ENFORCEABLE UNDERTAKING

given to the Secretary of the Australian Government Department of Health
for the purposes of section 42YL of the *Therapeutic Goods Act 1989*

by

NET PHARMACY PTY LTD (ACN 089 604 955)

and

[REDACTED]

Persons and authority

1. This undertaking is given to the Secretary of the Australian Government Department of Health by [REDACTED] and Net Pharmacy Pty Ltd (ACN 089 604 955) of 97-99 Dover Street, Cremorne VIC 3121 (**Net Pharmacy**) for the purposes of section 42YL of the *Therapeutic Goods Act 1989* (the **Act**).

Background

2. The Therapeutic Goods Administration (the **TGA**) is a part of the Australian Government Department of Health (**Department**), and is responsible for the national regulation of therapeutic goods including medicines, biologicals and medical devices.

3. Net Pharmacy is a business that advertises or causes the advertising of various medicines and biologicals to persons in Australia including electronically at a range of Uniform Resource Locators (**URL**) including:

   (a) www.netpharmacy.com.au;

   (b) www.peptidesonline.com.au (**Peptides Online Australia**);

   (c) www.peptidesonline.co.uk (**Peptides Online UK**);

   (d) www.nicit.com.au (**Nicit**); and

   (e) www.tailormadehealth.com.au (**Tailor Made Health**).

4. The medicines advertised for supply electronically at Peptides Online Australia and Peptides Online UK are principally purported to be performance and image enhancing substances, including Selective Androgen Receptor Modulators (**SARMs**), Melanotan II and growth hormone-releasing peptides (**GHRPs**). SARMs, Melanotan II and GHRPs are included in Schedule 4 to the current *Poisons Standard* as defined in subsection 52A(1) of the Act (**Poisons Standard**).

5. A number of liquid nicotine products for use in smoking cessation are or were advertised electronically at Nicit. Nicotine for human therapeutic use (unless in preparations for oromucosal or transdermal use), including nicotine in liquid form when intended to be used for smoking cessation, is included in Schedule 4 to the current Poisons Standard.

6. A range of therapeutic goods, notably including GHRPs and stem cell therapies, are or were advertised electronically at Tailor Made Health. As noted in paragraph 4, GHRPs are included in Schedule 4 to the current Poisons Standard. Stem cells are cells that, when represented to be for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons, are biologicals within the meaning of section 32A of the Act.

7. [REDACTED] is the sole Director/Secretary, and sole shareholder, of Net Pharmacy. [REDACTED] is also the sole proprietor (in his personal capacity) of Como Compounding Pharmacy (ABN 12 314 525 168) (**Como Compounding**), a compounding pharmacy that has advertised therapeutic goods at the URL www.comocompounding.com.au.

8. A range of compounding pharmacy services are or were advertised electronically at the URL www.comocompounding.com.au. A range of compounded medicines are or were advertised at that URL. Some of these advertisements referred to substances included in Schedule 4 to the Poisons Standard.

Relevant law

9. Section 42DL of the Act provides that it is an offence for a person to advertise, or cause to be advertised, therapeutic goods, if any of subsections 42DL(5) to 42DL(12) applies to the advertisement.

10. Subsection 42DL(7) applies if the advertisement contains a restricted representation (whether in express terms or by necessary implication) and neither an approval under section 42DF of the Act nor a permission under section 42DK of the Act is in force in relation to the restricted representation. A restricted representation is a representation about a serious form of a disease, condition, ailment or defect, as identified in the *Therapeutic Goods Advertising Code (No. 2) 2018* (**the Advertising Code**) (see section 42DD of the Act).

11. Subsection 42DL(10) applies if the advertisement refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the Poisons Standard, but are not included in Appendix H of the Poisons Standard, other than a reference authorised or required by a government or government authority (other than a foreign government or government authority).

12. Subsection 42DL(11) applies if the advertisement refers to a biological, other than a reference authorised or required by a government or government authority (other than a foreign government or government authority).

13. Subsection 42DL(12) applies if an advertisement refers to therapeutic goods that are not entered on the Australian Register of Therapeutic Goods (the **Register**) and are prescribed by the regulations for the purposes of that subsection, other than a reference authorised or required by a government or government authority (other than a foreign government or government authority). Subregulation 7(i) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) prescribes, for the purposes of subsection 42DL(12) of the Act, therapeutic goods that are neither the subject of an exemption, approval or

authority under the Act nor an exemption, approval or authority under regulations under the Act.

14. Subsection 42DLB(1) of the Act is a civil penalty provision. A person contravenes subsection 42DLB(1) of the Act if they advertise, or cause to be advertised, therapeutic goods if any of subsections 42DLB(2) to 42DLB(9) applies to the advertisement. Subsections 42DLB(4), 42DLB(7), 42DLB(8) and 42DLB(9) are (respectively) in the same terms as subsections 42DL(7), 42DL(10), 42DL(11) and 42DL(12), as summarised above.

Conduct of concern

15. The Secretary considers that Net Pharmacy has advertised or caused the advertising of medicines and biologicals electronically at Peptides Online Australia, Peptides Online UK, Nicit and Tailor Made Health where the advertisements contained the representations or references specified in column 2 of the table below, in contravention of the provision in column 3 of that table:

	Representation or reference	Section of the Act
1.	Restricted representations, for example cardiovascular disease.	Subsection 42DL(1) where subsection 42DL(7) applies. Subsection 42DLB(1), where subsection 42DLB(4) applies.
2.	References to substances, or goods containing substances, included in Schedule 4 to the Poisons Standard, for example: • Nicotine in preparations for human therapeutic use (other than use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use); • SARMs; • Melanotan II; and • GHRPs.	Subsection 42DL(1) where subsection 42DL(10) applies. Subsection 42DLB(1), where subsection 42DLB(7) applies.
3.	References to biologicals, for example stem cells represented to be for use in the treatment or prevention or disease, ailment, defect or injury affecting persons.	Subsection 42DL(1) where subsection 42DL(11) applies. Subsection 42DLB(1), where subsection 42DLB(8) applies.
4.	References to therapeutic goods that are not entered in the Register.	Subsection 42DL(1) where 42DL(12) applies. Subsection 42DLB(1), where subsection 42DLB(9) applies.

16. The Secretary considers that [REDACTED] has advertised or caused the advertising of medicines electronically at the URL www.comocompounding.com.au, where the advertisements contained the representations or references specified in column 2 of the table below, in contravention of the provision in column 3 of that table:

	Representation or reference	Section of the Act
1.	Restricted representations, for example representations relating to multiple sclerosis.	Subsection 42DL(1) where subsection 42DL(7) applies. Subsection 42DLB(1), where subsection 42DLB(4) applies.
2.	References to substances, or goods containing substances, included in Schedule 4 to the Poisons Standard, for example: • 4-Aminopyradine; • Minoxidil at concentrations of over 5%; and • GHRPs.	Subsection 42DL(1) where subsection 42DL(10) applies. Subsection 42DLB(1), where subsection 42DLB(7) applies.
3.	References to medicines that are not entered on the Register.	Subsection 42DL(1) where 42DL(12) applies. Subsection 42DLB(1), where subsection 42DLB(9) applies.

Period of undertaking

17. This undertaking commences when both of the following are satisfied:

    (a) the undertaking is executed by Net Pharmacy and [REDACTED]; and

    (b) the delegate of the Secretary signs the executed undertaking.

18. On commencement of this undertaking, Net Pharmacy and [REDACTED] (together referred to below as the **Undertaking Parties**) each undertakes to assume the obligations set out in paragraphs 21 to 37 below.

19. Where an undertaking is capable of being jointly complied with by both of the Undertaking Parties, the Undertaking Parties may comply with that requirement together (for example, by engaging a common external qualified compliance professional, or submitting a joint report to the TGA) or separately.

20. This undertaking terminates three years following its commencement.

Undertakings

Cessation of allegedly unlawful conduct

21. The Undertaking Parties each undertakes not to, whether themselves or through their directors, employees, servants or agents or bodies corporate under their control:

    (a) advertise or supply therapeutic goods to persons in Australia in contravention of the Act or the Advertising Code;

    (b) advertise or supply therapeutic goods electronically at Peptides Online Australia, Peptides Online UK or Nicit; or

    (c) aid, abet, counsel or procure, or otherwise authorise, assist or encourage in any way, any conduct by another person of a kind which the Undertaking Parties have undertaken not to engage in under paragraph 21(a) or 21(b) above.

Disclosure

22. The Undertaking Parties each undertakes to, within 7 days of the execution of this undertaking, provide to the TGA a list of all websites:

    (a) owned or operated by it (whether itself or through its directors, employees, servants or agents, or bodies corporate under its control); or

    (b) which facilitates its receipt of orders for the supply of therapeutic goods.

23. The Undertaking Parties each undertakes to, during the period of this undertaking, notify the TGA of any additional website of a kind described at paragraph 22(a) or 22(b) above within 14 days of:

    (a) In the case of a website described at paragraph 22(a), the date on which it first comes to own or operate the website; or

    (b) In the case of a website described at paragraph 22(b), the date on which it first becomes aware that it has received, or will in future receive, orders facilitated by that website.

24. The Undertaking Parties each undertakes to give to the TGA any documents or information requested by the TGA in relation to its advertising or supply of therapeutic goods (from the date of this undertaking) to persons in Australia within 14 days (or a longer period of time allowed by the TGA) after receiving a request from the TGA.

Engagement of an external qualified compliance professional

25. The Undertaking Parties each undertakes, within one month of the date of execution of this undertaking, to, at its own expense, engage an external qualified compliance professional to advise and assist with the implementation of regulatory procedures including the compliance program specified in paragraph 29 below to ensure that it does not contravene the Act or the Advertising Code.

26. 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 Net Pharmacy or any of the business activities of [REDACTED].

Nomination of external qualified compliance professional

27. Prior to the engagement of the external qualified compliance professional, the Undertaking Parties each undertakes to inform the TGA of the identity and expertise of one or more persons it proposes to engage.

28. If, within one month of the Undertaking Parties informing the TGA in accordance with clause 27 above, the Undertaking Parties and the TGA cannot agree on the external qualified compliance professional to be engaged, the TGA will nominate an external qualified compliance professional. The Undertaking Parties each undertakes to engage the external qualified compliance professional so nominated by the TGA.

Compliance program

29. The Undertaking Parties each undertakes to implement, maintain and review a compliance program for the preparation of advertisements for their medicines (the ***compliance program***).

30. The Undertaking Parties each undertakes to ensure that the compliance program is consistent with the Australian Standard AS 19600:2015 and the requirements specified in **Annexure A**.

Annual written report and interim reports

31. For the period of this undertaking, the Undertaking Parties each undertakes to require the external qualified compliance professional to provide an annual written report to the TGA regarding:

    (a) its (or the Undertaking Parties, if done jointly) compliance with the Act;

    (b) the compliance of its (or the Undertaking Parties, if done jointly) advertisements with the Advertising Code; and

    (c) a review of its (or the Undertaking Parties, if done jointly) compliance program.

32. The annual written report will, at a minimum, address and include the matters specified in **Annexure B**.

33. The Undertaking Parties each undertakes to ensure that:

    (a) the first annual review is completed by the external qualified compliance professional and the written report relating to that review is provided by that person to the TGA prior to 31 December 2020;

(b) the second annual review is completed by the external qualified compliance professional and the written report relating to that review is provided by that person to the TGA prior to 31 December 2021; and

(c) the third annual review is completed by the external qualified compliance professional and the written report is provided by that person to the TGA one month prior to the expiration of the period of this undertaking.

34. If the TGA reasonably suspects that the compliance program is not being implemented effectively by an Undertaking Party, the TGA may request that it prepare an interim report, in addition to the reports required under paragraph 33 above. On receipt of such a request, the Undertaking Party must:

(a) cause an interim report (to which paragraphs 31 and 32 apply) to be prepared by the external qualified compliance professional and provided to the Undertaking Party within 30 days of the request; and

(b) give a copy of the report to the TGA within 14 days after it is received by the Undertaking Party.

Provision of assistance by the Undertaking Parties to the external qualified compliance professional

35. The Undertaking Parties will each ensure that the external qualified compliance professional has access to the information the external qualified compliance professional requires for the purposes of their review of advertisements for their medicines, the Undertaking Parties' compliance program, and the preparation of the annual written report.

Review and reporting on compliance with the Act and the Advertising Code

36. The Undertaking Parties will each implement promptly, and with due diligence, any recommendations made by the external qualified compliance professional, that are reasonably necessary to ensure that it complies with the Act, the Advertising Code or the terms of this undertaking.

Provision of documents to the TGA

37. The Undertaking Parties each further undertakes to provide a copy of any document relating to the compliance program as required by the TGA for the period of this undertaking, within 14 days of being required to provide that document.

Acknowledgements

38. The Undertaking Parties each acknowledges that:

(a) this undertaking is given voluntarily; and

(b) the Secretary may make this undertaking publicly available on a public register and is obliged under the Act to publish details of the undertaking, as in force from time to time, on the internet; and

(c) the Secretary and/or the Commonwealth or officers thereof may from time to time, publicly refer to this undertaking including by means of, but not limited to, public statements, news media statements, and TGA or Department publications; 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 of the Undertaking Parties; and

(e) the Undertaking Parties will each bear all their costs of compliance with this undertaking.

THIS UNDERTAKING IS GIVEN BY:

Net Pharmacy Pty Ltd (ACN 089 604 955) by its sole director/secretary pursuant to section 127(1) of the *Corporations Act 2001* (Cth):

[REDACTED]

[REDACTED]
Sole director and company secretary

On 13 November 2020

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

Adjunct Professor John Skerritt

Delegate of the Secretary

On 27 November 2020

Annexure A

REQUIREMENTS FOR COMPLIANCE PROGRAM (see clause 30)

Appointment of compliance officer and compliance manager

39. The Undertaking Parties will each appoint an internal compliance officer and a compliance manager with suitable seniority and experience in the pharmaceutical industry to have responsibility for the compliance program:

40. The Undertaking Parties will, within 28 days of the commencement of this undertaking, each notify the TGA of the name and contact details of the compliance officer and compliance manager;

41. The Undertaking Parties will, during the period of this undertaking, each advise the TGA within 28 days of any change to the compliance officer or compliance manager, including their contact details.

Maintenance of a compliance committee

42. Net Pharmacy will maintain a compliance committee comprising the following members:

    (a) Managing Director;

    (b) Compliance Officer;

    (c) Compliance Manager.

43. The compliance committee will meet quarterly, or more frequently as required, to review all advertisements for Net Pharmacy's medicines to ensure compliance with Act and the Advertising Code.

Preparation and review of advertisements

44. The Undertaking Parties will each ensure that it prepares and reviews all advertisements for its medicines in a manner consistent with the compliance program prior to publication or broadcast of the advertisement.

Training on compliance with the Act and the Advertising Code

45. Any employee of either of the Undertaking Parties involved in the preparation, review or approval of advertisements, and all members of the compliance committee, will, within three months of the commencement of this undertaking, and otherwise yearly during the period of this undertaking, undertake practical training on compliance with the Act and the Advertising Code.

46. The Undertaking Parties will, at their own expense, each facilitate the training of relevant employees and, within 14 days of the completion of any such training, give to the TGA a written statement from the provider confirming the completion of that training in accordance with paragraph 45 above.

Annexure B

REQUIREMENTS FOR ANNUAL WRITTEN REPORT (see clause 32)

47. The annual written report must address and include the following:

(a) the external qualified compliance professional's assessment as to whether all advertisements comply with the Act and the Advertising Code; and

(b) copies of the policies and standard operating procedures of the Undertaking Party for the preparation and review of advertisements for the medicines and its compliance programs in respect of the medicines; and

(c) the external qualified compliance professional's assessment as to whether the Undertaking Party has in place an effective compliance program that complies with the requirements of this undertaking; and

(d) the external qualified compliance professional's assessment as to whether the compliance program of the Undertaking Party complies with Industry best practice; and

(e) details of the information gathered and examined during the review; and

(f) the name and relevant experience of the persons appointed as the compliance officer and the compliance manager; and

(g) actions recommended by the external qualified compliance professional to ensure the effectiveness of the compliance program; and

(h) a signed statement by the external qualified compliance professional that they have seen this undertaking, that they have prepared the annual written report and that, notwithstanding they were engaged by the Undertaking Party in question, the report contains their impartial and professional assessments and opinions.