Technical Alert

Advertising: TGA Social media acceptable use policy; CMA Annotated Version of the 2018 Code (No. 2); new Webinar.

NZ release – Artemisia annua (Wormwood) – liver events

Food claims: Guidance document released

Advertising – social media acceptable use policy

The new Therapeutic Goods Advertising Code (No. 2) contains prescriptive guidance regarding endorsements (section 16) and testimonials (17).

Consequently, advertisers are responsible for the types of testimonials, reviews and endorsements left by third parties on their websites and social media channels. For example, product reviews by consumers on a business Facebook page.

The TGA have provided that where a testimonial is non-compliant with the new guidance, that the advertiser will be required to remove the testimonial as soon as practicable.

To assist sponsors in meeting their obligations the TGA suggest advertisers publish a policy on their web-based and social media channels to guide consumers who are leaving reveiws. The TGA have published sample acceptable use policy (below) as an example:

Acceptable use policy

We welcome your comments on our page but we ask that you help us comply with the Therapeutic Goods Advertising Code. Please consider these guidelines before commenting. We will remove any comments that may result in us breaching the Code.

We love when you comment and tag your friends and family on our posts but we ask that you do not:

- endorse our product if you are:
  - an employee or contractor of a government authority, a hospital or a healthcare facility
  - a health practitioner, health professional or medical researcher
  - involved with the production, sale, supply or marketing of our product
  - not using your own name on this social media platform
- imply that a government authority, a hospital or a healthcare facility endorse our product
- make comments about how a product works for you outside of its intended purpose, as these comments can be dangerous or misleading - our products are developed for particular purposes, as stated on the label and/or in our advertising
- make comments about serious conditions, diseases, ailments or defects, such as comments about how a product helped with your treatment of a serious disease or how it will relieve a tagged person's serious condition

We also have an obligation to make sure any advertisements we make, including endorsements and testimonials, are not misleading. Therefore we promise to disclose:

- where a person has been, or will be, compensated for making a testimonial
- where we have actors making the testimonial, such as in cases where the original person who made the testimonial does not want to appear in our advertisement
- where the person making the testimonial is an immediate family member of anyone employed by our business

Advertising Code No 2. of 2018 – CMA annotated version

The 2018 Advertising Code is more challenging to follow than the 2015 Advertising Code. To help members navigate the Code CMA has produced an annotated version with highlights, links and other information to make Code easier to navigate for sponsors and advertisers of Complementary Medicines.

Note: These annotations are based on information based on our understanding of the Code through TGA documents and discussions as at November 2018. The information provided is non-binding, independent advice should be sought to ensure legislative requirements are met. When reviewing advertising please always ensure you are accessing the most up-to-date version of the Code and other Therapeutic Goods legislation.

Please use in conjunction with the TGA guidance:

'Advertising to the public: Complying with the Therapeutic Goods Advertising Code (No. 2) 2018'

The annotated version is available here for download by members here.

Webinar – Advertising Therapeutic goods: The Code Basics

In response to feedback and requests during the consultation phases for the new advertising framework, the TGA are offering on line education modules to assist advertisers and sponsors in meeting their obligations under the new Code, which will be implemented on 1 January 2019.

Next Tuesday 4 December the TGA will run a webinar aimed at introducing the new Code. Future modules will offer greater detail regarding compliance with the new Code.

This webinar will be useful for regulatory affairs consultants and associates, as well as staff involved in the advertising and marketing of therapeutic goods.

Details of the webinar are:

Date: Tuesday 4 December 2018

Time: 1pm - 3pm (AEDST)

Where: Online webinar

Cost: No cost

To register go here on the TGA website.

Food claims – Guidance document released

Updated guidance for foods products called "Getting your Claims Right" has now been released. It describes the various types of health claims that can be made about foods, and the corresponding requirements, including expression and evidence substantiation. The guidance provides companies making health claims about their products with the information they need to be compliant with the Standard 1.2.7 – Nutrition, health and related claims of the Food Standards Code.

The guidance has been produced by the Implementation Subcommittee for Food Regulation (ISFR), which CMA participated as a member of the ISFR nutrition and health claims Industry Reference Group.

The guidance is included on the Food Regulations website, which provides information about the joint Australia – New Zealand food regulation system. The work is steered by The Forum which has members from the relevant trans-Tasman regulatory bodies, and is supported by the Food Regulation Standing Committee (FRSC).

New Zealand Medsafe – Artemisia annua

The Director General of Health is renewing a public warning following more reports of serious liver harm from taking Arthrem and other products containing Artemisia annua extract (also known as Sweet Wormwood, Sweet Annie or Qing hao).

An initial alert in February this year was a result of 14 reports of liver harm. Since then there have been an additional 11 reports, some showing serious harm. Some of these new reports may have been from people taking these products earlier, but they may also have been from people continuing the take the product.

More information is available:

- NZ Ministry of Health here.
- NZ Medsafe here.

Currently, there is no information from the TGA regarding Artemisia annua products.

If you have products containing Artemisia species, particularly *Artemisia annua*, CMA recommends checking your pharmacovigilance system and adverse reaction reports for any reports of nausea (feeling sick), stomach pain, pale stools, dark urine, itching all-over, yellow eyes or skin, as part of sponsors' pharmacovigilance responsibilities in Australia, which are described here.

Anyone with the above symptoms should seek medical advice.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

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