AUSTRALIAN MADE CAMPAIGN LIMITED

PHARMACEUTICALS AND COMPLEMENTARY HEALTHCARE PRODUCTS - COMPLIANCE POLICY
May 2018

Summary

Australian Made Campaign Limited (AMCL) is the not-for-profit organisation which administers the country of origin certification trade mark known as the Australian Made, Australian Grown (AMAG) logo.

This document sets out AMCL's guidelines for assessing applications to use the AMAG logo on pharmaceuticals, complementary medicines and related products.

Background

The *Competition and Consumer Amendment (Country of Origin) Act 2017* was passed in February 2017, amending the country of origin safe harbours set out in Part 5-3 of the Australian Consumer Law (ACL). In particular, the criteria for 'made in' claims were changed by revising the definition of 'substantial transformation' (ST) and removing the cost of production requirement.

While these changes apply to all products, they have had a significant impact on country of origin labelling for complementary medicines.

The sole test for making a claim that a product was 'made in' a particular country is now that the good in question was **last substantially transformed** in that country.

Prior to the changes, the definition of ST in the ACL was:

> *Goods are substantially transformed in a country if they undergo **a fundamental change in form, appearance or nature** such that the goods existing after the change are new and different goods from those existing before the change.*

The revised definition of ST is:

> *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.*

Under the original definition, AMCL's position was 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).

Under the new definition, changes in form or state (e.g. a change from powder to a liquid) are less significant when considering whether ST has occurred.

ACCC Guidance

In March 2018, the ACCC published its guidance document *Country of origin labelling for complementary healthcare products: a guide for business*. This guide is intended to assist businesses to "*understand the application of the Australian Consumer Law (ACL) in relation to country of origin claims and in particular, when businesses can safely make a 'made in' claim about their products".*

The guidance, which reflects the changes to the ACL, represents a substantial departure from the position set out in the ACCC's 2004 publication, particularly in the treatment of encapsulation and tableting.

In relation to encapsulation, the ACCC's position is that, "*Encapsulating imported actives is unlikely to constitute a substantial transformation. While encapsulation results in a change to the form and appearance of the imported active, in our view it doesn't result in a fundamental change to its identity, nature or essential character when compared to the imported ingredient*''.

In regard to tablet manufacture, the ACCC's view is that "*a substantial transformation is likely to occur in Australia where imported actives and imported excipients undergo the full tableting process to transform bulk raw materials into a tablet here*". The "full tableting process" is described as a three step operation that comprises of "*the blending (wet or dry), granulation and compression of actives and excipients (including binders and disintegrants) into tablet forms*".

The guide also sets out the ACCC's position on other processes and product types including dry blending, herbal extraction, essential oils and semi-solid formulations (creams, lotions, etc.).

While the guide is primarily concerned with complementary medicines, it also has relevance to other pharmaceutical and medical products, such as prescription and over-the-counter medications and veterinary pharmaceuticals.

The guide is intended to supplement the information in the ACCC's 2017 publication *Country of origin claims and the Australian Consumer Law*. It reflects the ACCC's views at the time of writing and does not constitute legal advice.

In developing the guidelines in this document, AMCL has endeavoured to provide consistency with the principles and practical examples set out in the ACCC guide while providing a wider range of examples and product types.

AMCL Position

The AMAG Logo Code of Practice sets out criteria for products to carry the AMAG logo with a range of claims, including 'Australian Made', 'Australian Grown' and 'Product of Australia'. These criteria are consistent with the country of origin safe harbours set out in the ACL.

Whereas a manufacturer has the option of making a 'made in' claim without regard to the ACL safe harbours if they believe they are making a true (and not misleading) claim, **AMCL's rules require applicants to be assessed against the criteria in the Code**.

Therefore, when evaluating applications to use the AMAG logo with 'Australian Made' on a particular product, AMCL must be satisfied that the last substantial transformation of that product has occurred in Australia.

In determining whether substantial transformation has occurred, AMCL will take into account legal precedents (where available) and published guidance issued by the ACCC.

This document sets out AMCL's guidelines on substantial transformation in relation to pharmaceuticals, complementary medicines and related products. From May 2018, AMCL will use these guidelines when assessing applications to use the logo on such products.

Products which are not discussed in the table below will be assessed on a case by case basis.

These guidelines may be amended where necessary as a result of relevant legal decisions or ACCC enforcement actions or publication of additional guidance by the ACCC.

Processing in Australia	Origin of active* ingredient/s	Example	Substantially transformed?
Blending (dry materials)	no significant Australian content**	imported vitamins and minerals blended to make a multi-vitamin powder	no
	significant Australian content	powdered Australian grown herbs with imported vitamins and minerals	yes
Blending (liquids)	no significant Australian content	blend of 5 imported essential oils	no
	significant Australian content	essential oil blend of 3 Australian and 2 imported oils	yes
Encapsulation - soft gel	no significant Australian content	imported krill oil	no
	significant Australian content	Australian produced emu oil with imported Vit. E	yes
Encapsulation - hard gel	no significant Australian content	imported glucosamine and chondroitin powders	no
	significant Australian content	powdered Australian grown herbs with imported vitamins and minerals	yes
Tableting (including granulation step)	no significant Australian content	imported vitamins and minerals combined to make a multi-vitamin tablet	yes
	significant Australian content	Australian seaweed extract combined with imported mushroom extract and tabletted	yes
Tableting (using imported granules)	no significant Australian content	imported vitamins and minerals combined to make a multi-vitamin tablet	no
	significant Australian content	Australian 'kangaroo essence' combined offshore with other actives to form granules, compressed into tablets in Australia	no
Tabletting (using DC grade ingredients)	no significant Australian content	imported vitamins and minerals combined to make a multi-vitamin tablet	no
	significant Australian content	Australian manufactured calcium combined with imported vitamins K and D	yes
Oil extraction (single active)	imported	black seed oil pressed from imported seeds	yes
	Australian	eucalyptus oil distilled from locally grown leaves	yes

Processing in Australia	Origin of active* ingredient/s	Example	Substantially transformed?
Herbal extraction (tinctures, infusions) (single active)	imported	extract created using imported herbs in alcohol	yes
	Australian	extract created using Australian propolis in alcohol	yes
Suspensions, solutions (multiple actives)	imported and/or Australian ingredients	cough syrup made with multiple actives	yes
Suspensions, solutions (single actives)	imported	liquid vitamin B made in Australia using imported Vitamin B	no
	Australian	liquid calcium made in Australia using locally manufactured calcium	yes
Semi-solid formulations (creams, liniments, lotions, toothpaste)	imported and/or Australian ingredients	skin cream made in Australia from raw materials	yes
	imported or imported and Australian ingredients	imported lanolin cream with Vitamin E and perfume added in Australia	no
Confectionery-style products	imported and/or Australian ingredients	vitamin gummies with imported actives	yes
Wafers/orally dissolvable film	imported and/or Australian ingredients	ingredients processed to produce 'wafers' or film	yes
Dehydrating (single active)	imported	imported herbs dried and packed	no
	Australian	Australian grown herbs dried and packed	yes
Packaging	imported	imported Vitamin C powder packed into sachets	no
Bottling	imported	imported bulk cod liver oil bottled with added orange flavour	no

* **actives and excipients** - ingredients in complementary medicines fall into two categories: 'actives' and 'excipients'. Actives are responsible for the physiological or pharmacological actions performed by a therapeutic good. By contrast, excipients are not therapeutically active and do not perform a physiological or pharmacological action. Common excipients include fragrances, preservatives, fillers or binders. The addition of excipients to an active ingredient or ingredients is not sufficient to constitute a substantial transformation.

** **significant Australian content** refers to the proportion (by weight or number) of Australian-produced active ingredients in a product. Whether a product has significant Australian content will be assessed on a case by case basis.

A note on food products and complementary medicines

There is a degree of overlap between food products and complementary medicines.

To assist businesses to determine how their products should be labelled, the TGA has provided a Food-Medicine Interface Guidance Tool which can be accessed online here.

AMCL is unable to assist businesses to determine whether a particular product is a food or a therapeutic good. Businesses need to make this decision before applying for a licence to use the Australian Made, Australian Grown logo on a product. If the product is labelled as a therapeutic good, then AMCL will assess it as such.

Following the introduction of the *Country of Origin Food Labelling Information Standard 2016*, AMCL is unable to grant new licences for food products, except where those products are to be sold exclusively overseas. Existing licences for food products may only be renewed beyond 1 July 2018 for use on export products.

For further information, please call Australian Made Campaign Limited on 1800 350 520 or email compliance@australianmade.com.au