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**RACP submission: TGA proposed
Therapeutic Goods Advertising Code
guidance 2018 (October 2018)**

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to provide input to the Therapeutic Goods Administration (TGA)'s consultation on the proposed Therapeutic Goods Advertising Code guidance 2018.

The RACP values the Therapeutic Goods Advertising Code (the Code) as a bedrock of the therapeutic goods advertising regulatory framework that protects consumers in Australia. This submission draws on feedback received from our Fellows and from the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT).

Compared with the 2015 Code, the RACP is of the view that the 2018 Code has improved substantially. In general, we support changes contained in the 2018 Code, including but not limited to the consistency with current public health campaigns, prominent display of warning statements and special requirements for the advertisement of sunscreens. However, the RACP emphasises that the TGA must provide sufficient resources and enforcement capabilities to ensure compliance by imposing timely and effective sanctions for any advertising breaches and to deter repeated offences. The Code's success will largely depend on the general public's perception of therapeutic goods, including perceived transparency and trust.

The RACP has concerns regarding section 9(a) of the 2018 Code guidance – valid and substantiated advertising claims, particularly therapeutic use claims for complementary medicines. The RACP is of the view that evidence requirements (e.g. level of evidence) should apply to all types of therapeutic goods, be they complementary medicines or prescription medicines. The evidence requirements for any therapeutic use claims must be high quality and robust and be based on peer-reviewed publications in non-exclusively open access journals. Traditional use is not considered to be an appropriate level of evidence to support a therapeutic claim.

The RACP is also concerned about the display in community pharmacies of therapeutic goods advertising, some of which have limited scientific evidence to support claims of their efficacy and treatment outcomes and are endorsed by celebrities. We maintain that all health practitioners must fulfil their obligations in relation to advertising, as specified by the Australian Health Practitioner Regulation Agency (AHPRA). It is recommended that a reference to the provisions about advertising regulated health services set out in the Health Practitioner Regulation National Law be included.

The RACP feels it is appropriate for the Code to be grounded in WHO ethical criteria for Medicinal Drug Promotion 1988 and QUM framework. The RACP notes that this information has already been integrated into the Australian Regulator Guidelines for Advertising Therapeutic Goods and supports this information also remain in the Code guidance. but ensure that the role of each document is clear. On another note, we support the requirements for 'natural' claims about therapeutic goods and request that no changes be made to the current Appendix H mechanism of the Poisons Standard.

The RACP supports the use of the term 'reasonable consumer' instead of 'reasonable person' in the Code guidance, in that it factors in the various target audiences and that different audiences will have different knowledge, vulnerabilities and health literacy. It is generally acknowledged that there is low level of health literacy among Australians and that the impact of chronic illness can affect the capacity of a consumer to make a rational decision. It is important that the 2018 Code ensures that these groups of consumers are protected.

Furthermore, the College maintains reservations regarding one of the statements outlined in the 2018 Code – *'TGA generally expects purchasers of Traditional Chinese Medicines (TCM) to have an understanding of the particular terminology used in relation to the indications for such medicines as they are likely to be under the care of a TCM practitioner.'* This assumption may give rise to potential difficulties in circumstances where the reasonable consumer may not have specific knowledge and health literacy. In light of this, we believe that the Code should err on the side of consumer protection when defining a 'reasonable person' and 'reasonable consumer', but not based on the assumed knowledge and health literacy. Consumers should be assisted to navigate the therapeutic goods advertising environment.

Should you require any further information regarding this response, please contact Bella Wang, Policy Officer at Bella.Wang@racp.edu.au or on +61 2 9256 5432.