



Australian Government

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DIRECTION UNDER SECTION 42DV

ISSUED TO: Mr Ken Murray

ON: 7 September 2018

**ABOUT: Advertising of Gumby Gumby
capsules**

**BY: Nicole McLay
A/g First Assistant Secretary
Regulatory Practice and Support
Division
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:
tga.advertising@health.gov.au**

DIRECTION ABOUT AN ADVERTISEMENT

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

TO: Mr Ken Murray
Director
Gumby Gumby Australia & Variety Holdings Pty Ltd
[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 has been a contravention of the *Therapeutic Goods Act 1989* (the TG Act) including because there has been a contravention of the *Therapeutic Goods Advertising Code 2015* (the Code) in relation to the advertising for Gumby Gumby capsules,

DIRECT you, as the person apparently responsible for that advertising or for causing the advertising of the therapeutic goods, to:

1. **Cease** the advertisements of Gumby Gumby capsules on the following URLs:
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]

including any third party comments included in the advertisements.

2. **Cease** making claims or representations for Gumby Gumby capsules outright or in the form of testimonials that:
 - (i) They have or may have an effect on cancer of any sort, location or grade;
 - (ii) They have or may have an effect on arthritis, chronic fatigue syndrome, or skin diseases.
 - (iii) They have or may have any other therapeutic use whatsoever while ever the capsules are not included in the Australia Register of Therapeutic Goods (ARTG);
 - (iv) You can or are able to arrange the supply of these therapeutic goods which are not included in the ARTG and not excluded or exempted from that requirement.

CONDITIONS

under subsection 42DV(3) of the TG Act

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 7 days of the date of this Direction;
- (b) **cease**, permanently, publishing claims or representations listed above in paragraph 2, for example, by not including those claims or representations in any other advertising for which Mr Ken Murray appears responsible or to have caused (including any advertising by Gumby Gumby Australia and Variety Holdings Pty Ltd); and
- (c) **email** evidence of your compliance with this **Direction** to the email address listed on the first page of this Direction within 7 days of the date of this Direction.

OTHER INFORMATION

Important information about the reasons for making this **Direction** and its effect is set out in **Attachment A**. The possible consequences of failing to comply with this Direction are explained in **Attachment B**.

The sections of the TG Act relevant to the making of this **Direction** are set out in **Attachment C**.

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

Please Note, as required under subsection 42DV(6) of the TG Act, the TGA will publish this Direction on its website. Publication is planned in the week commencing 10 September 2018.

DATED: 7 September 2018

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Nicole McLay
A/g First Assistant Secretary
Regulatory Practice and Support Division
Therapeutic Goods Administration
Delegate of the Secretary
Australian Department of Health

Attachment A

Material findings of fact

I make the following material findings of fact.

The complaint

1. The TGA received a complaint on 3 August 2018 about the advertising of Gumby Gumby capsules on two Facebook pages and a YouTube video. The complainant was concerned that “The product being advertised is a [sic] cure for cancers of various types. It appears to be an unregistered product.” I have attached relevant extracts from the two Facebook pages in **Attachment E**.
2. The complaint included copies of material taken from Ken Murray’s personal Facebook page ([REDACTED]) and a permalink ([REDACTED]) on the Gumby Gumby Australia Facebook page ([REDACTED]) (now removed).
3. The advertising at the Gumby Gumby Australia Facebook page referred to in the previous paragraph showed Gumby Gumby capsules being promoted for use in the treatment of cancer and other serious conditions such as arthritis, emphysema, allergies, viral disorders, mild depression, fevers, chronic fatigue syndrome, blood pressure issues, autoimmune disease, skin diseases, high cholesterol, GI tract disorders, Meniere’s disease, and circulation disorders.
4. The Facebook page for Ken Murray referred to the treatment of “Basal Cell Carcinomas (BCC), around my neck, back & chest, which we’re metastasising into Throat Cancer and Prostate Cancer.” This page also stated that “My wife and I (sic) have personally talked with people who have beaten Leukaemia, Breast Cancer, Prostate Cancer, Lung Cancer, Pancreatic Cancer, Malignant Tumour the size of an onion in Uterus Cancer, Polyps in the intestine Cancer and Skin Cancer, by taking about 7 to 8 Gumby Gumby capsules in the morning at breakfast and 7 to 8 in the evening at dinner time ...or 5/5/5 at Breakfast/Lunch/Dinner.”
5. The TGA investigated the complaint and examined the advertising material provided by the complainant. As part of this investigation, the TGA also identified relevant additional advertising materials on Facebook, eBay, Vimeo and YouTube.

Gumby Gumby capsules as therapeutic goods

6. Therapeutic goods for commercial supply in Australia are required to be included in the ARTG prior to supply unless exempted or excluded from this requirement.

7. Gumby Gumby capsules meet the definition of therapeutic goods because they are represented to be for *therapeutic use*, within the meaning of subsection 3(1) of the *Therapeutic Goods Act 1989* (the TG Act) and none of the potentially applicable exclusions apply to that requirement. No order under section 7 has been made declaring these goods not to be therapeutic goods for the purposes of the TG Act. There is no applicable food standard or tradition of use of Gumby Gumby as a food in Australia or New Zealand in the form of capsules as presented. While Gumby Gumby may have a traditional use as a food or a medicine by the Indigenous Australian population, such use is not in the form of a processed, encapsulated powder. Therefore Gumby Gumby capsules are not food for the purposes of exclusion from the definition of 'therapeutic goods'. There are likewise no determinations under subsections 7AA(1) or 7AA(2) of the TG Act relevant to these goods.
8. A search by TGA of the ARTG on 7 September 2018 found no Gumby Gumby products, including Gumby Gumby capsules, included in the ARTG.

Facebook advertising

9. As at the date of my decision:
 - a. The Gumby Gumby Australia Facebook page has been removed ([REDACTED]).
 - b. Ken Murray's personal Facebook page is still present, which includes at least one post discussing his personal testimonial using Gumby Gumby for the treatment of cancer ([REDACTED]).

eBay advertising

10. The items at [REDACTED] and [REDACTED] are listed on eBay by Ken Murray ([REDACTED]).
11. The eBay user page for 'kenmurray' states: "I am the Director of Gumby Gumby Australia & we produce Gumby Gumby traditional food capsules ...and export them to all countries of the world. We have been granted an Australia Made Campaign licence to export Gumby Gumby (*Pittosporum Angustifolium*)" ([REDACTED]).
12. Clicking on the tile 'visit store' on the eBay user page for 'kenmurray' links to a Gumby Gumby Australia store ([REDACTED]).

13. The eBay store provides sales figures indicating that in excess of 6,000 units of Gumby Gumby capsules have been supplied across two listings for Gumby Gumby capsules¹. The number of units supplied is described on the eBay store page ([REDACTED]).
14. The user feedback on the two eBay items includes references to therapeutic use; this feedback is clearly visible to consumers visiting the listings. The claims include references to the use of Gumby Gumby in the treatment of cancer, arthritis and chronic fatigue syndrome. A list of examples of the therapeutic uses included in the eBay item feedback is included in **Attachment F**.

Vimeo advertising

15. A video of Ken Murray discussing the therapeutic uses of Gumby Gumby for the treatment of cancer is included on the Vimeo page at [REDACTED]. The written comments on this page, including comments by Ken Murray, include references to the use of Gumby Gumby in the treatment of breast cancer.

YouTube advertising

16. A similar video to the Vimeo video noted above was included on YouTube. It was removed following communication by the TGA with Ken Murray. It had included therapeutic claims for Gumby Gumby in relation to the treatment of different cancers such as basal cell carcinomas, leukaemia, lung cancer, pancreatic cancer, breast cancer and skin cancer, as well as prostate cancer.

Action taken by the TGA

17. A compliance officer at the TGA contacted Mr Ken Murray by phone and email on 15 August 2018 alleging contraventions of the TG Act in relation to the supply of an unapproved good and in relation to the advertising as well as identifying how compliance with the TG Act could be achieved. Mr Murray was invited to give a response by 23 August 2018. At the date of my decision, no such response has been received.

¹ [REDACTED] and [REDACTED]

Action taken for the advertisements for Gumby Gumby capsules

18. By 7 September 2018:

- a. the YouTube video and Gumby Gumby Australia Facebook page have been removed; and
- b. the post on Mr Murray's personal Facebook page, within the eBay store and the video on Vimeo (as referred to in the URLs set out in paragraph 1 of the Direction) remain.

Statement of reasons for making this direction

19. Gumby Gumby capsules with claims for human therapeutic use meet the definition of therapeutic goods in the TG Act (see paragraph 7 above).
20. Gumby Gumby capsules, as therapeutic goods, have not been included in the ARTG (see paragraph 8)
21. The advertising of therapeutic goods to the public in Australia must comply with the requirements specified in the TG Act. This includes compliance with the Therapeutic Goods Advertising Code (the Code). At the date of my decision, the version of the Code in force is the Therapeutic Goods Advertising Code 2015.²
22. 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."
23. While some URLs identified by the TGA as being in contravention of the TG Act have been removed not all of the URLs for which Mr Ken Murray is apparently responsible or that he has caused to exist (see paragraphs 9-12 above) have been removed; the URLs set out in Paragraph 1 of the Direction remain.
24. I also note that supply of this product has actually taken place based on the information included in the eBay store, as noted in paragraph 13 above.

² Copies of the TG Act, the Regulations and Code are available from www.legislation.gov.au/

Assessment of advertising compliance

References to prohibited representations

25. Subsections 42DL(5) and 42DLB(2) of the TG Act provide that it is a contravention of the TG Act if an advertisement contains a ‘prohibited representation’ about a therapeutic good without (relevantly) a permission under section 42DK of the TG Act.
26. A ‘Prohibited representation’ is specified in Part 1 of Appendix 6 of the Code (see section 42DJ(1) of the TG Act read with paragraph 6B(1)(a) and (b) of the TG Regulations). Part 1 of Appendix 6 to the Code includes any representation regarding the treatment, cure or prevention of neoplastic diseases [which relevantly includes cancer]. As such, the representations in the advertisements for Gumby Gumby capsules about the prevention and treatment of cancers are prohibited representations.
27. There is no permission under section 42K of the TG Act for these prohibited representations for Gumby Gumby capsules.
28. Accordingly, I am satisfied that there has been a contravention of subsections 42DL(5) and 42DLB(2) of the TG Act in relation to the advertising of Gumby Gumby capsules.
29. Sections 42DM and 42DMA of the TG Act provide that it is a contravention of the TG Act not to comply with the Code. Section 5 of the Code provides that an advertisement for therapeutic goods must not contain expressly or by implication a representation specified in Part 1 of Appendix 6.
30. I am satisfied that because Gumby Gumby capsules have been promoted for the treatment of cancer on Ken Murray’s Facebook page, in the Vimeo video, as well as within the comments / feedback of the listings on the eBay store (as referred to in the URLs set out at paragraph 1 of the Direction), there has been a contravention of Section 5 of the Code and therefore of sections 42DM and 42DMA of the TG Act.

References to restricted representations

31. Subsections 42DL(7) and 42DLB(4) of the TG Act provide that it is a contravention of the TG Act if an advertisement contains a ‘restricted representation’ about a therapeutic good without (relevantly) an approval under section 42DF or a permission under section 42DK of the TG Act.
32. A ‘restricted representation’ is specified in Part 2 of Appendix 6 of the Code (see section 42DD); it includes a list of diseases, conditions, ailments and defects for which the advertising of serious forms is restricted. Serious in this context may be summarised as meaning a condition requiring diagnosis, treatment or monitoring by a suitably qualified healthcare professional. Relevant examples from this list include: Diseases of joint, bone, collagen, and rheumatic disease; Gastrointestinal diseases or disorders; Nervous system diseases; and Skin diseases.

33. The third party comments on the eBay listings include references to serious forms of conditions that require diagnosis, treatment or monitoring by a suitably qualified healthcare professional. These include references to chronic fatigue syndrome (a nervous system condition), undiagnosed digestive problems and arthritis (a musculoskeletal disease) that are restricted representations.
34. There is no approval under section 42DF and there is no permission under section 42DK of the TG Act for these restricted representations for Gumby Gumby capsules.
35. Accordingly, I am satisfied that there has been a contravention of subsections 42DL(7) and 42DLB(4) of the TG Act in relation to the advertising of Gumby Gumby capsules.
36. Sections 42DM and 42DMA of the TG Act provide that it is contravention of the TG Act not to comply with the Code. Section 5 of the Code provides that an advertisement for therapeutic goods must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in Part 2 of Appendix 6, unless prior approval is given under the TG Act.
37. I am satisfied that because Gumby Gumby capsules have been promoted for serious forms of conditions that require diagnosis, treatment or monitoring by a suitably qualified healthcare professional (chronic fatigue syndrome (a nervous system condition), undiagnosed digestive problems and arthritis (a musculoskeletal disease)) that there has been a contravention of Section 5 of the Code and therefore sections 42DM and 42DMA of the TG Act.

Advertising of an unapproved therapeutic good

38. Gumby Gumby capsules are not included in the ARTG. It is a contravention of subsections 42DL(12) and 42DLB(9) of the TG Act to promote the use or supply of therapeutic goods not included in the ARTG. Section 7 of the *Therapeutic Goods Regulations 1990* (the Regulations) prescribes goods for the above advertising offence and civil penalty provisions at subsections 42DL(12) and 42DLB(9) of the TG Act. Subsection 7(i) of the Regulations is relevant to Gumby Gumby capsules in that they are not included in the ARTG and are “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”. Therefore I am satisfied that there has been a contravention of sections 42DL(12) and 42DLB(9) of the TG Act.

Summary

39. 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.