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Dear Sir/Madam

RE: Consultation on the options for future regulation of "low risk" products.

Thank you for the opportunity to comment on the proposals put forward in the 'Options for future regulation of "low risk" products' document.

Australian Botanical Products has been manufacturing TGA listed products for a variety of Sponsors who are prominent in the Aromatherapy segment of the market for approximately 20 years. During this period we have worked collaboratively with our customers to assist with issues of safety and compliance at critical stages of the product's life cycle.

It is important to note that many essential oils, whilst natural, can contain potent constituents. Areas of concern include;

- Poisoning.
- Skin sensitisation or irritation.
- Risks during pregnancy.

The topical and inhalation methods of application are well established for Aromatherapy products, however, there is a concerning amount of literature emerging that encourages the ingestion of Essential Oils. It would be a safety concern if Aromatherapy products were unregulated and were promoted as ingestible products.

Australian Botanical Products has considered the options presented and **firmly believes maintaining the status quo regulation of aromatherapy products [Option 1] will best maintain public health and safety.**

Option 1 – Maintain the status quo regulation of aromatherapy products

The current regulatory landscape provides a mechanism that ensures the consumer is presented with materials that are pure and safe to use. Sponsors of listed products are required to investigate purity, efficacy and safety of aromatherapy products before releasing the product to market. Manufacturers are required to be licenced by the TGA and are responsible for the safe release of therapeutic materials manufactured.

The interaction between the TGA, Sponsor and Manufacturer is a critical safety step at the design stage of any new therapeutic product. The sponsor is generally

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enthusiastic about the benefits of a new product and it is generally the TGA and/or manufacturer who must ensure;

- A formal notification of ingredients intended to be used is submitted.
- The intended ingredients do not exceed safe maximum levels.
- The desired ingredients are safe and have been designated as permissible ingredients.
- Associated safety warnings for each ingredient are identified relevant to the method of use.
- Therapeutic claims on the manufactured product are consistent with the claims submitted to the TGA.

In addition to the checks performed prior to manufacture and release, there is a post review mechanism that ensures;

- Therapeutic claims do not go beyond the accumulated evidence gathered.
- Manufactured items are consistent with the requirements stipulated in the Listing process.

Over the years we have encountered many Aromatherapy concepts that have been either modified or abandoned as a result of checks performed before manufacture. Common safety concerns prevented include;

- Sponsors indicating unrealistic benefits on products relying on anecdotal experience.
- The desire for packaging uniformity on the retail shelf at the expense of poisons compliance [e.g. omitting child resistant closures or RFIs].
- The introduction of new raw materials that have not been fully tested or reviewed.
- Having a "more is better" position and pushing levels of active ingredients beyond safe levels.
- Omitting safety warnings.

All of the concerns listed above are easy to remedy and do not add any significant cost to the development of new Aromatherapy products, but in a less regulated environment, **it is highly likely, one or more of these safety concerns will be overlooked**.

Maintaining the status quo would be a more internationally harmonised position and in line with most International Regulatory regimes.

Option 2 – Exemption from listing in the ARTG and/or GMP

Removing either "listing on the ARTG" or "medicine level GMP" will potentially compromise consumer safety.

As mentioned previously, the Listing process;

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- Prevents the introduction of unknown/untested/unsafe materials.
- Limits dosage to safe levels.
- Provides uniform and consistent safety warnings for materials and therapeutic applications.

Manufacturing by competent organisations ensures;

- Raw materials selected are tested for authenticity and suitability.
- Products are packaged is a safe manner and in compliance with Poisons regulations.

Furthermore, if one of these regulatory components is omitted, there will be less certainty that manufactured product will have sufficient active material to support the therapeutic claim being made. The proposal could potentially remove accountability of Sponsors and/or Manufacturers to ensure the correct ingredients and proportions are adhered to during manufacture. The consumer's safety and confidence would be compromised.

Unregulated Sponsors or Manufacturers may neglect [or lack the competency] to check all the considerations made in the existing Listing process. Regulating a product using a post market regulatory system [regardless of who is regulating] will result in unsafe product being released to market and a regulatory body having to "catch up" with compliance and safety concerns **after** an unsafe product has been released to market. Under this proposal, the consumer is at risk until a complaint is lodged and a resolution determined. If unsafe products were to be released, consumer confidence of the regulatory authority responsible for monitoring regulatory compliance would be undermined.

The cost and practicalities of policing a regulatory regime exempt from listing or GMP should also be examined. The current model incorporates a controlled post-market review in addition to responding to consumer complaints. A regime responding only to consumer complaints has the potential to be idle for some periods then inundated in other periods.

Option 3 – Declare essential oils not to be therapeutic goods.

In addition to many of the concerns raised in option 2, there are further concerns if Aromatherapy products are deregulated.

Essential Oils are growing in popularity as a natural alternative for treating symptoms of many ailments. Removing the ability to make a therapeutic claim would severely limit the choice of consumers looking for natural remedies.

There will continue to be products Listed or Registered with the TGA that will include Essential Oils as an active ingredient [e.g. Chest Rubs]. Why would it be permissible to have Eucalyptus Oil as an active ingredient in a therapeutic chest rub while suggesting the use of Eucalyptus oil for direct inhalation not be permissible? This would result in consumer confusion

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Low regulatory hurdles and rapid market access are not an improvement to the consumer's safety or confidence. The TGA regulatory guidelines are well suited to Aromatherapy products and deferring regulation to a non-specialist regulator would be a backward step and possibly expose the consumer to danger and health risks.

To summarise our position, **we firmly believe the status quo should be maintained.** We believe this market segment is a growing in popularity and is worth the resources allocated. Furthermore we believe the existing regulatory framework is currently preventing unsafe products being released into the market and the alternate options presented [2 & 3] are increasing risk and compromising the safety of the consumer.

Yours sincerely,

[redacted]

Brendan Smith

Operations Manager