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AMA submission – TGA regulatory framework for complementary medicines

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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's primary concern regarding Australia's regulatory framework for complementary medicines is that it continues to maintain current standards of quality and safety. This needs to be supported by clear and accurate information for consumers and health practitioners about the safety, quality and efficacy of complementary medicines.

Therefore the AMA supports the TGA's reform objectives, in particular, reducing the risk that consumers are misled and increasing the transparency of the evidence base for health claims.

The AMA notes that the TGA's consultation paper states that consumers should be able to 'self-select' complementary medicines based on 'information provided with the medicine [that] supports consumer health decisions'. 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.

The AMA's views below are provided in this context. We have limited our comments to those aspects of the proposed new framework which will impact on medical practitioners and their patients.

<u>New complementary medicine 'assessment pathway', risk-based hierarchy and claims</u>

The AMA does not oppose the introduction of a new pathway for complementary medicines to be entered on the ARTG.

The new pathway introduces additional requirements to the current listing pathway, with the sponsor required to provide high quality scientific evidence to the TGA for premarket

assessment. In addition, the TGA will also assess the medicine presentation, including the product label, to ensure claims are factual and not misleading.

The TGA's proposed approach to regulate the use of 'claimers' for complementary medicines that successfully complete this new pathway appears sensible. However the AMA recommends the impact on the quality use of these medicines should be evaluated following the TGA's consumer education campaign and the entry to market of products with the new claimer statements.

Limited permitted indications for low risk complementary medicines

The AMA supports the decision to develop a limited list of 'permitted indications' from which a complementary medicine sponsor must select in order to increase compliance with current regulations. The AMA notes that the proposed low level indications are consistent with terms in current regulations. We also support the requirement for the language used in the indications to reflect the lack of certainty of any efficacy.

We are pleased that the TGA intends to pursue sponsors of listed medicines that would not comply under the new requirements to amend their indications and marketing, rather than just 'grandfathering' them.

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