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Advertising Therapeutic Goods in Australia: Consultation paper on options to reform the regulatory arrangements for advertising therapeutic goods

Thank you for providing the AMA with a copy of the *Advertising Therapeutic Goods in Australia: Consultation Paper* for comment.

The AMA believes that patients should be in a position to make informed choices regarding the use of therapeutic goods. An informed choice is dependent upon receiving reliable, balanced health information, free from the influence of commercial considerations. Patients must be safeguarded against forceful advertising and/or marketing if they are to make informed choices regarding their health care.

It is for this reason the AMA opposes the introduction of direct to consumer advertising (DTCA) of prescription (S4 and S8) medicines and cautions the introduction of DTCA for pharmacist only (S3) medicines.

Studies on the impact of DTCA of prescription medicines show it can create unnecessary stress and worry in otherwise healthy patients, increase demands by patients for medicines that are inappropriate for them, unnecessarily increase healthcare costs and undermine the quality use of medicines.

We recommend that therapeutic goods advertising regulations should ensure that DTCA does not:

- undermine the role of the GP in patient care;
- exploit patients' vulnerability or lack of medical or health-related knowledge;
- attempt to induce unjustified fear or concern in patients/consumers regarding their own health in order to increase demand for the advertiser's products or services;
- encourage inappropriate self-diagnosis or treatment or in any way discourage patients from seeking the advice of their medical practitioner;
- attempt to promote an unreasonable expectation as to the applicability or efficacy of the advertised product or service;
- create inappropriate use of the goods or services; and
- be false, misleading, or deceptive. All claims made through DTCA should be readily substantiated.

In terms of optimising current arrangements, the AMA supports self-regulation of the therapeutic goods industry through codes of conduct designed to safeguard public health and safety, and supports current arrangements for advertisements directed at health professionals to comply with relevant industry codes.

The AMA supports a consistent approach to handling of advertisements and complaints processes across all media including broadcast media such as television and radio, print media such as newspapers and magazines, leaflets and brochures, the internet, point of sale locations, and other outdoor locations (eg., billboards, bus shelters, buses and taxis).

The AMA believes the complaints process must be transparent and that sanctions must be strong enough to provide sufficient deterrence. This could include consideration of options that make information related to products removed from the ARTG for advertising offences publicly available.

The AMA considers that the advertising of medicines should be based on the appropriate level of evidence of efficacy and believes the option to refer all complaints related to the efficacy of products to the TGA should be explored.

Further, Harvey et al[1] have suggested that 'complaint procedures are no substitute for adequate regulation at the time of market entry.' They suggest the regulation of listed medicines in Australia could be improved by requiring the manufacturers of listed medicines to provide evidence of efficacy of their product prior to listing on the Australian register of Therapeutic Goods (ARTG).

While many listed medicines such as weight loss products and complementary medicines, may be categorised as low risk, it does not mean it is appropriate for people to use them without the assurance that evidence for their effectiveness has been evaluated and approved by the appropriate authority. The AMA believes that the TGA has an obligation to ensure that such evidence is collected and evaluated both pre and post market.

The AMA looks forward to participating in further discussion on this important issue. Please direct any further correspondence to Ms Sally Cross, Senior Policy Adviser, Medical Practice & eHealth Section at scross@ama.com.au.

Yours sincerely

A/Prof John Gullotta
Chair
AMA Therapeutics Committee

24 August 2010

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[1] Harvey KJ, Korczak VS, Marron LJ & Newgreen DB. Commercialism, choice and consumer protection: regulation of complementary medicines in Australia. MJA Volume 188 Number 1. 7 January 2008.