The Complementary Healthcare Sector Country of Origin Labelling Taskforce
Industry House
10 Binara Street
Canberra ACT 2601

Dear Taskforce Members,

Complementary Medicines Australia (CMA) welcomes the opportunity to articulate the industry implications resulting from changes to the Australian Consumer Law criteria for a 'safe harbour' defence, and the subsequent policy interpretation and application of that criteria for the sector in the guidelines set by the ACCC in the 'Country of Origin Labelling for complementary healthcare products – a guide for business' (March, 2018).

CMA notes that the taskforce terms of reference states that:

> *"The purpose of the Complementary Healthcare Sector Country of Origin Labelling (CoOL) Taskforce (the taskforce) is to examine concerns raised by the complementary healthcare sector (the sector) about changes to the use of the Australian Made, Australian Grown (AMAG) logo, and investigate…"*
> *3.3 "Assess Australian consumer expectations relating to suggested changes by the sector regarding rules governing the use of the AMAG logo".*

CMA would like to clarify that the issues the industry have been raising are a result of the changes to the Australian Consumer Law (ACL) and follow-on interpretation of the revised guidelines for the sector. The use of the AMAG logo, which is guided by the ACL and any ACCC guidelines, is a critical, but secondary outcome of these considerations.

The position of the industry is not in reference to changes to the AMAG logo but rather the overarching legislation, in particular the Competition and Consumer Regulations that allow a mechanism to define a particular class of goods as described under the 'substantially transformed' definition, which would therefore allow genuine qualification to use the AMAG logo.

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

The CMA propose that wording to the following effect be included in the *Competition and Consumer 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."

Executive Summary

CMA, as a not-for-profit organisation, aims to promote and enhance all aspects of the complementary medicine supply chain. This includes supporting Australian manufacturers of high quality complementary medicines to continue to be appropriately recognised through use of the AMAG logo and claims.

Australia's complementary medicines are unique in the world. We are commonly recognised as the world leader in the category for safety and quality because we are the only country (aside from South Africa) who manufacture these health enhancement products as medicines, not foods. The regulatory distinction between these two categories is critical, and its basis lies in manufacturing. In Australia, manufacturers are required to comply with the Code of GMP called 'PIC/S' – the *Pharmaceutical Inspection Co-operation Scheme* – the same that the majority of pharmaceutical medicines world-wide comply with. Consequently our products are called 'complementary medicines' and not 'dietary supplements' as in the USA and elsewhere.

The world-class, high quality, TGA-GMP manufacturing reputation is what attracts consumers to 'Australian Made' products and thereby attracts brands to contract with Australian manufacturers. It is well recognised that Australia is a high-cost place to do business but we are excelling well above our weight in this category because of our excellent reputation for safe and high quality manufacture. The changes to the approach of the guidelines will have a detrimental effect on many businesses and Australia's manufacturing industry as many established products will no longer qualify to make a "Made in Australia" claim. The current ACCC guideline is hugely prohibitive and counter-productive to the competitive advantage enjoyed by Australian manufacturers as a result of maintaining the high quality pharmaceutical standards expected. From the perspective of the consumer, it must be noted that although few are currently aware of this, many off-shore facilities do not have the same level of oversight applied as domestic manufacturers in the regulatory assessment scheme, therefore there is some risk that the quality of the products may not be as unsurpassable in quality as the current, thriving local industry that we have.

The pharmaceutical manufacturing sector, which cannot leverage the Made in Australia claim in the same way as complementary medicines sector, has in recent decades seen the majority of local manufacturing facilities close and move into cheaper overseas factories. If the current policy interpretation continues uninterrupted so that Australian-made products are unable to identify themselves as such, then this will be the inevitable outcome for the complementary medicines manufacturing industry as well. We believe that this is inherently against the intent of original policy makers that first introduced the concept of providing licensed recognition of the 'Made in Australia' claim.

The TGA-GMP (PIC/S) pharmaceutical level requirements are of sufficient complexity that they fundamentally cause raw material 'goods', which are not medicines, and only in rare cases able to be consumed as foods, to be substantially transformed in Australia into goods that are recognised as a category of medicines. These reasons are fundamental to why the industry proposal outlined above is for the Competition and Consumer Regulations be amended to recognise medicines manufactured in a TGA-licensed Australian manufacturing facility as 'substantially transformed' and therefore by

extension be recognised as “Made in Australia”.

By doing so, the legislative application and reasonable consumer test remains as to whether “as a result of one or more processes (**i.e. medicine manufacture**) undertaken in that country, the goods (**i.e. medicines**) are fundamentally different in identity, nature or essential character from all of their ingredients or components (**i.e. a wide range of raw materials**) that were imported into that country. The ACCC permit the claim on goods that undergo far less ‘transformation’ within Australia than medicines do under TGA-GMP, for example, the cutting and sewing of overseas produced fabric from overseas components (wool, cotton, etc) into a suit.

This approach would also be in line with the ACCC’s original interpretation of substantial transformation. Under the original definition, it was the position of the ACCC that both encapsulation and tabletting processes, regardless of the number or origin of the active ingredients, were considered to be the substantial transformation step in the manufacture of health supplements. This policy was consistent with the guidance set out in the ACCC’s booklet *Complementary health care industry: country of origin and the Trade Practices Act (2004)*.[i]

The concerns raised by the industry, which have led to the establishment of this taskforce, demonstrate the value placed on the “Made in Australia” logo and associated representations, particularly in relation to exports. The higher input costs of labour, electricity and particularly, the resource-intensive demands of the GMP regulatory compliance that has given us this unique reputation means the industry does not and cannot compete globally on price. The competitive advantage leveraged by this sector based on high-quality testing and medicinal manufacturing standards simply translates to the consumer and brand market as being “Made in” Australia. Creating conditions that force the Australian manufacturing industry off-shore is not in the interests of Australian consumers, or the 30,000 strong work force that supports a 4.9 billion dollar industry with a $1.2 billion export market.

For export purposes, medicines must meet the regulatory requirements of the importing country. To meet China’s strict Labelling Law requirements for example, requires that the Country of Origin manufacturer details be communicated on the label of the product. The ‘one-year sale proof’ test also requires the imported product to be exactly the same as the version sold in the country of manufacture in terms of ingredients, dosage and levels. Yet at the same time, under the current guidelines, companies cannot communicate that these products are Made in Australia.

Consumers should have access to information that the complementary medicines they consume have been manufactured in Australia under the most rigorous regulatory framework in the world.
A consumer assessing a product off the shelf that has undergone such rigorous quality processes may question, if it is not “made in” Australia, then where is it made?

Background
In February 2017, amendments to the Australian Consumer Law (ACL) came into effect that changed the criteria for making a ‘made in’ Australia claim. The amendments for ‘made in’ claims included the removal of the previous 50 per cent cost of production requirement, and a revised definition of ‘substantial transformation’ safe harbour defence, as follows:

Goods are substantially transformed in a country if…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.*

Specific guidance for the complementary healthcare sector describing the interpretation of the new law, was published by the ACCC in March 2018, which in light of previous guidance, takes a significantly more conservative stance as to what may be called 'Made in' Australia. The revised ACCC guideline has resulted in a significant variation in interpretation as to what the ACCC consider to meet the substantially transformed test and is not consistent with guidance for other industries. For example, guidance for other sectors take a far less stringent approach to the application of substantial transformation. This includes, baking a frozen raw imported pie and curing imported pork and claiming Australian Made.

Soft Gel Encapsulated Marine Oils

From 2017, when the updated definition of substantially transformed passed into ACL, the ACCC have had a statement on their website that under the new definition, soft gel encapsulation of imported marine oil is unlikely to constitute a product that has undergone substantial transformation because encapsulation is unlikely to create a fundamental difference in identity, nature or essential character between the marine oil capsules (final product) and the imported marine oil. A Federal Court of Australia ruling has since been handed down on 3 December 2018, confirming a view that the encapsulation in Australia of imported fish oil and Vitamin D did not meet the definition of substantial transformation and hence a 'Made in Australia' claim was not permitted.

CMA notes that the Court's decision considered the physical attributes of the product and some aspects of the manufacturing processes for soft gel encapsulation. The case did not appear to discuss aspects pertaining to the Therapeutic Goods Administration Good Manufacturing Practice (GMP) requirements specifically, or to the extent of change in the goods from raw material goods into finished medicines. A final decision was made on the principle that what was being imported, 'Fish Oil and Vitamin D', was the same as what was being named on the label, which is capsules containing 'Fish Oil and Vitamin D'. CMA's view is that this court case, while conducted in earnest, missed some of the most key and fundamental points to Australian GMP manufacture and to the definition of 'substantially transformed'.

Support for Australian Made

Consumers understand that support for Australian manufacturing is a key tenant of a thriving economy and a healthy jobs market in Australia. More than that, in Australia and throughout many international countries, a wide range of consumers specifically seek out the exceptional quality of Australian made complementary medicines made in TGA-inspected GMP facilities.

CMA notes that the Terms of Reference to the Taskforce will "*Assess consumer's expectations relating to suggestions by the sector regarding rules governing the use of the AMAG logo*". As mentioned above, the sector wish to maintain the current AMAG logo, through the appropriate application of the substantial transformation test. Moreover, CMA has requested prior evidence of consumer sentiment that informed

the policy change to the guidelines and that has resulted in the current inconsistency of application of the test across sectors.

Understandably, the change in approach and review of AMAG license holders has caused considerable uncertainty for business in this sector who need to forward plan and make decisions about cost of manufacture, label compliance and product development.

CMA suggests that the Taskforce sincerely consider consumer sentiment of overseas, particularly Chinese, consumers who are a key market for the complementary medicine sector in Australia. It is CMA's understanding that consumers in Asian countries, view Australia as a trusted source of complementary medicine products thanks to its 'clean, green and safe' reputation, underpinned by a robust regulatory system for medicines. The use of the Australian Made logo strengthens this perception.

CMA actions in response to changes

CMA has maintained ongoing and regular contact with the ACCC and has been involved in contributing to the development of guidance for the sector following the change to the Australian Consumer Law. This has resulted in the expansion of the ACCC's original view that not any tablets except modified release tablets would meet the test, to currently recognise a range of tabletted products within the meaning of substantially transformed.

CMA still holds the view that the approach of the guideline is fundamentally incorrect, that the ingredients are essentially synonymous with the finished goods, is not a relevant interpretation of the ACL. The finished product as a "medicine" comprises many characteristics to the consumer that fundamentally transform the nature and essential character of the goods they are purchasing.

CMA continues to seek appropriate application of ACL to the sector by recognition of Australian made GMP medicines as having fundamentally met the substantially transformed test.

Specifically, the lowest cost, most simple Government mechanism of doing so is a regulatory inclusion to the Regulations that acknowledges complementary medicine finished products manufactured in Australia under GMP are 'substantially transformed' into finished consumer medicines from their raw materials or components.

Conclusion & Next Steps

The growing market for complementary medicines has been driven by a heightened awareness of health, wellness and safety, especially among Chinese consumers. Our manufacturing sector is one of Australia's growing industries and an export success story which has been enthusiastically promoted by agencies such as Austrade. It would be extremely regrettable if the current situation was left to remain unchanged to the detriment of the industry and the Australian economy.

At the cornerstone of the taskforce considerations should be the origins of the Made in Australia Campaign, which was established to encourage people to buy locally made goods and strengthen the

profile of local manufacturing industries that face significant survival challenges in the globally competitive economy.

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 correct and consistent application of Country of Origin and Australian Made provisions. To this extent, it is proposed that an urgent inclusion of TGA-GMP manufactured medicines be made to the Competition and Consumer Regulations, that would recognise these goods 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
January 2019

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.

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).'

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

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).

[i] Australian Competition and Consumer Commission (2004), Complementary health care industry : country of origin guidelines to the Trade Practices Act, The Commission, Dickson, ACT