30 October 2019

Department of Industry, Innovation and Science

Trade Facilitation

PO Box 2013

Canberra ACT 2601

Submitted online and by email to: [tradefacilitation@industry.gov.au](mailto:tradefacilitation@industry.gov.au)

Dear Sir or Madam,

**Eligibility for origin claims in the Complementary Medicines Sector**

**Consultation Regulation Impact Statement**

We refer to the notice inviting public comment regarding the above.

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include **improving health literacy**, **growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

CHP Australia welcomes the opportunity to provide this submission in relation to the Consultation Regulation Impact Statement (RIS).

Summary

Our 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.

In our view:

* A substantial amount of transformation occurs in converting bulk active ingredients (in some cases actual poisons) into high quality, safe, effective medicines.
* Substantial transformation does take place – to the extent required by law and to the extent that an ordinary consumer would expect it - even though there will be no change to the active ingredient(s).
* A reasonable consumer would not be misled or deceived by a “Made in Australia” claim on a product which had undergone the TGA approved step of “Manufacture of dosage form” in Australia.
* The TGA approved step of “Manufacture of dosage form” will be a good basis for identifying the transformation of imported ingredients into an Australian product
* Any reforms arising from this consultation need to also accommodate over-the-counter medicines and prescription medicines.

For the reasons outlined below, we support Option 3(a).

All therapeutic goods

As we have indicated in the past, this issue affects all therapeutic goods and not just complementary medicines. The country of origin reforms, the changes to the Australian Consumer Law and the resulting changes in access to the Australian Made logo apply equally to all medicines.

The manufacturing processes, the levels of transformation and the consumer expectations/understandings will be broadly the same regardless of the regulatory classification of the medicine (compare for example the level of transformation required to make a fish oil liquid-filled capsule with that required to make an ibuprofen liquid-filled capsule).

Any reforms arising from this consultation will need to also accommodate over-the-counter medicines and prescription medicines.

The Safe Harbour

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 Australian Consumer Law (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).

Consumer expectations

In our view, the starting point for any examination of country of origin labelling is a full consideration of the product, the claim and the reasonable consumer’s likely response. What will a reasonable consumer think when they see a claim that a medicine has been made in Australia?

We think that a reasonable consumer seeing a “made in Australia” claim on a medicine 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

In such a situation the claim that the product was made in Australia will not be misleading (and will therefore not amount to a breach of s18 of the ACL).

In our view, it is highly unlikely that a reasonable consumer will think that the claim also means that all the active (and inactive) ingredients were synthesised and/or fundamentally changed in Australia prior to the finished product being manufactured in Australia.

As we understand it, the ACCC’s view (and the view expressed in the recent Fish Oil case[[1]](#footnote-1)) is that regardless of the likely opinion of the ordinary reasonable consumer viewing the claim (and regardless of the operation of s18 of the ACL), the amount of transformation that takes place in manufacturing a medicine is insufficient to comply with the safe harbour and so the Australian Made logo cannot be applied to the product.

Our view is that a reasonable consumer would not be misled or deceived by a “Made in Australia” claim or logo on a product which had undergone the TGA approved step of “Manufacture of dosage form” in Australia.

This misalignment between the application of the safe harbour and the operation of s18 in relation to therapeutic goods must therefore be addressed.

Addressing of the issue

The current issue can be described as follows:

* The change to the definition of “substantial transformation” and the application of this new definition to therapeutic goods has led some parties to form the very narrow view that the manufacture of a complex therapeutic good from its constituent ingredients is not a *substantial* transformation, because the active ingredient in the finished product remains unchanged following its incorporation into the finished product.
* Subsequently, there has been a disproportionate focus on the safe harbour defence to the apparent exclusion of s18 of the ACL.
* In our view, a reasonable consumer would not be misled or deceived by a “Made in Australia” claim on a product which had undergone the TGA approved step of “Manufacture of Dosage Form” in Australia because products which undergo this step do satisfy the substantial transformation test.
* However, recent cases have made this less clear and have created business uncertainty.
* This uncertainty must now be addressed either by:
  + changing the wording of the test, or, failing that:
  + clarifying pursuant to s255(3)(b) that goods which undergo the TGA approved step of “Manufacture of Dosage Form” in Australia do satisfy the substantial transformation test.
* This clarification would provide industry with the certainty that the extensive manufacturing process they undertake in Australia for these products is being properly acknowledged.
* This clarification needs to apply to the substantial transformation test itself, as well as access to the claim and access to the logo.

Manufacturing

As we have indicated in our previous submissions on this topic (See Attachments 1 and 2), therapeutic goods manufacture is not merely blending and portioning of ingredients into convenient lots, it not is a mere repacking, it is not akin to slicing and dicing, it does not just produce something that is somewhat different to the ingredients, it is not simply adding convenience or decoration, it is not “finishing off the product” or merely changing the form or appearance of the ingredients.

Rather, therapeutic goods manufacture is a high skill, high technology process that transforms ingredients (some of which might be 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 potential poisons safe to consume.

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[[2]](#footnote-2) (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 could otherwise be a poison is thereby assured.

With all this in mind, it is therefore clear that the TGA approved step of “Manufacture of dosage form” will be a good basis for identifying the transformation of imported ingredients into an Australian product.

While the Consultation RIS rightly acknowledges that “Manufacture of dosage form” involves a “transformative action” [page 26], the *substantial* nature of this transformation appears to have been downplayed. The substance and complexity of the transformation is evidenced by the close, detailed, prescriptive and rigorous control imposed by the TGA.

In our view, undertaking the TGA approved step of “Manufacture of dosage form” should permit the use of the Made in Australia claim and the Australian Made logo.

Constancy of the active ingredient

As we have stated in previous submissions, 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.

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.

Australian Consumer Law

As the Consultation RIS acknowledges, 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 *active ingredients* themselves have to remain unchanged in the *finished product*).

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 good is therefore sufficient to meet the 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.

Our view is that a tablet manufactured from active ingredients and 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. A reasonable consumer would not be misled or deceived by a “Made in Australia” claim on such a product.

However, the recent ACCC guidance (and the recent Fish Oil case) have created confusion because they have taken the very narrow view that the finished good is not “fundamentally different in identity, nature or essential character from all of their imported ingredients” because the active ingredient in the finished product remains unchanged following its incorporation into the finished good.

If this narrow view of “substantial transformation” prevails and the safe harbour of s 255 is not available to finished *therapeutic goods* because of the necessary constancy of the *active ingredient(s)*, then either a change to the wording of the test is required or a change to the Regulations (per section 255(3)(b)) is required.

Section 255(3)(b)

Section 255(3)(b) of the ACL provides a mechanism for the Regulations to include examples of processes or combinations of processes which do amount to a “substantial transformation” for the purposes of the safe harbour defence.

Given the uncertainty which now surrounds therapeutic goods and country of origin, we would support an action under s255(3)(b) which specifies that undertaking the TGA approved step of “Manufacture of dosage form” at an approved Australian site does satisfy the substantial transformation test in s255(2)(b).

RIS Option 1 *Status quo*

Not supported, for a range of reasons but principally because it will not address the very real issue now being faced by manufacturers and sponsors of therapeutic goods.

RIS Option 2 *Industry-led regulated branding*

Not supported for a range of reasons, but principally because of the huge time and cost implications involved together with the complications of developing something that is acceptable to the whole of industry and that would be trusted by consumers.

RIS Option 3a *Complementary medicines manufactured in Australia are eligible to use the AMAG logo*

Supported, and for the reasons outlined above, this option should be implemented with regard to all medicines. This option also makes it clear that medicines which undergo the TGA approved step of “Manufacture of dosage form” in Australia can access the Made in Australia claim and the Australian Made logo.

RIS Option 3b *As per Option 3; plus a statement on the packaging listing that the ingredients are imported*

Not supported for a range of reasons, but principally because this option (like option 3c) will create further distinctions between foods, therapeutic goods and other non-food categories where the AMAG logo is used (for example beauty, skin care, cosmetics, clothing, footwear and furniture) given that “around 31% of logo usage falls into the broad ‘other consumer’ category”. [page 24 of the RIS]

RIS Option 3c *As per Option 3; plus a visual representation of the proportion of ingredients that are imported.*

Not supported for a range of reasons, but principally because this would effectively re-introduce the financial and record keeping complexities that were removed along with the 50% production cost element of the safe harbour defence and (like option 3b) will create further distinctions between foods, therapeutic goods and other non-food categories where the AMAG logo is used.

Please don’t hesitate to contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steve Scarff

Regulatory and Legal Director

*Attachment1* The ASMI Position Statement on Country of Origin Labelling (prepared for the Complementary Medicines Taskforce 31/01/2019)

*Attachment 2* ASMI submission to the ACCC re their draft *Country of origin labelling for complementary healthcare products* (29 January 2018)

1. *Nature’s Care Manufacture Pty Ltd v Australian Made Campaign Limited [2018] FCA 1936* [↑](#footnote-ref-1)
2. The processing will be even more complex should the characteristics of the active ingredient be modified to either accelerate or slow down its release into the body. [↑](#footnote-ref-2)