

Response by the International Aromatherapy & Aromatic Medicine Association Incorporated (IAAMA) to the Australian Government, Department of Health, Therapeutic Goods Administration Consultation: Options for the future regulation of "low risk" products: Aromatherapy Products.

Aromatherapy is accepted in Australia, and worldwide, as a reputable and efficacious treatment.

IAAMA is the peak membership association in Australia for Aromatherapy Practitioners representing professional aromatherapy practitioners, students of aromatherapy and interested members of the general public and other professions. Professional practitioner members of IAAMA are required to hold an approved qualification in Aromatherapy and undertake continuing professional development each year to maintain their professional status.

Accredited Aromatherapy training in Australia is provided by Registered Training Organisations (RTOs) registered with the Australian Government, Department of Training and Education. Aromatherapy has been included in the HLT07 Health Training Package since Release 4.0 on 30 November 2006. Accredited training is recognised by a range of private health insurance providers. The current qualification is HLT52315 Diploma of Clinical Aromatherapy, which is offered by RTO's in every mainland state of Australia. Aromatic Medicine is available as an extension skill set.

Topical application, inhalation or massage is indicated in the consultation document as the intended use for Aromatherapy products; however, literature is being released, at an increasing rate, which encourages the ingestion of essential oils. IAAMA does not support ingestion of essential oils unless under the close supervision of a practitioner properly trained and accredited in aromatic medicine.

In an unregulated environment, where essential oils and products would be available without having been subjected to appropriate scrutiny, aromatherapy products promoted for ingestion would be a significant safety concern.

Professional aromatherapists require access to essential oils and associated products that have the assurance of safety and quality, produced using good manufacturing practice standards. TGA registration provides this assurance.

Suppliers of essential oils choose TGA registration to provide this assurance to their customers – including professional aromatherapists and retail outlets such as pharmacies. The loss of the ability to register their products would adversely affect their ability to provide the assurances demanded by their customers.

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Option 1 – Status Quo regulation of aromatherapy products Preferred

Maintaining current regulations ensure the consumer – both general public and practitioner – is able to choose products that have been assessed for safety & quality. They are also assured that manufacturing practices for these products are compliant with Australian standards. In an unregulated market the consumer is denied the right to knowledge about safety, quality and manufacturing practices and denied the choice of using safe, quality products.

The majority of international regulatory requirements would be closely aligned to Option 1.

Option 2 – Exemption of Listing in the ARTG and/or GMP Not Supported

This option could potentially result in supply of products that are not assessed for safety or quality. It is essential that the Permissible Ingredients Determination continues to be integrated into Australian regulatory practices as manufacturers may choose not to refer to this valuable resource to maintain product safety using correct ingredients and proportions. Confidence in the safety and quality of essential oil & aromatherapy products and in the regulatory authority in Australia would be compromised.

IAAMA feels it is very important to have PRE-market regulations rather than rely only on post market regulatory action after a problem is identified.

Option 3 – Declare essential oils not to be therapeutic goods Not Supported

This option raises even more concerns as removing all regulations would severely limit the choices available to consumers when looking for quality essential oil and aromatherapy products and increase the possibility of adverse outcomes for users. Declaring essential oils to not be therapeutic will cause confusion for consumers as the interest in the use of essential oils and aromatherapy products grows in popularity because many well-established products use essential oils as an active ingredient.

Removing regulation so there is less "red tape" and quickly being able to access the market does not improve consumer safety or confidence in the market.

Summary

The World Health Organisation (WHO) lists the risks associated with traditional and complementary therapy products, practitioners and self-care, one of which is the "use of poor quality, adulterated or counterfeit products". (WHO Traditional Medicine Strategy 2014-2023, World Health Organisation 2013)

We believe that the role of the TGA is to ensure Australians have the opportunity to choose high quality products that are safe for use.

For this reason we support Option 1 to retain the regulatory safeguards currently in place.

On behalf of the members of International Aromatherapy & Aromatic Medicine Association, IAAMA Council,

