

# CMA Discussion Paper: Country of Origin Labelling



## Executive Summary

Currently, there is no legal requirement in Australia for complementary medicine or pharmaceutical companies to state where products are manufactured, but if manufacturers make such claims these must comply with the *Australian Competition and Consumer Act*, which replaced the *Trade Practices ACT 1974* on 1 January 2011. As the regulatory environment progresses with its reforms to transparency and labelling requirements, including a focus on the health and safety of the informed consumer, it is now more than ever an opportune time for industry to consider its position on country of origin/manufacture labelling.

The CMA supports the promotion of a level playing field for Australian manufacturers of complementary medicines. In 2012, members of the CMA Manufacturing and GMP Committee met on this important issue and noted that a legislative change would be required before it was mandatory for country of origin labelling for listed and registered medicines. A number of considerations need to be balanced – for example, the provision of country of origin information to consumers versus the importance of individual companies being responsible for their labelling, marketing and promotion, as well as relevant manufacturing and sourcing decisions.

In Australia, in comparison to complementary medicines, CoOL is a requirement for the most basic of food products, fresh fish, processed goods, clothing, and also imported medicines or medical preparations for internal or external use. Therefore, it is a little surprising that therapeutic goods do not currently have a similar legal requirement. However, commencing a campaign to make country of origin labelling mandatory would require broad CMA member support and companies to be prepared to invest in the promotion of locally manufactured products.

## Draft CMA Position Statement

*The CMA encourages members of the complementary medicines industry to include country of origin information on product labels, to allow consumers to make informed choices and to assist in the promotion of Australian manufacturing. Any claim or impression that is made about the country of origin must be accurate and not misleading or deceptive.*

*Ideally, the minimum level of information for use on product labels is a qualified claim such as 'Made in Australia from imported and local ingredients' or 'Packaged in Australia from local and imported ingredients', although it should be noted that this does not inform consumers of the proportion of the ingredients that are local vs imported.*

*Where applicable, the CMA encourages industry to use the following clear and easy-to-understand statements for CoOL:*

### **'Product of Australia'**

- *The country of the claim must be the country of origin of each significant ingredient or component of the product*

- All, or virtually all, processes involved in the production or manufacture must have happened in Australia
- Similar expressions such as “Produce of” and “Produced in” should be unified under “Product of Australia”

**‘Manufactured in Australia’ / ‘Made in Australia’**

- The product was manufactured in Australia from imported and Australian components
- The goods must have been substantially transformed in Australia
- 50 % or more of the costs of production must have been incurred in Australia

The provision defines “substantial transformation” as:

- 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 examples based on the substantial transformation (ST) test criteria are as follows:

- Imported **single** ingredients in oil, liquid or powder which are packaged without further processing
  - Do not meet the ST test
- Imported **single** ingredient products in oil, liquid or powder from which processes such as encapsulation or tableting occur
  - Likely to satisfy the ST test
- Imported **multiple** ingredients mixed in Australia in one form which are then made into products in another form like powders into liquid, cream or granules for encapsulation or tableting (E.g. Multi-vitamin capsules)
  - Likely to satisfy the ST test

**“Packaged in Australia”**

- The product was packaged in Australia from imported and Australian components

**Background**

According to *the Competition and Consumer Act 2010*, issued by the Australian Competition and Consumer Commission (ACCC), country of origin labelling is defined as follows:

1. “Made in”, “Australian Made”, “Manufactured in”
  - The goods must have been substantially transformed in the country claimed to be the origin
  - 50 % or more of the costs of production must have been carried out in that country
2. “Product of”, “Produce of”, “Produced in”
  - The country of the claim must be the country of origin of each significant ingredient or significant component of the goods

- All, or virtually all, processed involved in the production or manufacture must have happened in that country

It has to be noted that these definitions are simply guidelines designed to give manufacturers / consumers basic information. There still remains a degree of legal uncertainty and the fear that manufacturers will be subject to private litigation. Moreover, there are many ambiguities which need to be clarified, such as the term “cost of production”.

In contrast, the Customs administered *Commerce (Trade Descriptions) ACT 1905* and the *Commerce (Imports) Regulations 1940* require imported medicines or medicinal preparations for internal or external use to have and maintain origin labelling. When goods claim to be ‘Made in Australia’ they must have incurred 50% or more of their total manufacturing costs in Australia. In the case that a product is assembled in different countries, the country of origin must be the place where the medicine is most substantially transformed.<sup>1</sup> As already described, compared to non-imported complementary medicines, imported medicines have a stricter and clearer regulation that must be followed.

Where it is not possible for a ‘Made in’ claim, either due to uncertainty around the question of substantial transformation and whether 50% costs of production is met, or to adjust to seasonal changes in availability of individual ingredients, manufacturers may make a qualified claim. Common examples of a qualified claim are ‘Made in Australia from imported ingredients’ or ‘Packaged in Australia from local and imported ingredients’.

Further, in the case of foods in Australia, country of origin labelling is required to appear on the label regardless of which country that may be. There is a growing body of opinion that as country of origin labelling is required for food, then complementary medicine should be treated the in the same way.

#### Consumer demand for country of origin labelling

According to a recent CHOICE survey on foods:

- 66% of consumers found it very important to have information on whether a product is manufactured or produced in Australia;
- 83% think it is important to support Australian owned companies and keep profits in Australia.
- 85% think it is crucial or very important for them to be able to identify if the food they buy has been grown in Australia;<sup>2</sup>
- a third of consumers said they always buy Australian food when available;
- 62% said they try to buy Australian but their decision depends on factors including the type of food and price.

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<sup>1</sup> *Labelling Requirements for Imported Medicines*, Australian Customs Service, [http://www.customs.gov.au/webdata/resources/files/FS\\_labellingRequirements.pdf](http://www.customs.gov.au/webdata/resources/files/FS_labellingRequirements.pdf), accessed 14<sup>th</sup> Sep 2013.

<sup>2</sup> Country of Origin Labelling, CHOICE, <http://www.choice.com.au/reviews-and-tests/food-and-health/labelling-and-advertising/nutritional-labelling/country-of-origin-labelling-survey-results.aspx>, accessed 14<sup>th</sup> Sep 2013.

The major consumer attitudes to 'made in Australia' and 'product of Australia' are considered as being associated with the following:

- safety standards (e.g. less exposure to chemicals and pesticides during the product process);
- quality standards;
- support for the Australian economy and industries;
- environmental factors (e.g. taking into consideration the environmental impact of transporting food products across the world).

Interestingly, a recent survey that was conducted by Australian Made Australian Grown in July 2013 revealed that buying Australian-made matters more for 55% of consumers now than it did a year ago, and they regularly buy local, even if it comes at a cost. Just one tenth of the surveyed consumers said that they would not buy Australian products if they were more expensive.<sup>3</sup>

### Simple labelling

According to the food label survey by CHOICE, although 38% of consumers are asking for food labels to disclose the origin of all ingredients in a product, and 24% are asking to at least see the origin of the ingredients in the greatest proportion, this is considered an unrealistic demand under the current circumstances.<sup>4</sup> With nutritional and herbal supplements, most of the ingredients are likely from more than one country, so stating "Made in Australia with local and imported ingredients" is considered more realistic than labelling the country of origin for every single ingredient, especially considering the time and money that would have to be spent on this.

However, there is some consumer confusion regarding the various 'Made in Australia' claims. One-third of consumers still believe 'Made in Australia' means that all ingredients are from Australia, as well as the manufacturing occurring in Australia. The claim 'Made in Australia from imported and local ingredients' thus appears contradictory to some consumers. Only 40% of consumers showed a good understanding for the definition of 'Product of Australia'. Clearly, there is a lack of understanding of country of origin labels and definitions. Therefore CHOICE recommends that, where possible, companies stick to simple, straight-forward country of origin labelling.

### Exporting in the Asian Century

This 'Asian Century' provides an opportunity to focus on increasing the export potential of the Australian complementary medicines industry. This is especially important considering the limited size of Australia's market in comparison to larger markets in Asia, Europe, and the Americas. The Australian complementary medicines industry has an opportunity to leverage 'Made in Australia' labelling along with our world-leading quality and safety standards.

According to '*Australian Functional Food, a healthy choice for functional food investment*' published by Invest Australia, Australia's food industry has a reputation for good quality and proximity to global markets. Due to the public awareness of the link between diet and health, the functional food

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<sup>3</sup> The Office Site of Australian Made, <http://www.australianmade.com.au/latest-news/2013/new-research-reveals-consumers-care-about-buying-local/>, Accessed 14<sup>th</sup> Sep 2013.

<sup>4</sup> *Country of Origin Labelling*, CHOICE, <http://www.choice.com.au/reviews-and-tests/food-and-health/labelling-and-advertising/nutritional-labelling/country-of-origin-labelling-survey-results.aspx>, accessed 12<sup>th</sup> Sep 2013.

industry has been growing dramatically. This high growth is expected not only in developing countries such as Latin America and Eastern Europe due to economic growth and increased disposable income, but also in larger markets including Japan, the US, and Western Europe due to a strong demand for functional foods as a result of an aging population, rising healthcare costs, and concern for food safety and environmental impacts.<sup>5</sup>

According to Australian Made Australian Grown, there is clear evidence of increased export potential through the use of their logos, which are registered certification trademarks used to assist consumers to identify Australian made and grown products. The products must be registered with Australian Made Campaign Limited (AMCL) and must meet the criteria in their Code of Practice before logos may be used. 94 % of Australian consumers recognize the logos and they have a higher reputation over any other country of origin identifier.

*The CMA could encourage Australian complementary medicine companies to employ the use of AMCL logos such as “Product of Australia”, “Australian Grown”, and “Australian Made”.*<sup>6</sup>

#### International comparators

In New Zealand country of origin labelling on foods is voluntary and suppliers (usually manufacturers, transporters or sellers) may choose not to display these details. But they must have contact details for distributors or manufacturers in New Zealand, so that consumers can request the information.

In the United States, with the globalisation of production activities, ‘Made in USA’ claims can also be complicated. According to the Federal Trade Commission (FTC), unqualified U.S. origin claims should be substantiated by evidence that the product is all or virtually all made in the United States. The “all or virtually all” standard for unqualified U.S origin claims must meet the following essential requirements:

- 1) The last substantial transformation of the product must take place in the United States
- 2) The final assembly or processing must take place in the United States
- 3) The amount of foreign content must be negligible or non-existent<sup>7</sup>

However, the definition of these requirements still remains unclear. For example, the fixed point for all products at which they suddenly become “all or virtually all” made in the U.S. does not exist; it therefore depends on a case-by-case basis.

Further, as is the case with Australia, the guidelines issued by the FTC regarding how it will apply this country of origin standard mainly focus on electronics and machines etc, which have very different manufacturing processes than CM manufacturers; making it even harder and more confusing for CM manufacturers to follow the guidelines.

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<sup>5</sup> *Australian Functional Food, a healthy choice for functional food investment*, Invest Australia,

<sup>6</sup> *2010 Survey of Exporting Logo Users*, Australian Made, <http://www.australianmade.com.au/media/54043/2010-SURVEY-OF-EXPORTING-LOGO-USERS.pdf>, accessed 13<sup>th</sup> Sep 2013.

<sup>7</sup> *Enforcement of Policy Statement on U.S. Origin Claims*, Federal Trade Commission, December 1997