

8 August, 2012.

TGA Labeling and Packaging Review
PO Box 100
Woden ACT 2606

Dear Sir/Madam,

Firstly, Totally Natural Products would like to take this opportunity to thank the Therapeutic Goods Administration (TGA) for the opportunity to provide feedback on the TGA Medicine Labeling and Packaging Review Consultation Paper, Version 1, May 2012.

The TGA Medicine Labeling and Packaging Review cover the following aspects of labeling and packaging:

- Prominence of active ingredients on medicine labels
- Look-alike sound-alike names and look-alike packaging
- Look-alike medicine branding
- Standardised Information Format: the Medicine Information Box
- Dispensing label space
- Blister Strip Labeling
- Small containers
- Pack inserts

We are a sponsor of Complementary Medicine and it is in this context that we would like to provide feedback to the Review mentioned above. We note that the TGA are custodians of the following overarching objectives of the National Medicine Policy:

- Timely access to the medicines that Australians need at a cost individuals and the community can afford
- Medicines meeting appropriate standards of quality, safety and efficacy
- Quality use of medicines
- Maintaining a responsible and viable medicines industry

We would like to reinforce, that as part of any change TGA implements, it is responsible for ensuring the ongoing commercial viability of industry. The Complementary Medicines industry, which employs thousands of tax-paying Australians, is highly competitive and under increasing pressure from within and outside of Australia. Any change initiated by the TGA must also contain commercial considerations which ensure the ongoing viability of industry.

There are a number of aspects of the above mentioned Review which we would like to comment on.

Whilst the TGA purports that the Review is primarily concerned with the presentation of the information on medicine containers or on boxes within which medicines are supplied, we are concerned with the implications associated with Figure 2 (The components of a medicine label) featured in the Review. Figure 2 suggests that the space on the sides of a carton will only be used to communicate the address and contact details of the sponsor. We strongly oppose this proposed change. According to the TGA **“industry must be able to provide information to potential consumers about the nature and benefits of therapeutic products”**¹. Notwithstanding the fact that this is in the context of the Quality Use of Medicine.

As such, we believe a sponsor should have every right to tell consumers about the benefits of their products on the packaging. The obvious proviso is that any claims made must be consistent with the indications as listed on that product’s ARTG, where acceptable evidence is available to support those claims.

In fact we feel that by not having the opportunity to tell consumers about our product is anti-competitive, anti-business and anti-consumer. It is anti-competitive because it will make products appear more generic as it will minimise sponsors’ potential to differentiate their product from other formulas on the market.

If the proposed change is to remove text from the sides of cartons, we see this as anti-business because the TGA will be denying sponsors the right to tell consumers about the sponsor’s brand on its packaging. This will reduce or eliminate the sponsor’s opportunity to differentiate their brand in the marketplace, resulting in a more generic environment in which to operate. Such an environment like this is not conducive to a healthy, vibrant industry. The proposed changes by the TGA will deny companies from protecting or increasing their brand equity.

Also, to display the active ingredient immediately below the brand name, with the first letter of the active ingredient directly below the first letter of the brand name will virtually remove the design differential each sponsor utilises. This will result in little or no differentiation between one sponsor and another, which is anti-competitive.

Plus it would be impractical to display the active ingredient with equal prominence with the brand name. As stated above, often Complementary Medicines have numerous active ingredients. Therefore, the front panel of the packaging will look aesthetically abhorrent. We would not have the packaging space to display all active ingredients at 100% of the font size of the medicine brand name on the main/front label. From a branding perspective, it would not be sufficient to use a different font style or colour, differentiating the brand name and active ingredient(s). There should be a difference in font style, letter spacing or font colour.

Finally, such proposed changes are anti-consumer because consumers have a right to know more about the products they are buying.

The proposed TGA change is tantamount to the Plain Packaging Legislation the Federal Government is imposing on tobacco companies. Not that we oppose this

¹ Advertising regulatory framework – Options for reform, May 2012.

action, but it seems sponsors of Complementary Medicine are being punished for doing nothing wrong. Tobacco kills, but our products are safe. The TGA is taking away sponsors rights to tell customers about the benefits of our products, which as mentioned above is counter to the TGAs position about informing consumers of their product's benefits. We pay for the space on our packaging and the TGA is denying us use of it. Does the TGA intend to compensate sponsors for the commercial impact the proposed packaging changes will have on brand equity and lost sales as well as the associated costs for any change-over from existing packaging formats?

Unlike OTC/Prescription Medication, Complementary Medicines often have more than a single mode of action or therapeutic benefit. Representing the therapeutic indication of the product in a similar manner to OTC products does not give the consumer a clear understanding of product's indications.

Also Complementary Medicine formulas quite often have more than one active ingredient. This can result in multiple therapeutic indications for the product. As such, a single therapeutic indication will not reflect the true nature of the product. This will only lead to a lack of clarity and increased consumer confusion associated with the product.

The proposed changes would make the appearance of Complementary Medicine generic as consumers would not be able to understand any differentiation. This is inconsistent with objectives associated with the National Medicine Policy. These changes are also commercially inappropriate.

The second aspect of the Review we oppose are the proposed changes to pack inserts.

The proposed regulatory changes for inserts are:

1. Advertising material will not be permitted to be included as a pack insert or incorporated into an approved pack insert.
2. A pack insert must be in a form separate to the packaging; i.e. it cannot be printed on the inside of a carton.

We do not understand why advertising material can not be included in a pack insert, especially for Complementary Medicines, which are considered low risk. Removing this right is opposed to the TGA's own position that "industry must be able to provide information to potential consumers about the nature and benefits of therapeutic products".

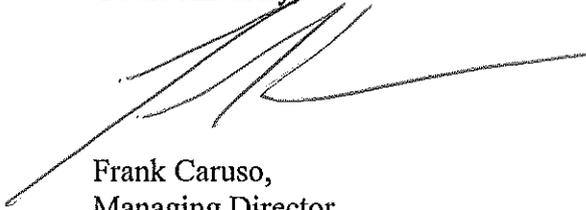
We see no safety or 'quality use of medication' implications by including responsible advertising material in a pack insert for Complementary Medicines. Whilst some medicines require an 'approved' pack insert Complementary Medicine does not, except in the case where the container may be too small to include all the relevant information on it. So any threat associated with confusing consumers or distracting consumer from important health information, which would be included in an insert is non-existent.

Consumers are exposed to advertising associated with all forms of medicine every day of the week via newspapers, magazine, radio, television and the web. Pack inserts represent an alternative medium to these other media. As such, we see no justification

what-so-ever for denying sponsors the right to responsibly advertise their business and products via such a medium.

Again thank you for allowing us the opportunity to respond to The TGA Medicine Labeling and Packaging Review and we trust you will look favourably on the feedback we have given.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Frank Caruso', written over a horizontal line.

Frank Caruso,
Managing Director.