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AMA submission – Review of TGA medicines and devices regulations – complementary medicines regulation

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The AMA's submission on the draft chapter 'Regulation of Complementary Medicines' released for consultation on 20 February 2015 focuses on issues that impact on medical practitioners and the care of patients.

The AMA's primary concern is that Australia's regulatory framework for complementary medicines continues to maintain current standards of quality and safety. This needs to be complemented by clear and accurate information for consumers and medical practitioners about the safety, quality and efficacy of complementary medicines. This is important given that Australians spend $3.5 billion on complementary medicines and therapies each year – around 13% of individuals' total health expenditure[1].

Our comments are made within this context.

The AMA has not attempted to comment on all the regulatory questions posed in the draft chapter relating to sponsor requirements and approval processes. We have articulated what we consider should be the objectives of a regulatory framework, rather than the specifics of how it should operate.

Regulatory framework

Quality and safety should remain the key focus of Australia's regulatory framework for assessing and approving complementary medicines for sale in Australia.

The AMA recognises that evidence-based aspects of complementary medicine can be part of patient care. However there is limited efficacy evidence regarding most complementary medicine: the majority of complementary medicines do not meet the same standards of safety, quality and efficacy as mainstream medicines as they are not as rigorously tested.

Unproven complementary medicines and therapies pose a risk to patient health either directly through misuse or indirectly if a patient defers seeking medical advice. The AMA therefore does not accept the argument made by some stakeholders that, because the compounds which make up

[1] Expenditure is sourced from the National Institute of Complementary Medicine website; percentage is derived from comparison with AIHW *Health Expenditure Australia 2012-13* Table 3.10 on individuals' funding of health expenditure.

complementary medicines themselves are low risk, there should be a relaxation of current regulatory standards.

The AMA also does not accept that evaluating complementary medicines against medical criteria 'fails to recognise the inherent differences between complementary medicines and pharmaceutical medicines'. Companies selling complementary medicines market them to the public on the basis that they provide a therapeutic benefit; they should be assessed on that basis.

Similarly, the AMA considers that if a therapeutic claim is made about a 'food', for example, a dietary supplement consumed for therapeutic purposes rather than as a food choice that is an alternative to balanced nutrition, then it should meet the same regulatory requirements as other therapeutic products.

The current regulatory approach combining listing requirements and audits represents a reasonable balance between the needs of sponsors and consumers.

Evidence requirements

The AMA does not consider that the evidence requirements for listed medicines are overly onerous. We welcomed the improved and strengthened evidence requirements incorporated into the TGA document *Evidence Required to Support Indications for Listed Medicines* in 2012.

It is important that consumers have access to accurate information and are clearly informed about the level and type of evidence that is available to support indications for complementary medicines in order to make well-informed choices.

Advertising

Given that complementary medicines are not required to meet the same standards of efficacy as registered medicines, it is particularly important to ensure that the public is protected from misleading and fraudulent claims about the therapeutic benefits of scientifically unproven products.

Some regulation is essential so that clear and true statements are made regarding the efficacy and standards of evidence relied on.

The AMA supports a regulatory framework that ensures direct-to-consumer advertising of complementary medicines does not:

- 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;
- make unsubstantiated claims; or
- be false, misleading, or deceptive.

The AMA considers it highly unlikely that a self-regulatory approach would provide sufficient protection to the public.

The AMA supports the proposal that listed complementary medicines be required to include a disclaimer in all advertising materials and on product labels advising consumers that statements/claims have not been independently assess by the TGA for efficacy. This single action, in addition to current controls, would go a long way to ensuring the public understood that TGA listing does not equal scrutiny or assurance of the product's benefits.

Compliance and deterrents

TGA compliance reviews and the ANAO audit report of 2011 clearly demonstrate that the current compliance regime and deterrents are inadequate. The TGA should be sufficiently funded to undertake more comprehensive audits of sponsor information, otherwise the system for listing evidence will continue be open to fraud and misuse.

Deterrents should also be strengthened; as a minimum, the current loop-hole allowing sponsors to re-list suspected non-compliant medicines should be closed.

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