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Details of Filing

Document Lodged: Concise Statement
File Number: NSD2213/2018

File Title: SECRETARY OF THE DEPARTMENT OF HEALTH v PEPTIDE

CLINICS PTY LTD ACN 165 404 286

Registry: NEW SOUTH WALES REGISTRY - FEDERAL COURT OF

AUSTRALIA



Dated: 4/03/2019 9:29:32 AM AEDT Registrar

Important Information

Wormich Soden

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

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Respondent



AMENDED CONCISE STATEMENT

(amended on 1 March 2019 pursuant to Order 2 of the Orders of Jagot J made on 5 February 2019 and Order 1 of the Orders of Jagot J made on 19 February 2019)

FEDERAL COURT OF AUSTRALIA DISTRICT REGISTRY: NEW SOUTH WALES DIVISION: COMMERCIAL AND CORPORATIONS

NO NSD 2213 OF 2018

SECRETARY OF THE DEPARTMENT OF HEALTH Applicant PEPTIDE CLINICS PTY LTD (ACN 165 404 286)

A. IMPORTANT FACTS GIVING RISE TO THE CLAIM

The Respondent and the Peptide Clinics Website

- 1. Since at least 2015, Peptide Clinics Pty Ltd (Respondent) has operated an online retail business through its website located at Universal Resource Locator (URL) www.peptideclinics.com.au (Website). Through the Website, the Respondent sells products that are "therapeutic goods" within the meaning provided by s 3(1) of the Therapeutic Goods Act 1989 (Cth) (TG Act). The Respondent describes the therapeutic goods it sells as 'Peptides' or 'Peptide Treatments'.
- 2. The Website also contains and or has contained information published by the Respondent that asserts a number of purported benefits of Peptides and Peptide Treatments sold by the Respondent including anti-ageing, body building, body fat and weight loss, injury repair, tanning, heart health, mood regulation (including reducing anxiety and depression), libido/sexual function enhancement, preventing sleeplessness, bone health and optimising health and fitness goals.
- The Respondent also advertises Peptides and Peptide Treatments through its 3. Instagram account (at URL https://www.instagram.com/peptideclinics) and Facebook page (at URL https://www.facebook.com/peptideclinics) (together, Social Media Channels).
- 4. At all relevant times From at least 2015 to 21 December 2018, the Website has described a five step process for purchasing Peptides and Peptide Treatments from the Respondent:

Step 1: Qualify for Peptide Treatment

Step 2: Access Online Clinic

Step 3: Doctor Evaluation

Step 4: Nurse Consultation

Step 5: Medication dispatched

Filed on behalf of the Applicant

Prepared by: Sonja Marsic

AGS lawyer within the meaning of s 55I of the Judiciary Act 1903

Address for Service: The Australian Government Solicitor, Level 42, MLC Centre, 19 Martin Place, Sydney, NSW 2000 Sonja.Marsic@ags.gov.au

File ref: 18009187

Telephone: 02 9581 7505 Lawyer's Email: Sonja.Marsic@ags.gov.au Facsimile: 02 9581 7650 DX 444 Sydney

- 5. Pursuant to Step 1, a consumer completeds and submitteds to the Respondent via the Website an online "medical questionnaire". Immediately upon submitting the questionnaire the consumer receiveds an email requesting the confirmation of his or her email address, which enableds the consumer to log in to the Website. Upon providing such confirmation by clicking the link in the email and logging in to their account, the consumer wasis advised via the Website that a "medical professional" wouldwill review their medical questionnaire within 24 hours.
- 6. A short period of time later, the consumer receiveds an email indicating that they may access a part of the Website not available to the public at large (**Back End**). At the Back End, the consumer hads access to additional information about and could ean purchase Peptides and Peptide Treatments, including the Advertised Products defined at paragraph 8 below. This is Step 2 of the five step process described in paragraph 4 above.
- 7. Following correspondence between the Applicant and the Respondent, in November 2018, the Respondent made a number of changes to the Website and its Social Media Channels. However, the Respondent continues<u>d</u> to advertise therapeutic goods at the Back End of the Website <u>until 21 December 2018</u>.
- 7A. The Website was amended on 21 December 2018. On and from 22 December 2018, the Website has described a revised five step process for purchasing Peptides and Peptide Treatments from the Respondent:

Step 1: Registration

Step 2: Complete an Initial Medical Questionnaire

Step 3: Doctor Consultation

<u>Step 4: Nurse Consultation (to ensure every patient understands how to properly administer their medication)</u>

Step 5: Medication dispatched

- 7B. Steps 1 and 2 of the revised process are identical to step 1 described in paragraph 5 above, save that once a consumer confirms their account, they are prompted to select a date and time for a telephone consultation with a medical practitioner.
- 7C. During the telephone consultation the consumer speaks to a medical practitioner or a person purporting to be a medical practitioner. The consumer is asked about matters including their previous peptide use and reason for wanting to use peptides. No physical examination occurs during this process. The medical practitioner or purported medical practitioner recommends certain of the Advertised Products defined at paragraph 8 below, for use by the consumer depending on the consumer's goals.
- 7D. Sometime shortly after the medical practitioner or purported medical practitioner recommends the Advertised Products to the consumer, the consumer is telephoned by a servant, employee or agent of the Respondent who explains which of the Advertised Products have been recommended for them and the cost of those products.

 Consumers are advised that the consultations allow them to purchase Advertised Products for a period of 6 months. At this stage, the consumer may purchase the Advertised Products over the telephone through the use of a credit card or by bank transfer (details of which are to be emailed to the consumer). There is no consultation with a nurse as described in step 4 in paragraph 7A above.

Advertisement of Schedule 4 Substances

- 8. From 6 March 2018 to around 23 November 2018, the Respondent advertised, within the meaning of s 3(1) of the TG Act (advertised), the therapeutic goods sold by the Respondent and identified in Schedule 1 to this Concise Statement (Advertised Products) on the publicly accessible part of the Website (Front End). These advertisements could be accessed by any consumer who searched for products in the search bar on the "login" webpage, moved their cursor over the tabs "PEPTIDES", "COMPOUNDING" and "EDUCATION" on the "login" webpage of the Website or accessed various webpages in the Peptide Treatments and Blog sections of the Website.
- 9. From 6 March 2018 to around 7 November 2018, the Respondent advertised the Advertised Products on its Social Media Channels.
- 9A. On and from around 8 November 2018, the Respondent has advertised, in the sense of promoting the use or supply of, therapeutic goods on its Instagram page by:
 - 9A.1 using the word "peptides"; or
 - 9A.2 alternatively, using the word "peptides" in the context of the Instagram page as a whole, including:
 - 9A.2.1 the Instagram name "peptideclinics";
 - 9A.2.2 the use of Peptide Clinics' trading name "Peptide Clinics Australia";
 - <u>9A.2.3 the imagery of a double helix conveying a medical association as its profile picture;</u>
 - 9A.2.4 Peptide Clinics' URL hyperlinked to its Website;
 - <u>9A.2.5 the statement to the effect that Peptide Clinics prescribes "clinical</u> grade AUS peptides made under expert medical supervision"; and
 - 9A.2.6 the enjoinment "Use the hashtag #peptideslifestyle",
 - and thereby has referred to substances or, alternatively, to goods containing substances included in Schedule 4 of the current Poisons Standard.
- 9B. On and from around 8 November 2018, the Respondent has advertised, in the sense of promoting the use or supply of, therapeutic goods on its Facebook page by:
 - 9B.1 using the word "peptides"; or
 - 9B.2 alternatively, using the word "peptides" in the context of the Facebook page as a whole, including:
 - 9B.2.1 the Facebook name "Peptide Clinics";
 - 9B.2.2 use of the trade name "Peptide Clinics";

- 9B.2.3 the Facebook tag "@peptideclinics";
- 9B.2.4 the statement "The secret to health and wellness starts here. Join more than 50,000 satisfied patients and register today",
- 9B.2.5 the imagery of a patient in consultation with a doctor wearing a stethoscope conveying a medical association;
- 9B.2.6 the statement that Peptide Clinics is "Recommended by 8 People";
- 9B.2.7 the rating of "4.1 out of 5" apparently "[b]ased on the opinion of 25 people"; and
- 9B.2.8 the statistics that "29,982 people like" the Facebook page and that "29,912 people follow" the Facebook page,
- and thereby has referred to substances or, alternatively, to goods containing substances included in Schedule 4 of the current Poisons Standard.
- 10. On and <u>fF</u>rom 6 March 2018 to 21 December 2018, the Respondent advertised the Advertised Products at the Back End of the Website. These advertisements <u>wereare</u> visible to consumers who <u>wereare</u> given access to the Back End and who viewed webpages accessible from the 'TREATMENTS' and 'EDUCATION' drop down menus.
- 10A. On and from 22 December 2018, the Respondent, through its servants, employees or agents, has advertised, in the sense of promoting the use or supply of, the Advertised Products by offering those products for sale to consumers over the telephone when those consumers undertook the process described in paragraphs 7A to 7D above.
- 11. Each of the Advertised Products is listed in Schedule 4 of the current Poisons Standard as indicated in Schedule 1 to this Concise Statement. A number of the Advertised Products are also listed in Appendix D to the current Poisons Standard as indicated in Schedule 1 to this Concise Statement. In New South Wales, it is an offence to possess, or attempt to obtain possession of, the substances listed in Appendix D, being 'prescribed restricted substances' for the purpose of s 16 of the *Poisons and Therapeutic Goods Act 1966* (NSW) without authority. Equivalent legislative provisions exist in all other State and Territories.
- 11A. On and from at least 6 March 2018, the Respondent advertised, in the sense of promoting the use or supply of, therapeutic goods on the Front End of the Website by:
 - 11A.1. using the word "peptides"; or
 - 11A.2. alternatively, using the word "peptides" in the context of the Front End as a whole, including by:
 - 11A.2.1 the use of Peptide Clinics' trading name "Peptide Clinics Australia";
 - 11A.2.2 deploying imagery such as stethoscopes conveying a medical association; and

11B.2.3 the repeated use of Peptides Clinics' logo which incorporates the imagery of a double helix conveying a medical association, the trading name "Peptide Clinics Australia" and the slogan "Be The Best You",

11A.2.4 between 6 March 2018 and 21 December 2018 making statements such as

<u>"Peptides Australia – The Trusted Source to Buy Premium Peptides in Australia".</u>

"There is a secret to health and wellness and it starts here at the leading industry source for peptides online in Australia. More than 50,000 satisfied patients are already benefiting from our premium peptides",

"Wondering where you can order clinical grade peptides within Australia?",

"Peptide Clinics Australia is an online, medically-controlled, results-focused peptide and hormone treatment provider whose medical practitioners treat patients by prescribing premium peptides and alternative health products to patients throughout Australia",

"In Australia, peptides are considered a Schedule 4 drug" and

<u>"to legally buy clinical grade peptides in Australia, a patient will have to acquire an legitimate Doctor's approval",</u>

11A.2.5 on and from 22 December 2018 making statements such as:

"Our doctors only prescribe the highest quality products",

"People Love Peptide Clinics Australia",

"The secret to health and wellness starts here",

"Join more than 50,000 satisfied patients and register today",

"Our doctors only prescribe the highest quality products which are compounded in Australia",

"Peptide Clinics Australia services thousands of satisfied customers with premium peptides".

"Registering as a patient of Peptide Clinics is easy and convenient. Our doctors and support team will support your needs throughout the medical assessment, prescription and order process".

"We are Australia's #1 supplier of clinical grade peptides and proudly help over 50,000 satisfied patients",

"In Australia, peptides are considered a Schedule 4 drug" and

"to legally buy clinical grade peptides in Australia, a patient will have to acquire a legitimate Doctor's approval",

and thereby has referred to substances or, alternatively, to goods containing substances included in Schedule 4 of the current Poisons Standard.

Advertisements containing restricted representations

12. On and from 6 March 2018 until around 23 November 2018, the following webpages were accessible from the Website:

- 12.1. the webpage at URL www.peptideclinics.com.au/heart-muscle-damage/, which advertises therapeutic good variously described as "TB-500" or "Thymosin Beta-4" and contains representations that expressly or impliedly refer to a serious form of cardiovascular disease.
- 12.2. the webpage at URL www.peptideclinics.com.au/how-to-increase-bone-density/, which advertises a therapeutic good described as "SARMS Forte" and contains representations that expressly or impliedly refer to a serious form of joint, bone, collagen, and rheumatic disease.
- 12.3. the webpage at URL www.peptideclinics.com.au/treatments/osteopenia/, which advertises therapeutic goods and contains representations that expressly refer to osteopenia, a disease of the bone.
- 13. The diseases, or alternatively, conditions and ailments, referred to in the preceding paragraph were each serious forms of those diseases, conditions or ailments within the meaning of s 5(2) of the *Therapeutic Goods Advertising Code 2015* (2015 Advertising Code) and Part 2 of Appendix 6 of the 2015 Advertising Code since they are generally accepted:
 - 13.1. not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or
 - 13.2. to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.
- 14. Consequently, the representations referred to in paragraph 12 above were restricted representations within the meaning of s 42DD of the TG Act.
- 15. At no time has the Secretary of the Department of Health granted approval to the Respondent under s 42DF(1) of the TG Act or a permission under s 42DK(1) of the TG Act to use the restricted representations.

Advertisements containing prohibited representations

- 16. On and f From 6 March 2018 to around 21 December 2018, the Respondent has advertised the use of "5HTP" (5-Hydroxytryptophan) and Oxytocin, being therapeutic goods, for treatment of 'anxiety', as well as more general references to the use of Peptides for anxiety, depression and 'mood regulation' (for example, the webpage at URL www.peptideclinics.com.au/treatments). These advertisements contained representations that expressly and impliedly referred to the treatment, cure or prevention of mental illness.
- 17. The representations referred to in the preceding paragraph are referred to in s 5(1) and Part 1 of Appendix 6 of the 2015 Advertising Code and are therefore prohibited representations within the meaning of s 42DJ(1) of the TG Act.
- 18. At no time has the Secretary of the Department of Health granted permission under s 42DK of the TG Act to use the prohibited representations.

Non-compliance with the <u>a</u>Advertising <u>c</u>Code<u>s</u>

19. From 6 March 2018 to around 23 November 2018, the Respondent advertised therapeutic goods on its Website in a way that would mislead, or be likely to mislead,

consumers directly or by implication or through emphasis, comparisons, contrasts or omissions, and which thereby did not comply with s 4(2)(c) of the $\underline{2015}$ Advertising Code, including at the following URLs

- 19.1. The Website;
- 19.2. www.peptideclinics.com.au/treatments;
- 19.3. www.peptideclinics.com.au/how-to-increase-melanin-production;
- 19.4. www.peptideclinics.com.au/uv-radiation-sun-exposure;
- 19.5. www.peptideclinics.com.au/tanning-options;
- 19.6. <u>www.peptideclinics.com.au/treatments/sun-safety-australia/msh-melanocyte-stimulating-hormone</u>;
- 19.7. www.peptideclinics.com.au/store/treatments/safe-enhanced-tanning.html;
- 19.8. www.peptideclinics.com.au/safe-enhanced-tanning-and-vitamin-d; and
- 19.9. www.peptideclinics.com.au/treatments/sun-safety-australia.
- 20. From 6 March 2018 to around 23 November 2018, the Respondent has contravened s 4(2)(f) of the 2015 Advertising Code and, from 1 January 2019, s 10(c) of the Therapeutic Goods Advertising Code (No 2) 2018 (Cth) (2018 Advertising Code) by advertising Schedule 4 substances on its Website for uses for which they are inappropriate, to wit: advertised the Advertised Products on its Website in a way that encouraged the use of the Advertised Products for uses including:
 - 20.1. from 6 March 2018 to around 23 November 2018, it advertised the Advertised Products for anti-ageing, bodybuilding, fat loss, injury repair, tanning, heart health, mood regulation and sleep loss (From 6 March 2018 to around 23 November 2018, on the webpage at URL www.peptideclinics.com.au/treatments); and
 - 20.2. from 6 March 2018 to around 21 December 2018, it advertised the Advertised Products for anxiety, anti-ageing, bodybuilding, fat loss, female sexual dysfunction, hair loss, injury repair, libido enhancement, muscle building, premature ejaculation, skin pigmentation/tanning and/or sleep assistance (en and from 6 March 2018 under the 'TREATMENTS' tab visible when logged in to the Back End of the Website);
 - 20.3. from 6 March 2018 to 21 December 2018, it advertised the Advertised Products for anxiety, anti-ageing, bodybuilding, muscle building, fat loss/weight loss, female sexual dysfunction, injury repair, tanning, libido enhancement, hair loss and/or sleep assistance, on the webpages with URLs www.peptideclinics.com.au and https://www.peptideclinics.com.au/store/vip/medical/index/; and
 - 20.4. on and from 22 December 2018, it has advertised Schedule 4 Substances for anti-ageing, muscle building, fat loss/weight loss, tanning, injury repair, libido

enhancement, hair loss, sleep assistance and/or confidence, on the webpage with URL https://www.peptideclinics.com.au/store/vip/medical/index/ through its incorporation of these "uses" as available treatment options in the Medical Questionnaire.

when such uses would be inappropriate, and which thereby did not comply with s 4(2f) of the Advertising Code.

- 21. From 6 March 2018 to around 23 November 2018, on the webpage at URL www.peptideclinics.com.au/treatments/sun-safety-australia/, the Respondent advertised therapeutic goods in a way that implied that the use of Melanotan II for the purpose of self-tanning is safe or alternatively, cannot cause harm, when in fact it is not safe and can cause harm, and which thereby did not comply with s 4(2)(i) of the 2015 Advertising Code;
- 22. On and fFrom 6 March 2018 to 21 December 2018, the Respondent advertised on the Website, including at the following webpages, the Advertised Products in a way that implied that the Advertised Products were safe or alternatively, cannot cause harm, when in fact they are not safe and can cause harm, and which thereby did not comply with s 4(2)(i) of the 2015 Advertising Code.
 - 22.1. https://www.peptideclinics.com.au/store/vip/medical/index/.
 - 22.2. www.peptideclinics.com.au, under the tabs 'Why Choose us?' and 'Online Medical Evaluation, Approval and Despatch [sic]'; and
 - 22.3. https://www.peptideclinics.com.au/peptides-australia/
 - 22.4. the webpages accessible under the 'TREATMENTS' and 'EDUCATION' tabs at the Back End of the Website.
- 22A. On and from 22 December 2018, the Respondent advertised on the Website, including at the following webpages, substances or, alternatively, to goods containing substances included in Schedule 4 of the current Poisons Standard in a way that implied that those substances were safe or alternatively, cannot cause harm, when in fact that are not safe and can cause harm, and which thereby did not comply with s 10(d)(i) of the 2018 Advertising Code:
 - 22A.1 the Website;
 - 22A.2 https://www.peptideclinics.com.au/store/vip/medical/index/; and
 - 22A.3 https://www.peptideclinics.com.au/peptides-australia/.
- 23. From 6 March 2018 to around 23 November 2018, the webpage referred to at paragraph 21 referred to a clinical study purportedly finding that "only 5% of the sunscreens that were tested held up to safety standards" and "another 40% were said to contribute to developing skin cancer" thus referring to scientific information, which was not presented in a manner that was accurate, balanced and not misleading, and which thereby did not comply with s 4(4) of the 2015 Advertising Code.

Application of Part 5-1 of the TG Act to Back End advertisements

- 24. From 6 March to 21 December 2018, t\(T\) o the extent that a medical practitioner was is responsible for "approving" the consumer's access to the Back End of the Website, he or she was is not in a doctor/patient relationship with that consumer, because:
 - 24.1. There <u>was has been</u> no engagement between the medical practitioner and the consumer, including by the medical practitioner to discuss the responses to the medical questionnaire with the consumer;
 - 24.2. The information gathered in the medical questionnaire <u>was is</u> not sufficient for the medical practitioner to take a medical history, determine whether any further examination is required or to recommend a course of treatment;
 - 24.3. The medical practitioner <u>did has</u> not evaluated or diagnosed a condition, nor <u>were</u> are they able to on the basis of the medical questionnaire;
 - 24.4. The medical practitioner ha<u>ds</u> a conflict of interest that mean<u>ts</u> they <u>were</u> are not acting in the consumer's best interests.
- 25. From 6 March 2018 to 21 December 2018, iln "approving" the consumer accessing the Back End of the Website and thereby advertising the Advertised Products to the consumer, the requirements of s 42AA(4) of the TG Act were not satisfied since:
 - 25.1. for the reasons set out in paragraph 24 above, the consumer was not a "patient" of any medical practitioner engaged by the Respondent at the time the consumer was "approved" to access the Back End of the Website; and
 - 25.2. further or alternatively, advice or information was not provided directly by a medical practitioner or nurse engaged by the Respondent to a patient in the course of granting the consumer access to the Back End of the Website; and
 - 25.3. further or alternatively, at no time before the consumer was granted access to the Back End of the Website was he or she in a course of treatment with a medical practitioner engaged by the Respondent.
- 25A. On and from 22 December 2018, to the extent that a medical practitioner was engaged in the process described at paragraph 7C, he or she is not in a doctor/patient relationship with that consumer, because:
 - 25A.1 of the matters in paragraphs 24.2 to 24.4 above; and
 - 25A.2 the medical practitioner does not explain the risks of using those products to the consumer.
- 25B. On and from 22 December 2018, in undertaking the process described in paragraphs
 7A to 7D and thereby advertising the Advertised Products to the consumer, the
 requirements of s 42AA(4) of the TG Act were not satisfied since:
 - 25B.1 for the reasons set out in paragraph 25A above, the consumer was not a "patient" of any medical practitioner engaged by the Respondent at the time during the process;

<u>25B.2</u> <u>further or alternatively, at no time during the process was the consumer in a course of treatment with a medical practitioner engaged by the Respondent.</u>

B. THE RELIEF SOUGHT FROM THE COURT

- 26. The Applicant seeks the relief set out in the accompanying Originating Application, comprising:
 - 26.1. declarations pursuant to s 21 of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**);
 - 26.2. orders for injunctive relief under s 42YN of the TG Act;
 - 26.3. orders for interim injunctive relief under s 42YO TG Act;
 - 26.4. pecuniary penalties pursuant to s 42Y of the TG Act; and
 - 26.5. costs under s 43 of the FCA Act.

C. THE PRIMARY LEGAL GROUNDS FOR THE RELIEF SOUGHT

- 27. By reason of the conduct described in paragraphs 1 and 8 to 11A, which involves advertisements referring to substances or goods containing substances included in Schedule 4 to the current Poisons Standard, the Respondent contravened s 42DLB(1) of the TG Act since s 42DLB(7) applies. A contravention occurred in each of the respects outlined in paragraphs 1 and 8 to 11A on each occasion that such an advertisement was presented to a consumer.
- 28. By reason of the conduct described in paragraphs 1 and 12 to 15, which involves advertisements containing restricted representations, the Respondent contravened s 42DLB(1) of the TG Act since s 42DLB(4) applies. A contravention occurred in each of the respects outlined in paragraphs 1 and 12 to 15 on each occasion that such an advertisement was displayed to a consumer.
- 29. By reason of the conduct described in paragraphs 1 and 16 to 18, which involves advertisements containing prohibited representations, the Respondent contravened s 42DLB(1) of the TG Act since s 42DLB(2) applies. A contravention occurred in each of the respects outlined in paragraphs 1 and 16 to 18 above on each occasion that such an advertisement was displayed to a consumer.
- 30. By reason of the conduct described in paragraphs 1 and 48-19 to 2324, which involves advertisements that do not comply with the 2015 Advertising Code and the 2018

 Advertising Code, the Respondent contravened s 42DMA(1) of the TG Act. A contravention occurred in each of the respects outlined in paragraphs 1 and 19 to 23 above on each occasion that such an advertisement was displayed to a consumer.

D. THE ALLEGED HARM SUFFERED

- 31. The harm suffered by consumers by reason of the contraventions outlined above includes serious harm and risk of serious harm to their health and safety. The use, particularly the use without appropriate medical supervision, of the Advertised Products carries substantial risks to human health.
- 32. The public generally is exposed to harm and/or risk of harm by the publication of misleading information that suggests that the Advertised Products are safe and appropriate for the advertised uses (when they are not).

- 33. The public generally is also exposed to harm and/or risk of harm by the publication of misleading information about important public health issues such as healthy body image and the use of sunscreen in the prevention of skin cancer.
- 34. The harm caused is of particular concern as the Respondent's conduct misleads the public into thinking that the consumer's use of the products is being supervised or approved by a medical practitioner (when it is not).
- 35. The harm suffered also includes financial loss in purchasing the Advertised Products from the Respondent.
- 36. By supplying those Advertised Products that are listed in Appendix D of the current Poisons Standard to consumers without providing the consumers with a prescription, nor informing consumers that the products cannot be lawfully possessed without a prescription, the Respondent exposes consumers to the risk of prosecution.

CERTIFICATE OF LAWYER

I, Sonja Marsic, certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 28 November 2018 1 March 2019

Sonja Marsic

AGS lawyer

for and on behalf of the Australian Government Solicitor Solicitor for the Applicant

SCHEDULE 1 TO CONCISE STATEMENT

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
1.	AOD 9604	N/A	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
2.	Bremelanotide (PT-141)	March 2018: afamelanotide (cross- referenced to melanocyte stimulating hormone)	Yes (as afamelanotide)	No	Yes	No	Yes	Yes – to Melanotan II	No	Yes
		June and October 2018: Alpha- melanocyte stimulating hormone, or melanotan II								
3.	CJC-1295	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
4.	Finasteride	N/A	Yes	No	Yes	No	Yes	No	No	Yes
5.	Follistatin 315-R	Follistatins	Yes	Yes	Yes	Yes	Yes	No	No	Yes
6.	Growth Hormone Releasing Peptide (GHRP)-2	Growth Hormone Releasing Peptides	Yes	Yes	Yes	Yes	Yes	No	No	Yes

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
7.	Growth Hormone Releasing Peptide-6 (GHRP-6)	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
8.	GH combinations comprised of the following: CJC-1295 + Ipamorelin	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
	CJC-1295 + GHRP-6									
9.	HBS Prescription Serum, comprised of: Minoxidil(10%) Dutasteride Latanoprost Melatonin	N/A	Yes	No	Yes	No	Yes	No	No	Yes
10.	IGF-1 (Insulin Like Growth Factor-1) LR3	Insulin Like Growth Factor-I Insulin Like Growth Factors except when separately specified in this Schedule	Yes	Yes	Yes	Yes	Yes	No	No	Yes

# Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
11. Ipamorelin	N/A	Yes	Yes	Yes	Yes	Yes	No	No	Yes
12. Mechano growth factor	Insulin Like Growth Factor-I	Yes	Yes	Yes	Yes	Yes	No	No	Yes
	Insulin Like Growth Factors except when separately specified in this Schedule								
13. Melanotan II	Until 1 June 2018: afamelanotide (cross- referenced to melanocyte stimulating hormone)	Yes (as afamelanotide) – introduced into Schedule 4 in the Poisons Standard June 2018 as melanotan II with effect from 1 June 2018.	No	Yes	No	Yes	Yes	Yes	Yes
14. Melatonin	N/A	Yes	No	Yes	No	Yes	Yes	Yes	Yes
15. Minoxidil	Minoxidil except when included in Schedule 2 Schedule 2: Minoxidil in	Yes	No	Yes	No	Yes	No	No	Yes
	preparations for dermal use containing 5% or less of minoxidil								

#	Substance	Schedule 4 – Alternative name	Present in Schedule 4 of Poisons Standard March 2018?	Appendix D substance in Poisons Standard March 2018?	Present in Schedule 4 of Poisons Standard October 2018?	Appendix D substance in Poisons Standard October 2018?	Front End Website	Instagram	Facebook	Back end Website
16.	Oxytocin	N/A	Yes	No	Yes	No	Yes	No	No	Yes
17.	Selectic Androgen Receptor Modulators (SARMs) s22 (Forte)	Selective Androgen Receptor Modulators	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18.	Thymosin Beta 4	N/A	Yes	No	Yes	No	Yes	No	Yes	Yes