

# Department of Health

Therapeutic Goods Administration

## THERAPEUTIC GOODS ACT 1989

**DIRECTION UNDER SECTION 42DV** 

**ISSUED TO: Auzsupps Pty Ltd** 

**ON: 6 AUGUST 2019** 

**ABOUT: Advertising of therapeutic goods** not entered in the ARTG

**BY:** Nicole McLay **Assistant Secretary Regulatory Education and Compliance Therapeutic Goods Administration** (Delegate of the Secretary of the **Australian Department of Health)** 

**Therapeutic Goods Administration PO Box 100** Woden ACT 2606

**Contact Officer Name:** [REDACTED]

**Contact Officer Telephone:** [REDACTED]

**Contact Officer Email:** [REDACTED]

#### DIRECTION ABOUT AN ADVERTISMENT

## Made Under Section 42DV of the Therapeutic Goods Act 1989

TO: Auzsupps Pty Ltd

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Email: [REDACTED]

I, Nicole McLay, delegate of the Secretary of the Australian Department of Health in the Therapeutic Goods Administration (**TGA**), being satisfied, for the reasons set out in **Attachment A**, that there have been contraventions of the *Therapeutic Goods Act 1989* (**the TG Act**) in relation to the advertising of goods not entered on the Australian Register of Therapeutic Goods (**ARTG**), **DIRECT** you, as the persons apparently responsible for that advertising or for causing the publication of that advertising, to:

- 1. (a) **Cease** all advertisements of therapeutic goods which refer to any substance included in Schedule 4 to the current Poisons Standard (including, but not limited to, the product listed at paragraph 5 of Attachment A to this Direction) published at the website **[REDACTED WEB ADDRESS]**.
  - (b) **Cease** all advertisements of therapeutic goods which refer to any substance included in Schedule 4 to the current Poisons Standard (including, but not limited to, the product listed at paragraph 5 of Attachment A to this Direction) published on the Facebook page at **[REDACTED WEB ADDRESS]** and the Instagram pages at **[REDACTED WEB ADDRESS]** and on any other social media pages.
- 2. (a) **Cease** all advertisements of therapeutic goods which are not entered in the ARTG (including, but not limited to, those listed at paragraph 8 of Attachment A to this Direction), on the website [**REDACTED WEB ADDRESS**].
  - (b) **Cease** all advertisements of therapeutic goods which are not entered in the ARTG (see examples provided at paragraph 8 of Attachment A to this Direction) on the Facebook pages at **[REDACTED WEB ADDRESS]** and the Instagram pages at **[REDACTED WEB ADDRESS]** and on any other social media pages.

#### **CONDITIONS**

## under subsection 42DV(3) of the TG Act

- 3. This **Direction** is subject to the following conditions that you must:
  - (a) **complete** each action you are directed to carry out including as required by these conditions within 14 calendar days of the date of this **Direction**;
  - (b) **email** evidence of your compliance with this **Direction** to the email address listed on the first page of this Direction within 14 calendar days of the date of this Direction.

## **OTHER INFORMATION**

- 4. Important information **about** the reasons for making this **Direction** and its effect is set out in **Attachment A.**
- 5. The possible consequences of failing to comply with this Direction are explained in **Attachment B.**
- 6. The sections of the TG Act relevant to the making of this **Direction** are set out in **Attachment C.**
- 7. This is an 'initial decision' and is reviewable. Your review rights are set out in **Attachment D**.
- 8. Relevant extracts from the advertising of substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard referred to in paragraph [5] of **Attachment A** to this Direction are included in **Attachment E**

- 9. Relevant extracts from the advertising of goods not entered not entered in the ARTG referred to in paragraph 8 of **Attachment A** to this Direction are included in **Attachment F**.
- 10. As required under subsection 42DV(6) of the TG Act, the TGA will publish this **Direction** on its website as soon as practicable.

DATED	: 6 August 2019
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Nicole McLay

Assistant Secretary
Regulatory Education and Compliance
Therapeutic Goods Administration
Delegate of the Secretary
Australian Government Department of Health

#### Attachment A

## **Material findings of fact**

I make the following material findings of fact.

## The complaint and the investigation

- 1. On 10 April 2019, the TGA received a complaint about the therapeutic goods advertising which is the subject of this Direction through the TGA's Advertising Complaints portal. A further two complaints were subsequently received by the TGA on 16 April 2019 and 18 April 2019.
- 2. The complaint referred to the advertising by Auzsupps Pty Ltd of products containing both substances included in Schedule 4 and Schedule 9 of the current Poisons Standard, including Selective Androgen Receptor Modulators (SARMs or SARMS) and cannabidiol oil (CBD Oil).
- 3. Among the Advertisements were a range of advertisements featuring substances, or goods containing substances included in Schedule 4 to the current Poisons Standard (the Schedule 4 products). The substances contained in the Schedule 4 products included but were not limited to:
  - a. SARMS
  - b. YK-11
  - c. RAD-140
  - d. LGD-4033
  - e. MK-2866
  - f. CBD Oil
- 4. These products are no longer being advertised on the Auzsupps website.
- 5. The complaint also referred to other therapeutic goods being advertised by Auzsupps Pty Ltd which are not permitted to be advertised under the TG Act because they are not entered in the ARTG. Among these products was 'Coma', a product which the material present on the Auzsupps website stated contained Phenibut, a Schedule 9 substance.
- 6. Whilst the ingredient label and adjacent advertising copy for the 'Coma' product has been amended to remove references to Phenibut, this product is currently being advertised on [REDACTED WEB ADDRESS] as containing "Velvet Bean Extract (Standardized to L-Dopa 98%)". Levodopa (L-Dopa) is a substance that is included in Schedule 4 to the current Poisons Standard.

- 7. In the course of investigating the complaint, the TGA identified a range of products which are not permitted to be advertised under the TG Act because they are not entered in the ARTG.
- 8. Among the goods not entered in the ARTG which continue to be advertised on your website are the following:
  - a. Growth Boost
  - b. Hexadrone Male Anabolic
  - c. Regener8 Men's Health
  - d. Cut + Shred
- 9. Section 42DL of the TG Act prohibits the advertisement of therapeutic goods which are not entered in the ARTG, subject to exceptions which do not apply in this case.
- 10. A search of the ARTG by the TGA found that none of the products referred to at paragraph 8 above are entered in the ARTG.

## Communication between the TGA and Auzsupps Pty Ltd Sports Supplements

- 11. On 18 April 2019, the TGA sent you a warning letter stating that the TGA considered that advertisements on the website [**REDACTED WEB ADDRESS**] were in contravention of Part 5-1 of the TG Act.
- 12. The warning letter requested that you immediately remove all references to Schedule 4 and Schedule 9 substances, as well as all therapeutic goods not included in the ARTG, and cease supplying and advertising such goods (including on social media sites). The letter further invited you to make submissions to the TGA in response to the matters raised in that letter by 26 April 2019.
- 13. The warning letter additionally advised that the TGA was considering issuing a Direction to you, pursuant to section 42DV of the TG Act, requiring you to cease the unlawful advertising of unregistered therapeutic goods on your website and social media pages.
- 14. On 24 April 2019, the TGA received a response from Auzsupps Pty Ltd advising of their intention to comply with the TG Act.
- 15. On 26 April 2019, Auzsupps Pty Ltd advised the TGA that all products containing scheduled ingredients had been removed from the website [REDACTED WEB ADDRESS] and all social media platforms including Facebook and Instagram. As of the date of this direction, whilst the advertising by Auzsupps has been amended, the website still contains a range of advertisements featuring products which contain substances included in Schedule 4 to the current Poisons Standard and products which are not permitted to be advertised under the TG Act because they are not entered in the ARTG (the Advertisements).

### Statement of reasons for making this direction

- 16. Under section 42DV(1) of the Act, where the Secretary is satisfied that there has been a contravention of the Act in relation to the advertising of therapeutic goods, the Secretary, or her delegate, may issue a direction to the person apparently responsible for that advertising or for causing the advertising of the therapeutic goods to do a number of things, including ceasing the relevant advertisements.
- 17. For the reasons set out below, I am issuing the above Direction to you on the basis that the Advertisements are in contravention of s 42DL of the Act, and that you are the person apparently responsible for, or for causing, the Advertisements.
- 18. Subsection 42DL(3) of the Act provides that a person commits an offence if:
  - (a) the person:
    - (i) advertises, by any means, therapeutic goods; or
    - (ii) causes the advertising, by any means, of therapeutic goods; and
  - (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.
- 19. Section 3 of the TG Act defines therapeutic goods as goods 'that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be... for therapeutic use...', subject to exceptions which do not apply in this case. Therapeutic use is further defined as meaning use in or in connection with, among other matters, 'influencing, inhibiting or modifying a physiological process in persons'.
- 20. I am satisfied that the products referred to at paragraphs 5 and 8 above fall within this definition, noting that they are being presented on your website as products which are capable of influencing physiological processes in persons, and am therefore satisfied that they are therapeutic goods within the meaning of section 3 of the TG Act.
- 21. The definition of 'advertise' in subsection 3(1) of the TG Act relevantly provides that:

advertise, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

- (a) is on the label of the goods; or
- (b) is on the package in which the goods are contained; or
- (c) is on any material included with the package in which the goods are contained."

- 22. I am satisfied that the references to the products referred to at paragraphs 5 and 8 on the websites and social media pages referred to above meet the definition of 'advertise' under the TG Act, insofar as they consist of statements and pictorial representations which are intended to promote the use or supply of those products.
- 23. Subsection 42DL(10) of the Act applies to an advertisement:
  - ... if it refers to 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 (not including a foreign government or foreign government authority).
- 24. I am satisfied that the website includes advertisements which refer to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard, including 'Coma'. In the absence of any authorisation or requirement by a government or government authority, I am therefore satisfied that subsection 42DL(10) of the Act applies to the Advertisements, to the extent that they refer to the 'Coma' product.
- 25. Subsection 42DL(12) of the Act applies to an advertisement:
  - ... if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
- 26. Regulation 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'.
- 27. I am satisfied that the products referred to at paragraphs 5 and 8 above are not entered in the ARTG. I am further not aware of any exemption, approval or authority which would apply to these products. Accordingly, I consider that subsection 42DL(12) of the Act applies to the Advertisements.
- 28. On the basis of my conclusion that the goods are therapeutic goods, that you have advertised the goods or caused those goods to be advertised, and that subsections 42DL(10) and 42DL(12) (as relevant) apply to the Advertisements, I am satisfied that the Advertisements are in contravention of section 42DL(2) of the Act.
- 29. I am further satisfied that the Advertisements create a risk of serious harm to the health and safety of consumers. In this respect, I note that products which contain substances listed in Schedule 4 to the current Poisons Standard are required by law to be supplied only by prescription issued by a qualified medical practitioner. The sale of such substances without appropriate medical supervision creates a real risk of abuse and substantial harm to consumers of the products.

30. In coming to my decision, I have considered relevant parts of the Act, the Regulations, the ARTG and the Poisons Standard, as well as the warning letter, your response to the warning letter on 26 April 2019 and screenshots of the Advertisements.

## **Decision**

For the reasons set out above, I am satisfied that various contraventions of the TG Act to which I have referred have occurred. Accordingly, I make the Direction set out in paragraphs 1 and 2 of this letter together with the associated conditions identified in paragraph 3.

#### EFFECT OF NOT COMPLYING WITH THIS/THESE DIRECTIONS

If you contravene a Direction made under subsection 42DV(1) or a Condition of a Direction made under subsection 42DV(2) of the TG Act, you may breach criminal offence provisions under section 42DW or contravene a civil penalty provision under section 42DX which could lead to court action against you.

The TGA could also issue you an infringement notice as an alternative to these actions (Part 5A-2 of the TG Act).

In conjunction with pursuing civil or criminal sanctions, the TGA may also seek an injunction from the Federal Court of Australia to immediately cease your advertising (Part 5A-4 of the TG Act).

#### **Please Note:**

The TGA can alert the public to the TGA's concerns about particular therapeutic goods advertising through the use of public warning notices (section 42DY).

Further, subsection 42DV(6) of the TG Act provides:

As soon as practicable after giving a direction under subsection (1) or (2), the Secretary **must** cause the direction to be published on the Department's website.

#### Additional contraventions of the Act

The specific products listed in this Directions notice are not intended to represent all the products that are being advertised in contravention of the TG Act by Auzsupps Pty Ltd.

You should perform a review of the website to ensure that you remove all products which are being advertised in non-compliance with the Act. You may wish to seek legal advice, or advice from a regulatory consultant, in connection with this issue.

If further action is required, including if the products listed in Annexures E and F (and/or other non-compliant products) continue to be advertised, the Department reserves its rights to pursue enforcement action, including escalating this matter to civil penalty proceedings or criminal prosecution, with respect to all of the contraventions of the Act by Auzsupps Pty Ltd in this matter.

# Relevant extracts from the *Therapeutic Goods Act 1989*

## Part 5-1—Advertising and generic information

## 42DL Advertising offences—general

- (1) A person commits an offence if:
  - (a) the person:
    - (i) advertises, by any means, therapeutic goods; or
    - (ii) causes the advertising, by any means, of therapeutic goods; and
  - (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement; and
  - (c) either:
    - (i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or
    - (ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

- (2) A person commits an offence if:
  - (a) the person:
    - (i) advertises, by any means, therapeutic goods; or
    - (ii) causes the advertising, by any means, of therapeutic goods; and
  - (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

- (3) A person commits an offence if:
  - (a) the person:
    - (i) advertises, by any means, therapeutic goods; or
    - (ii) causes the advertising, by any means, of therapeutic goods; and
  - (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Contravening provisions

- (5) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:
  - (a) no permission under section 42DK is in force in relation to the prohibited representation;

- (b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.
- (6) This subsection applies to the advertisement if it does not contain a required representation about the goods.
- (7) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:
  - (a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;
  - (b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.
- (8) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.
- (9) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:
  - (a) a statement of the availability of the goods as a pharmaceutical benefit; or
  - (b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or
  - (c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.
- (10) This subsection applies to the advertisement if it refers to 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 (not including a foreign government or foreign government authority).
- (11) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
- (12) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

## Continuing offences

- (13) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.
- (14) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

## Division 6 – Directions about advertisements or generic information

## 42DV Directions about advertisements or generic information

#### **Advertisements**

- (1) If, in relation to the advertising of therapeutic goods, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for advertising the therapeutic goods, or for causing the advertising of the therapeutic goods, to do one or more of the following:
  - (a) cease the advertisement;
  - (b) make a retraction;
  - (c) make a correction;
  - (d) recover any advertisement that is still in circulation;
  - (e) destroy the advertisement;
  - (f) cease making a particular claim or representation made by the advertisement.

#### Generic information

- (2) If, in relation to the dissemination of generic information about therapeutic goods to the public or a section of the public, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for the dissemination, or for causing the dissemination, to do one or more of the following:
  - (a) withdraw the generic information;
  - (b) make a retraction;
  - (c) make a correction;
  - (d) recover any generic information that is still in circulation;
  - (e) destroy the generic information;
  - (f) cease making a particular claim or representation made by the generic information.

#### Conditions

- (3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.
- (4) Without limiting subsection (3), the conditions may relate to one or more of the following:

- (a) the period for doing a thing the subject of the direction;
- (b) in relation to the making of a retraction or correction, either or both of the following:
  - (i) the form and manner of the retraction or correction;
  - (ii) the period for which the retraction or correction must be made publicly available;
- (c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

(5) A direction under subsection (1) or (2) is not a legislative instrument.

**Publication** 

(6) As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department's website.

## 42DW Offences—contravening direction under section 42DV

- (1) A person commits an offence if:
  - (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2) in relation to therapeutic goods; and
  - (b) the person does an act or omits to do an act; and
  - (c) the act or omission contravenes the direction or a condition of the direction; and
  - (d) either:
    - (i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
    - (ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and
  - (e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

- (2) A person commits an offence if:
  - (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
  - (b) the person does an act or omits to do an act; and
  - (c) the act or omission contravenes the direction or a condition of the direction.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

- (3) A person commits an offence if:
  - (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
  - (b) the person does an act or omits to do an act; and
  - (c) the act or omission contravenes the direction or a condition of the direction.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

# 42DX Civil penalty for contravening direction under section 42DV

A person contravenes this section if:

- (a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

## Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

# Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the TG Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the TG Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

## Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989*" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: 'minister.hunt.DLO@health.gov.au' and copied to 'decision.review@health.gov.au'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: Minister for Health
Suite M1 40

c/- Parliament House CANBERRA ACT 2600

If upon reconsideration by the Minister (or the Minister's delegate), you are dissatisfied with that decision, you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision (see the *Administrative Appeals Tribunal Act 1975* (AAT Act)).

**NOTE:** This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the TG Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

## **Schedule 4 substance referred to in this Direction**

Product	Coma
Dosage Form	Capsule
Reference to schedule 4 substances	Velvet Bean Extract (Standardized to L-Dopa 98%) – L-Dopa is Levodopa  Griffonia Seed Extract (Standardized to 5-HTP 98%) – 5-HTP greater than 100mg
Reference to schedule 9 substances	GABA – Beta-Phenyl-Gamma-Aminobutyric Acid – cross reference Phenibut
URL	[REDACTED WEB ADDRESS]

# **Claims for therapeutic use:**

In an age of over-stimulation from a variety of sources including dietary stimulants (such as caffeine), lifestyle factors (such as stress) and visual stimulants (such as electronic screens), it is becoming increasingly difficult to achieve proper rest. First released in March 2019, Coma was built upon these foundations and in only a few months has become one of Auz Supps best sellers! To stack with Growth Boost for enhanced rest and recovery Click Here and save!

## [IMAGE REDACTED]

## Products not entered on the ARTG and referred to in this Direction

Product	Growth Boost
Dosage Form	Capsule
Reference to schedule 9 substances	GABA – Beta-Phenyl-Gamma-Aminobutyric Acid – cross reference Phenibut
URL	[REDACTED WEB ADDRESS]

# Claims for therapeutic use:

Unfortunately, we are all susceptible to stress, poor sleep, poor appetite and aging as part of the human condition. All of these factors can be detrimental to lifestyle, weight control and anabolism. Growth Boost contains a potent blend of extracts and amino acids including Puerarin which has been widely used in Chinese medicine, and is currently being studied for its impact on GHRH receptors. If you loved MK-677, then this product is for you!

# [IMAGE REDACTED]

Product	Hexadrone – Male Anabolic
<b>Dosage Form</b>	Capsule
Reference	6-chloro-androst-4-ene-3-one-17b-ol  This product appears to have an androgenic effect and therefore considered to be a legal anabolic steroid
URL	[REDACTED WEB ADDRESS]

## Claims for therapeutic use:

Hexadrone (6-chloro-androst-4-ene-3-one-17b-ol) represents the latest in non methylated proanabolic technology. Its recent popularity has been largely attributed to its anabolic:androgenic ratio of 300:1. Given that it is non-methylated, Hexadrone does not carry the typical hepatotoxic properties common in other pro-anabolics, and does not convert to estrogen via aromatase, making it the ideal side-effect friendly choice where serious lean dry gains are desired!

## [IMAGE REDACTED]

Product	Regener8 Men's Health
Dosage Form	capsule
Reference	Arimistane (Androsta-3 5-diene-7 17-dione) This product is a Aromatase Inhibitor.
URL	[REDACTED WEB ADDRESS]

## Claims for therapeutic use:

Feel invigorated and perform at your best in and out of the gym with Regener8. Contained within lies an advanced blend of high quality, potent phytochemicals, used by cultures around the world for centuries to optimize men's health. Each ingredient has been meticulously researched, trialed and selected to give you the final piece of the puzzle and the ultimate fuel for male improvement.

# [IMAGE REDACTED]

Product	Cut + Shred – GW Evolution
<b>Dosage Form</b>	capsule
Reference	GW-0742 – A selective PPAR agonist similar to Cardarine (GW501516)
URL	[REDACTED WEB ADDRESS]

# Claims for therapeutic use:

Being the counterpart of GW-501516, Cut+Shred has been extremely well received by our customers, many reporting on its endurance effects (see reviews below). To further benefits found with Cut+Shred, stack with Thermic Effect and Thyrostim (coming soon).

# [IMAGE REDACTED]