

## ENFORCEABLE UNDERTAKING

*Therapeutic Goods Act 1989*

Section 42YL

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

by

Yossef Wahib trading as Aussie Mega Supplements (ABN 31 972 575 135).

### Persons and authority

1. This undertaking is given to the Secretary of the Australian Government Department of Health and Aged Care (**Department**) for the purposes of section 42YL of the *Therapeutic Goods Act 1989* (**the Act**) by Yossef Wahib trading as Aussie Mega Supplements (ABN 31 972 575 135), of [REDACTED] VIC 3023 (**AMS**).

### Background

2. The Therapeutic Goods Administration (**TGA**) is a part of the Department and is responsible for the national regulation of therapeutic goods including medicines, biologicals and medical devices.
3. Yossef Wahib is a sole trader trading under the business name AMS, who operated an online store that supplied products and supplements for the purposes of health and cosmetics. Some of these products are therapeutic goods within the meaning of the Act.
4. AMS supplied and advertised therapeutic goods that were not registered or listed in the Australian Register of Therapeutic Goods (**the Register**) to persons in Australia electronically through the Uniform Resource Locator (**URL**) [www.ebay.com.au/str/aussiemegasupplements](http://www.ebay.com.au/str/aussiemegasupplements) (**the Website**).
5. Among the therapeutic goods that were advertised for supply on the Website were 'EVA B17 Prostate Repair – 90 capsules – 700mg' (**Prostate Repair Capsules**), 'EVA B17 Astaxanthin – 90 capsules – 930mg' (**Astaxanthin Capsules**), and 'EVA B17 Blood Repair – 90 capsules – 700mg' (**Blood Repair Capsules**).
6. Products supplied by AMS and tested by the TGA were found to contain Amygdalin, which is listed in Schedule 10 of the current Poisons Standard,<sup>1</sup> as a substance of such danger to health as to warrant prohibition of supply and use.

<sup>1</sup> Therapeutic Goods (Poisons Standard—October 2023) Instrument 2023 (legislation.gov.au)

## Relevant law

7. Section 19B of the Act provides that it is an offence for a person to import into Australia, export from Australia, manufacture in Australia or supply in Australia, therapeutic goods for use in humans, in circumstances where the goods are not registered or listed in the Register in relation to the person, not exempt from a requirement to be registered or listed in the Register, not the subject of an approval or authority under section 19 of the Act and not the subject of an approval under section 19A of the Act.
8. Subsection 42DL(1) of the Act provides that it is an offence for a person to advertise, or cause the advertising of, therapeutic goods, if any of subsections 42DL(5) to 42DL(12) apply to the advertisement.
9. Subsection 42DL(12) applies where the advertisement 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).
10. Subsection 42DLB(1) of the Act provides that a person contravenes a civil penalty provision if they advertise, or cause to be advertised, therapeutic goods if any of subsections 42DLB(2) to 42DLB(9) applies to the advertisement.
11. Subsection 42DLB(9) applies where the advertisement refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of subsection 42DLB(9), other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).
12. Regulation 7(i) of the *Therapeutic Goods Regulations 1990 (the Regulations)* provides that that therapeutic goods that are neither the subject of an exemption, approval or authority under the Act nor an exemption, approval or authority under the Regulations, are prescribed therapeutic goods for the purposes of subsections 42DL(12) and 42DLB(9) of the Act.

## Conduct of concern

13. The Secretary has formed a reasonable belief that AMS has contravened section 19B of the Act, subsection 42DL(1) where subsection 42DL(12) applies, and subsection 42DLB(1) where subsection 42DLB(9) applies, by manufacturing, supplying and advertising Prostate Repair Capsules, Astaxanthin Capsules and Blood Repair Capsules.
14. The Secretary has noted that the Blood Repair Capsules ordered and advertised were listed as 700mg while the products received were labelled as 750mg.
15. In addition, AMS appears to have failed to comply with the Act by supplying therapeutic goods beyond the products outlined in **paragraph 5** above. Another store on eBay was selling and advertising Fenbendazole (500mg) bottles supplied by

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AMS. The label of the product read "Suggested use: Adults for wellbeing 1 veggie capsules once a day, half an hour before food, oral" and "For cancer treatment: 1 capsule 2 times a day, half an hour before food, oral".

#### **Acknowledgement of breach**

16. AMS acknowledges that the conduct detailed in **paragraphs 4- 6** and **13 - 15** above is likely to have contravened the Act.
17. AMS has taken action to address the non-compliance with the Act including by:
- (a) ceasing operation of the business in July 2023;
  - (b) removing the Products and other unregistered therapeutic goods from the Website;
  - (c) stopping supply of the Products and other unregistered therapeutic goods; and
  - (d) ceasing the manufacture of unregistered therapeutic goods.

#### **Period of Undertaking**

18. This undertaking commences when both of the following are satisfied:
- (a) The undertaking is executed by AMS; and
  - (b) The delegate of the Secretary signs the executed undertaking.
19. This undertaking terminates on the third anniversary of the day on which it comes into effect.

#### **Undertakings**

20. On commencement of this undertaking, AMS undertakes to assume the obligations set out in **paragraphs 21 to 28**.

#### **Conduct of AMS**

21. AMS undertakes not to, whether itself or through its employees, servants or agents or bodies corporate under its control:
- (a) import, export, manufacture, supply or advertise therapeutic goods to persons in Australia in contravention of the Act;
  - (b) aid, abet, counsel or procure, or otherwise authorise, assist or encourage in any way, any conduct by another person of a kind which AMS has undertaken not to engage in under **paragraph 21(a)**.

#### **Education of suppliers**

22. Within 7 calendar days of this undertaking being published on the TGA website, AMS will write to any current or former suppliers of AMS products to provide a hyperlink to

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the publicly available copy of the enforceable undertaking and notify them that AMS has ceased import, export, supply, manufacture and advertising of therapeutic goods

***Recall of unregistered therapeutic goods***

23. Within 14 calendar days of this undertaking being accepted by the Secretary, AMS will seek to voluntarily recall all unregistered therapeutic goods supplied to any current or former suppliers of AMS products.
24. Within 28 calendar days of this undertaking being accepted by the Secretary, AMS will provide the TGA with proof of all attempts to recall these products mentioned in **paragraph 23** including, if applicable, the payment of any costs to reimburse current or former suppliers of AMS products.

***Miscellaneous***

25. Within 7 calendar days of AMS resuming operation of its business or AMS commencing a business that imports, exports, manufactures or supplies therapeutic goods, to inform the TGA and if applicable, to provide a URL to any website homepage, e-commerce store homepage or social media profile used by the business.

***Engagement of an external qualified compliance professional***

26. Within 14 calendar days of AMS resuming operation of its business, AMS undertakes to, at its own expense, engage an external qualified compliance professional to advise and assist with the implementation of regulatory procedures to ensure that it does not contravene the Act or the Advertising Code.
27. Within 7 calendar days of AMS engaging an external qualified compliance professional, AMS will give to the TGA the identity and contact details of the external qualified compliance professional that it has engaged.
28. 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 AMS or any related business.

***Costs of compliance***

29. AMS will bear all its costs of compliance with this undertaking.

***Acknowledgements***

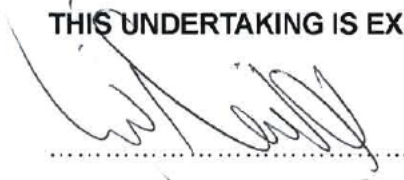
30. AMS acknowledges that:
  - (a) This undertaking was given voluntarily by Yossef Wahib trading as Aussie Mega Supplements (ABN 31 972 575 135);
  - (b) Pursuant to s 42YL(3) of the Act, the Secretary must make this undertaking and information about this undertaking publicly available including by publishing it on the TGA's website;

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- (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;
- (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 AMS;
- (e) the Secretary's acceptance of this enforceable undertaking does not affect the power of the Secretary to investigate or pursue a criminal prosecution, to seek a pecuniary civil penalty or use any other power available to the Secretary under the Act in relation to any contravention or breach, or possible contravention or possible breach of the Act arising from future conduct (not referred to in the Background section of this enforceable undertaking); and
- (f) This undertaking has no operative force until accepted by the Secretary.

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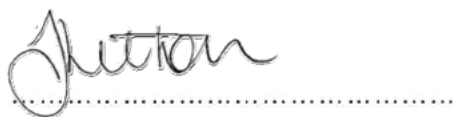
**THIS UNDERTAKING IS EXECUTED BY:**



**Yossef Wahib trading as Aussie Mega Supplements (ABN 31 972 575 135)**

**This 14. day of DECEMBER 2023**

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



**Tracey Lutton**

**Assistant Secretary of the Regulatory Compliance Branch**

**Delegate of the Secretary**

**This 15. day of December 2023**