Therapeutic Goods Administration: Consultation on the draft Therapeutic Goods Advertising Code 2018 and associated guidelines

Submission of the Australasian College of Dermatologists

April 2018

About the Australasian College of Dermatologists

The Australasian College of Dermatologists (ACD) is the sole medical college accredited by the Australian Medical Council for the training and continuing professional development of medical practitioners in the specialty of dermatology. As the national peak membership organisation, the College represents over 500 specialist dermatologist Fellows (FACD) and 100 trainees across the country.

The College is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders on skin health and dermatological practice.

Purpose

The Therapeutic Goods Administration (TGA) has undertaken a review of the existing Therapeutic Goods Advertising Code 2015 to address recommendations of the Expert Panel - Review of Medicines and Medical Devices Regulation and the subsequent Government response. The ACD welcomes the opportunity to put forward this submission on the proposed amendments to the draft Therapeutic Goods Advertising Code 2018 and the accompanying guidance document.

ACD response

In order to ensure safe and ethical advertising of therapeutic goods to the public, it is critical that a solid and usable advertising framework exists. The revisions to the draft Code proposed by the TGA are commendable, in that the Code considers and accounts for a range of contemporary issues facing health consumers. The burgeoning 'health and wellbeing' space, the flood of complementary products on the market, and the expanding array of over-the-counter (OTC) medicines available have all resulted in increased consumer choice but also in some degree of consumer confusion. Digital advertising and marketing platforms have evolved rapidly, allowing for new methods for promotion and sale of therapeutic goods which can be challenging to police effectively. Clear and enforceable restrictions on the advertising of OTC, pharmacy and complementary medicines and medical devices are essential for public safety and access to quality information, and to continually strive for an evidence-based approach to health care.

The College is pleased to note that the proposed changes to the Advertising Code appear straightforward and have been documented in a useful manner in the Comparison summary. The additions of several new sections outlined below are supported by the College. The guidance document, while currently incomplete, should be of assistance to advertisers for the practical application of the Code and to members of the public in its interpretation.

Section 11(2)(d)

An advertisement for a medicine must contain…information about where further information about the medicine, including adverse reactions, precautions, contraindications and method of use, can be found or obtained.

The College supports this new provision to alert consumers of where further important information about the medicine can be obtained. Explicitly drawing attention to where this information can be found is a positive step towards improving consumer health literacy and promoting the safe use of medicines.

For specified OTC and prescription medicines, this type of information is detailed within the Consumer Medicine Information (CMI) leaflet, available as a package insert, at pharmacies or downloadable from websites of the product sponsor and the TGA. What is less clear is how this provision will be adhered to for therapeutic goods without CMIs or other easily accessible resources that present evidence of adverse reactions, precautions or other relevant information. For complementary medicines, or those low-risk products captured within the current medicine regulatory framework but not necessarily considered medicines by consumers, it may be more challenging for this provision to be met by advertisers. The College hopes that by its introduction into the Code, this provision will tacitly encourage sponsors to curate relevant information and present it in a transparent, accessible and consumer-friendly format.

The corresponding section of the guidance document (page 24) is marked as 'still under development'; it is anticipated that further explanation around these issues will be provided in the next iteration.

<u>Understanding risk</u>

Whilst not explicitly referred to in the Code, the way in which information around precautions, side effects and adverse events is currently delivered poses some difficulties with respect to the general public's understanding and interpretation of risk. Without relevant contextualisation and careful explanation by healthcare professionals, the current approach may inadvertently cause patient distress, low compliance rates and unnecessary suffering due to treatment avoidance. Warnings regarding a serious complication would benefit from information on actual and relative risk. There are concerns that highlighting medication risk without context contributes to avoidance of conventional medical treatments and may be fuelling the growth of the non-evidence based 'natural' health and well-being market. This is a very significant issue that should be addressed and could be considered as part of the next revision of the Advertising Code.

Section 20 Allergies

If therapeutic goods have a history of causing a serious allergic reaction in a particular patient group, advertising for those therapeutic goods must contain a warning applicable to that patient group, prominently displayed or communicated.

The inclusion of this new provision is an important step towards improving safety of patients with known allergies to particular ingredients or products.

The guidance document provides examples of such allergens as shellfish, nuts or beestings. What constitutes a 'serious allergic reaction' is not defined, nor is the level of evidence required to determine a 'history' of causing such reactions. The College suggests that this section of the guidance document be expanded and the TGA consider the relevance of other known contact allergens, given the widespread use of certain allergy triggers in therapeutic goods and medical devices. While the College sees no value in alarming consumers unnecessarily, a broader view on allergic reactions could be taken.

Dermatologists frequently treat patients who have experienced skin reactions to allergens. Patch-testing can be used to diagnose allergic contact dermatitis – a type IV hypersensitivity reaction characterised by an itchy

red skin rash that arises from a chemical in contact with the skin. This includes allergy to ingredients found in certain types of therapeutic goods, such as skin medications, soaps and detergents, hair dyes, shampoos and depilatory waxes.[1,2]

The Australian Baseline Series for patch-testing includes 60 of the most frequent and relevant contact allergens. Several ingredients commonly found in therapeutic goods are within the top 25, including methylisothiazolinone/methylchloroisothiazolinone (MI/MCI; a preservative used in a variety of skin care products and topical pharmaceuticals); nickel; fragrances; tea-tree oil (found in 'natural' commercial skin care products for conditions such as acne, wounds and eczema), and bufexamac, a medicament banned in Europe and the USA but which has caused a number of cases of severe allergic contact dermatitis in Australia.[3,4] Others in the series include various preservatives and p-phenylenediamine (PPD; used in hair dyes).[4]

Contact urticaria is an allergic reaction to specific proteins that occurs within 10-30 minutes of the allergen touching the skin, leading to welts, itching and swelling, and sometimes accompanied by a runny nose, sneezing or asthma. Contact urticaria may ultimately develop into a life threatening condition (anaphylaxis). Natural rubber latex used in rubber gloves or medical products such as airway masks, catheters and dressings, is a common cause of contact urticaria.[2]

Australian dermatologists have undertaken numerous studies to examine the frequency and severity of contact allergic reactions, which may be used to inform epidemiological estimates. In a recent retrospective study of health care workers assessed in an Australian tertiary referral dermatology clinic, 49.7% had experienced allergic contact dermatitis. Natural rubber latex allergy was also relatively frequent (13.0%). The major substances causing allergic contact dermatitis were rubber glove chemicals (thiuram mix and tetraethylthiuram disulfide), preservatives (isothiazolinones), excipients in hand cleansers, and antiseptics.[5]

The College would be open to working more closely with the TGA to explore the value of allergic reaction warnings in advertising of dermatological therapeutic goods, with respect to patient safety and harm minimisation outcomes across the Australian population.

Section 21 Consistency with public health campaigns

If a relevant public health campaign is current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign and the other objects of this Code.

The College commends the TGA for this new provision. Harmonising advertising of therapeutic goods with public health campaigns will help to prevent undermining of health messaging as a result of highly visible, commercially-funded advertising campaigns. For example, cohesion with sunscreen marketing has contributed to the success of public health campaigns promoting sun protection to reduce skin cancer risk. Evidence for association of lifestyle factors with disease risk continues to grow, and increased government investment in public campaigns about preventable disease is warranted. This provision will help to protect future public health messaging from being obscured by commercial incentives.

Section 23 Complementary medicines

If an advertisement for a complementary medicine includes a claim based on evidence of a history of traditional use and paradigm, the reliance on this traditional use must be disclosed in the advertisement and the disclosure must be displayed or communicated in the advertisement.

The TGA has recently undertaken numerous regulatory reforms relating to complementary medicines. This new provision aligns with these reforms and is supported by the College. It is important for the sponsors of

complementary medicines to be accountable to health consumers regarding evidence of use and efficacy, as well as to regulators, so that these products can be used safely and appropriately.

Section 27 Sunscreens

Advertising of sunscreens must: (a) depict sunscreens as being only one part of sun protection; and (b) include statements or visual representations, prominently displayed or communicated, to the effect that:

(i) prolonged high-risk sun exposure should be avoided; and

(ii) frequent re-application or use in accordance with directions is required for effective sun protection.

Skin cancers – including melanoma and non-melanoma skin cancer – are the most commonly diagnosed cancers in Australia each year. As the single greatest risk factor for skin cancer is excessive exposure to ultraviolet (UV) radiation, sunscreens have an essential role in UV protection and risk reduction. However the notion that UV protection can singlehandedly be afforded by sunscreen application is a prevailing misconception amongst many consumers, despite years of public health campaigns promoting the five sun protection behaviours. For the best protection, the College and the Cancer Council recommends covering clothing, a broad-brim hat, shade, sunglasses and sunscreen when the UV index reaches 3 or above.[6,7]

The Cancer Council's longitudinal National Sun Protection Survey has shown that encouragingly, sunscreen use has increased over time, with the percentage of adults reporting sunscreen use on summer weekends increasing from 33% in 2003-04 to 42% in 2016-17. However there has been either no improvement or a decrease in other behaviours, including wearing of hats and sun protective clothing and seeking shade.[8] Of additional concern is the finding that many Australians are not applying sunscreen correctly, along with a negative shift in perception of sunscreen safety.[9]

Continued vigilance is clearly needed to promote all five sun protection behaviours. This provision allows for sharing of responsibility and alignment of messaging between the commercial and public sectors. Visual representations will encourage understanding and recognition of sun protection behaviours, regardless of demographic and level of health literacy.

References (accessed April 2018)

1. The Australasian College of Dermatologists. *The A to Z of Skin: Allergy patch testing*. https://www.dermcoll.edu.au/atoz/allergy-patch-testing/

2. Occupational Dermatology Research and Education Centre (ODREC). http://www.occderm.asn.au/

3. Pan Y, Nixon R. Allergic contact dermatitis to topical preparations of bufexamac. Australas J Dermatol 2012; 53:201-10

4. Toholka R, Wang YS, Tate B, Tam M, Cahill J, Palmer A, Nixon R. *The first Australian Baseline Series: Recommendations for patch testing in suspected contact dermatitis*. Australas J Dermatol. 2015 May;56(2):107-15.

5. Higgins CL, Palmer AM, Cahill JL, Nixon RL. *Occupational skin disease among Australian healthcare workers: a retrospective analysis from an occupational dermatology clinic, 1993-2014*. Contact Dermatitis. 2016 Oct;75(4):213-22.

6. The Australasian College of Dermatologists. *Position Statement: Sun protection and sunscreens* (March 2017). https://www.dermcoll.edu.au/wp-content/uploads/ACD-Position-Statement-Sunscreen-March-2017-updated.pdf

7. Cancer Council Australia. *Fact sheet: Sunscreen; endorsed by the Australasian College of Dermatologists.* https://wiki.cancer.org.au/policy/Fact_sheet_-_Sunscreen

8. Cancer Council Australia. *Media release: We're still a sunburnt country* (19 Nov 2016). https://www.cancer.org.au/news/media-releases/we%E2%80%99re-still-a-sunburnt-country.html

9. Cancer Council Australia. *Joint media release with the Australasian College of Dermatologists: Almost half of Australians confused about sunscreen* (20 Oct 2017). https://www.cancer.org.au/content/pdf/News/MediaReleases/2017/20102017%20MEDIA%20RELEASE%20-%20Sunscreen%20myths-FINAL.pdf

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