

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

Chemforce Pty Ltd (ACN 623 724 372)

Persons and authority

1. This undertaking is given to the Secretary of the Australian Government Department of Health by Chemforce Pty Ltd (ACN 623 724 372) of 47 Lofberg Road, West Pymble, New South Wales 2073 (**Chemforce**) 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. The TGA has found that Chemforce operates a business that advertised or caused the advertising of 'RibaMin' (the **Product**) to persons in Australia electronically at the Uniform Resource Locator (**URL**) www.chemforce.com.au (the **Website**).
4. The advertisement on the Website included claims to the effect that the Product was '*a specific combination of known, tested FDA approved drugs that provides a unique SET of properties with sufficient potency to attack the virus, protect the necessary cells and systems in the body and provide symptomatic relief*'. The advertisement further claimed that the Product was an '*effective treatment for COVID-19 virus*' and that it is '*safe*'.
5. The TGA notes that Chemforce's stated intention in advertising the Product (as stated on the Website and in subsequent correspondence) was to assist it in finding an investor to perform a clinical trial with respect to the Product, and that Chemforce removed the advertisement on the Website after being alerted by the TGA that it was unlawful. Chemforce has voluntarily entered into this undertaking to provide the TGA with assurance as to Chemforce's ongoing compliance with the Act.

Relevant law

6. Section 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.
7. Subsection 42DLB(4) applies where the advertisement contains a restricted representation where no approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation.
8. Subsection 42DLB(6) applies where the advertisement contains a statement, pictorial representation or design suggesting or implying that 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 in specific limited circumstances.

9. Subsection 42DLB(9) applies where the advertisement refers to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and is prescribed by the regulations for the purposes of that subsection. Regulation 7(i) of the *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**) prescribes, for that purpose, therapeutic goods that are not subject to an exemption, approval or authority under the Act nor under regulations under the Act.
10. 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. Subsections 42DL(7), (9) and (10) are (respectively) in the same terms as subsections 42DLB(4), (6) and (9) above.

11. Section 42DMA(1) of the Act is a civil penalty provision. A person contravenes subsection 42DMA(1) of the Act if they advertise, or cause to be advertised, therapeutic goods and the advertisement does not comply with the *Therapeutic Goods Advertising Code (No.2) 2018* (Cth) (the **Code**). Section 42DM of the Act provides that it is an offence for a person to advertise, or cause to be advertised, therapeutic goods if the advertisement does not comply with the Code.

Conduct of concern

12. The Secretary considers that Chemforce has advertised or caused the advertising of the Product on the Website, in circumstances where the advertisements contained the representations or references, or (in the case of Item 5) omitted the information, specified in column 2 of the table below, in contravention of the provision in column 3 of that table:

Representation, reference or omitted information	Section of the Act
1. Restricted representations, being references to COVID-19	Subsection 42DL(2) where 42DL(7) applies. Subsection 42DLB(1), where subsection 42DLB(4) applies.
2. Statements suggesting or implying that the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government authority), being a statement that the Product is ' <i>FDA approved</i> '	Subsection 42DL(2) where 42DL(9) applies. Subsection 42DLB(1), where subsection 42DLB(6) applies.

3.	References to a therapeutic good that is not entered in the Australian Register of Therapeutic Goods and is prescribed by the Regulations, being the Product	Subsection 42DL(2) where 42DL(10) applies. Subsection 42DLB(1), where subsection 42DLB(9) applies.
4.	Representations that the goods are safe or that their use cannot cause harm or that they have no side-effects	Section 42DM(2) by failing to comply with subparagraph 10(d)(i) of the Code. Section 42DMA by failing to comply with subparagraph 10(d)(i) of the Code.
5.	A list of the ingredients present in the Product, as required in advertisements for therapeutic goods that are not available for physical examination before purchase	Section 42DM(2) by failing to comply with subparagraph 12(3)(e) of the Code. Section 42DMA by failing to comply with subparagraph 12(3)(e) of the Code.

Period of undertaking

13. This undertaking commences when both of the following are satisfied:
 - (a) the undertaking is executed by Chemforce; and
 - (b) the delegate of the Secretary signs the executed undertaking.
14. On commencement of this undertaking, Chemforce undertakes to assume the obligations set out in paragraphs 14 to 29 below.
15. This undertaking terminates three years following its commencement.

Undertakings

Cessation of activities concerning therapeutic goods

16. Chemforce undertakes not to, whether itself or through its directors, employees, servants or agents or bodies corporate under their control:
 - (a) advertise therapeutic goods to persons in Australia; or
 - (b) import therapeutic goods into Australia, or supply therapeutic goods in Australia, that are not entered in the Australian Register of Therapeutic Goods.

Disclosure

17. Chemforce undertakes to give to the TGA any documents or information requested by the TGA in relation to its advertising, importation or supply of therapeutic goods to persons in Australia within 14 days (or a longer period of time allowed by the TGA) after receiving a request from the TGA.

Variation

18. Chemforce may at any time apply to the Secretary for consent to vary this undertaking, under subsection 42YL(2) of the Act, to allow it to engage in conduct relating to therapeutic goods (including the importation and supply of therapeutic goods for the purposes of a clinical trial).
19. Any application for consent to vary this undertaking should include:
 - (a) details as to the conduct that Chemforce wishes to engage in;
 - (b) details of the exemption, approval or authority under the Act pursuant to which Chemforce intends to engage in that conduct; and
 - (c) the measures that Chemforce intends to take to ensure that its activities comply with the Act, which should include the engagement of an appropriately qualified compliance professional who is external to Chemforce and does not have any direct or indirect financial interest in Chemforce.

Acknowledgements

20. Chemforce 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 Chemforce; and
 - (e) Chemforce will bear all its costs of compliance with this undertaking.

THIS UNDERTAKING IS GIVEN BY:

Chemforce Pty Ltd (ACN 623 724 372)
pursuant to section 127(1) of the
Corporations Act 2001 (Cth):

[REDACTED]

[REDACTED]

Signature

Signature

21 April 2021

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

Signed electronically

First Assistant Secretary
Gillian Mitchell

Delegate of the Secretary

23 April 2021