The Hon. Karen Andrews, MP
Minister for Industry, Science and Technology
Parliament House, Canberra
karen.andrews.mp@aph.gov.au
cc: The Hon. Stuart Robert MP,
cc: Senator Kim Carr

25 October 2018

Dear Minister,

Complementary Medicines Australia (CMA) writes to you to confirm that the sentiments raised at Senate Estimates today are what members of the complementary medicines industry have been asserting, that the current application of the ACCC *Country of Origin Guidelines for complementary healthcare products* will have significant detrimental impacts on the industry's $1.2 billion export market and threaten a 30,000 strong work force that supports a 4.9 billion dollar industry.

The revised Country of Origin guidance, released in March this year, means that by extension over 200 licensees to the Australian Made logo are currently in danger of having their 'Made in Australia' credentials revoked and the hurdles increased. If complementary medicines that are manufactured and tested in Australia cannot claim "Made in Australia", the result will cause unnecessary yet serious impact on the industry and wider global reputation including reduction in investment into Australia, job losses and hinder industry growth.

We urge you to prevent one of the few remaining growth manufacturing industries in Australia from being jeopardised. It is counter-productive to the competitive advantage enjoyed by manufacturing complementary medicines in Australia as a result of maintaining the high quality pharmaceutical standards expected here. Instead it would force businesses to consider following the path of many pharmaceutical companies in needing to exit Australia and move off-shore.

The higher input costs of labour, electricity and regulatory compliance means our industry does not and cannot compete globally on price. Competitive advantage is based on our high-quality testing and manufacturing standards. Australian consumers need to know that the vitamins they consume have been manufactured in Australia under the most rigorous regulatory framework in the world. Forcing the Australian manufacturing industry off-shore is not in the interests of Australian consumers, or the thousands of workers employed in the industry.

It is well known that many consumers, especially those in the Asia-Pacific region, look for the 'Made in Australia' claim or the 'Made in Australia' logo as proof of authenticity and the high quality, trusted, standards synonymous with complementary medicines made in Australia.

CMA, on behalf of industry, will continue to work with the Government to ensure support for manufacturers and a level of certainty for businesses, in the consistent application of Country of Origin and Australian Made provisions. To this extent, it is proposed that an urgent amendment be made to the *Competition and Consumer Regulations 2010*, that would acknowledge all finished medicinal

products manufactured in Australia, under Good Manufacturing Practice (GMP), as meeting the criteria for substantial transformation in this country.

Yours sincerely,

Mr Carl Gibson
Chief Executive Officer
Complementary Medicines Australia

Agreed to and co-signed by the Australian Complementary Medicines Industry

Dusko Pejnovic
CEO, Lipa Pharmaceuticals

Stephen Walker, General Manager
Sanofi Consumer Healthcare

Russell Scott
*CEO,* Ferngrove Pharmaceuticals Australia Pty Ltd

Dr Aniss Chami, CEO Vitex Pharmaceuticals

Russell Parker CEO – Melrose and Orchard

Richard Henfrey, CEO, Blackmores

Executive Chairman & Founder
Caruso's Natural Health

Jeffrey Yeh,
Operations Director
Homart Pharmaceuticals

Justin Howden, Group Head
Global Government Affairs and Industry Development
Swisse Wellness

Michelle Aitkin, Head Regulatory
Evolution health

Howard Biggs, General Manager
Personalcare at PharmaCare Laboratories

**Rational for proposed change to the Competition and Consumer Regulations 2010**

The *Competition and Consumer Act* 2010 , subsection 255(3)(b), provides a mechanism for including in the Regulations examples of particular classes of goods that have undergone certain process that would otherwise have the same result as those described in subsection 2(b), the 'substantially transformed' definition.

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Subsection 255(3)(b) of the Act provides that:

'Without limiting subsection (2), the [Competition and Consumer] regulations may include examples (in relation to particular classes of goods or otherwise) of processes or combinations of processes that, for the purposes of that subsection, have the result described in subsection (2)(b).'

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Therefore, it is proposed that wording to the following effect be included in the Regulations for the purposes of 255(3)(b):

**"In relation to the class of goods that are finished medicinal products, the combination of processes specified for this part are the 'manufacture of dosage form' and 'packaging and labelling', when performed in accordance with prescribed Manufacturing Principles within the Therapeutic Goods Act."**

This mechanism would efficiently and succinctly address the unintended consequences that have arisen due to the amended Australian Consumer Law. That is; the production of medicines, which when manufactured under processes of Good Manufacturing Practice, substantially transforms them into goods that are fundamentally different in *identity*, *nature*, or *essential character* from the raw material components used in their production.

By doing so, the legislative application and reasonable consumer test remains as to whether "as a result of one or more processes undertaken in that country, the goods are fundamentally different in identity, nature or essential character from all of their ingredients or components that were imported into that country."

**Explanatory note:**

1. Therapeutic goods, by Australian law, include goods that are represented in any way to be, or that are because of the way in which the goods are presented, likely to be taken for therapeutic use.

2. *Finished medicinal products* (also referred to 'finished products*') are a class of therapeutic goods that are represented to be and presented in a way that they are likely to be taken for therapeutic use by consumers. They are fundamentally different in identity, nature, or essential character from all of their imported ingredients or components – none of which are goods that are represented to be, or are presented as goods that have the identity, nature, or essential character goods that are designed to be taken for therapeutic use.

3. Whilst the majority of ingredients (chemical or biological) cannot be consumed *at all* in their imported raw material form, even an ingredient that could be consumed, such as fish oil, could not meet the identity of

being a *finished medicinal product*, because raw fish oil in it's existing form, is by Australian legislative definition a food product, which is not represented to be or presented in a way that it is likely to be taken for therapeutic use, nor is it required to be processed under prescribed Manufacturing Principles for therapeutic goods.

4. The class of goods known as *finished medicinal products* are goods that are fundamentally different in nature, identity, and essential character from all of its individual ingredients (active ingredients or excipients) and all of its other necessary components (packaging and labelling components).

5. In order for goods to be represented to be, and presented for supply as, *finished medicinal products*, a combination of two manufacturing processes must occur, both of which are required TGA steps of medicine manufacture:

    1. "Manufacture of dosage form"
       This step involves a series of complex manufacturing processes that is necessary to present a *finished medicinal product* in its final pharmaceutical form intended for therapeutic use and are therefore processes that are essential in the transformation in the nature, identity and essential character of the goods.
    2. "Packaging and labelling".
       By representing the therapeutic purpose of the goods, this step forms part of the necessary transformation of the identification of goods into *finished medicinal products*.

6. Both of these steps are processes which are required to be performed under specified Manufacturing Principles for the *Therapeutic Goods Act 1989*.
   *https://www.tga.gov.au/acronyms-glossary#summary-f

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## Competition and Consumer Act 2010

(2) Goods were **substantially transformed** in a country if:

(a) the goods met, in relation to that country, the requirements of item 1 or 2 in the second column of the table in subsection (1); or

(b) as a result of one or more processes undertaken in that country, the goods are fundamentally different in identity, nature or essential character from all of their ingredients or components that were imported into that country.

**(3)** Without limiting subsection (2), the regulations:

(a) may prescribe (in relation to particular classes of goods or otherwise) processes or combinations of processes that, for the purposes of that subsection, do not have the result described in subsection (2)(b); and

**(b)** may include examples (in relation to particular classes of goods or otherwise) of processes or combinations of processes that, for the purposes of that subsection, have the result described in subsection (2)(b).