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CMA Submission addressing the Consultation Regulation Impact Statement for the Legislative & Governance Forum on Consumer Affairs

Clarifying eligibility for origin claims in the Complementary Medicines Sector

Complementary Medicines Australia (CMA) welcomes the opportunity to respond to the Consultation Regulatory Impact Statement relating to Country of Origin representations. This submission articulates the Complementary medicines sector's supported way forward to changes required to the Australian Consumer Law ('ACL'), which would provide clarity for the application of key tests to making a Country of Origin labelling ('CoOL') claim and reinstate eligibility to use the Australian Made ('AMAG') logo.

The changes outlined in this submission, subject to agreement with the states and territories, would:

- Rectify the unintended consequences the food labelling CoOL reform process had on the sector; the intent of the reforms at that time was that very few products would be affected by the application of the new test.
- Provide greater consistency in the application of the substantial transformation test across consumer goods.
- Reinstate the sector's access to the premium Australian Made logo, supporting the contribution of complementary medicines to the economy.
- Enhance transparency, and subsequently enhance consumer's assessment of the country of origin of products.

CMA calls on the Government to expedite the required legislative update to the Australian Consumer Law (ACL) to ensure the advanced manufacturing of health products continues in Australia.

Position

Complementary Medicines Australia supports Option 3a. *Complementary medicines manufactured in Australia are eligible to use the AMAG logo*. The sector advocates to maintain the current AMAG logo, through the appropriate application of the ACL and substantial transformation test to the sector by recognition of Australian made medicines manufactured according to the principles of "Good Manufacturing Practice" (GMP). This position is in line with the commitment made by Government after a Taskforce[1] into the matter, announced on the 5 April 2019.[2]

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 process or combination of processes that have the result of 'substantial transformation' as described in subsection 2(b).

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 Australia in accordance with prescribed Manufacturing Principles within the *Therapeutic Goods Act."***

The position of the industry promotes recognition that finished medicinal product manufacture under GMP creates a substantially transformed consumer good, which is a medicine, by utilising a mechanism in the overarching legislation to specifically define a particular class of goods as 'substantially transformed'. This, by virtue, allows genuine Australian manufacturers the qualification to use the AMAG logo.

Australian manufacturing is widely known to hold significant barriers to survival in an increasingly mobile global trade platform with rapid distribution capabilities. The Made in Australia Campaign was originally established to encourage people to buy locally made goods and strengthen the profile of local manufacturing industries that face significant survival challenges in this globally competitive economy.

Impact on Industry

This is a crucial reform for the Government. The impacts already felt by the sector and should status quo be maintained include:

- **Loss of competitive advantage and key differentiator**: devalue Australian Complementary health products, particularly in export markets and would send a signal to international markets of a drop in Australia's hard-earned quality and safety reputation.
- **Halt a booming industry**: discourage investment/expansion/innovation in Australia - one of Australia's few growing manufacturing sectors.

[1] Department of Industry, Innovation and Science, (2019) *Country of Origin Labelling Complementary Healthcare Taskforce Report*, Canberra Australia.
[2] The Hon Karen Andrews MP, (2019) *Backing the Complementary Healthcare Industry* [Press Release] 5 April. Available at: https://www.minister.industry.gov.au/ministers/KarenAndrews/media_releases

- **Uncertain future for industry**: Manufacturing arrangements taken to offshore locations with more accommodating production costs and market entry.
- **Cost to business**: relabelling, modified marketing, lower retail price point.
- **Loss of jobs**: no investment means no future industry.

Executive Summary

CMA, as a leading peak industry body, 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 Country of Origin representations.

The issues the industry have been raising over the last 18 months 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 revised ACCC guidelines for the sector, is a critical, outcome of the considerations raised in this submission.

Australia's complementary medicines are unique in the world in that they are commonly recognised as being world leading in the category for safety and quality due to Australia being one of few countries who manufacture these health enhancement products as medicines, not foods. The regulatory and consumer safety distinction between these two categories is critical, and its basis lies in medicinal grade 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, Australian 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, including international 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 safety and quality.

The changes to the ACL, as part of the food labelling reform, have had a detrimental effect on many complementary medicine businesses and Australia's manufacturing industry, as many established products have not been eligible to make a "Made in Australia" claim. The current approach is hugely prohibitive and counter-productive to the competitive advantage enjoyed by Australian manufacturers as a result of maintaining the exceptional level of pharmaceutical standards expected.

From the perspective of the consumer, transparency has been reduced as an unintended consequence of these reforms, where previously consumers were able to seek out products labelled as Australian Made. It is known that consumers place a high value on representations of Australian Made. Denying access to the use of the logo will likely lead to a change in consumers purchasing behaviour, impacting gross industry sales.[3]

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 were to continue and

[3] Department of Industry, Innovation and Science (2019) *Colmar Brunton Consumer Research Report*

Australian-made products were unable to identify themselves as such, then this will be the inevitable outcome for the complementary medicines manufacturing industry. 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.

Substantially transforming ingredients to medicines

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 finished medicines suitable for use as therapeutic agents. These reasons are fundamental to the industry proposal outlined in this submission to amend the Competition and Consumer Regulations to recognise medicines manufactured in a TGA-licensed Australian manufacturing facility as 'substantially transformed' and therefore by extension qualify to 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 same claim on goods that undergo far less 'transformation' within Australia than medicines do under TGA-GMP, for example, the cutting and sewing of fabric produced in other countries from overseas grown components such as wool or cotton into a suit.[4]

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 led to the establishment of a Government 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 Australia its unique reputation means the industry does not and cannot compete globally on price. Highly specific scientific technical expertise unique to the Australian GMP requirements for complementary medicines is a particularly relevant aspect. 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 5.2 billion dollar industry[5] with a $1.2 billion export market.[2]

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

[4] ACCC, (2019) *Country of origin claims and the Australian Consumer Law*

[5] Complementary Medicines Australia (2019) *Australia's Complementary Medicine Industry Audit Canberra, Australia: Available at: http://www.cmaustralia.org.au/*

be 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 laws, companies cannot communicate that these products are Made in Australia.

While Australia currently remains largely reliant on imports of raw ingredients for the production of complementary medicines, findings from the government taskforce suggest that Australian firms add significant value to outgoing products. For example, in relation to vitamins, analysis by the Office of the Chief Economist shows the Australian industry adds about 63 per cent ($11 per kilogram) of value to vitamins that we export.

Food regulations vs therapeutic goods

Products that are classed as therapeutic goods (this includes complementary and other medicines) are regulated by the Therapeutic Goods administration (TGA) at a federal level while foods are largely regulated by state and territory food regulatory bodies.

The food sector and other consumer goods sectors would not be negatively impacted by the introduction of Option 3a); as proposed in the DIIS consultation; that complementary medicines manufactured in Australia are eligible to use the AMAG logo, rather it would provide greater clarity and certainty for business.

Made in

A 'made in' claim is a representation about the production process undertaken to create a good. A product can be described as having been *made* in a country if it underwent its last *substantial transformation* in that country. That is, it underwent major processing in Australia such that it can claim Australian origin.

Businesses will have the benefit of the ACL's 'made in' safe harbour defence if the product underwent its last substantial transformation in the country named.

Substantial transformation

The revised definition of substantial transformation removed the 50 per cent production cost test from the 'Made in' safe harbour defence and aimed to clarify what had to occur to imported ingredients for a domestic producer to claim to have substantially transformed those imports.

According to Australian Consumer Law (*Competition and Consumer Act 2010*), a good is substantially transformed in a country if:

- it was 'grown in' or 'produced in' that country, **or**
- as a result of one or more **processes** undertaken in that country, the end product is fundamentally different in identity, nature or essential character from all of its imported ingredients or components.

CMA believes that defining the **processes** that constitute substantial transformation by incorporation into regulations, as proposed in this submission and which have the Governments principal support, would provide more certainty and allow for greater clarity.

This approach is appropriate and would not impact the current AMAG application on the food sector or other consumer goods. The defining ability in the Regulations is exactly for this purpose of acknowledging there are other processes that can meet the substantial transformation test.

Support for Australian Made

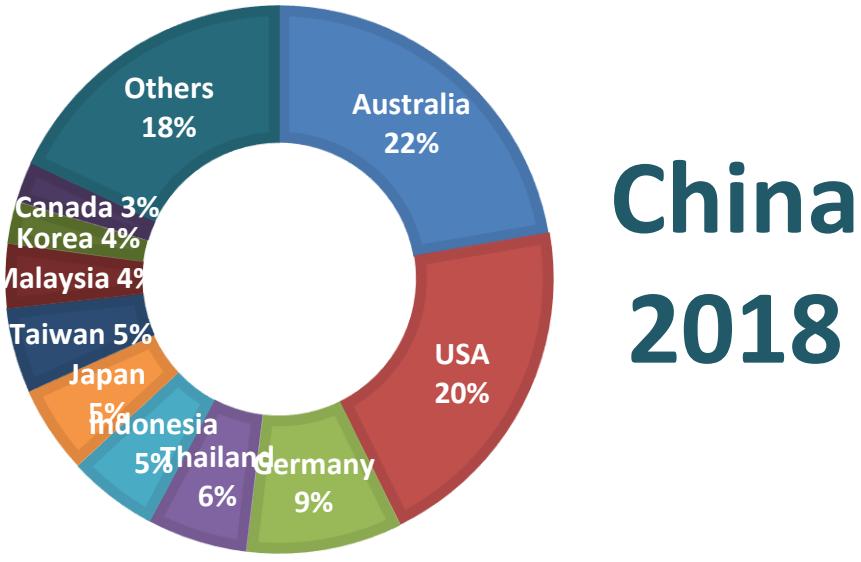
Consumers understand that support for Australian manufacturing is a key tenant of a thriving economy and a healthy jobs market in Australia. As in the USA and other countries, many Australian consumers have a strong personal interest and passion in supporting local industries and job creation.

Moreover, a wide range of consumers specifically seek out the exceptional quality of Australian made complementary medicines made in TGA-inspected GMP facilities.

Consumers should have access to information that the complementary medicines they consume has 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? What are the medicinal or quality regulations of those countries?

Support for Australian Made in China and other countries

Similarly, international consumers strongly seek out the excellent Australian reputation for ethical, safe, and high quality manufacturing. Based on our reputation to date, Australia has become the largest source of Nutrition and Health Food Imports with import volume of AU $940 million (US $670 Million), followed by USA US$ 620 million, and Germany US$280 million. Australia year on year growth of imports into China of Nutrition and Health Food Imports is an incredible 60.8%.[6]



[6] China Chamber of Commerce for Import and Export of Medicines and Health Food Products (2019) China Import Data- Health Foods, Beijing: s.n.

The consultation paper recognised the existing use of the logo by some sponsors who currently penetrate the Chinese market. Market penetration in China and other countries occurs by several mechanisms, including:

- the daigou trade, which is already well known in Australia as popular for complementary medicines. Daigou is the name for a group of Chinese who are residing abroad, buying on behalf of their families and friends back in China;
- cross border e-commerce;
- direct "brick and mortar" stores when regulatory approval and access is gained.

In 2016, the daigou business was worth an estimated A$800M in Australia. According to a research conducted by a Chinese media lab the market could grow to a jaw dropping 150 billion USD globally by 2018[7]. Growth is still booming. Chinese health food segment growth is 8.4% (2017-18). With a total potential size of $68B USD, imports alone are expected to grow by $3b USD to reach $11b by 2024[8]. Without international consumers being able to easily discern the difference between Australian manufactured complementary medicines and other dietary supplements, Australia will lose its most significant and important marker of its identity.

Support for Australian businesses, large and small

The consultation paper recognises the existing use of the AMAG logo by some sponsors in the complementary medicines space.

For large businesses, the application of a simple recognition of an established Government process (licensed Australian GMP manufacture) as promoted by our submission, produces a straightforward, low-red-tape option that will facilitate the further use of the logo across brands, and further the expansion of our high quality industry into China, but importantly, into other countries, including Asia and the Middle East.

For small businesses and start-ups, the cost of starting new business and using an Australian manufacturing facility can be cost prohibitive in Australia. The benefits of using the AMAG logo to penetrate new markets, thereby facilitating the ability to create and maintain a viable local business, is seen as an exciting possibility for innovation in the sector. Further, it stimulates the opening of new manufacturing facilities that can support the needs of sponsors who initially need smaller batches, or those seeking specialty services.

Regulatory Impact - Complementary Medicines Industry

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. The current situation could be considered an example of the Government kneecapping itself. A sector that is growing at a pace faster than the economy cannot be left with this uncertainty.

[7] Australia China Daigou Association; presentation (2019); Available at: http://www.cmaustralia.org.au/
[8] Euromonitor International Australia (2019), Complementary Medicines, Market Data 2017-2018, Sydney: Euromonitor International Australia.

Understandably, the change in approach and review of over 200 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.

Manufacturers are currently having to make business decisions on the regulatory landscape as to whether business survival is best served by remaining or even expanding facilities in Australia, or whether to move offshore into New Zealand, China, other countries in the Asia Pacific, or even further abroad. Therefore, the urgency of this decision cannot be underestimated.

CMA actions in response to changes

CMA has maintained ongoing and regular contact with the Government and administrators of the ACL over the reform process (see appendix 2). This lead to 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'. However, ongoing issues with serious impacts and unintended consequences on the whole of the sector required further examination and advocacy to result in the formation of a multi government Taskforce to examine the overarching issue of GMP finished medicine manufacturing in respect of Country of Origin labelling.

CMA maintains the view that the development of clear policy is required that recognise ingredients are not synonymous with consumer products that are finished medicinal goods, and that therefore, the relevant interpretation of the ACL can account for a finished product as a "medicine" which comprises many characteristics fundamentally transforming the nature and essential character of the goods.

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.

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, published by the ACCC in March 2018, took a significantly more conservative stance than previous Government guidance as to what may be called 'Made in' Australia. The revised guideline resulted in a significant variation in interpretation as to what the ACCC considered to meet the substantially transformed test, but which the sector considered was fundamentally inconsistent with guidance for other industries and comparable processes. Guidance for other sectors take a far less stringent approach to the application of substantial transformation, including, baking a frozen raw imported pie, or curing imported pork and claiming Australian Made.

Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry. CMA members represent greater than 80% of all product sales within Australia. Membership includes the entire value chain, including sponsors, retailers, manufacturers, raw material suppliers, distributors, consultants, allied health professionals and educators. A principal reference point for members, the Government, the media and consumers to communicate about issues relating to the complementary medicines industry, CMA promotes industry advancement, whilst ensuring consumers have access to complementary medicines of the highest quality.

Complementary Medicines Industry

The complementary medicine industry is an exemplary manufacturing industry undergoing significant growth and transformation into a world recognised leader in its field. Our complementary medicines industry:

- Has 142 licensed listed manufacturing facilities in Australia
- Generated 5.2b in revenue in 2018
- Grew by $2b over the last 5 years
- Exported $936m of complementary medicine products, 60% to Asia
- Supports 29,100 local technical and skilled jobs

Department of Industry, Innovation and Science (February 2019), *Country of Origin Labelling Complementary Healthcare Taskforce Report prepared for Minister Andrews. Complementary Medicines Australia Snapshot 2018.*

Thank you for your time in considering the important issues raised in this submission.

Sincerely,

Carl Gibson
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Complementary Medicines Australia
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Origin claims Complementary Medicines Sector	OPTIONS	SECTION 1 - IMPACT ANALYSIS		
	4.1 Describe the policy options considered to address the problem or meet the objectives.	**5.1** Summarise the **benefits** (positive impacts) on businesses, community and government of each option, providing evidence and quantification where possible.	**5.2** Summarise the **costs** (negative impacts) on businesses, community and government of each option, providing evidence and quantification where possible (e.g. compliance costs, administrative costs).	**5.3** Summarise **assessment** of each option. State whether it delivers a public net benefit or cost and provide a **justification** for the preferred option.
	Option 1 Status Quo	The benefit for the Government would include not having to invest resources into clarifying this unintended consequence, saving time and costs that way but to the detriment of the larger economic contribution of CMs to the economy. Maintaining the status quo is said to benefit those business that are already compliant with the ST test, including those business that are using Australian Grown raw materials. Such business can and do have the option to further define their	Australian Manufacturers of complementary medicines will remain bound by the ACL substantial transformation test and its current negative application to the sector. Impacting at minimum 200 previous license holders to the AMAG logo and the opportunity costs not captured by business who would have otherwise invested in Australian made complementary medicines to move their interests offshore, further impacting the Australian economy. As detailed in the submission, understanding the potential missed opportunities foregone by choosing one investment over another (due to a policy	The reinstatement of eligibility to use the Australian Made logo to the CM sector would have a net benefit to the industry, consumers and the Government. The industry, by providing greater certainty for business and manufacturers in the genuine use of the AMAG logo and CoOL representations. Consumer – by providing clarity to consumers who self-select CMs that where labelled as 'Australian Made' that they are manufactured to the highest quality in Australia

		competitive advantage in this case with the use of additional context and prescribed wording on the label or promotional material such as Australian Grown, Australian Made etc.	change on AU made) cannot be understated here. The cost implication impacts any of the 148 TGA licensed manufacturing sites that may manufacture CMs for domestic or export sales. Maintaining status quo, does <u>NOT</u> maintain consistent approach across users of the AMAG logo across all sectors of the economy. As mentioned in the consultation paper the reforms to the ACL had an unintended impact of the CM sector such that the Taskforce considered it valuable to consider reinstatement of the use of the logo to the sector.	and are eligible to use the AMAG logo. The net benefit to the Government, would be clarity across the highly valued AMAG logo the consumer good categories without impacting its current application on the foods sector.
	Option 2: Industry-led self-regulated NEW Logo	An industry controlled voluntary symbol that can be used in marketing to consumers, would provide an opportunity to distinguish this category of goods however it would require extensive effort for consumers and industry education and awareness to garner the recognition and trust level of the current AMAG logo and system. It would be even more confusing	The CM industry does <u>not</u> support the creation of a new Logo to support that these quality products are manufactured in Australia. That is the purpose of the creation of the Australian Made logo, one that is well recognised, trusted and valued by consumers. This would create additional confusion and is a further step backwards than maintaining the status quo.	Option 2 would deliver a public net costs to re-invent a voluntary system and provide for education, awareness and monitoring tools in the CM sector.

		to consumers why multiple systems exists and would water down the current standing of the AMAG brand.		
	Option 3:a Complementary medicines manufactured in Australia are eligible to use the AMAG logo	The CM sector would be positively affected by the introduction of option 3a) in that it would reinstate greater clarity and certainty for business to make genuine Australian Made claims and qualify to use the AMAG logo in its product labelling and marketing. This option would not impose addition conditions as outlined in options 3b and 3c in order to rectify the voluntary use of this logo in this first instance. This option does not competitively disadvantage business that already meet the substantial transformation test as these businesses have the correct policy application applied to them in the first instance. In addition, there are other label claimers to distinguish the competitive advantage of business who comply with the	The food sector and other consumer goods sectors would not be negatively impacted by the introduction of Option 3a) as this is a tool to prescribe a particular class of goods in the regulations to allow for greater clarity and which would not be mutually exclusive to other categories similarly considering merits of a similar application if so desired/required.	The net benefit for the CM sector, the Australian CM manufacturing industry and 73% of consumers who purchase CMs outweighs maintaining status quo or all the other options presented in this consultation paper. This option would be the most practical and cost saving option for industry and the Government to rectify the policy implication that has occurred,

		ST test and have ingredients locally grown; for example, to claim this as such via additional labelling.		
	Option 3:b Option 3 plus a statement on the packaging listing that the ingredients are imported	This option should not be a mandatory requirement of complying with Option 3a)	This option should not be a mandatory requirement of complying with Option 3a)	
	Option 3:c Option 3 plus a visual representation of the proportion of the ingredients that are imported	This option should not be a mandatory requirement of complying with Option 3a)	A visual representation of the proportion of the ingredients imported would not be appropriate to mandate for the complementary medicines sector. Manufacturers source active and excipient ingredients from global supply chains and sources may change rapidly due to seasonal variations and global availability, for example, herbal ingredients are susceptible to climactic fluctuations and the source country may need to be varied. The source of excipient ingredients, such as gelatin, or other excipients which fill and bind the medicine can vary constantly depending on manufacturer availability. This would vary the proportions significantly on a regular basis and create large red tape issues between sponsors who are responsible for labels, and	Additional cost would be incurred for the implementation of this approach across labels. Industry are already transitioning to a raft of significant label compliance reforms with the TGA and another mandated label change cannot be supported at this time.

	Option 3:c Option 3 plus a visual representation of the proportion of the ingredients that are imported		contract manufacturers who often source ingredients. Further costs are incurred due to costs of varying labels, which are a significant cost of medicine production and the application of which has a complex approval and application process in itself under GMP production. Further, there is potential to try to massage the proportion using Australian sources of insignificant amounts of ingredients, such as water or corn maltodextrin, which could create an unlevel playing field for industry, without providing an accurate or helpful comparative source of consumer information. Due to these technical challenges and significant red tape incurred, it would be problematic to try and produce a consistent and reliable label that would clearly represent this requirement. It would not represent a significant gain for consumer information due to the nature of these products as medicines, but it would act as red tape and cost deal-breaker for businesses considering using the AMAG logo and eliminate all the substantial advantages described for Australia throughout this submission.	

Appendix 2 Timeline of Advocacy

- CMA provided submissions to the Department of Industry on CoOL - 2 July 2015; September & October 2016.
- CMA provided a submission to the ACCC Small Business Department on CoOL: 2015, 2016
- February 2017: The 'safe harbour' requirements for making a 'made in Australia' claim in Australian Consumer Law changed, including the definition of 'substantial transformation'.
- March 2017: ACCC produced a guide 'CoO Claims and the Australian Consumer Law' – no Complementary medicines specific guidance was included in this version.
- 10 May 2017: ACCC writes to CMA about changes to made in claims – detailing its position on encapsulation
- 5 June 2017: AMCL and CMA met with ACCC Deputy Chairman, Michael Schaper, to address issues including soft gel encapsulation of imported marine oils
- March 2018: ACCC released CoO guidelines for the complementary health sector
- 23 August 2018: CMA and industry meetings with Senator Kim Carr's office raising issues with the interpretation of the ACL in the Guidance document
- 25 September 2018 – CMA attends AMCL Board lunch with ACCC Deputy Chairman, Mike Keogh
- September/October 2018: In September, Australia-based complementary health product manufacturer, Nature's Care Manufacture Pty Ltd filed an action against the ACCC challenging its interpretation of the new definition of substantial transformation
- 25 October 2018 – questions raised on this issue in Senate Estimates
- 25 October 2018 – CMA writes an industry joint letter to Minister Karen Andrews calling for support for manufacturers and a level of certainty for businesses, in the consistent application of Country of Origin and Australian Made provisions
- November 27-28 2018: Parliament briefings
- 6 December 2018 - CMA and Industry meeting with The Hon. Karen Andrews, MP

- 8 December 2018: The Minister for Industry, Science and Technology Karen Andrews announced the formation of a 'Complementary Medicine Taskforce'.
- 18 December 2018: CMA writes to Hon. Karen Andrews, MP to request Complementary Medicine Expertise on Complementary Medicine Taskforce
- 20 December 2018 – CMA provides feedback to the Department of Industry to assist with their Regulation Impact Statement (RIS) survey on industry
- 25 January 2019 – CMA submission to the Taskforce on CoOL Labelling
- 31 January 2019 – CMA writes to ACCC requesting moratorium on compliance action while taskforce gets underway
- 31 January 2019 – CMA and industry delegation present to the taskforce on CoOL labelling
- 5 April 2019: Minister Andrews issued a media release announcing that the Federal Government will introduce 'changes' which would see complementary medicines manufactured in TGA-approved Australian production facilities qualify to carry a 'made in Australia' claim and the Australian Made logo.
- June 2019: It is understood that both a regulation and legislative change are required to give effect to the decision of Government outlined in Minister Andrews' media release.
- 30 July 2019 – CMA, AMCL, Austrade and Department of Industry meeting Canberra – aim to ensure changes to the ACL can progress expeditiously
- Aug-Sept 2019 – state and territory minister briefings prior to CAF continue
- 31 August CAF meeting – CoO Labelling issue not included on the agenda. Understood that the Chair of CAF provided a verbal update on this issue.
- October 2019 – Current: Pending formal release of the D-RIS