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BioCeuticals Ltd Submission -
TGA Consultation -
Regulation Impact Statement -
General requirements for labels for medicines

BioCeuticals is Australia's leading provider of nutritional and therapeutic supplements. Renowned for manufacturing and delivering high quality foods for specific nutritional purposes and integrative medicines to healthcare practitioners, BioCeuticals aims to consistently raise the standards of natural-based therapies.

With quality, innovation and integrity as guiding principles, BioCeuticals is at the forefront of ensuring complementary and alternative medicines (CAMs) become an integral part of the Australian allied healthcare industry.

BioCeuticals has a strong commitment to research, functional formulas and reliable practitioner support. Our supplements are recognised by qualified healthcare practitioners as well as patients; a fact that reflects our reputation as a progressive force in integrative health.

BioCeuticals welcomes the opportunity to contribute to the Consultation for General Requirements for Medicine Labels.

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Following a review of the Consultation for General Requirements for Medicine labels we would like to provide the following feedback.

Of the 3 options being considered, our preference is *Option 3: Introduction of a new TGO79*, as we believe this will facilitate the most beneficial and effective outcome for industry and consumers.

While we agree that steps to promote consumer safety and efficacy through changes to labelling guidelines are required, we disagree that complementary medicines (CMs) and pharmaceutical medicines should be regulated under the same labelling order given the minimal potential for adverse events associated with CMs compared with pharmaceutical medicines. Therefore, we would like to suggest some modifications to the proposed TGO79 draft in order to reduce the adverse impact on industry by some aspects of the current draft while still ensuring improved consumer safety regarding medicine labels.

We note in the '*Comparing TGO79 with TGO69 Changes to the requirement for labelling medicines*' document (p14) the proposed changes to the expression of herbal ingredients includes specifying both the extract weight and equivalent fresh/dry weight. We think this will place unnecessary burden on industry in terms of taking up excessive label space and will be of minimal benefit to the consumer in terms of the safety or efficacy of the medicine. Therefore we suggest that the expression of herbal ingredients remains as the equivalent fresh/dry weight and where relevant the standardised equivalent quantity.

It is also proposed that for listed medicines, the minimum font size be increased to not less than 6 point arial. We suggest that font width is not regulated, as we think that as long as font is the correct height and is clearly legible there is no additional consumer benefit to having increased font width.

The '*Comparing TGO79 with TGO69 Changes to the requirement for labelling medicines*' document (p18) requires that the name of the medicine must be presented in a cohesive manner with the active ingredients. We object to this proposal as we think as long as the active ingredient information is included on the front panel in the correct format it does not provide any additional benefit to the consumer, and it also restrict the addition of information between the product name and ingredient information in the form of a by-line under the product name.

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The consultation has made note of the financial impact to industry associated with the changes proposed in TGO79, however we think this is a significant underestimation of what the economic costs would be. If all changes proposed in TGO79 come into effect, this will be of considerable cost to our company including changing of all labels, changing of some bottles due to font size increases, staff hours required to make these changes and update documentation, and wastage of labels not used by the time TGO79 comes into effect. We estimate this cost to be well in excess of \$500 000. Therefore, in order to minimise our financial cost, our preference is for a 3 year transition period for the commencement of TGO79.

SIGNATURE 

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