International Aromatherapy & Aromatic Medicine Association Inc

IAAMA

The Hon Greg Hunt MP
PO Box 6022
House of Representatives
Parliament House
Canberra ACT 2600
Minister.Hunt@health.gov.au

25 September 2017

Proposed TGA regulatory reforms to aromatherapy products

Dear Minister Hunt,

I am writing to you in my capacity as President of the International Aromatherapy & Aromatic Medicine Association Incorporated (IAAMA), the peak membership association in Australia for Aromatherapy Practitioners. IAAMA represents professional aromatherapy practitioners, students of aromatherapy, interested members of the general public and other professionals.

I specifically refer to the recent public consultation conducted by the Therapeutic Goods Administration (TGA) between March and May 2017, 'Options for the future regulation of 'low risk' products', as part of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR). The TGA Consultation paper (pp.41-42) presents three reform options for the regulation of aromatherapy products:

1. Maintain regulatory status quo
2. Exemption from listing on the Australian Register of Therapeutic Goods (ARTG) and/or GMP
3. Declare essential oils not to be therapeutic goods, transferring regulatory oversight of these products to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The IAAMA is of the strong view that Option 1 ('maintain regulatory status quo') is the only option that upholds the MMDR Review's core objective of ensuring that any changes to the regulation of essential oils 'does not undermine public health and safety' (see Appendix A). This option is also the preferred position of industry and upholds stakeholder and community standards.

The TGA Consultation paper's stated objection to continuing to regulate aromatherapy products (Option 1) as a *"questionable use of TGA's resources"* appears to be a polemic position; it is not evidence-based and was not developed in consultation with industry or consumer stakeholders. A core function of the TGA is to monitor and evaluate the safety of therapeutic goods and manage risks associated with products, in line with community expectations. Failure to maintain this regulatory framework for aromatherapy products used as therapeutic goods could be regarded as 'questionable'. The TGA receives cost-recovery income from aromatherapy products listed on the ARTG, thus the regulatory impact would appear to be positive, at worst neutral.

The current regulatory framework upholds quality and safety standards, thereby ensuring the 'low risk' status of aromatherapy products on the market. Essentials oils are potentially toxic chemical substances when not supplied according to good manufacturing practice (GMP) standards and where appropriate advertising standards are not regulated and post-market monitoring is absent.

Proposed deregulation of aromatherapy products under either Options 2 or 3 does not satisfy the requirement that regulatory reforms under the government response to the MMDR Review do not 'undermine public health and safety'. It would appear self-evident that the removal of current regulatory requirements relating to aromatherapy products would result in lower quality products

flooding the market, increasing the likelihood of adverse reaction events and post market regulatory action.

With regard to Option 3, the Consultation paper provides no context or evidence to support what appears to be an ideological supposition that essential oils are 'not therapeutic goods'. This does not accord with aromatherapy being recognised as a therapeutic modality by other arms of government, health funds, consumers or published research (which TGA makes no reference to). No basis has been provided to remove the avenue for aromatherapy products to make appropriate therapeutic claims.

Aromatherapy is accepted in Australia, and worldwide, as a reputable and efficacious treatment. Professional practitioner members of the IAAMA and other professional practitioner associations 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 Federal Department of Training and Education. Aromatherapy has been included in the HLT07 Health Training Package since November 2006 and accredited training is recognised by a range of private health insurance providers. The current qualification is HLT52315 Diploma of Clinical Aromatherapy (https://training.gov.au/Training/Details/HLT52315), which is offered by RTO's in every mainland Australian State. Aromatic Medicine is also available as an extension skill set.

The primary intended use for aromatherapy products is topical application, inhalation or massage. These routes of administration are associated with potential risks to consumers if not used according to accepted directions and/or if consumers use aromatherapy products of unknown/ substandard quality. Of particular concern, literature is increasingly being promoted to consumers encouraging the ingestion of essential oils. IAAMA does not support this, unless they are administered by practitioners accredited in aromatic medicine.

In an unregulated environment, the supply of aromatherapy products of unknown quality promoted for internal use is a significant public safety concern. Indeed, it appears there is an increase in adverse reactions being reported to the TGA associated with inappropriate internal use of such products. The World Health Organisation (WHO) lists 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)*.

Professional aromatherapists require access to essential oils and associated products that have the assurance of safety and quality, produced according to GMP standards. TGA regulation provides this assurance. Thus suppliers of essential oils choose TGA regulation to provide this assurance to their customers, which include professional aromatherapists and retail outlets such as pharmacies. The loss of the ability to list their products on the ARTG would adversely affect their ability to provide the assurances demanded by their customers. It would also adversely impact Australian businesses.

IAAMA considers 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 seek your assurance that the TGA listens to industry feedback and retain the regulatory safeguards currently in place under Option 1.

I look forward to your response and would be happy to elaborate on our concerns as required.

Yours sincerely,

Karen MacKenzie
President

CC: Alex Caroly: Alex.Caroly@health.gov.au
Alex Best: Alex.Best@health.gov.au

Appendix A

IAAMA position on TGA Consultation - *Options for the future regulation of 'low risk' products* - Aromatherapy products

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.