



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DIRECTION UNDER SECTION 42DV

ISSUED TO:

PRACMED HEALTHCARE PTY LTD
ACN 135 384 502

and

MR ROGER LEWIS

██
██

ON: 10 November 2023

**ABOUT: Advertising indications and
restricted representations
without the relevant approvals**

BY: Gaelene Pyke
Delegate of the Secretary of the
Australian Department of Health
and Aged Care

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Contact Officer Name:

██

Telephone: 02 6289 4627 (Branch)

Email:

complementary.medicines@health.gov.au

DIRECTION ABOUT AN ADVERTISEMENT

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

TO: PRACMED HEALTHCARE PTY LTD

[REDACTED]
[REDACTED]
[REDACTED]

And

MR ROGER LEWIS

[REDACTED]
[REDACTED]

By express post and email: [REDACTED]

I, Gaelene Pyke, delegate of the Secretary of the Australian Department of Health and Aged Care in the Therapeutic Goods Administration (**TGA**), being satisfied, that there has been a contravention of ss 21B(4) and 42DLB of the *Therapeutic Goods Act 1989* (the **TG Act**) in relation to the advertising of vitamins or supplements, being therapeutic goods, by Pracmed Healthcare Pty Ltd (**Pracmed Healthcare**) as follows:

- a. the advertising of vitamins or supplements, where these are therapeutic goods, for an indication that the vitamins or supplements have a specific therapeutic use for weight loss or bariatric surgery patients, where such an indication has not been accepted in relation to the inclusion of the goods in the Australian Register of Therapeutic Goods (**ARTG**);
- b. the advertising of vitamins or supplements, where these are therapeutic goods, for an indication that the vitamins or supplements have a specific therapeutic use for improving cognitive functions, where such an indication has not been accepted in relation to the inclusion of the goods in the ARTG;
- c. the advertising of vitamins or supplements, where these are therapeutic goods, and the advertisement refers to therapeutic goods that are not entered in the ARTG and are prescribed by the *Therapeutic Goods Regulations 1990* (the **Regulations**) for the purposes of s 42DLB(9) of the TG Act in circumstances where a relevant authorisation or requirement does not apply to the reference; and
- d. the advertising of vitamins or supplements, where these are therapeutic goods and where the advertisements contain a restricted representation (within the meaning of s 42DD of the TG Act) relating to morbid or severe obesity where no relevant approval

(under s 42DF of the TG Act) or permission (under s 42DK of the TG Act) is in force in relation to the restricted representation

DIRECT Pracmed Health **and Mr Roger Lewis** (as the persons apparently responsible for the advertising) to:

1. **cease** making all claims, references or representations made by advertisements referred to in the column entitled ‘claims/representations/references/statements’ of the table at **Attachment A**;
2. **cease** making all claims references or representations made by advertisements (including removing third party comments or customer reviews included in such advertisements) about vitamins or supplements, where these are therapeutic goods, for an indication that the goods have a specific therapeutic use for improving cognitive functions or a specific therapeutic use for weight loss or bariatric surgery patients where those are not indications accepted in relation to the inclusion of the goods on the ARTG, on any website or social media platform (a **relevant website**) for which you are responsible (but only to the extent the relevant website is accessible by persons located in Australia);
3. **cease** making advertisements about vitamins or supplements, where these are therapeutic goods, and these advertisements refer to therapeutic goods that are not entered in the ARTG and are prescribed by the Regulations for the purposes of s 42DLB(9) of the TG Act, and no relevant authorisation or requirement applies in relation to the reference.
4. **cease** making all restricted representations relating to morbid or severe obesity in advertisements about vitamins or supplements, where these are therapeutic goods, where no relevant approval or permission is in force in relation to the restricted representation, on any relevant website for which you are responsible (but only to the extent the relevant website is accessible by persons located in Australia).

CONDITIONS

under subsection 42DV(3) of the TG Act

5. This **Direction** is subject to the following conditions:
 - a. Pracmed Healthcare and Mr Roger Lewis must:
 - i. do the things the subject of this Direction by **1 December 2023**; and
 - ii. following that day, continue to do those things for an indefinite period.
 - b. Pracmed Healthcare and Mr Roger Lewis must email evidence of compliance with this Direction to the email address listed on the first page of this Direction by **8 December 2023**, including a list of all relevant websites covered by this

Direction in relation to claims or representations (including restricted representations) covered by this Direction.

- c. For the avoidance of doubt, the condition in 4(b) does not require Pracmed Healthcare or Mr Roger Lewis to email evidence of compliance with this Direction for the indefinite period following 8 December 2023.

OTHER INFORMATION

The possible consequences of failing to comply with this Direction are explained in **Attachment B**.

This is an initial decision and is reviewable. Your review rights are set out in **Attachment C**.

Please Note, as required under subsection 42DV(6) of the TG Act, the TGA will publish this Direction on its website. Publication is planned as soon as practicable after your submission due date of **20 November 2023** to any objections you may have in relation to the publication of information contained in the Direction.

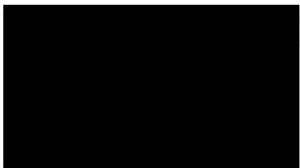

DATED: 10 November 2023

(Signed electronically)

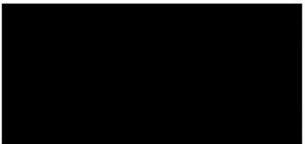
Gaelene Pyke


Assistant Secretary A/g
Medicines Regulation Division
Therapeutic Goods Administration
Delegate of the Secretary
Australian Department of Health and Aged Care

Attachment A

No.	Therapeutic goods	Website page URL	Claims/representations/references/statements	Relevant contravention
1.	BN Caps (AUST L 371617)		Statements that the good has the specific therapeutic use for weight loss/bariatric surgery patients, including: <ul style="list-style-type: none"> • Are BN Caps right for me? BN Caps are a convenient solution for increasing dietary needs for some nutrients. This may arise when your diet alone can't meet your daily needs for vitamins and minerals. This may be due to illness, activity, gastrointestinal surgery, or digestive tract diseases that implicate malabsorption.	<p><u>Section 21B</u></p> <p>A person contravenes s 21B(4) of the Act if they advertise, by any means, therapeutic goods included on the ARTG for an indication, and that indication is not an indication accepted in relation to its inclusion on the ARTG.</p> <p>Any indication that makes references to Weight Loss Surgery, or words to that effect is not an indication accepted in relation to the inclusion of the goods, set out in the 'Therapeutic goods' column, in the ARTG.</p> <p>Instead, the indications accepted in relation to the goods are general indications which are limited to therapeutic uses in healthy adults or the specific sub-populations identified in the included indications. Of note, weight loss or bariatric surgery patients are not a sub-population identified in the indications.</p>
	BN Iron Tablet (AUST L 377771)		Statements that the good has the specific therapeutic use for weight loss/bariatric surgery patients, including: <ul style="list-style-type: none"> • How much iron should I take per day? Iron requirements vary throughout the lifespan. Menstruating women with WLS require 18-60mg daily, men need 9mg, and menopausal women require 9-18mg. Iron absorption is affected by bariatric procedures, and absorption is impacted for life.	<p><u>Section 42DLB(1) where subsection (4) applies</u></p> <p>A person contravenes s 42DLB(1) of the Act where subsection (4) applies in circumstances where the person advertises, by any means, or causes the advertising, by any means, a therapeutic good and the advertisement contains</p>

No.	Therapeutic goods	Website page URL	Claims/representations/references/statements	Relevant contravention
				<p>a restricted representation (whether in express terms or by necessary implication), and an approval under section 42DF of the Act nor a permission under section 42DK of the Act is in force in relation to the restricted representation.</p> <p>An advertisement about therapeutic goods that refers to a form of a disease, condition, ailment or defect identified in the <i>Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (the Code)</i> as a serious form of a disease, condition, ailment or defect is a restricted representation (see s 42DD of the Act). Section 28(a) of the Code provides a form of a disease, condition, ailment or defect is a serious form if it is medically accepted that the form requires diagnosis or treatment or supervision by a health practitioner who is suitably qualified, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management.</p> <p>The advertisements found at the link set out in the column 'Website page URL' and example statements are provided in the column 'claims/representations/references/statements' promotes the use and supply of the goods, set out in the 'Therapeutic goods' column, in relation to severe obesity and morbid obesity by promoting the use of the medicines following weight loss or bariatric surgery. This surgery is only performed on patients with morbid/ severe obesity. Such conditions are serious medical conditions within the meaning of s 28 of the Code, and references to such conditions are restricted representations, which must not be used in advertising</p>

No.	Therapeutic goods	Website page URL	Claims/representations/references/statements	Relevant contravention
				<p>unless expressly approved or permitted by the Secretary under ss 42DF or 42DK of the Act.</p> <p>There are no current approvals or permissions under ss 42DF or 42DK of the Act which apply to the representation made concerning the goods in relation to treating morbid/severe obesity.</p>
2.	BN Chews (AUST L 371616)		<p>Statement that the good is indicated for cognitive function:</p> <ul style="list-style-type: none"> • ...Vitamin B12 supports forming healthy blood cells – both are key for feeling energetic and clear-minded – less foggy, and boost cognitive performance 	<p><u>Section 21B</u></p> <p>A person contravenes s 21B(4) of the Act if they advertise, by any means, therapeutic goods included on the ARTG for an indication, and that indication is not an indication accepted in relation to its inclusion on the ARTG.</p> <p>The indications set out in the 'claims/representations/statements' column are indications which are not accepted in relation to the inclusion of the corresponding good in the ARTG.</p>

No.	Therapeutic goods	Website page URL	Claims/representations/references/statements	Relevant contravention
3.	BN Caps (AUST L 371617)		Including an image of BN Caps AUST L 37167 which is no longer included in the ARTG.	<p><u>Section 42DLB(1) where subsection (9) applies</u></p> <p>A person contravenes s 42DLB(1) of the Act where subsection (9) applies where the person advertises, by any means, or causes the advertising, by any means, a therapeutic good and the advertisement refers to therapeutic goods that are not entered in the ARTG and those goods are prescribed under r 7 of the Regulations, and no relevant authorisation or requirement applies in relation to the reference.</p> <p>The entry for BN Caps AUST L 37167 was cancelled by Pracmed Healthcare on 28 June 2023. An advertisement which includes the image of a cancelled therapeutic good is a reference to a therapeutic good which is not entered in the ARTG.</p> <p>Further, the good is a prescribed good for the purposes of s 42DLB(9), as the goods were not subject to an exemption, approval or authority under the TG Act or Regulations (r 7(i) of the Regulations). There are also no relevant authorisations or requirements which apply in relation to the reference.</p>

Attachment B

Effect of not complying with this direction

If you contravene a direction or a condition of a direction made under subsections 42DV(1) or (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.

In conjunction with pursuing civil or criminal sanctions, the TGA may also seek an injunction from a Federal Court to immediately cease your advertising.

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

Attachment C

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.Butler.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 MG 50
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.