

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

ATP SCIENCE PTY LTD (ACN 160 027 985)

Person and authority

1. This undertaking is given to the Secretary of the Commonwealth Government Department of Health (the **Department**) by ATP Science Pty Ltd (ACN 160 027 985) of Unit 2 9-11 Babb Doyle Street Loganholme Queensland (**ATP Science**) 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 Department, and is responsible for the national regulation of therapeutic goods including complementary medicines, over-the-counter medicines, prescription medicines, biologicals and medical devices.
3. ATP Science carries on the business of manufacturing and supplying diverse consumer products including therapeutic goods as well as foods. Some of these consumer products are therapeutic goods because they are represented to be, or that are likely to be taken to be for therapeutic use. Such use includes use in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or influencing, inhibiting or modifying a physiological process in persons. Further, because the therapeutic goods are represented to achieve or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human they are medicines for the purposes of the Act.
4. ATP Science advertises and causes the advertising of the products it supplies, including electronically at the website it established and maintains at the Uniform Resource Locator au.atpscience.com.au, and on third party platforms such as Youtube and SoundCloud.

Relevant law

5. Under the Act it is an offence, giving rise to a contravention of a civil penalty provision, for an advertisement of therapeutic goods to contain a prohibited representation about the goods, where there is no permission in force in relation to the prohibited representation (see subsections 42DL(1) and 42DL(5) and 42DLB(1) and 42DLB(2) of the Act). A prohibited representation includes any representation regarding the treatment, cure, prevention diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to cancer or mental illness (see subsection 42DJ(1) of the Act, subregulation 6B(1) of the *Therapeutic Goods Regulations 1990* (the **Regulations**) and section 30 of the *Therapeutic Goods Advertising Code (No. 2) 2018* (the **Advertising Code**)).
6. Under the Act it is an offence, giving rise to a contravention of a civil penalty provision, for an advertisement of therapeutic goods to contain a restricted representation about the goods, where there is neither an approval nor a permission in force in relation to the restricted representation (see subsections 42DL(1) and 42DL(7) and 42DLB(1) and 42DLB(4) of the Act). A representation will be a restricted representation where it refers to a form of a disease, condition, ailment or defect identified by section 28 of the Advertising Code as a serious form of a disease, condition, ailment or defect (see section 42DD of the Act).
7. Under the Act it is an offence, giving rise to a contravention of a civil penalty provision, for an advertisement to refer to therapeutic goods that are not entered in the Australian Register of

Therapeutic Goods (the **Register**) and that are prescribed by the Regulations (see subsections 42DL(1) and 42DL(12) and 42DLB(1) and 42DLB(9) of the Act and regulation 7 of the Regulations).

Conduct of concern

8. The Secretary considers that ATP Science is the person responsible for advertising the products that are medicines that ATP Science makes available for supply, included in its advertisements the alleged 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.	Prohibited representations, for example references to anxiety, depression and insomnia	Subsection 42DL(1) where subsection 42DL(5) applies.
		Subsection 42DLB(1), where subsection 42DLB(2) applies.
2.	Restricted representations, for example references to allergic inflammation or inflammatory bowel condition	Subsection 42DL(1) where subsection 42DL(7) applies.
		Subsection 42DLB(1), where subsection 42DLB(4) applies.
3.	References to medicines that are not entered in the Register, for example: <ul style="list-style-type: none"> • Alpha Mars • Alpha Prime • Alpha Venus • Amp V • Aurum Oil • Block E3 • Cort Rx • Multifood • Prototype 8 • Resilience • Subcut • T432 Plus • ZMST 	Subsection 42DL(1) where 42DL(12) applies.
		Subsection 42DLB(1), where subsection 42DLB(9) applies.

Action to address the Secretary's concerns

9. ATP Science has agreed to address the Secretary's concerns by withdrawing the alleged representations and references from use and providing the following undertaking.

Period of undertaking

10. This undertaking commences when both of the following are satisfied:
 - (a) the undertaking is executed by ATP Science; and
 - (b) the delegate of the Secretary signs the executed undertaking.
11. On commencement of this undertaking, ATP Science undertakes to assume the obligations set out in paragraphs 13 to 25 below.
12. This undertaking terminates two years following its commencement.

Undertakings

Application of the undertaking to all medicines

13. This undertaking applies in relation to each of ATP Science's products which the TGA considers to be medicines, irrespective of whether the product is entered on the Register.

Engagement of an external qualified compliance professional

14. ATP Science undertakes, within one month of the date of execution of this undertaking, to, at its own expense, engage an external qualified compliance professional (***Consultant***) to advise and assist with the implementation of regulatory procedures including the compliance program specified in paragraph 16 below, to assure compliance with the Act and Advertising Code.
15. For the purposes of this undertaking, a Consultant is a person, including a legal practitioner, with experience in advising on compliance matters concerning the regulation of therapeutic goods in Australia and who has no financial interest in ATP Science.

Compliance program

16. ATP Science undertakes to implement, maintain and review a compliance program for the preparation of advertisements for its medicines (the ***compliance program***).
17. ATP Science undertakes to ensure that the compliance program is consistent with Australian Standard AS 3806-2006 (Compliance Programs) and the requirements specified in **Annexure A**.

Annual written opinion

18. For the period of this undertaking, ATP Science's engagement of the Consultant will include a requirement for the Consultant to review ATP Science's compliance program annually and provide a written opinion to the TGA regarding:

- (a) the compliance of ATP Science with the Act; and
- (b) the compliance of ATP Science's advertisements with the Advertising Code.

19. The written opinion will, at a minimum, address and include the matters specified in **Annexure B**.

20. ATP Science undertakes to ensure that:

the first annual review is completed by the Consultant and the written opinion relating to that review is provided to the TGA prior to the expiration of the next calendar year;

the second annual review is completed by the Consultant and the written opinion relating to that review is provided to the TGA prior to the expiration of the period of this undertaking.

Provision of assistance by ATP Science to the Consultant

21. ATP Science will ensure that the Consultant has access to the information the Consultant requires for the purposes of their review of ATP Science's compliance program and the preparation of their written opinion.

Implementation of Consultant's Recommendations

22. ATP Science will implement promptly, and with due diligence, any recommendations made by the Consultant that are reasonably necessary to ensure that ATP Science complies with the Act and the Advertising Code and the terms of this undertaking.

Provision of documents to the TGA

23. ATP Science further undertakes to provide a copy of any document relating to the compliance program or the advertisements for ATP Sciences' medicines as reasonably required by the TGA for the period of this undertaking.

Publication of a correction in relevant media

24. ATP Science will publish on its Australian subdomain (www.au.atpscience.com) a correction statement for a period of 180 days with respect to its advertisements of the above-named alleged therapeutic goods in a form reasonably suitable to the delegate, which must include a statement that no goods supplied by ATP Science are, or at anytime have been, suitable for the prevention, treatment, alleviation or cure of any form of:

- (a) mental illness, including but not limited to depression;
- (b) cancer;
- (c) autoimmune disease;
- (d) Alzheimer's Disease; or
- (e) any other serious disease, condition, ailment or defect.

Acknowledgements

25. ATP Science 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, 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 ATP Science; and
- (e) ATP Science will bear all its costs of compliance with this undertaking.

Executed by

ATP SCIENCE PTY LTD (ACN 160 027 985)

by its authorised officers pursuant to section 127(1) of the
Corporations Act 2001

Jeff Doidge (Managing Director)

for and on behalf of ATP Science Pty Ltd ACN: 160 027 985

This 17th day of April 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

This 4th day of May 2020

Annexure A

REQUIREMENTS FOR COMPLIANCE PROGRAM (see clause 16)

Appointment of compliance officer and compliance manager

26. ATP Science will appoint an internal compliance officer and a compliance manager with suitable seniority and relevant experience or training in the regulation of therapeutic goods to have responsibility for the compliance program:
- (a) ATP Science will, within 28 days of the commencement of this undertaking, notify the TGA regarding the name and contact details of the compliance officer and compliance manager.
 - (b) ATP Science will, for the period of this undertaking, 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

27. ATP Science will maintain a compliance committee comprising the following members or their equivalents:
- (a) Managing Director
 - (b) Marketing Director
 - (c) Chief Operating Officer
 - (d) Research and Development Director
28. The compliance committee will meet quarterly, or more frequently as required, to review all advertisements for its medicines to ensure compliance with Act and the Advertising Code.

Preparation and review of advertisements

29. ATP Science will prepare and review all advertisements for its medicines, consistent with the compliance program prior to its approval and circulation of that material.

Training on compliance with the Act and the Advertising Code

30. Any employee of ATP Science, and all members of the compliance committee, involved in the preparation, review or approval of advertisements will, within three months of the commencement of this undertaking, and otherwise annually throughout the period of this undertaking, undertake practical training on compliance with the Act and the Advertising Code.
33. ATP Science will, at its own expense, conduct the training and, within 14 days of the completion of any such training, provide the TGA with a written statement from the provider confirming the completion of that training in accordance with paragraph 30 above.

Annexure B

REQUIREMENTS FOR ANNUAL WRITTEN OPINION (see clause 18)

34. The annual written opinion must address and include the following:
- (a) the Consultant's opinion as to whether all advertisements comply with the Act and the Advertising Code; and
 - (b) copies of ATP Science's policies and standard operating procedures for the preparation and review of advertisements for the medicines and its compliance programs in respect of the medicines; and
 - (c) the Consultant's opinion as to whether ATP Science has in place an effective compliance program that complies with the requirements of this undertaking; and
 - (d) the Consultant's opinion as to whether ATP Science's compliance program 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, if any, recommended by the Consultant to ensure the effectiveness of the compliance program; and
 - (h) a signed statement by the Consultant that they have seen this undertaking, that they have prepared the annual written opinion and that, notwithstanding their engagement by ATP Science, the opinion contains their impartial and professional opinion regarding ATP Science's compliance with the Act and Advertising Code.