5.4 This undertaking applies to the Covered Websites.

Undertaking

- 5.5 Under section 42YL of the Act, Midnight Health has offered, and the Secretary has agreed to accept the following undertakings:

- (a) Midnight Health 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) Midnight Health will produce a written report (**MH Report**) to the TGA setting out compliance with the terms of this enforceable undertaking, and any actions taken or planned to address issues identified by the Consultant and/or Legal Consultant, at the later of:
 - (i) six-months after the commencement of the undertaking; or
 - (ii) the date one month after receipt by Midnight Health of the last of the Root Cause Analysis Report and Legal Consultant Report; and
- (c) Midnight Health will pay the costs of its compliance with this undertaking.

Engagement of an External Qualified Compliance Professional

- 5.6 Midnight Health has engaged a Consultant to advise and assist with the measures specified in paragraph 5.7.
- 5.7 Midnight Health's engagement of the Consultant will include a requirement for the Consultant to, within six months of this undertaking coming into effect, provide a Root Cause Analysis Report.

Provision of Documents to the TGA – Root Cause Analysis

- 5.8 Within 7 calendar days of this undertaking coming into effect, Midnight Health must provide to the TGA contact details of the Consultant that Midnight Health has engaged.
- 5.9 Midnight Health will provide the TGA with a copy of the MH Report as set out in paragraph 5.5(b) above. If there are actions identified as outstanding as at the date of the MH Report, Midnight Health will provide the TGA with a further report once these have been implemented.

Engagement of a Legal Consultant

- 5.10 Midnight Health undertakes to engage a Legal Consultant to advise and assist with the measures specified in paragraph 5.11.
- 5.11 Midnight Health's engagement of the Legal Consultant will include a requirement for the Legal Consultant to provide a written opinion, which would address the following:
 - (a) the Legal Consultant's opinion as to whether the Websites comply with the Act and the Code;
 - (b) the Legal Consultant's opinion as to whether Midnight Health has in place an effective compliance program that ensures the Websites comply with the Act and the Code.
 - (c) actions, if any, recommended by the Legal Consultant to:
 - (i) bring the Websites into compliance with the Act and the Code; and

- (ii) improve Midnight Health's policies, processes or procedures to ensure ongoing compliance with the Act and the Code; and

Provision of Documents to the TGA – Legal Consultant Report

- 5.12 Within 7 calendar days of Midnight Health engaging the Legal Consultant, Midnight Health must provide to the TGA the identity and contact details of the Legal Consultant that Midnight Health has engaged.
- 5.13 Midnight Health will provide the TGA with a copy of the MH Report as set out in paragraph 5.5(b) above. If there are actions identified as outstanding as at the date of the MH Report Midnight Health will provide the TGA with a further report once these have been implemented.

6. Acknowledgement

6.1 Midnight Health acknowledges that:

- (a) this undertaking was given voluntarily by Midnight Health;
- (b) the Secretary must publish details of this undertaking on the TGA's website (see subsection 42YL(3) of the Act);
- (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 this undertaking, including paragraph 3.7 above.

Executed by

Executed by Midnight Health Pty Ltd (ACN 647 966 738) in accordance with Section 127 of the Corporations Act 2001 (Cth).

[Redacted signature of director]

Signature of director

[Redacted signature of director/company secretary]

Signature of ~~director~~ company secretary
(Please delete as applicable)

[Redacted name of director]

Name of director (print)

[Redacted name of director/company secretary]

Name of ~~director~~ company secretary (print)

Accepted by a Delegate of the **Secretary** of the **Department of Health, Disability and Ageing** under section 42YL of the *Therapeutic Goods Act 1989* (Cth).



Signature of Delegate of the Secretary



Name of Delegate of the Secretary

Date: 25/09/2025