ASMI
AUSTRALIAN
SELF MEDICATION
INDUSTRY

POSITION STATEMENT

Country of Origin Labelling for Complementary Medicines

Prepared for the Complementary Medicines Taskforce

31/01/2019

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Country of Origin Labelling for Complementary Medicines

ASMI Position

Manufacturing a therapeutic good in Australia from imported constituents (including imported active ingredients) is sufficient transformation to warrant a "Made in Australia" claim and changes are now necessary to make this clear.

Background

The Commonwealth Government has formed a Complementary Medicine Taskforce to examine the impact of changes to country of origin labelling requirements.

Country of Origin Labelling for Complementary Medicines (indeed for all non-prescription medicines) is a topic that ASMI and our members are keenly interested in and we are looking forward to assisting the Taskforce throughout its work.

ASMI members agree that manufacturing a therapeutic good in Australia from imported constituents (including imported active ingredients) is sufficient transformation to warrant a "Made in Australia" claim and that changes are now necessary to make this clear.

The narrow focus on the constancy of the active ingredients (e.g. "Fish oil is fish oil" – see below) is not appropriate, creates uncertainty for all stakeholders and makes it very difficult to apply the new "substantial transformation" test to therapeutic goods.

To provide certainty for the therapeutic goods industry, changes are necessary at least to the ACCC guidelines and to the way that the concept of "substantial transformation" is applied to therapeutic goods. Should such changes prove insufficient then changes to the ACL should be considered (either a change to the definition of substantial transformation in section 255(2) or by way of the examples contemplated under section 255(3)).

ASMI Members

Expectedly, there have been a range of views expressed by the ASMI membership:

- Some members have indicated that the recent changes will not have an impact on them (for example because they do not include a country of origin statement, or because they don't use the Australian Made logo at all, or because the products that display the logo have clearly and unambiguously undergone their last substantial transformation in Australia).

- Some members have indicated that the recent changes will have an impact on them (for example because the changes to the safe harbour criteria have created uncertainty as to whether they can continue to use the logo, or because the changes to the safe harbour criteria have created uncertainty as to which country (if any) should be specified on the label, or because the presence of the logo will influence their decision to acquire products, or because the absence of the logo will have a negative financial impact on the viability of their individual products, product ranges or manufacturing sites).

- For various reasons, some members have opted not to include a label statement as to origin at all, given that a country of origin statement is not mandatory for the labels of Australian therapeutic goods.

- One member has advised that certain countries[1] require the country of manufacture to be stated on the label. Exports from Australia to those countries therefore must have a country of origin statement on their label and so certainty around the Australian legal requirements is essential for the businesses exporting to those countries.

- One member has described clarity around country of origin labelling requirements as being "critical" to their business.

- One member has recently recruited a team specifically to market their products in China and anticipates that the potential loss of the Made in Australia claim will have a "direct and undermining effect" on this business initiative, as "all available evidence indicates that Made in Australia is important to Chinese purchasers".

- One member has advised that the current uncertainty makes them "think twice" before introducing new products if they are not confident of being able to claim them as made in Australia.

This Position Statement has the support of the ASMI membership.

[1] For therapeutics, cosmetics and devices. These include: Brunei, Indonesia, Malaysia, Singapore, Hong Kong, Korea, Taiwan, GCC countries (Bahrain, Kuwait, Saudi Arabia, Qatar, Oman & UAE). For cosmetics and devices these include: the EU. For therapeutics these include NZ.

Summary of Issues

ACCC Guidelines

On 29 January 2018, ASMI made a submission to the ACCC in response to their draft guidelines "Country of origin labelling for complementary healthcare products". While the March version of the ACCC Guidelines was an improvement over the earlier draft, many of our concerns remain.

We remain concerned that the ACCC Guidelines:

- Are inconsistent with the new "substantial transformation" definitions in the ACL
- Focus too much on the constancy of the active ingredients
- Are inconsistent with other ACCC guidelines on Country of Origin labelling
- Do not properly reflect consumers' expectations
- Do not properly appreciate the level of processing and transformation involved in making a therapeutic good out of its constituent ingredients
- Depart from the stated intent of the recent simplification of the "safe harbour" defences
- Will have a number of potential consequences, including an impact on all therapeutic goods (and not just complementary medicines)

A more complete discussion of these issues is contained in our 29 January 2018 submission, which has been separately provided to the Taskforce.

Nature's Care Case

ASMI has concerns about the recent Federal Court Decision of Nature's Care Manufacture Pty Ltd v Australian Made Campaign Limited [2018] FCA 1936, noting that:

- At paragraph 13, Perram J identifies the "central prohibition" in s 18 of the ACL regarding misleading or deceptive conduct. However, on finding that the safe harbour in s 255 of the ACL did not apply in this case, there was no subsequent inquiry made into whether there was a breach of s 18. The assumption seems to have been that a failure to satisfy the safe harbour criteria is automatically a breach of s 18 (i.e. if you are unable to use the statutory defence then you are necessarily in breach of s 18). This is not how we understand the safe harbour to work. If you meet the safe harbour criteria you can make the claim safe in the knowledge that you have a statutory defence. If you do not meet the safe harbour criteria then whether or not a claim is misleading (or likely to mislead) will depend on the facts of the matter. Perram J did not apply s 18 to the facts, there was only an application of s 255 to the facts.

- At paragraph 51, Perram J states that "Fish oil is fish oil". This focus on the constancy of the active ingredient mirrors the ACCC's focus in the guidelines and is entirely at

odds with the principles underpinning the manufacture of therapeutic goods. The active ingredient(s) must remain unchanged in order for the desired therapeutic effect(s) to be achieved and for the product's efficacy and safety to be accurately predicted and a substantial amount of transformation is involved turning raw materials into therapeutic goods.

- The decision also leaves open the question of the country where the soft-gel capsules actually originated from. We know that the fish oil was imported from Chile. Would consumers be misled, for example, by a claim that the capsules were made in Chile? Would an exporter of the capsules be meeting their legal obligations in the importing country if they stated on the label that the capsules were made in Chile?

"Produce of" vs. "Made in"

Section 255 of the ACL provides separate requirements for the "grown in", "produce of" and "made in" claims. For the "produce of" claim, there is a focus on the "country of origin of each significant ingredient or significant component" together with the "processes involved in the production or manufacture of the goods". We note that the country of origin of the ingredient is not part of the requirements for the "made in" claim.

In the Nature's Care case (as in the ACCC guidelines) because there has been a focus on the constancy of the active ingredient, we believe that undue emphasis is now being placed on the source country for the active ingredient(s). The result of this emphasis is a narrowing of the distinction between the "produce of" and the "made in" claims so that the requirements for a "made in" claim are now essentially the same as the requirements for a "produce of" claim (since both are now highly dependent on where the active ingredient came from). This narrowing and overlap of the definitions is not consistent with the legislative framework. After all, what is the point of having a "made in" claim if it is essentially the same as the "produce of" claim?

Australian Consumer Law

The recent change to the definition of "substantial transformation" in s 255 of the ACL appears to have introduced difficulties when applying the definition to therapeutic goods (because the "identity, nature and essential character" of the active ingredient(s) has to remain unchanged in the finished product). Is the safe harbour of s 255 now unavailable to therapeutic goods because of the necessary constancy of the active ingredient(s)? If so, is a change to the test/definition required?

Adding to the uncertainty, the change to the definition when coupled with a focus on the safe harbour of s 255 to the exclusion of the "central prohibition" in s 18 (see above) has apparently led to a reduction in the range of therapeutic goods that could reasonably claim to have been made in Australia.

Taskforce Considerations

We request that the Taskforce consider whether there is a problem with the:

1. New definition itself (which might require a change to the ACL),
2. Interpretation of the new definition, or,
3. Application to therapeutic goods (which could be addressed through guidance).

ASMI Position

ASMI members agree that manufacturing a therapeutic good in Australia from imported constituents (including imported active ingredients) is sufficient transformation to warrant a “Made in Australia” claim and that changes are now necessary to make this clear.

To provide certainty for the therapeutic goods industry, **changes are necessary** at least to the ACCC guidelines and to the way that the concept of “substantial transformation” is applied to therapeutic goods.

For some ASMI members the recent changes and the presence (or absence) of the Australian Made logo **will have business impacts** and these impacts will be magnified by the current uncertainties.

The final test of any country of origin statement is whether it is misleading, deceptive or likely to mislead or deceive (per s18 of the ACL). And this is to be ultimately determined by reference to the reasonable consumer viewing the statement.

The **“safe harbour” is a statutory defence only** (it is not the final test of whether s18 of the ACL has been breached). It is a preliminary tool. If you meet the safe harbour you can make the claim safe in the knowledge that you are protected. If you do not meet the safe harbour then you have to go through the exercise of determining whether a “reasonable consumer” would be misled or likely to be misled (taking into account all the circumstances of the matter).

A **substantial amount of transformation occurs in converting bulk active ingredients** (in some cases actual poisons) into high quality, safe, effective medicines (for a full discussion see our 29 January 2018 submission).

A number of other **countries require an origin statement** on the labels of products imported into their country and so certainty is required for businesses exporting to those countries.

ASMI has concerns about the ACCC guidelines (see above).

ASMI has concerns about the recent Nature's Care case (see above).

There seems to be a narrowing of the distinction between "produce of" and "made in" and so what is the point of having both if you are going to make "made in" synonymous with "produce of"?

Solution

The ACCC guidelines should be revised to reflect the complexities of therapeutic goods manufacture (i.e. that substantial transformation does take place - to the extent that an ordinary consumer would expect it - even though there will be no change to the active ingredients) and to reflect the approach to be taken should the safe harbour criteria not be met (i.e. to clearly position the safe harbour as a preliminary tool - and not the final test of compliance with the ACL).

Should such revisions prove insufficient then changes to the ACL should be considered (either a change to the definition of substantial transformation under section 255(2) or by way of the examples contemplated under section 255(3)).

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29 January 2018

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Dear Emma,

Country of origin labelling for complementary healthcare products – draft for consultation

Further to your correspondence of 21 December re the above.

I would like to thank you for involving us in the targeted consultation of your draft guideline on "Country of origin labelling for complementary healthcare products" ("the Draft Guide").

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

Introduction

ASMI welcomes publication of the ACCC's views on country of origin labelling for complementary medicines. We note your advice as follows in relation to the use of the guide:

> *"When reviewing the document please note that it does not constitute legal advice in its current draft form and will also not constitute such advice in its finalised form. While it reflects the ACCC's current views, ultimately the interpretation of the law will be up to the courts. The ACCC always recommends that businesses seek independent legal advice when deciding how to label their products."*

Nevertheless, the ACCC's publicly stated opinion on the matter will impact business behaviour and it is for this reason that the Draft Guide should be revised as described below.

Summary

We have a number of concerns with the Draft Guide which in our opinion takes too narrow a view of where a complementary medicine might reasonably be said to have been made.

In summary, the Draft Guide:

- Is inconsistent with the new "substantial transformation" definitions in the ACL
- Focusses too much on the constancy of the active ingredients
- Is inconsistent with other ACCC guidelines on Country of Origin labelling
- Does not properly reflect consumers' expectations
- Does not properly appreciate the level of processing and transformation involved in making a therapeutic good out of its constituent ingredients
- Departs from the stated intent of the recent simplification of the "safe harbour" defences
- Will have a number of potential consequences, including an impact on all therapeutic goods (and not just complementary medicines)

Each of these are discussed separately below.

The Australian Consumer Law (the ACL)

Subsection 255(2)(b) of the ACL states that:

> *Goods were 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.* [Emphasis added]

A change in the identity or nature of a product is therefore sufficient to meet the new "Made in" test.

Where, for example, the transformation of separate ingredients into a tablet takes place in Australia, it should be appropriate to describe the finished product as having been made in Australia because the tablet is a new product with identifiably different characteristics compared with the original ingredients, despite the therapeutic effect of the active ingredient remaining unchanged. ASMI's view is that a tablet manufactured from active ingredients and a number of excipients in accordance with a strict formula and under highly regulated conditions would clearly be different in identity, nature or essential character to the raw materials used and a reasonable consumer would share that view.

However, the ACCC views expressed in the Draft Guide appear to be based on the position that anything that is simply a mixture is not a substantial transformation of its ingredients, even if the mixture is processed, for example, by tabletting or encapsulation. This approach perhaps is founded on the principle that the ingredients of a simple mixture do not change their *identity*, at least in the case of mixtures that can be separated back into their constituents. The approach, however, fails to recognise that, under the ACL definition of "substantial transformation" the mixture can be "fundamentally different in … nature or essential character" from their ingredients. As stated above, a tabletted combination of an active ingredient with a number of excipients according to a strict formula and made under highly regulated circumstances does have a nature and essential character that is quite different from the powdered active ingredient. A simple proof of this concept is substitutability – if a consumer wanted a packet of aspirin tablets and was

given instead a jar of unregulated acetylsalicylic acid on the basis that the two are not "fundamentally different", they would in ASMI's view have a legitimate grievance (as well as potentially being in jeopardy). The "identity" of aspirin might arguably be found in the active ingredient, but the nature and essential character of an aspirin tablet in the Australian market lies also in its formulation and strictly regulated manufacture. ASMI would accept, for example, that an aspirin tablet and an aspirin capsule do not differ materially in identity, nature or essential character – the form is a matter for consumer preference – but both are substantially transformed from their active ingredient.

Constancy of the active ingredient

It has to be noted at the outset that the entire premise behind therapeutic goods formulation, manufacture, marketing and control is that the "effect on the body" of the bulk active ingredient(s) will not be altered by incorporation into a finished product.

We cannot emphasise this enough - the active(s) must remain unchanged in order for the desired therapeutic effect(s) to be achieved and for the product's efficacy and safety to be accurately predicted.

If a manufacturer incorporates an active ingredient into a tablet, then the regulator, the manufacturer, the healthcare professional and the consumer all expect that the effect on the body of that active ingredient will remain unchanged during the manufacturing process and throughout the shelf-life of the product.

Despite this, the Draft Guide contemplates (on page 5) that it will be "helpful" to consider whether the final product has "a fundamentally different effect on the body compared to its imported ingredients". This is a grave misconception and appears to colour the entire Draft Guide. It is difficult to conceive how such a therapeutic good could be made available!

Other ACCC Guidelines

The ACCC opinion on complementary medicines appears to be that since the active is still chemically the same there has been no substantial transformation. However, in other ACCC guides, this continuity of the imported starting material is no barrier to making a "made in Australia" claim. For example, in the March 2017 publication *Country of origin claims and the Australian Consumer Law*[1], we are advised (on page 12) that the following all amount to substantial transformations (even though the ingredients retain their identity in the final product):

- Cutting and sewing imported fabric to make a t-shirt
- Cutting, sewing and finishing imported leather to make shoes
- Combining imported soap noodles with pigments, fragrances and other components to create bars of soap

In that same publication (on page 9) we are also advised that:

> *A claim that a good was made, manufactured, or otherwise originated in a particular country is simply a representation about <u>where the good itself was created</u>. … This means that a good doesn't need to contain any ingredients or components from a country to be able to claim that it was 'made' in that country.* [Emphasis added]

[1] https://www.accc.gov.au/publications/country-of-origin-claims-and-the-australian-consumer-law

The content of the March 2017 publication appears to be at odds with the opinions expressed in the Draft Guide.

In a similar fashion the April 2017 publication *Country of Origin food labelling*[2], also appears to be at odds with the Draft Guide. For example, on page 8, we are advised that the following all amount to substantial transformation (once again, even though the ingredients retain their identity in the final product):

- Mixing imported meat with sauces, spices and vegetables to make a ready-to-bake Meatloaf
- Curing and drying imported pork to make bacon
- Mixing imported ingredients together and using the mixture to bake a cake
- Baking a frozen raw imported pie
- Mixing imported prawns and squid, seasoning and processing them to make a mixed seafood snack
- Cooking imported dried pasta, rice or legumes

And in that same publication (on page 7) we are advised that:

> *A food is made in a country if it underwent its last substantial transformation in that country. The emphasis of this origin claim is therefore on the production of a food rather than its content.*

It is also worth noting that the ACCC website[3] contains the following advice:

> *The 'made in' claim means that food underwent its last substantial transformation in the country specified (this doesn't necessarily mean that any ingredients are from that country). Certain processing such as slicing, canning, freezing, coating or repacking food will be insufficient to justify a 'made in' claim.* [Emphasis added]

The ACCC's current focus on the need for a complementary medicine to have a fundamentally different effect on the body compared to its imported ingredients is therefore puzzling and inconsistent with previous publications. ASMI's view is that, like other goods, the question should be whether the processing "has clearly resulted in a new product with identifiably different characteristics[4]".

Recommendation: The Draft Guide should be revised to be consistent with existing publications and to recognise the necessary absence of change in the active ingredients incorporated into therapeutic goods.

Consumer expectations

As the Draft Guide (and previous ACCC publications) all note, the safe harbours are a statutory defence against an allegation that the country of origin claim is false, misleading or deceptive under the Australian Consumer Law ("the ACL"). The safe harbours provide "the benefit of a statutory defence" by describing "situations where you can safely make a country of origin claim without it raising concerns under the law" and thereby give "peace of mind" and "certainty" to businesses.

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[2] https://www.accc.gov.au/publications/country-of-origin-food-labelling

[3] https://www.accc.gov.au/business/advertising-promoting-your-business/country-of-origin-claims/country-of-origin-food-labelling

[4] https://www.accc.gov.au/publications/country-of-origin-claims-and-the-australian-consumer-law (at page 10)

ASMI notes the following statement on page 2 of the Draft Guide:

> *Failure to satisfy the safe harbour criteria for a particular claim doesn't necessarily mean that a business is unable to make such a claim. You may still choose to make that type of origin claim provided an ordinary reasonable consumer wouldn't consider it to be false, misleading or deceptive.*

While the safe harbours are useful tools, the real test of a claim is whether it is false, misleading or deceptive under the ACL. A proper assessment of any claim needs to involve an examination of all the circumstances together with an estimate of the reaction of a reasonable consumer exposed to the claim.

In our view, the Draft Guide focusses too much on a narrow interpretation of substantial transformation, omits a proper consideration of the circumstances and omits an estimate of the reasonable consumer's likely reaction.

So, what will the reasonable consumer think when they see a claim that a complementary medicine has been made in Australia?

We think that a reasonable consumer seeing a "made in Australia" claim on a complementary medicine (or any therapeutic good for that matter), will assume that:

- The tablet, lozenge, capsule, liquid or cream *itself* was made in Australia (e.g. these *tablets* were made in Australia), and
- The product was made in an Australian facility, applying Australian manufacturing standards, complying with Australian regulatory obligations and employing Australian workers under Australian working conditions

The consumer may also anticipate that some of the profits from the product will stay in Australia.

In our view, it is highly unlikely that a consumer will think that the claim means that the active ingredients were synthesised and/or fundamentally changed in Australia.

Recommendation: The Draft Guide should be revised to better reflect the circumstances surrounding claims made about medicines and to better reflect the reasonable consumer's likely reaction to those claims.

Recommendation: Independent consumer research should be undertaken to determine what impressions or expectations consumers do form on seeing a "made in Australia" claim on their medicine.

Therapeutic goods manufacture

The Draft Guide appears to be based on the premise that therapeutic goods manufacture is merely blending and portioning of ingredients into convenient lots, that it is a mere repacking, that it is akin to slicing and dicing, that it only produces something that is *somewhat* different to the ingredients, that it is simply adding convenience or decoration, that it is "finishing off the product" or merely changing the form or appearance of the ingredients.

Nothing could be further from the truth.

Therapeutic goods manufacture is a high skill, high technology process that transforms poisons into safe, stable and effective medicines. The application of expertise, technology and intellectual property converts potentially poisonous bulk active ingredient(s) into vehicles for delivering safe and effective measured doses.

Therapeutic goods manufacturing makes poisons safe to consume.

So what actually happens in an Australian licensed manufacturing facility?

After all the necessary research, development, compliance and regulatory activities, the following typically occurs under the careful oversight of highly skilled workers, in a highly controlled manufacturing environment:

- Receipt and testing of the starting materials
- Receipt and testing of the packaging components
- Combining the ingredients into a bulk mixture in a precisely fixed ratio
- Testing the bulk mixture
- Processing the bulk mixture into its final form (e.g. tablet, lozenge, capsule, liquid, cream, etc.)
- Testing the final form
- Packaging the final form and storing under controlled conditions prior to distribution

In this way (and only in this way) the identity, the purity, the uniformity of dose, the safety, the efficacy and the shelf-life of the finished product are achieved.

The safe, effective and predictable dosing of what would otherwise be a poison is thereby assured.

Recommendation: The Draft Guide should be revised to properly reflect the complex transformation involved in the manufacture of medicines.

Recent simplification of the safe harbours

ASMI is concerned that the Draft Guide appears to be inconsistent with the motivations behind the recent simplification of the safe harbour defences in relation to country of origin labelling.

In 2015/2016, the Department of Industry, Innovation and Science undertook a series of consultations looking at (among other things) simplifying the safe harbour defences.

At that time the removal of the 50% production cost was presented as a mere simplification of the existing requirements (i.e. instead of having to satisfy both limbs of a two-limb test, manufacturers would only have to satisfy one test). There was no suggestion that the definitions themselves would be changing. The very clear message at that time was that products meeting the criteria before the simplification exercise would continue to be able to make a country of origin claim afterwards.

In short, the reforms were supposed to make things simpler and clearer (without changing the standard to be applied).

In February 2017, the revised safe harbours for country of origin came into force. At that time, the Department of Industry, Innovation and Science, clearly indicated that[5]:

[5] https://industry.gov.au/industry/industrysectors/foodmanufacturingindustry/pages/country-of-origin-labelling.aspx

> *The amendment is primarily intended to simplify the tests used to justify a country of origin 'made in' claim by clarifying what substantial transformation means and removing the 50 per cent production cost test.* [Emphasis added]

The key issue from our perspective is that the revised "substantial transformation" definition was intended to remove the ability of companies to rely on the costs incurred in minor processing, packing or repacking to make a "Made in Australia" claim. This was emphasised in the Second Reading speech given by the Minister, who stated that the intention of the new changes was to:

> *"…make it clearer that minor processes such as packaging, slicing or canning are not sufficient to justify origin claims like 'made in', consistent with consumer expectations and international norms*[6]"

Published guidelines for food and other products follow this approach.

Despite this, the Draft Guide appears to be introducing a very narrow definition of substantial transformation which is inconsistent with the representations made during (and after) the 2015/2016 consultations which supposedly only led to simpler and clearer requirements.

Recommendation: The Draft Guide be revised to better reflect the recent simplification exercise conducted by the Department of Industry, Innovation and Science.

Potential (unintended) consequences

In addition to the issues with the Draft Guide raised above, we are concerned about the following potential consequences:

1. The narrow approach described in the Draft Guide will apply equally to all medicines, even though the Draft Guide is expressed to be specific to complementary medicines (since the manufacturing assumptions and principles are broadly the same regardless of the regulatory classification of the medicine). So prescription medicines and over-the-counter medicines will end up being assessed against this same narrow perspective. Applying a narrower interpretation of "substantial transformation" for medicines compared with food could also increase confusion for consumers.

2. The pool of products that will be able to make a "made in Australia" claim will be greatly reduced (since very few active ingredients are actually made in Australia). A large number of active and inactive raw material ingredients will always need to be sourced overseas, as they are not commercially made or grown in Australia (for example active ingredients such as paracetamol and ibuprofen are not made in Australia and herbs used in Ayurvedic medicines are traditionally grown in India).

3. The export potential of medicines made in Australia will be diminished if they are unable to make a "made in Australia" claim (since the good reputation of Australian manufacturing standards and our strict regulatory oversight is what drives exports).

4. There will be increased uncertainty around country of origin claims for medicines and increased red tape associated with making those claims. Faced with such uncertainty, there is a risk that manufacturers will just remove the voluntary country of origin statement from their medicines labels, thereby reducing information for consumers. For example, consider

[6] Second Reading Speech, Mr Laundy, Assistant Minister for Industry, Innovation & Science, 1 September 2016

a single active tablet made in Australia using an Indian source for the active ingredient – under the Draft Guide the product could not be described as "made in Australia" and would probably be described as "made in India". Would consumers think that the tablet was accurately described as having been made in India? Now consider the same single active tablet made in India using an Australian source for the active ingredient - under the Draft Guide the tablet would be described as being made in Australia, but wouldn't consumers be more likely to think of the tablet has having actually been made in India[7]?

Further suggestions

In addition to the suggested revisions above, we would encourage the ACCC to:

- Withhold publication of the Draft Guide until the above issues have been addressed.
- Continue to work with the whole of industry to understand industry processes and imperatives.
- Work with consumers to understand their expectations of country of origin claims.
- Work with the Therapeutic Goods Administration to better understand therapeutic goods regulation and to ensure consistency of approach between different regulators (on this point we are especially concerned that the "note" on page 3 of the Draft Guide explains that the ACCC's view on what amounts to substantial transformation in relation to therapeutic goods is "separate and different" to whether a product has been "manufactured" according to the TGA).
- Work with the Department of Industry, Innovation and Science to ensure consistency of approach between different Government agencies (see our comments above under "Recent simplification of the safe harbours").

We remain available to meet with you to discuss any of the above should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

[7] The consistent theme throughout the Draft Guide is that the country of origin of the starting material is likely to be the country of origin of the finished product (since the preparation of the finished product is unlikely to amount to a substantial transformation). However the example on page 11 of the US grown gingko biloba being tabletted in Korea takes an even more confusing approach, suggesting that the product was neither made in Korea nor made in the USA.