Country of Origin Labelling Complementary Healthcare Taskforce

Report

February 2019

Contents

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Executive Summary

In February 2017, driven by consumer dissatisfaction and mistrust in country of origin claims, changes were made to Country of Origin Labelling (CoOL) laws. These reforms changed the basis for gaining access to the Australian Made, Australian Grown (AMAG) logo. Unlike food products, complementary healthcare products are not required to apply origin labelling but if firms choose to do so they need to ensure the claims are not false, misleading or deceptive. Further, if they want to use the AMAG logo with an 'Australian Made' representation, the AMAG Rules and Code of Practice requires that they meet the 'safe harbour' substantial transformation test in the Australian Consumer Law (ACL).

The Complementary Healthcare Sector (the Sector) expressed concerns that these changes meant that many of their products would no longer meet the tightened requirements of the substantial transformation test. The guidelines from the Australian Competition and Consumer Commission (ACCC) to the Sector issued in March 2018 confirmed this was likely to be an issue for some products. A recent Federal Court case found fish oil encapsulation as falling outside the revised test. The Sector argues that it has been unfairly disadvantaged by changes targeting food products, particularly through loss of access to the AMAG logo. To avoid the negative consequences for businesses and jobs, the Sector proposed a regulatory fix which would allow Therapeutic Goods Administration (TGA) compliance to be the basis of using the AMAG logo.

In response, the Government established a Taskforce to prepare advice on these claims. This Taskforce was asked to assess how the current CoOL policy framework interacts with the Sector and assess the commercial impacts of the current substantial transformation test on products generally referred to as vitamins, minerals and supplements (VMS). As the key issue for the Sector revolves around the use of the AMAG logo, an iconic symbol in the minds of consumers, the Taskforce was also required to assess Australian consumer expectations of the AMAG logo for the Sector. The Taskforce was asked to consider broader market or industry impacts regarding CoOL and AMAG logo use beyond the complementary healthcare sector and identify appropriate next steps for responding to the Sector's concerns. The Taskforce used research including an exclusive survey and consultation with affected groups to seek to arrive on its advice.

The Taskforce recognises the Complementary Healthcare Sector has become an important and growing export sector, and it has a positive reputation in Australia and overseas over a diverse product range. In particular the Taskforce noted China had been a particularly strong growth market, and agreed that continuing to develop reputation and brand for Australian exports was going to be critical in an increasingly competitive export market. Within the VMS segment of the industry, the Taskforce estimates annual exports are worth around $936m; domestic sales around $2.9bn; and around 2,800 people are employed in the manufacture of vitamins and supplements (described in more detail in Chapter 4).

The Taskforce found the extent to which the premium AMAG logo has contributed to this success and to the industry's potential was a more complex story than first presented. On balance, this specific logo would appear not to have been a dominant factor in growth and marketing to-date. For example, the two leading exporters do not currently use this logo on their products and over 70 per cent of VMS product sales (by value) in the domestic market do not carry the logo. While 20 of the 24 firms that responded to the industry survey stated that country of origin claims are 'very important' to their business, only 14 use the AMAG logo. The respondents who used the AMAG logo reported it had a positive effect on sales and the perceived quality of their products.

The survey data highlights an important point for marketing VMS products. The industry has not provided information about the number or value of product lines that would and would not meet the tightened 'Made in Australia' requirements. The AMAG logo is only one way to create a link to Australia. Products are free to claim 'Made in Australia' without meeting the safe harbour substantial transformation test provided the statement on the label is not false, misleading or deceptive. A number of VMS products carry this origin claim without displaying the AMAG logo.

In considering whether the Sector should have access to the AMAG logo restored, the Taskforce also had to consider the implications for the brand in contested cases (such as the encapsulation of imported fish oil). The CoOL reforms were partly aimed at restoring confidence in country of origin claims, and represent a large investment in that branding by brand users, the Commonwealth and State governments, driven heavily by research of consumer preferences.

While the 2017 changes to the definition of substantial transformation were an improvement, the results of this work are not always black and white, with some contested interpretations of substantial transformation being raised with the Taskforce. The Sector argues that in the eyes of the consumer, the high regulatory standards of product and process safety stipulated by the TGA, not the source of ingredients, qualifies their products for an Australian country of origin claim. While the Taskforce had some sympathy for this argument, the consumer research it commissioned does not support this contention – while consumers value the Australian quality processes highly they considered the AMAG logo a premium brand which should not be associated with imported ingredients. In fact, consumers are likely to have expectations which exceed the current Certified Trade Mark (CTM) rules and Code of Practice underpinning the use of the AMAG logo.

The Taskforce has made a number of findings. The first is that the Taskforce sees the value of transforming ingredients and products in Australia to Australian standards, and accepts that it is in the national interest to grow this Sector. The second is that the AMAG logo is a premium brand. Its use in cases of simple transformation without disclosure of some origin information risks compromising its value in the long term. This includes where there has not been substantial transformation that can be described as manufacturing. The third is where substantial transformation is used as a basis for AMAG claims, s47C

s47C Many of the product lines are not an issue, though the industry has not provided detailed information on the number and value of product lines affected. The industry has been growing without the AMAG brand. Potential fixes using the AMAG logo for products that have not been substantially transformed from their imported ingredients raise a significant potential to be false, mislead and deceive consumers.

The Taskforce therefore considered a range of options, from no change, to examining alternative mechanisms and brands to help the industry develop its export capability, to a range of regulatory solutions which would improve access to the AMAG logo while mitigating negative consequences for its value. This can be broadly reduced to the following five options. While the Taskforce did not determine a preferred option, it notes the choice would be largely driven by relative weighting on value to the industry, consumer expectations and confidence in the AMAG logo, and length and complexity of implementation.

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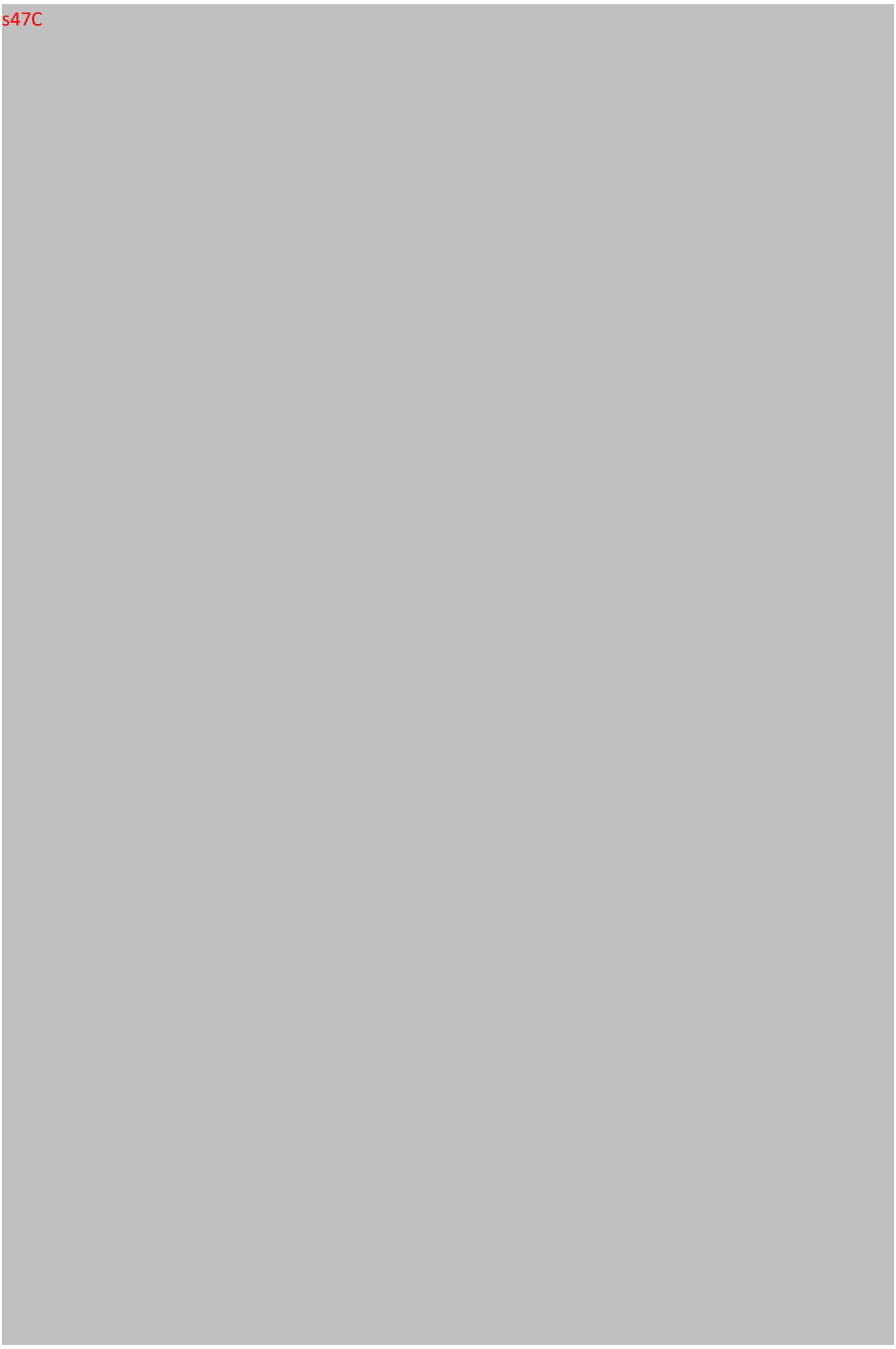

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Taskforce and Terms of Reference

On 5 December 2018, the Hon Karen Andrews MP, Minister for Industry, Science and Technology announced the Complementary Medicine Taskforce (the Taskforce).

The Terms of Reference of the Taskforce sought to:

1. Assess how the current CoOL policy framework, including the Australian Competition and Consumer Commission (ACCC) guidance regarding the substantial transformation test, interacts with the Complementary Healthcare Sector (the Sector). This shall include reporting on industry concerns about how this policy and guidance may be impacting upon business decisions within both the Sector, and AMCL in licensing use of the AMAG logo.
2. Assess the commercial impacts of the current substantial transformation test under the Australian Consumer Law (ACL) on the complementary healthcare sector regarding products generally referred to as vitamins, minerals and supplements.
3. Assess Australian consumer expectations relating to suggested changes by the Sector regarding rules governing the use of the AMAG logo. This will include consideration of impacts on consumer choices in purchasing products, and the need to protect and ensure the integrity of 'Australian made' claims and the AMAG logo.
4. Give consideration to broader market or industry impacts regarding CoOL and AMAG logo use beyond the complementary healthcare sector.
5. Identify appropriate next steps for responding to the Sector's concerns

The scope of the consultation process extended to:

- manufacturers and suppliers of complementary healthcare products in Australia through an industry survey facilitated undertaken by DIIS;
- consumers of complementary healthcare products in Australia; and
- other relevant stakeholders including complementary medicine associations, AMCL, consumer experts.

Opportunities to participate in the consultation process, including engaging with the survey were made available to relevant stakeholders through distribution via the industry peak body. The Australian Made Campaign Limited (AMCL) also sent invitations to relevant AMAG logo licence holders, and the survey was available via the department's website.

The Taskforce comprises representatives from the following Commonwealth agencies:

- Department of Industry, Innovation and Science;
- Department of the Prime Minister and Cabinet;
- Treasury;
- Department of Foreign Affairs and Trade;
- Austrade;
- Department of Agriculture and Water Resources;
- Australian Competition and Consumer Commission; and
- Department of Health.

Taskforce members have formally met on three occasions. Members have also engaged with the department inter-sessionally, contributing data and direction to the Taskforce.

The full Terms of Reference are provided at Appendix A.

1 Summary of industry concerns

The announcement of the Taskforce followed concerns raised by representatives of the Complementary Healthcare Sector (the Sector), including the peak body Complementary Medicines Australia (CMA), about changes to the use of the AMAG logo on complementary healthcare products.

This follows the changes made by the Australian Government in February 2017 to the Australian Consumer Law (ACL) and Australia's Country of Origin Labelling (CoOL) requirements, which introduced new country of origin labelling requirements on food products and changed the criteria for all businesses making a 'Australian Made' claim. These changes were in response to consumer demand for better and more transparent information on where products originated from.

For the Sector, this means many of their products do not meet the new definition of substantial transformation under the ACL as amended in 2017, contained in the *Competition and Consumer Act 2010*. The revised definition of substantial transformation removed the 50 per cent production cost test from the 'Made in' safe harbour defence and clarified what had to occur to imported ingredients for a domestic producer to claim to have substantially transformed those imports. In the absence of substantial transformation of imported ingredients, a producer cannot rely on the ACL safe harbour defence for a 'Made in' country of origin claim. In these circumstances, the AMAG logo cannot be granted. [1]

The Sector states that the AMAG logo is a key marketing tool for both domestic (especially in the Daigou market) and export markets, particularly markets like China, and that Australian companies are being negatively impacted by the new CoOL requirements. Currently there are up to 185 licensees of the AMAG logo from the Sector, including firms licenced to use the logo that may not have production or manufacturing capacity in Australia.[2] [3] While some of these products may be able to continue to make 'Australian Made' claims, many will no longer be able to do so as they do not meet the criteria for its use. CMA have stated that lack of access to the AMAG logo will cause unnecessary and serious impacts on the industry. CMA cite a likely reduction in investment and job losses as potential consequences, jeopardising the growth of the Sector.[4]

The ACCC has advised the Sector that failure to satisfy the safe harbour criteria for a particular claim does not mean that a business is unable to make a claim of 'Made in Australia'. Companies in the Sector may still choose to make this claim provided an ordinary, reasonable consumer would not consider that claim be false, misleading or deceptive.[5] However in the absence of substantial transformation and qualifying for the safe harbour defence, the AMAG logo is not able to be used to represent this claim.

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[1] The safe harbour defences in the ACL, provide a degree of legal protection for businesses that choose to make country of origin claims about their goods. If an origin claim satisfies a safe harbour (i.e. substantial transformation) a business will have the benefit of a statutory defence against an allegation that the country of origin claim is false, misleading or deceptive under the ACL.

[2] The TGA have 142 listed manufacturers. The CMA consider 82 of these to be part of their industry group

[3] AMCL submission to the Taskforce at Appendix N

4 The Taskforce received and considered submissions from industry representatives including peak bodies and individual firms.

[5] ACCC 2018. Country of origin labelling for complementary healthcare products, a guide for business.

Industry claims that Australia is on the verge to overtake the USA as the number one supplier of complementary medicines into China[6]. The opportunity offered by the Chinese market continues to be significant. This growth story into China is well known for Australia's producers, however it is less well known what impact lack of access to the AMAG logo will have on this sector in particular. The Sector contends that the AMAG logo may be of value when accessing new and emerging markets.

1.1 What are complementary medicines?

Complementary medicines are therapeutic goods, consisting wholly or principally of one or more designated active ingredients.[7] The term complementary healthcare and complementary medicine are used interchangeably by stakeholders in the Sector, although the terms are commonly understood to cover a diverse range of products with intended therapeutic benefits including:

- Vitamins, minerals and supplements;
- Herbal, homeopathic and traditional medicines;
- Sports supplements;
- Aromatherapy products; and
- Weight loss products.

The largest category of complementary healthcare products and the focus of this report is vitamins, minerals and supplements (VMS). Specifically, non-prescription VMS products which are consumed orally and contain one or more Therapeutic Goods Administration (TGA) approved ingredients supplementing the diet. This includes various formulations and presentations of VMS products. It should be noted that while the list above captures the range of products in the Sector, data used in this report is generally concentrated on the VMS area as per the terms of reference. Information referenced in the report may include this broader range of products; when the term complementary healthcare or medicine is used, it is referring to this broader product range, whilst when VMS is referred to, it is specific to the VMS subset of listed complementary medicines. This is due to data sources not precisely aligning with product categories.

In Australia, the VMS manufacturing industry produces products designed to improve health and wellbeing, including sleep and stress relief, maintaining immune and digestive system health, support nutritional needs and various other indications. This includes general health products including pills, oils, tablets and powdered mixes containing vitamins, herbs, minerals and specialty supplements such as:

- Multi-vitamins and single vitamins;
- Dietary supplements comprised of herbal and traditional ingredients (e.g. echinacea, ginseng, primrose oil, olive leaf extract, spirulina and ginkgo biloba); and
- Non-herbal supplements (e.g. fish oils and omega fatty acids, calcium, glucosamine, probiotics, proteins and other mineral supplements).

[6] Noting that the largest proportion of product exported from Australia (from companies including Blackmores and Swisse) at the moment does not rely on Australian made claims

[7] *Therapeutics Goods Regulations 1990, Schedule 14* outlines designated active ingredients.

Box 1: The regulation of complementary medicines in Australia

In Australia, complementary medicines are regulated as therapeutic goods under the *Therapeutic Goods Act 1989* by the Therapeutic Goods Administration (TGA). The TGA provides a national system of regulatory controls relating to the quality, safety, efficacy, performance and timely availability of therapeutic goods used in Australia or exported from Australia. All medicines, including complementary medicines, must be entered in the Australian Register of Therapeutic Goods (ARTG) in order to be legally imported, exported, manufactured or supplied to consumers.

The regulation of complementary medicines includes lower risk medicines that can be 'listed' on the ARTG, whereas higher risk medicines must be 'registered' on the ARTG. Of the 11,000 plus complementary medicines entered in the ARTG, the vast majority are in the lower risk *listed* category with only about 140 products in the higher risk *registered* category. Listed medicines are not individually evaluated for safety, quality or efficacy before they are released onto the market; instead, they are automatically included in the ARTG following completion of an application and certification by the product sponsor that their product meets all the applicable legislative requirements, including that they hold evidence to support the claims made for the medicine. Further details on the regulation of complementary medicines, and the certification and licencing of manufacturing facilities is available at Appendix B.

2 'Australian Made' logo

The 'Australian Made, Australian Grown' (AMAG) logo, the triangular logo encasing a kangaroo, is a registered certification trade mark developed in 1986 by the Australian Government primarily as a consumer information tool – through which Australian businesses could assure Australian and other consumers that their products were genuinely Australian because they met certain rules.

Figure 1: Australian Made logo

The logo provides information to consumers in Australia and overseas that goods using the logo have met particular requirements under Australian Consumer Law (ACL) to be able to be display the logo. It is the most recognised and trusted country of origin symbol in Australia, enjoying a 99.6 per cent recognition level amongst Australian consumers and is considered a very strong marker that the product that carries it is of Australian origin.[8] Details of consumer surveys regarding the logo commissioned for this report can be found at Section 5.

Following the 2017 CoOL reforms, the Commonwealth assumed responsibility for use of the AMAG logo on food products sold in Australia under the terms of the *Country of Origin Food Labelling Information Standard 2016.* [9] The Australian Made Campaign Limited (AMCL) retains responsibility for licensing use of the AMAG logo on all other products sold in Australia and overseas, and on Australian food products sold internationally.[10]

A list of all variations of AMAG trademarks can be found at Appendix C.

2.1 Australian Made Campaign Limited

AMCL is a not-for-profit public company established in 1999 by the Australian Chamber of Commerce & Industry and the network of state and territory chambers of commerce, with the cooperation of the Federal Government. The primary function of AMCL is the administration of the AMAG logo. AMCL regulates use of the logo by issuing 12-month renewable licences which allow businesses to use the logo.[11]

Over 2,700 companies are currently licensed to use the AMAG logo on more than 16,000 products. Appendix D provides a brief history of the AMAG logo.

2.2 The Sector's use of the Logo

The Taskforce was able to access data for just over 90 per cent of domestic sales in 2018.[12] Of that share of the market at least 4 in 5 domestic sales (by value) do not carry the AMAG logo. This figure is derived from retail market share values for companies in the Sector, and whether those companies are registered to use the AMAG logo.

Of the remaining 10 per cent of the market that we do not have information on, we make no assumption on whether the AMAG logo is used on some, none, or all of their products. At a

[8] Roy Morgan Research, 2017.
[9] The Food Information Standard is available at https://www.legislation.gov.au/Details/F2017C00920
[10] The Australian Government introduced new CoOL reforms that became mandatory on 1 July 2018 for many food products.
[11] AMCL 2019. Website About Australian Made
[12] ibid

minimum, of the total market (100 per cent of VMS products sold in Australia) at least 73.6 per cent of those products by value, do not carry the AMAG logo.[13] [14]

A table listing market share by company is available at Appendix E.

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[13] Euromonitor 2019, Passport database, Consumer Health in Australia

[14] Australian Made Campaign Limited licensee registration database July 2018

[15] Sanofi 2019, Submission to Complementary Healthcare Country of Origin Labelling Taskforce.

3 Country of Origin Labelling (CoOL)

Country of Origin Labelling (CoOL) is common in many industrialised nations and can be a primary information requirement, especially for food that is traded domestically and globally. The objective of the CoOL policy framework is to ensure businesses provide consumers with the information they want, including where the ingredients are from and where the product has been manufactured, in order to make purchasing decisions in line with their preferences. The framework aims to balance consumer demand for this information with the cost to business of providing it.

3.1 The CoOL reforms

Origin labelling has been an issue for consumers for a number of years, with a number of Senate inquiries having investigated the subject. Through these processes, it became clear that consumers did not understand origin statements and felt they did not provide appropriate information. Labelling regulations did not require businesses to provide the proportion of Australian ingredients and only a small proportion of businesses opted to do so.

The frozen berries hepatitis scare in early 2015 brought the issue to a head and Commonwealth agencies were directed by the Government to explore options for reform. This led to a detailed consultation process which included the commissioning of qualitative and quantitative market research and a cost-benefit analysis.

Market research showed the importance of origin labelling to the Australian community and revealed that consumers mostly wanted to know the amount of Australian content in the foods they bought. Research also indicated that labels featuring the AMAG logo, a bar chart and a statement indicating the proportion of Australian ingredients best conveyed this information.

Consumers found terms like ‘Made in’ and ‘Product of’ particularly confusing. Almost 60 per cent of consumers mistakenly believed a ‘Made in Australia’ claim indicated that the product was entirely processed in Australia, rather than that it complied with the 50 per cent production cost test.

The reforms were not intended to influence consumer preferences. Rather, they aimed to ensure businesses provided consumers with the information they need at the purchasing point to make informed decisions. A more detail explanation of the CoOL reform process can be found at Appendix F.

3.2 Country of Origin Labelling Legislation

The *Competition and Consumer Amendment (Country of Origin) Act 2017* came into force on 22 February 2017. The Act revised the safe harbour defences for origin claims on all products (food and non-food) by removing the 50 per cent production cost test previously included in the safe harbour defence for ‘Australian Made’ origin claims. The Act also clarified and tightened the definition of ‘substantial transformation’ which is now the only requirement for making an ‘Australian Made’ claim.

The change to the definition of ‘substantial transformation’ makes it clearer that substantial transformation requires the final product to be fundamentally different from its imported ingredients in identity, nature or essential character. These changes were made to better reflect consumer expectations about what constitutes ‘Made in’ and also to better align with the position that trading partners have adopted.

A product containing entirely imported ingredients is still eligible to make an ‘Australia Made’ claim under the safe harbour defence if the product underwent its last substantial transformation in Australia.

3.3 Key Changes affecting the Complementary Healthcare Sector

For the Sector, the key changes in the law were the removal of the 50 per cent production cost test and the change in definition of substantial transformation. Removal of the 50 per cent production cost test also removed the capacity of the Sector to use cost of production claims to help establish an 'Australian Made' origin claim and use the associated safe harbour defence.

As the Sector relies almost exclusively on imported raw ingredients, the removal of the 50 per cent production cost test limits the Sector's 'made in' safe harbour defences to the revised substantial transformation definition.

3.4 Australian Competition and Consumer Commission (ACCC) Guidance for the Complementary Healthcare Sector

The Australian Competition and Consumer Commission (ACCC) has provided extensive guidance for businesses on country of origin labelling and its compliance and enforcement regime since the reforms were announced. For further information regarding the role of the ACCC with regards to the compliance and enforcement approach to country of origin labelling please refer to Appendix G.

In March 2018, the ACCC released the *Country of origin labelling for complementary healthcare products guide for business*[16] following calls from industry for detailed guidance on the application of the safe harbour defences to complementary healthcare products. In the guide, the ACCC outlines a number of production scenarios that it considers likely to either meet or not meet safe harbour defences.

The primary consideration when determining substantial transformation is a comparison between ingredients and process undertaken, and that goods need to be fundamentally different in identity, nature or essential character from imported ingredients. For example, the guidance advised that encapsulating imported actives (e.g. fish oil) is unlikely to constitute a substantial transformation. While encapsulation results in a change to the form and appearance of the imported active, in the ACCC's view it does not result in a fundamental change to its identity, nature or essential character when compared to the imported ingredient.[17]

It is understood that the CoOL reforms are likely to render some non-food products ineligible for the 'Made in' claim that they may have previously used. The ACCC maintains that the guidance was designed to assist businesses and consumers to understand its enforcement approach, and reflect the ACCC's interpretation of new laws as passed by the Commonwealth Parliament. Ultimately, companies are required to seek their own legal advice, and the interpretation of the law is a matter for the courts. Most recently, the Federal Court interpreted the ACL's 'substantial transformation' test in the Nature's Care case (see Nature's Care court case at Section 3.5 below).

3.5 Nature's Care court case

In 2018, vitamin manufacturer Nature's Care Manufacture Pty Ltd (Nature's Care) applied to renew its licence from AMCL so that it could continue to use the AMAG logo for its Fish Oil 1000 + Vitamin D3 soft gel capsule product. The capsules are comprised of pure fish oil manufactured in Chile, Vitamin D manufactured in China, glycerol manufactured in Malaysia or Indonesia, water collected in Australia and gelatine power manufactured in Australia. The pure fish oil and Vitamin D are blended in Australia to form the product filling. The glycerol, water and gelatine powder are cooked together

[16] https://www.accc.gov.au/system/files/Country%20of%20origin%20labelling%20for%20complementary%20healthcare%20products-A%20guide%20for%20business.pdf

[17] ACCC Country of Origin Labelling for Complementary Healthcare Products: A guide for business. March 2018.

to form a gelatine sheet. Encapsulation takes place in Australia by injecting the product filling between two gelatine sheets as they are closed under pressure to form a capsule.

The ingredients go through five stages of production for encapsulation, which occurs in Australia.

AMCL had been granting a licence to Nature's Care to use the AMAG logo for the capsules since 2012. However, following changes to the ACL, and the release of the ACCC's *Country of origin labelling for complementary healthcare products guide*[18], AMCL declined to extend Nature's Care licence to use the AMAG logo. AMCL did not accept that the capsules were 'Made in Australia' and indicated that it would not license Nature's Care to use the AMAG logo on the capsules from 31 December 2018.

Nature's Care challenged the decision by AMCL to not licence the use of the AMAG logo in the Federal Court. On 3 December 2018 the Federal Court of Australia (Justice Perram) delivered judgment on this matter. Justice Perram found that the product is not 'substantially transformed' i.e. 'made in' Australia within the meaning of section 255 of the ACL; see Appendix H. The Court ruled that the physical differences in form and appearance identified by Nature's Care **"do not establish that the capsules are fundamentally different to the fish oil or vitamin D3 which were imported in their nature, identity or essential character."** For further detail please refer to the Case Note at Appendix I.

3.6 Domestic labelling to be consistent with labelling on exports

Businesses exporting goods must comply with Australian laws dealing with labelling as well as the labelling laws of the importing country.

For goods leaving Australia, a range of laws apply to exports including the *Commerce (Trade Descriptions) Act 1905*. Section 13 of this Act prescribes rules relating to trade descriptions of exports. These include a requirement that an export should not bear a false trade description. The *Commerce (Trade Descriptions) Act 1905* would be contravened if goods being exported carried a trade description that falsely indicated the country where the goods were made.

It would be a contravention of the *Commerce (Trade Descriptions) Act 1905* if a product intended for export carried the AMAG logo, if that same product, sold domestically, was not allowed by law to carry the AMAG logo. The relevant sections of the Commerce (Trade Descriptions) Act 1905 are contained in Appendix J. The *Commerce (Trade Descriptions) Act 1905* is administered by the Department of Home Affairs, with the Australian Border Force being the principal authority responsible for compliance actions.[19]

[18] https://www.accc.gov.au/publications/country-of-origin-labelling-for-complementary-healthcare-products-a-guide-for-business

[19] https://www.abf.gov.au/exporting-subsite/files/fact-sheets/exporter-obligations-reporting-requirements.pdf

4 The Complementary Healthcare Industry

4.1 Industry size and composition

Quantifying the size of the VMS Sector can be challenging due to different ownership, production, marketing and distributional arrangements. Reliable data about the Sector is also difficult to determine as the industry does not sit neatly within industry classification structure used by the Australian Bureau of Statistics (ABS). There are a number of different markets within the VMS Sector. Euromonitor's Consumer Health in Australia (February 2019) report estimates the retail sales of consumer health products in Australia in 2018 was as follows:

- dietary supplement sales worth $2.1bn;
- vitamin sales worth $747m; and
- $2bn of sports nutrition, weight management, and herbal and traditional wellbeing products.[20]

Over the past five years, the retail sales of vitamins and dietary supplements have been growing at 8.8 per cent per annum, and are forecast to grow at 4.0 per cent per annum over the next five years. Sports nutrition has also grown strongly in the past five years (9.2 per cent per annum), with forecast sales continuing to remain strong in the next five (7.8 per cent growth per annum).[21]

Businesses of all sizes are active in this industry ranging from small firms utilising contract manufacturers, to multinational pharmaceutical companies, owning, developing and producing hundreds of product lines. Some companies in the industry specialise in a narrow range of products, while for others, VMS represents a small portion of their larger pharmaceutical business.

Analysis undertaken by IBISworld reported 2,800 people are employed in the manufacture of vitamins and supplements.[22] This is in line with the Office of the Chief Economist estimates based on ABS data that there are about 2,000 people employed in the vitamin manufacturing segment of the VMS Sector.[23] In addition to the manufacturing of the products, there are a number of people employed along the supply chain to bring the products to market. The industry's peak body, CMA, on the basis of research conducted by Remplan in 2016, reports that the Australian complementary medicines industry is estimated to directly employ people in 13,200 jobs across the product supply chain.[24] This 13,200 would include the 2,000 involved in manufacturing.

Both export and import levels in the industry are high and increasing.[25] South East Asian markets have been the source of strong export growth over the last five years. Export growth is expected to continue, in particular in the China and Singapore markets.[26] Other emerging markets in the Asia-Pacific region offer significant opportunities for future expansion and the Sector argues there is benefit in utilising the well-recognised AMAG logo in entering new markets.

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[20] Euromonitor International Passport Database, Consumer Health 2019.
[21] ibid
[22] IBISWorld Industry Report OD5417 Vitamin and Supplement Manufacturing in Australia September 2018
[23] Office of the Chief Economist calculations; Euromonitor International Passport Database, Consumer Health 2019; ABS cat. no. 8155 Australian Industry, 2016-17; ABS cat. no. 6291.0.55.003 - Labour Force, Australia, Detailed, Quarterly, Nov 2018.
[24] CMA Australia's Complementary Medicines Industry Snapshot 2018.
[25] ABS 5368.0 International Trade in Goods and Services, Australia, Dec 2018
[26] IBISWorld Industry Report OD5417 Vitamin and Supplement Manufacturing in Australia September 2018.

4.2 Australian VMS Manufacturing

TGA data indicates there are 148 licenced Australian manufacturing locations in the Sector in Australia performing one or more of the following steps:

- Manufacture of dosage form;
- Labelling & packaging;
- Testing Microbial;
- Testing chemical & physical; and
- Release for supply.

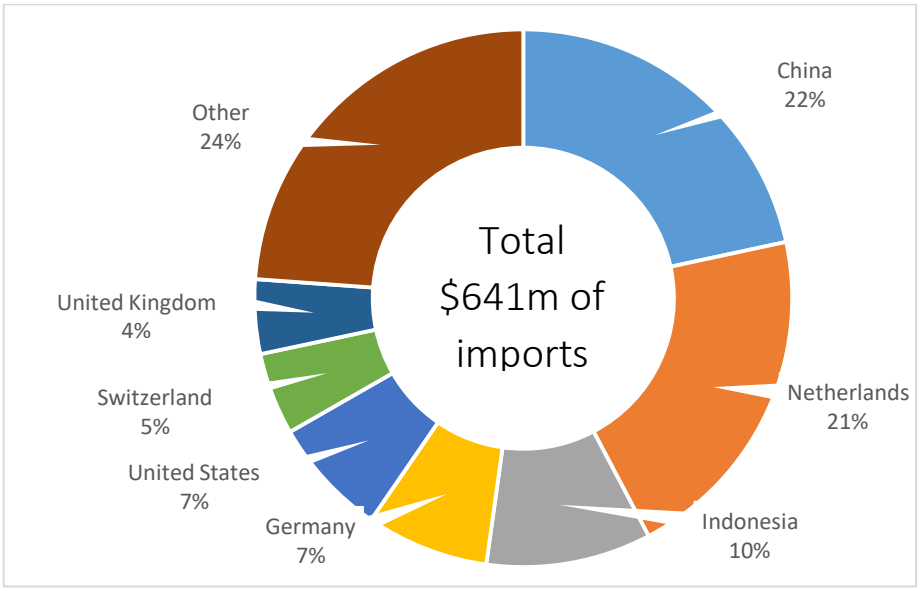
The TGA notes that there is also a regulated non-mandatory sixth step – Secondary packaging.

VMS production is heavily reliant on imported ingredients. Generally, the ingredients fall into two main categories – actives and excipients. Actives are ingredients responsible for the physiological or pharmacological actions performed by a therapeutic good. By contrast, excipients are not therapeutically active and do not perform a physiological or pharmacological action. Common excipients include fragrances, preservatives, fillers or binders.[27]

In addition to actives and excipients imported in bulk, finished or partially finished VMS products either in retail-ready packaging or in bulk form are also imported by the VMS Sector.

The following chart indicates the key markets where imports for the Sector are sourced from.

Figure 2: Main sources of vitamin, mineral and supplement imports to Australia 2018



Note: The Harmonized System codes representing the sector in official trade statistics is at Appendix K
Source: Austrade calculations. ABS 5368.0 International Trade in Goods and Services, Australia, Dec 2018.

As the above chart demonstrates, VMS imports from China, Indonesia and the Netherlands amount to over half of all imports used in the Australian VMS Sector. The US and Germany are the next largest sources of imports into Australia.

[27] ACCC 2018. Country of origin labelling for complementary healthcare products, a guide for business. P 5.

Vitamin and supplement imports are expected to account for 57.3 per cent of domestic demand in 2018-19.[28] This level is largely due to firms importing many ingredients used to locally manufacture vitamins, including fish oil, evening primrose oil, glucosamine and vitamin C. It also reflects the extent to which Australia's major vitamin suppliers rely on international markets. For example, Swisse sources approximately one-quarter of its ready to consume products from Europe. Similarly, Blackmores sources production from the US, Canada, Germany and Holland.

4.3 Australian VMS Manufacturers

All states host VMS production facilities however no production facilities are located in the Northern Territory or the Australian Capital Territory. Facilities are concentrated in Queensland, Victoria and New South Wales. The TGA is responsible for licencing manufacturing sites that are involved in the supply chain of listed medicines in Australia.

The Sector supports advanced manufacturing in Australia; Vitex and Swisse are members of the Advanced Manufacturing Growth Centre designed to transform Australian manufacturing to be globally competitive and generate demand for jobs. s45

Table 1: Distribution of Complementary Medicine Manufacturing Facilities in Australia

State	Number of TGA licenced manufacturing sites*
VIC	34
QLD	30
SA	9
NSW	69
WA	6
Total	148

*Source: TGA Complementary Medicines manufacturing licence registry. * Under TGA regulation and licencing for complementary medicines, there are five mandatory manufacturing steps for listed medicines: Manufacture of dosage form, Labelling & packaging, Testing Microbial, Testing chemical & physical, Release for supply. A manufacturer could only be licensed to perform 1 step, e.g. labelling and packaging, or all steps, but each manufacturer must hold a licence for that step(s).*

4.4 Industry Peak Bodies

There are two key peak bodies representing stakeholders in the complementary medicines industry; Complementary Medicines Australia (CMA) and the Australian Self Medication Industry (ASMI). CMA are the peak industry body for the complementary medicines industry in Australia, and represent over 70 per cent of all product sales and stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. ASMI is the peak body representing companies involved in the manufacture and

[28] IBISWorld Industry Report OD5417 Vitamin and Supplement Manufacturing in Australia September 2018.

distribution of consumer healthcare therapeutic goods (non-prescription over-the-counter and complementary medicines including VMS) in Australia.

4.5 VMS Sales

Retail sales of VMS products in Australia have grown strongly over the last five years, but the growth is expected to be more stable over the next five years as per tables 2 and 3 below.

Table 2: Sales of Vitamins and Supplements in Australia (AUD Million)

Year	2013	2014	2015	2016	2017	2018
Sales	1,928.3	1,983.6	2,521.4	2,683.2	2,818.2	2,937.8

Source: Euromonitor, Consumer Health in Australia 2019

Table 3: Sales of Vitamins and Supplements Australian - forecast (AUD Million)

Year	2019	2020	2021	2022	2023
Forecast Sales	2,989.8	3,041.0	3,090.8	3,131.5	3,165.6

Source: Euromonitor, Consumer Health in Australia 2019

4.5.1 Domestic Markets

In 2018, the booming growth rate of the Sector in recent years steadied as Australian consumer demand levelled out for vitamins and dietary supplements. In 2018 Australian-owned Blackmores was the market leader for vitamin sales. Blackmores registered solid sales growth over the course of the year extending its lead over second-placed Sanofi and third-placed Swisse, with very little separating the three players in terms of vitamin sales. Together, these three companies account for well over half of total sales of vitamins in Australia and they are among the leading trend-setters, regularly launching new products that conform to emerging consumer trends. Their products are popular with local and foreign consumers alike for their high quality, innovative features and market positioning.

Alongside Blackmores and Swisse, several major brands dominate the market including Berocca, Bioglan, Nature's Own, Cenovis, Ostelin, MICROgenics, Bio-Organics and Recoverlyte. Key contract manufacturers include Vitex and Lipa Pharmaceuticals. Whilst many of the brands owned by Sanofi use the AMAG logo, it should be noted that both Blackmores and Swisse do not currently use the AMAG logo in their product labelling or branding. Further information on firms' Australian market shares and AMAG logo use is available at Appendix E. This information contributed to the assessment of the commercial impacts of origin labelling requirements as described in section 2.2.

4.5.1.1 Domestic Sales Channels

Sales of VMS products to Australian consumers occurs through two sales channels – store based and non-store based which includes home shopping, internet retailing and direct selling. As indicated in table 4 below, Australian consumers primarily gain access to VMS products through in-store sales.

Table 4: Distribution of vitamins and dietary supplements by percentage of sales value

Channel	**Per cent of total sales**
Store-Based Retailing	81.4
Non-Store Retailing (including home shopping, internet retailing and direct selling)	18.6

Source: Euromonitor, Consumer Health in Australia 2019

In both distribution channels, discount players such as Chemist Warehouse are attracting increasing numbers of consumers with highly discounted prices on a very wide range of products across the Sector. The rise of discount pharmacies has come at the expense of traditional independent neighbourhood pharmacies, many of which have lost sales due to the competition they face from

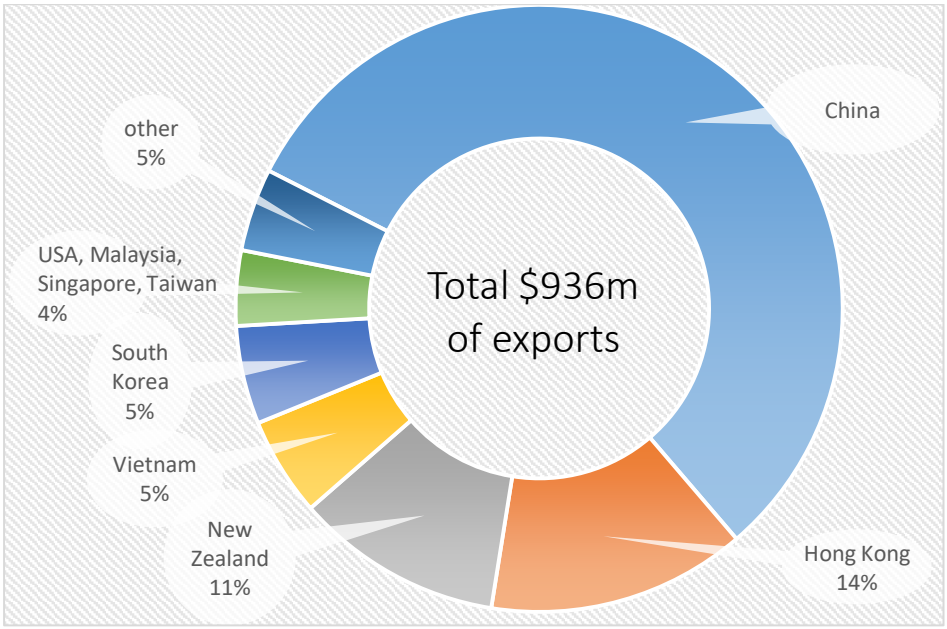
discount physical and online stores.[29] However, with online retailing benefiting from the recent entry of online retail giant Amazon, internet retailing is likely to remain the most dynamic retail channel for vitamins into the future.

4.5.2 International Markets

In 2018, Australia exported $936m of complementary medicine products according to the current definition of export commodities developed by Austrade and CMA.[30] Of this, $714m were vitamins.

Growth in VMS exports in 2018 continued to be driven by demand from Chinese consumers. The following chart identifies the importance of China and Hong Kong to Australia's VMS exports. These two markets combined receive 70 per cent of the value of Australia's exports in this Sector. The industry has also said that trade with New Zealand is driven by the end user in China.

Figure 3: Main destinations of Australia's VMS exports 2018



Note: The Harmonized System codes representing the sector in official trade statistics is at Appendix K
Source: Austrade calculations. ABS 5368.0 International Trade in Goods and Services, Australia, Dec 2018.

The $936m export figure likely underestimates the total value of VMS exports for two reasons. First, the statistics produced by Austrade for the CMA do not include all products considered to be VMS (and to a greater extent complementary medicines). One of the main products being fish oils, which are considered an Oil and Fat Manufacturing Industry product according to the ABS classification system. As fish oils are classified as one commodity, there is difficulty distinguishing between a food product and a complementary medicine product, or between fish oil in a tank compared to fish oil in a capsule. The second reason is due to Daigou trade. From research provided to the CMA, this accounts for roughly 20 per cent of Australian domestic sales but those sales are not captured in official export figures. Based on this, Daigou vitamin 'exports' could be worth an additional $130m; and VMS 'exports' in total could be worth an additional $500m.

[29] Euromonitor, Consumer Health in Australia 2019
[30] Austrade calculations. ABS 5368.0 International Trade in Goods and Services, Australia, Dec 2018.

As discussed in section 4.2, Australia is reliant on imports of raw ingredients for the production of complementary medicine products. Initial findings suggest that Australian firms may add significant value to the outgoing products. For example, in relation to vitamins, analysis by the Office of the Chief Economist shows the Australian vitamins industry adds about 63 per cent ($11 per kilogram) of value to vitamins it exports. [31]

4.5.2.1 International Sales Channels

Sales of Australian manufactured vitamins and dietary supplements have increased substantially in recent years due to rising demand among Chinese consumers. This has resulted in VMS manufacturers increasing their supply and expanding into new distribution channels. By the end of 2018, many Australian VMS manufacturers had either expanded directly into China or had reached Chinese consumers in different ways, including targeting Daigou buyers and online retail platforms such as Tmall, Taobao, Kaola.com, Xiaohongshu and JD Global.[32]

Diagou, also known as professional shoppers, buy Australian manufactured vitamins for resale to end consumers in China. These shoppers often promote products via blogs, social media websites and other online channels.

4.5.3 Claims of connection to Australia

The industry survey (further details at section 4.6 of this report) found that two-thirds of survey respondents utilised Australian origin claims on 90 per cent or more of their product range. Just over half of the surveyed firms reported use of the AMAG logo on their products, these firms reported export earnings of $77m from all products sold overseas in 2017-18.

In line with the survey results, the Taskforce's desktop review of the various online retail platforms used to sell VMS products into China, it was clear that of the many brands that Australian consumers would recognise, a number did not carry the AMAG logo or make Australian origin claims on product labelling. In some cases, an Australian connection was conveyed to the purchaser through imagery linked to the products on web pages. For instance images of the Sydney Opera House, or Sydney Harbour Bridge were used. In many examples, there were digital Australian flags overlaying the product picture. These overlays were not used to alter the image of the products label, but appeared to be a visual reference to the consumer to indicate the products connection with Australia. Most sites allowed the consumer to clearly read all parts of the label and if available, view AMAG logo placement.

In some cases, the imagery connecting a product to Australia was more prominent than any AMAG logo placement on a product's label. A number of firms, including two of the largest who did not complete the industry survey, noted during consultation that they have been successful in getting their brand recognised as 'Australian Made' without the logo in the Chinese market, predominantly through the Diagou trade. However, these same surveyed firms, as well as the two who didn't complete the survey, informed the Taskforce that they would like to use the logo in the future, when they expanded to new markets where their brands were not synonymous with being Australian.

[31] Analysis based on an assumption that the import value of vitamins is $18 per kilogram (based on $96m and 6m kilograms imported) and the export value is around $29 per kilogram (based on $180m and 6m kilograms exported).

[32] Euromonitor 2018. Consumer Health in Australia

4.6 Assessing the commercial impacts origin labelling requirements on VMS firms.

As outlined above, the Taskforce undertook a survey to gather industry views on the CoOL legislation changes from members of the complementary medicines industry.

The survey was distributed to members of both CMA and the ASMI peak bodies. Austrade also provided notification of the consultation to 40 non-CMA members which are active in the Sector and have received export market development grants. AMCL also provided notification of the survey to relevant licensees of the AMAG logo. The survey was open from 22 January to 12 February 2019.

The survey sought responses to questions relating to:

- Characteristics of businesses;
- Activities they are involved in;
- Imported ingredients;
- Exports;
- Use of the AMAG logo; and
- Impact of the CoOL changes, including any impact on production methods.

The survey received 26 responses, of which 24 were from businesses involved in the manufacturing of VMS. About a quarter of the industry responded to the survey.[33]

While all exporting VMS manufacturers who responded to the survey were aware of the changes, one respondent (a raw material supplier) was not aware of the February 2017 changes to CoOL requirements.

A number of firms, including two of the largest brands and one of the largest contract manufacturers did not complete the survey.

4.6.1 Business characteristics

Firms who responded to the survey ranged across the spectrum of turnover levels (Table 5) and employee numbers (Table 6). Most firms that answered the survey had a wholly Australian-based workforce, or very close to it.

Table 5: Firms by turnover range

	$50k to less than $200k	$200k to less than $2m	$2m to less than to $10m	$10m to less than $50m	$50m to less than $100m	$100m or more
Number of firms	3	1	8	3	3	5

Table 6: Firms by employment range

	1-4 employees	5-19 employees	20-199 employees	200 or more employees
Number of firms	4	6	9	5

[33] The TGA have 142 listed manufacturers. The CMA consider 82 of these to be part of their industry group. CMA represents 70% of all product sales and the entire value chain.

4.6.2 Manufacturing Steps

Among the firms surveyed, contract manufacturers were more likely to complete the five manufacturing steps than firms managing production in-house (Table 7). This indicates that firms surveyed are more likely to contract most of their products' manufacturing to other firms, and then take control of the branding/marketing ('Labelling and packing') and distribution ('Release for supply').

Table 7: Firms by manufacturing steps

	In-house	Contract	N/A
Manufacture of dosage form	9	15	5
Labelling and packaging	13	13	4
Testing microbial	3	19	4
Testing chemical and physical	8	17	4
Release for supply	13	14	3

Note: Firms may be involved with in-house and contract manufacturing.

4.6.3 Imported ingredients

All but one of the firms surveyed imported raw materials; yet more than half do not import any finished or near finished products. The products imported by VMS manufacturers are largely raw or slightly processed:

- Half of respondents imported 80 per cent or more of their raw material, while four firms imported less than 40 per cent of their raw material.
- Meanwhile, only a fifth of respondents imported less than 40 per cent of their bulk or raw ingredients from overseas.
- For products in a finished or near finished state, 88 per cent of responding firms indicated that less than half of their ingredient imports were in a finished or near finished state. Only one firm imported 80 per cent or more of its ingredients in a finished or near finished state.

When asked about individual products, several respondents explained that their import decision is based on the lack of some products within Australia and is sometimes influenced by seasonal availability. In addition, some products are patented and therefore only available from one country.

This is consistent with feedback from consultation where industry representatives advised the Taskforce that Australia does not produce some of the key ingredients required to manufacture complementary medicine products, and therefore are required to import them.

4.6.4 Export sales

The reliance of VMS manufacturers' business on exports sales varies considerably:

- A quarter of responding firms reported exporting 80 per cent or more of their total production, while nearly half of respondents exported less than 50 per cent of their output.

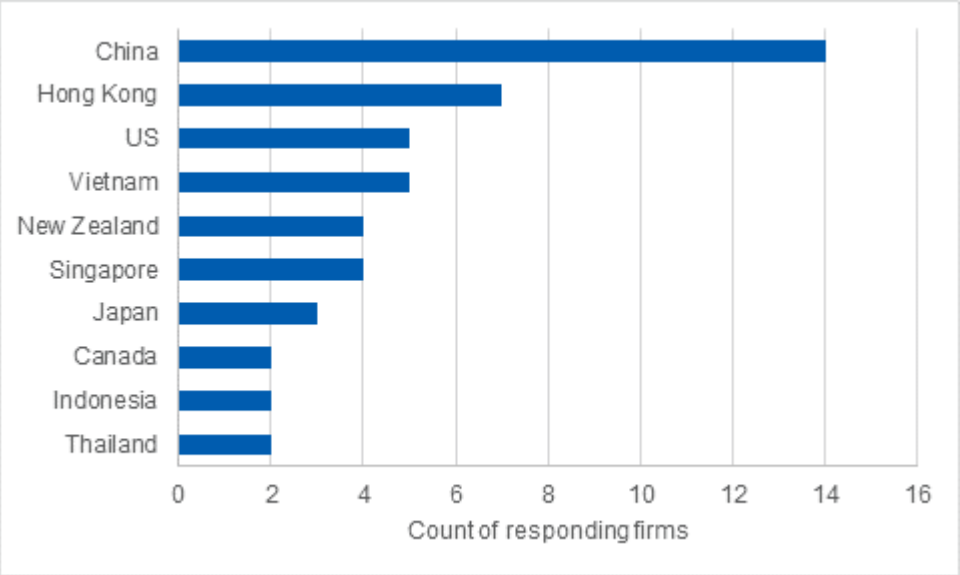
As a result, there was considerable variation in firms' revenue from export sales over the 2017-18 financial year. Of the ten firms that provided data in relation to this area:

- Four reported earning less than $1 million from export sales.

- Four reported earning between $1-5 million.
- Only two firms reported $40 million or more in export revenue.

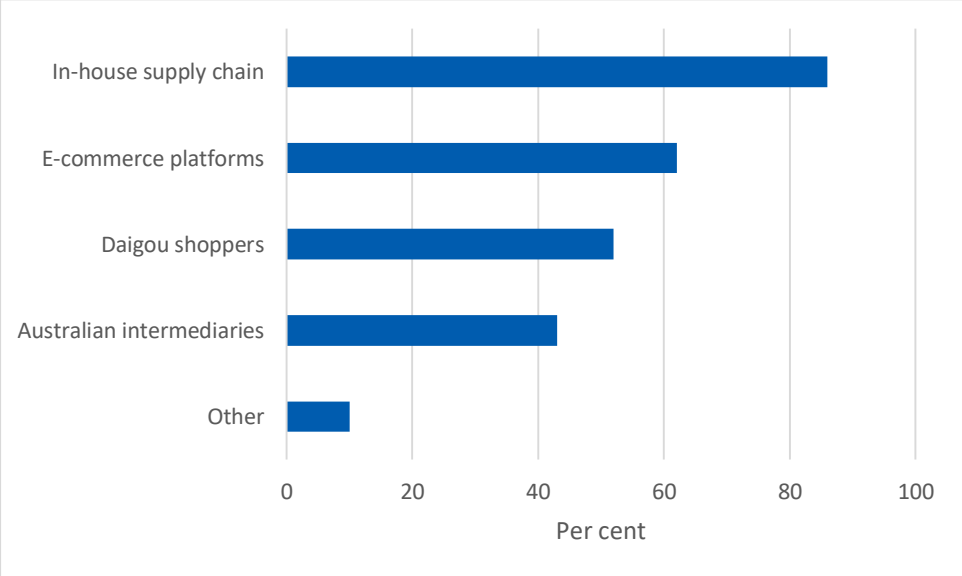
Eight of the top 10 export destinations cited by respondents were located in Asia & the Pacific, with the top export destinations being China, Hong Kong, the United States and Vietnam (Figure 6). This is consistent with export statistics.

Figure 6: Main export countries



Survey respondents who exported VMS products used a range of export channels. Whilst in-house supply chains remain the most common sales channel for exporting VMS products, online platforms and intermediaries are also widespread (Figure 7).

Figure 7: Sales channels for exporting countries



Note: As the question allowed multiple answers, the total exceeds 100 per cent.

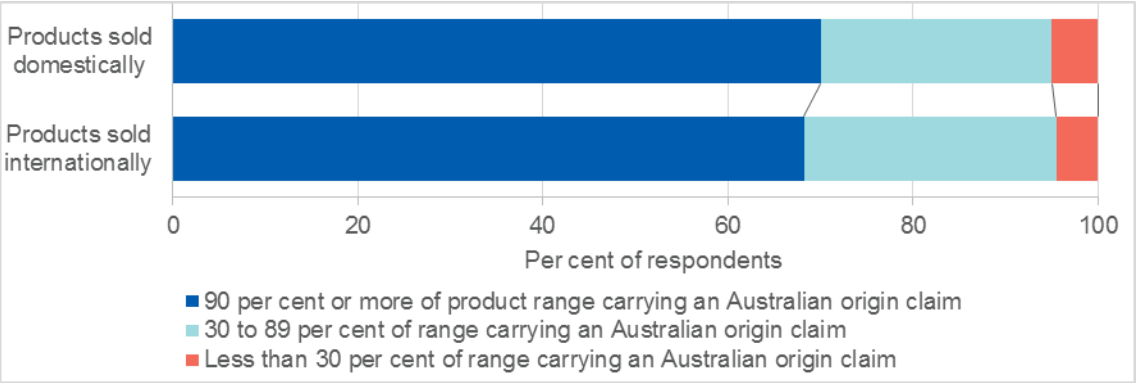
Daigou shoppers are intermediaries outside of China that purchase commodities for customers in mainland China. Demand for Daigou shoppers is driven by product unavailability and the high mark-ups (30-40 per cent) for imported goods sold through retail markets in China. Daigou shoppers make up a significant proportion of non-official exports. Firms surveyed by the Taskforce have indicated that Daigou shoppers could account for 10-30 per cent of their domestic sales.

4.6.5 Australian origin claims

Two-thirds of survey respondents used Australian origin claims on 90 per cent or more of their product range (Figure 8). Only two respondents reported using such claims on less than 30 per cent of their range.

Firms that use Australian origin claims said they use them equally for both international and domestic markets. One respondent further noted their business aims to base as much of their supply chain in Australia, including the manufacture of their packaging and labelling.

Figure 8: Share of respondents' range of VMS products that carry an Australian origin claim in domestic and international markets



4.6.6 AMAG logo

Despite the AMAG (Australian Made, Australia Grown) logo being a well-recognised brand, both domestically and internationally, only around half of surveyed firms used the 'Australian Made' logo on their products.

- For the firms that said they do use the logo, they used it on at least 80-100 per cent of their product range.
- For the firms that said they do not use the logo, most said they would wait for the rules to be further refined. However, one firm noted that they did not believe the use of the logo was lawful.

A number of firms, including two of the largest who did not complete the survey, noted during consultation that they have been successful in getting their brand recognised as 'Australian made' without the logo, including in the Chinese market. However, these same surveyed firms, as well as the two who didn't complete the survey, informed the Taskforce that they would likely use the logo in the future, when they expanded to new markets where their brand is not synonymous with being Australian.

Survey results confirm the importance of the Australian origin branding to the VMS manufacturing industry. Surveyed firms unanimously considered that Australian origin claims were an important reputational asset in competitive international markets and a critical plank of their marketing strategies:

- The price premium enjoyed by 'Australian made' products was said to compensate for the additional costs associated with manufacturing those products in Australia.
- Australia was consistently reported to be a "highly regarded" and "trusted" source country for VMS products, with Australian products reputed to be of "superior quality and safety" (particularly due to an assumption of high purity for the ingredients used). Survey respondents further said that this reputation underpins "consumer confidence" in Australian-produced VMS.
- In the domestic market, Australian origin claims were deemed "less important but still reassuring to local consumers who are interested in where the product is made."

Respondents noted that the credibility or "implied quality" of 'Australian made' VMS products was primarily attributable to the TGA's oversight of industry processes in Australia. They consistently highlighted that it was the TGA quality control and enforcement system that distinguished Australian products from other competing countries in Asia and North America, where complementary medicines are regulated as foods. The traceable nature of Australia's supply chains was also cited as another pillar of trust for Australian VMS products.

The quality and safety implied with 'Australian made' goods is seen as a significant marketing tool for complementary medicine manufacturers.

- All firms that used the logo believed it to be beneficial to their firm.
- Only three respondents did not believe the use of the logo increased their international competiveness (although these firms still believed it to be beneficial to their business).
- The use of the logo influenced a majority of the firms' business decisions (employment, marketing or investment).
- Only three respondents said their firm did not make business decisions based on the use of the logo.

Some respondents noted those reputational benefits were in part a return on logo licensees' own investment in marketing and establishing the 'Made in Australia' brand both domestically and overseas, including through industry groups.

In terms of the logo's impact on price, views were mixed:

- Whilst almost two thirds of respondents said that using the logo does not affect the price they can charge, most agreed that the logo affects customers' perception of quality and their willingness to buy.
    - Some said the logo is critical for sales in China and that it adds significant value and credentials to their brand.
    - One firm suggested that the logo "used to be important but has become a commoditised logo. Every company under the sun uses it but because it is not regulated it has no impact anymore". Another firm said "it was a benefit back in the early days but now it's just expected".
    - While there is limited official research on the Daigou trade, media reports have suggested that Daigou shoppers are able to sell goods at 20-30 per cent higher in overseas market than the Australian RRP. This includes brands that have a strong Australian brand but contain no origin labelling.
- Some respondents explained that including an Australian origin claim on their labelling or packaging affects what they can charge for their VMS products. The higher perceived quality allows them to justify premium pricing for an authentic product.

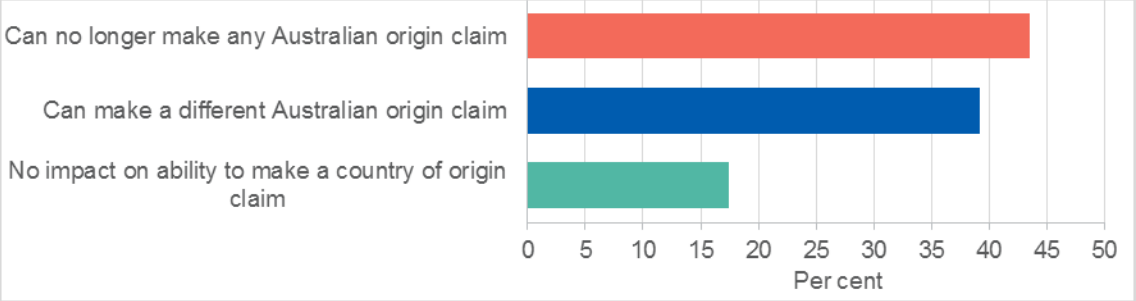
Over 70 per cent of responding firms agreed that using the AMAG logo affects the quantity of products they sell. Some explained that it is difficult to provide evidence to this effect since many firms have only ever used the AMAG logo. However, they argued that the loss of the AMAG logo would cause doubt in overseas customer's minds about the quality of products.

4.6.7 Impact of CoOL legislative changes

In terms of the impacts of the changes (Figure 9):

- More than a third of respondents reported they can no longer make any Australian origin claim on their products.
- Another third responded that they can no longer make the same claim but can make a different Australian origin claim.
- Only four respondents reported no impact from the legislative change on their ability to make a country of origin claim.

Figure 9: Impact of country of origin labelling law on VMS manufacturing firms' ability to make country of origin claims



Respondents noted the full impact from the legislative changes on their businesses were yet to be determined, with most respondents waiting to see the outcome of the present review.

The main impacts consistently reported by respondents at the time of the survey related to:

- Physical changes to their labelling and packaging. This included removing all Australian claims or replacing the logo with a bar chart or statement. Several respondents noted the packaging redesign itself had a high financial cost and resulted in significant waste.
- Consumer confusion. Several VMS manufacturers and distributors reported having to explain the changes in response to questions from customers, who tended to assume the products were no longer 'Made in Australia'. Respondents attributed this to Australia's new 'made in' definition being different to that applied in other countries (e.g. China, with respondents arguing the definition used for exports should be that of the target country).

Several respondents raised concerns about the increased administrative time-cost and complexity under the new country of origin regime, noting it may require employing dedicated compliance. One respondent suggested the negative impacts of the new regime would be disproportionately borne by small companies.

While only one respondent reported having experienced a reduction in sales, most other respondents anticipated reduced sales in the short to medium term. They noted that an inability to use Australian origin claims suppressed their main competitive advantage (implied consumer trust).

The potential impact estimated by respondents varied:

- One estimated that 50 per cent of their business was at risk.
- Another said that the change had "the potential to devastate [their] Chinese sales".

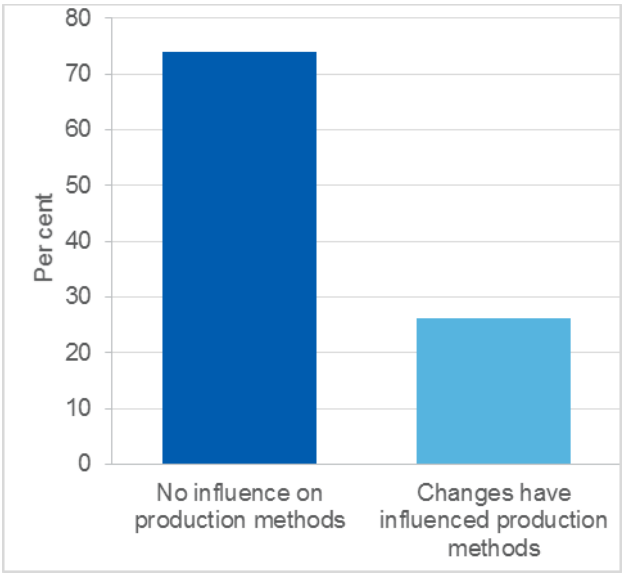
The removal of an Australian origin claim was seen as a major reputational risk. A respondent wrote that "taking it away from use in our products will have a greater affect as it will be seen by our customers that we have either lost government endorsement or that the products are no longer 'Made in Australia'."

- One respondent said the logo is highly regarded within the Chinese market and that "customers question then refuse to purchase our products because we are no longer able to use the AMAG logo". One firm stated that the change to the logo "will damage the market and industry extremely badly".
- Another reasoned that there will be a loss of employees in science and innovation as manufacturers move offshore to reduce costs to make a level playing field.
- Another firm said they will be out of business without use of the logo and urged decision makers to consider the effect of these changes on the industry's ability to export and earn foreign exchange for Australia.

Almost three quarters of respondents said the changes to country of origin law had not influenced their production methods or how they source ingredients (Figure 10).

- Most reported they have to source some raw materials overseas because the ingredients they used were either not available in Australia, or not available in the required quantity, quality, or time of year.
- Some noted that adapting to the new requirements by sourcing only 'Australian made' ingredients may reduce the quality of their products, as they currently source the best quality, most appropriate ingredients to fit specific formulations.

Figure 10: Influence of country of origin labelling law on production methods and sourcing ingredients



While no company had already relocated activities offshore, seven respondents (just over a quarter of the sample) said they had either started to consider offshore manufacturing options or were

planning to do so in the near future. Of these, one respondent reported having made the decision to offshore the segment of their range affected by the new legislation.

Considering offshoring production was attributed to the loss of the business' competitive advantage against cost-cutting overseas competitors. A majority of respondents highlighted that it was the marketing benefits of Australian origin claims (and the associated price premium for labelled products) that justified the added costs of locating their VMS manufacturing and packaging processes in Australia.

5 Consumer Research

5.1 Purpose and Research Objectives

Colmar Brunton was commissioned to conduct research to examine consumer preferences for the use of the AMAG logo on a range of complementary healthcare products. Colmar Brunton conducted qualitative research, through a number of small face-to-face focus group conversations involving 78 participants, and quantitative research, carried out through an online survey of 2091 respondents.

The aim of the research was to gather information that provides an accurate, representative and defensible view of the importance of the AMAG logo on purchasing decisions and consumer expectations of the use of the logo on vitamins, minerals and supplements.

The specific objectives of the research included understanding:

- The importance of the AMAG logo to the complementary healthcare consumer; and
- Consumer preferences for the use of the AMAG logo on an array of complementary healthcare products including:
    - When the logo should be used; and
    - Under what circumstances would logo use be an inappropriate designation of 'Made in Australia'?

A note on consumer data: Unless otherwise stated all consumer data, opinions and preferences regarding the Sector, the AMAG logo and thoughts on what constitutes 'Australian Made' in this report is based on domestic consumer responses.

5.2 Key Drivers of Choice: Price and Brand

Of the Australian consumers surveyed, 78 per cent either purchase or use complementary healthcare products. While there was great variety in where the products were purchased, the most common drivers for consumer choice of products were price (62 per cent) and brand (50 per cent). The research showed that country of origin is not something Australian consumers immediately looked for or noticed when purchasing complementary health products, as reflected by survey and focus group responses. Upon probing during the focus group sessions, most said they would prefer 'Australian made'.

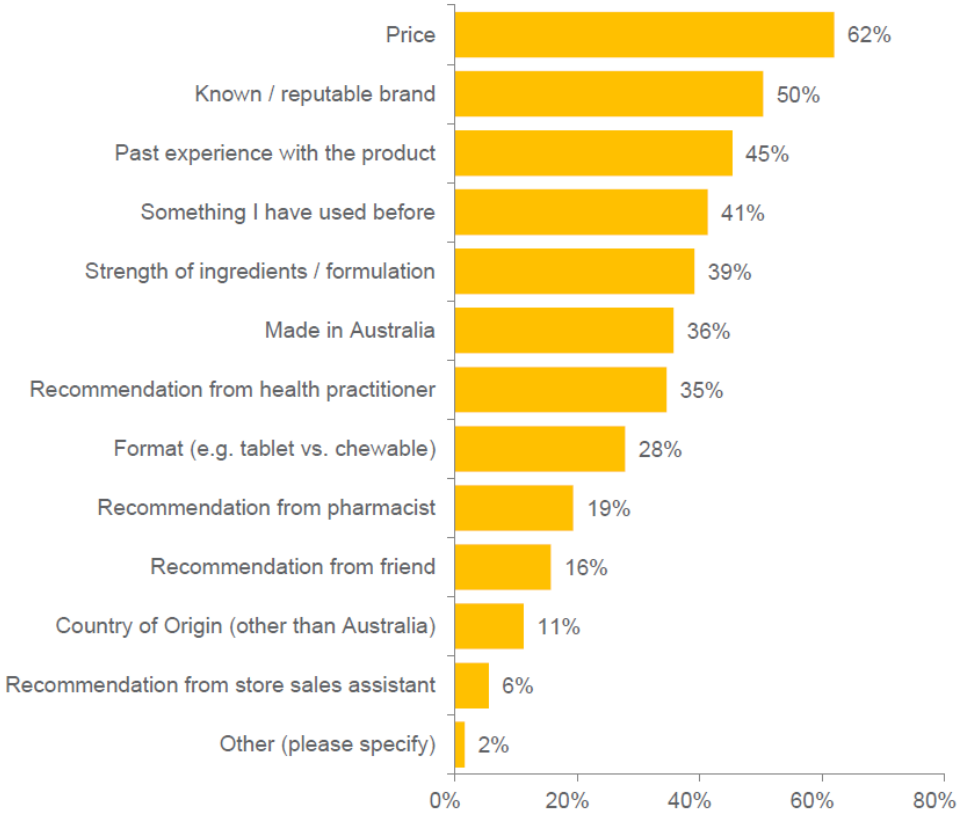
The research indicated that brand choice is based predominantly on a perceived faith or trust in that brand. These views are based on its perceived reputation, prominence, familiarity and perception of quality. Some consumers admitted that they would prefer a known brand that was not 'Australian made' over an unknown brand that was 'Australian made' if the quality and value for money was perceived to be higher. It was also found that price is also a considerable factor or driver in consumers' choice of vitamins, minerals and supplements. Specifically, there was a relationship between increased price and perceived product quality.

The quality of VMS is evaluated on the physiological changes or improvements noticed by consumers. Past experience was also important for some who had trialled and experimented with different brands and products. The strength of the ingredients and the form of product is also considered by many when choosing complementary medicines.

Only 11 per cent of surveyed consumers nominated country of origin (other than Australia) as a deciding factor when purchasing complementary healthcare products. Consumers stated that as long as the products are 'Made in' a country perceived to be quality, trustworthy and with rigorous quality control, such as the US, UK and Europe, consumers did not mind where these products were made.

"It doesn't need to be made here to be quality."

Figure 11: Consumer VMS purchasing decisions



Source: Colmar Brunton Consumer Research Report - Appendix L.

5.2.1 Importance of Buying Australian Made

There was a strong theme of perceived quality of products 'Made in Australia'. The online survey results demonstrated that 65 per cent of Australians expect the quality of complementary healthcare products 'Made in Australia' to be better than products made elsewhere, while 22 per cent felt they would be the same. Further to that, 54 per cent of Australians felt that the effectiveness of complementary healthcare products 'Made in Australia' would be better than those made elsewhere, while 32 per cent felt it would be comparable. This stems from the understanding that products sold in Australia would have undergone strict quality testing.

"To be sold here it has to be approved by the TGA." 18-44 year old from Adelaide

5.2.2 What the AMAG logo represents to Consumers

When consumers were shown the AMAG logo, participants responded positively to this label, trusting it almost immediately. Consumers feel the AMAG logo guarantees them a wholly Australian product – from the sourcing of ingredients through to the manufacture and packaging.

"This logo shows that something is tried and tested… it's trustworthy and familiar."

"This [logo] has rules and quality control around it."

Hearing the current AMAG labelling rules, contradicted consumers' expectations and filled consumers with doubt regarding actually how high the standards are in Australia when it comes to regulation of complementary healthcare products, given some products can be claimed as 'Australian Made' when they contain imported ingredients. Many assumed that the complementary

healthcare products they purchased that were 'Made in Australia' were from local ingredients and were surprised when they heard others saying this was not necessarily the case.

Overall, most agreed that the country of origin terminology, despite being simple, created confusion as consumers identify three key elements in the overarching process – sourced ingredients, manufacture and packaging.

By having a catch all 'Australian Made' meant that consumers would expect all stages of this process to occur in Australia without the claim appearing misleading.

When the participants were made aware of the changes to the AMAG logo labelling laws, there was some debate around the definition of CoOL, with some understanding it as referring to where ingredients are sourced, others felt that it represented where products were manufactured, and others thought it was a combination of both. Despite this, very few could recall seeing CoOL on VMS. Comments from participants indicate the public are largely unaware of any media, focus or attention being placed on CoOL.

Once consumers had questioned the origin of ingredients, they became concerned about the 'Made in Australia' message being misleading as although 'Made in Australia', it may in fact be from imported ingredients. Without expressing the source of the ingredients with the logo, consumers may become confused and believe the product is wholly Australian, when it is not.

5.2.3 What Consumers Think Passes the Test to Use the AMAG Logo and 'Made in Australia'

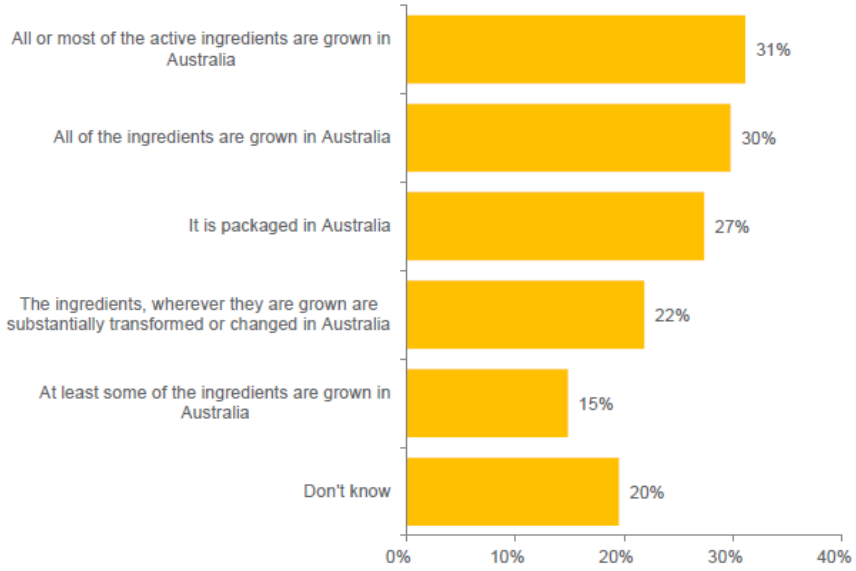
The participants agreed products that are 'Made in Australia', even with imported ingredients, should be able to use the AMAG logo, however it must be accompanied by the origin of ingredients and proportion.

The participants agreed that is more misleading to claim 'Made in Australia' and exclude the fact that some ingredients are imported, than to not provide any type of origin labelling at all.

Most participants believed that both the current and previous AMAG labelling rules were too relaxed. Although the new rules were seen to be a slight improvement by some, they were still perceived as not strict enough. Consumer views on what is appropriate to describe a product as 'Made in Australia' are at Figure 12.

Realising, based on the current and previous rules, that organisations who import ingredients (despite still making the products in Australia) could still use this logo, created anger amongst consumers and risked tarnishing the credibility of this logo.

Figure 12: Consumer Views on the Definition of 'Made in Australia'



Source: Colmar Brunton Consumer Research Report - Appendix L.

Participants were given a series of examples pre and post being informed about the meaning of substantial transformation and what constitutes a 'Made in Australia' claim. A summary of their interpretation is at Figure 13.

Figure 13: Consumer Views on VMS Products that Constitute 'Made In Australia'

Would the following be able to claim 'Made in Australia'? (Green shading represents a 'Yes' to passing the test)

Example	Would it pass the test?			
	Pre-informed		Post-informed	
	% yes	% no	% yes	% no
A cough syrup solution made with multiple active ingredients where the ingredients are Australian	79%	8%	77%	9%
Imported Vitamin C powder, made into tablets and packed into sachets in Australia	22%	62%	21%	63%
Australian grown herbs, dried and packed	85%	5%	81%	7%
Imported bulk cod liver oil bottled in Australia with added orange flavour	20%	64%	20%	64%
Imported herbs dried and packed in Australia	21%	65%	23%	63%
Raw materials imported to Australia and manufactured into a cream	32%	50%	53%	32%
Liquid vitamin B capsules, encapsulated in Australia using imported Vitamin B	24%	57%	22%	61%
Vitamins and minerals imported in granules combined (blended) in Australia to make a multi-vitamin tablet	28%	53%	35%	48%
Vitamins and minerals imported in raw form and made into granules in Australia then combined to make a multi-vitamin tablet	36%	47%	47%	37%
Black seed oil is extracted (through pressing) in Australia, from imported seed	35%	46%	48%	36%
A cough syrup solution made with multiple active ingredients where the ingredients are Australian	79%	8%	77%	9%

Source: Colmar Brunton Consumer Research Report - Appendix L.

5.3 What Consumers Want on VMS Products

When prompted to consider CoOL on VMS products, consumers indicated that they would like to see CoOL apply to vitamins, minerals and supplements as seen below.

If product is made in Australia, from 100% Australian ingredients:	If product is made in Australia, from a mix of local and imported ingredients:	If product is not made in Australia:
		

The above depictions and overall observations from this study suggest that surveyed consumers would prefer greater clarity regarding the proportion of ingredients that are from Australia when purchasing VMS products. The research undertaken by Colmar Brunton built on previously undertaken research and provided valuable insights regarding consumer preferences for the labelling on VMS products.

5.4 What Consumer Representatives want for consumers.

In a submission received by Dr Ken Harvey on behalf of Choice, Public Health Association of Australia, Health Action International Asia Pacific and Friends of Science in Medicine, these consumer representatives want to see the same labelling on complementary medicine products that apply to priority food labelling. Furthermore they expressed support of upholding the current safe harbour defences including the definition of substantial transformation, as reducing the strictness around the safe harbour defences would not be in the interest of consumers or the reputation of the AMAG logo. See Appendix M.

6 Conclusion

6.1 Interaction of the Sector with the CoOL Policy framework and ACCC guidance

The Sector claims that limiting access to the AMAG logo for some of its products, will result in unnecessary and serious impacts on the Sector. Job losses, reduced investment, reduced domestic growth, a dampening of export growth and the possible offshoring of production are identified by the Sector as potential outcomes. The catalyst for these concerns were the changes made by the Australian Government to the substantial transformation test under the ACL through the CoOL reforms.

Before the CoOL reforms, many products in the Sector were able to qualify as substantially transformed under the test as it stood, and relied in part on an origin claim demonstrating a 50 per cent domestic production cost incurred on transforming an imported product. This test benefited the Sector as creating a VMS product from imported ingredients incurred a number of costs. VMS manufacturers added value to raw imported ingredients in a number of ways including quality testing, product development and production costs. However through the CoOL reform investigative process it was found that, across industry, the 50 per cent production cost test was an expensive and confusing test to administer. For consumers, it meant little in defining the origin of a product. It is for these reasons the test was removed.

6.2 Commercial Impacts of the current substantial transformation test on the Sector

In addition to removing the 50 per cent production cost test, the CoOL reforms changed the definition of substantial transformation. A product that does not meet the substantial transformation test cannot claim 'Made in Australia' under the safe harbour defences. If a product with imported ingredients cannot make a 'made in' claim under the safe harbour defences then the product is unable to use the AMAG logo. The ACCC provided advice specific to the Sector in March 2018 on which VMS manufacturing processes were likely and unlikely to meet the substantial transformation test. AMCL relied on the ACCC advice in framing their publicly available guidelines regarding access to the AMAG logo.

In the absence of ACCC advice, the Sector and especially AMCL would have found it difficult to judge whether a product, having been processed in a certain way, satisfies the safe harbour criteria. ACCC's advice provides clarification on this, and in the case of encapsulating imported fish oil, proved to be accurate.

As explored in Section 4, the complementary healthcare industry as a whole has enjoyed strong growth over the last five years, driven by increased consumer demand for high quality, safe VMS products in both domestic and international markets. In 2018 China and Hong Kong accounted for 70 per cent of the $936m of official exports of VMS products from Australia, whilst Australian consumers purchased $2.9b of VMS products. In assessing the commercial impacts of the current substantial transformation test the Taskforce utilised market research and reports, a proprietary sales database, AMAG licensee register, official trade statistics from the ABS, and submissions directly from industry.

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Research for this report indicates that strong sales growth has been achieved by firms which are known for producing high quality safe Australian products that do not depend on AMAG logo use. Domestically, where AMAG logo usage is known for just over 90 per cent of the VMS market, 4 out of 5 products do not carry the AMAG logo. Investigation of international markets and consumer preferences was beyond the scope of this review, however research has shown that in the key Chinese market, Australian VMS exports to China via online platforms, generally market a product's connection to Australia without relying on the AMAG logo.

The report's industry survey illustrated concerns the Sector has with the change to the substantial transformation test and consequential loss of the AMAG logo for many products. The Taskforce acknowledges these genuine concerns however the actual commercial impact of the changes was not able to be assessed.

Further discussion on origin labelling and the impact of changes to Australia's origin labelling law is available in Section 4.6 of this report from the firms which provided submissions to the Taskforce's consultation. It should be noted that due to data limitations, quantification of the impact for the entire Sector is not possible. Further, due to production methods and competitive dynamics of the industry, the impact of the changes to AMAG logo access may not be distributed evenly across all firms in the Sector. For instance it is unknown whether impacts of the CoOL changes will effect contract manufacturers more directly as they try to win international production contracts or whether small firms moving into export markets without brand recognition will be impacted disproportionately.

6.3 Australian consumer expectations of the Australian Made, Australian Grown logo usage

The Taskforce set out to assess the consumer understanding and expectations relating to the rules governing the AMAG logo and factors affecting consumer choices in purchasing VMS products. Consumer research indicated strong support and preference for Australian made products, but until focus group participants were prompted, this was not something they noticed or looked for when buying VMS products. With reference to the perception of the AMAG logo, consumers place great value on the logo and believe it represents a guarantee of a mostly Australian product – from the sourcing of ingredients through to the manufacture and packaging – a higher standard than required under the substantial transformation test.

Brand and price rank higher in the factors that influence an Australian consumer's purchasing habits for the Sector's products.

When prompted to consider CoOL on VMS products, the most important factor for consumers was the proportion of the product made of Australian ingredients, and where ingredients sourced from overseas were from. Information such as where the product was manufactured and packaged was seen as less important in the context of information provided by CoOL. It would be entirely consistent with consumer research undertaken by the Taskforce if VMS products are to carry the kangaroo in triangle logo, then that logo should be accompanied by an indicator of the proportion of Australian ingredients and a statement on what the logo is representing for that product.

7 Options for Next Steps

The Taskforce was required to develop options for next steps in the process to respond to the Sector's concerns. In developing the following options for next steps the Taskforce has taken into consideration both industry concerns and consumer preferences for the AMAG logo. The options identify likely timeframes for government to bring the options into operation. For regulatory/legislative changes involving the ACL, timeframes have assumed appropriate consultation with states and territories through the Intergovernmental Agreement (IGA) for the Australian Consumer Law (ACL). Under the IGA, each state and territory has enacted legislation that applies the ACL, and any amendments to the ACL (including information standards) requires consultation with, and agreement by, the states and territories.)

Investigations on how to implement options were out of scope for this report although for some options, broad implementation pathways have been identified. Implementation of options would require additional investigation to identify most appropriate ways to proceed.

The Taskforce has identified the following options with a range of pros and cons. Choice would be largely driven by relative weighting on value to the industry, consumer expectations and confidence in the AMAG logo, and length and complexity of implementation path.

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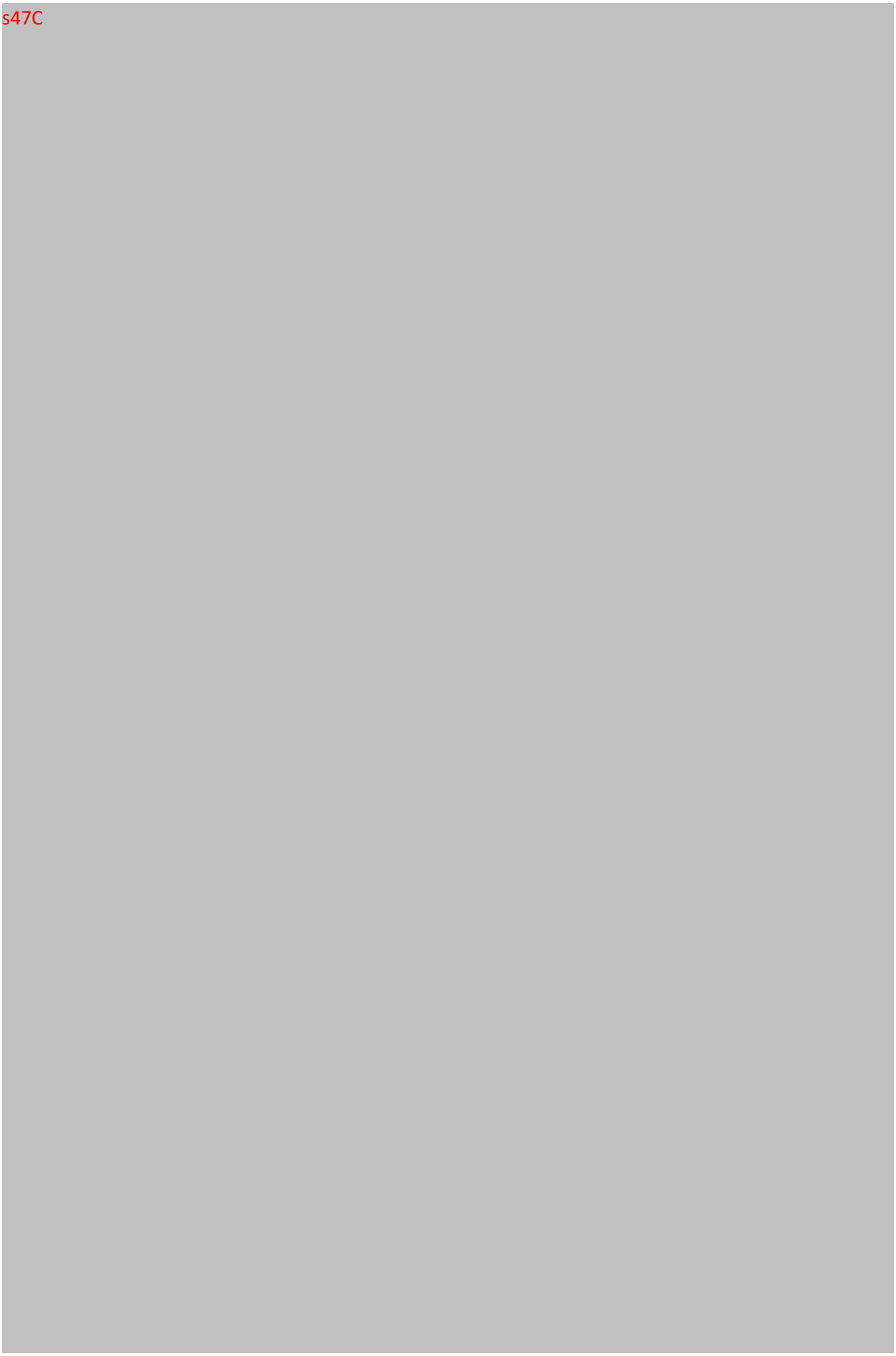

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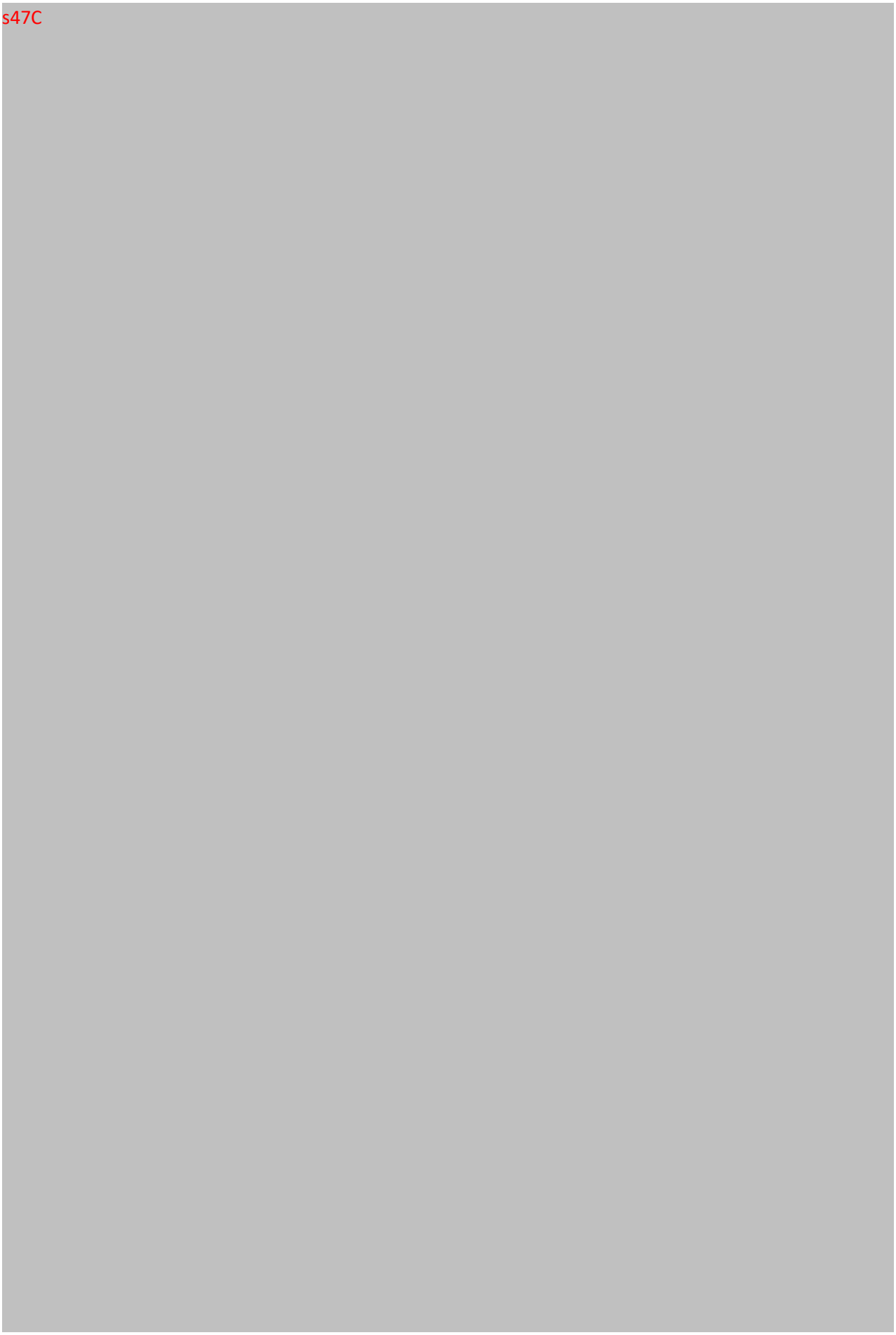

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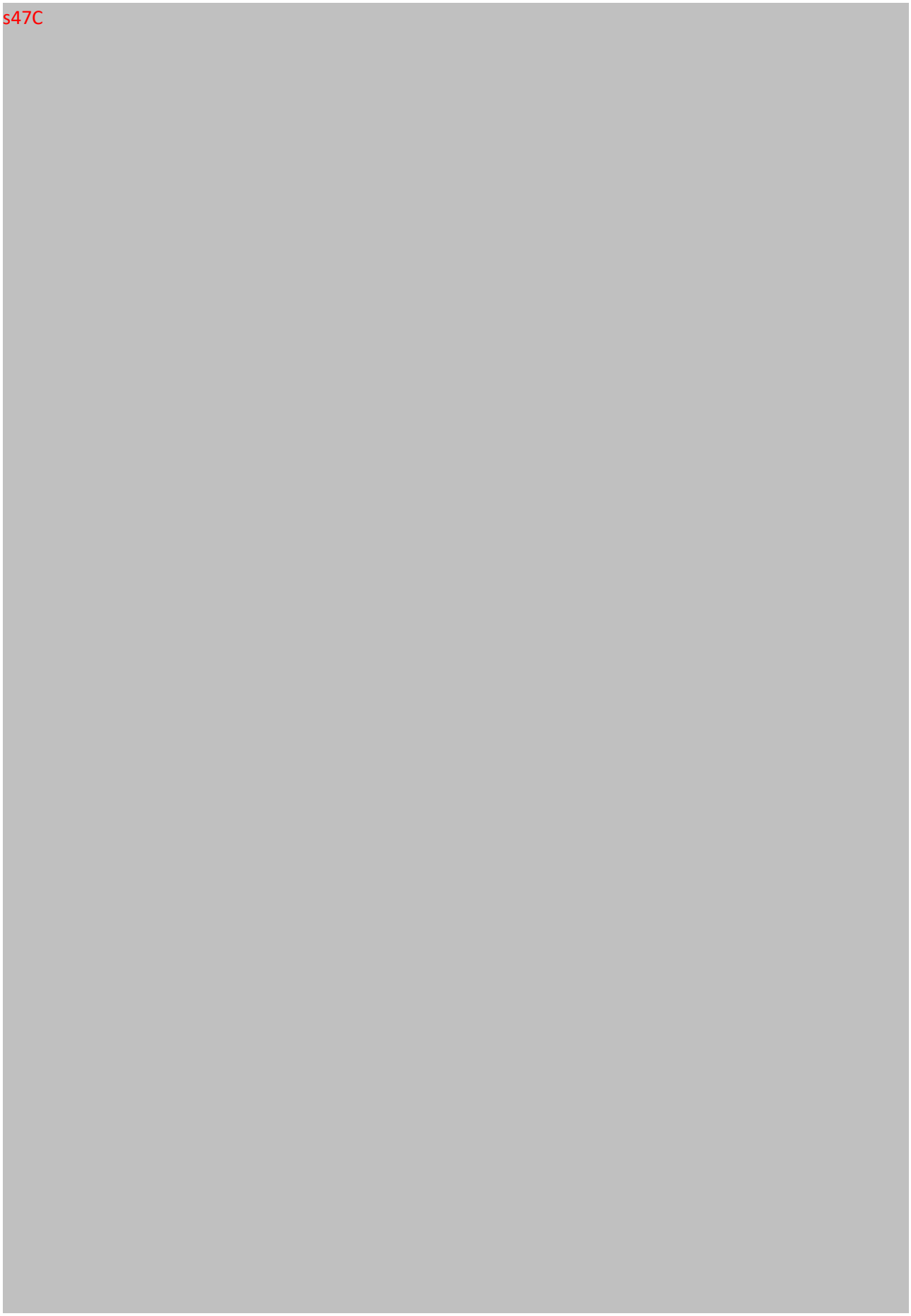

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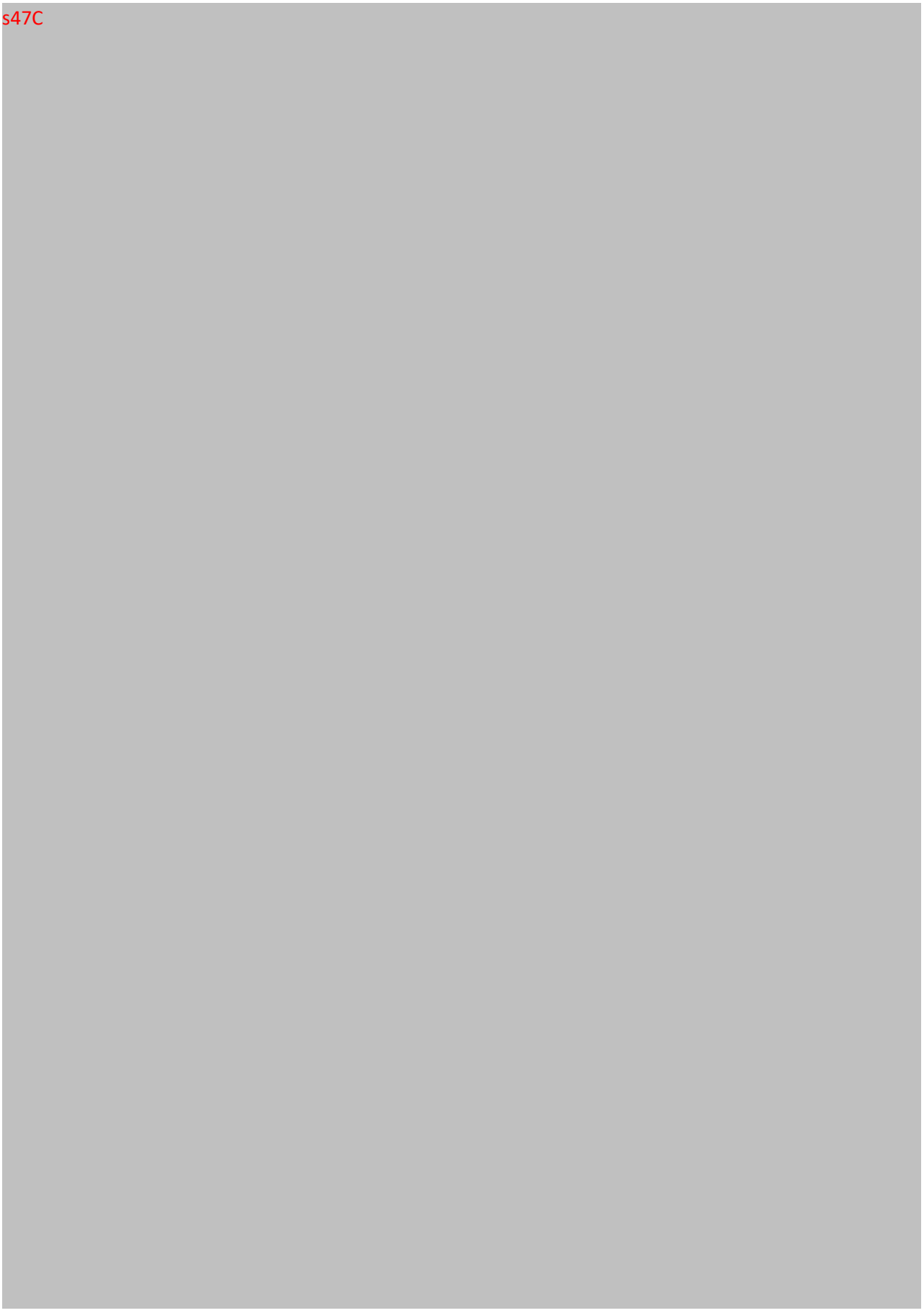

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Appendix A – Complementary Healthcare Sector and Country of Origin Labelling Taskforce Terms of Reference

1. Background

The purpose of the Complementary Healthcare Sector Country of Origin Labelling (CoOL) Taskforce (the Taskforce) is to examine concerns raised by the Complementary Healthcare Sector (the Sector) about changes to the use of the 'Australian Made, Australian Grown' (AMAG) logo, and investigate options that may address these concerns while maintaining consumer confidence in the authenticity of 'Made in Australia' claims.

The Sector reports that a rapid increase in international sales of vitamins, minerals and supplements has led to greater domestic investment and job creation. The Sector has identified that claiming Australian origin and using the AMAG logo is a key marketing advantage when selling into both domestic and export markets.

The overall sector revenue is reported by industry as $4.9 billion in 2017 across 82 Australian-based manufacturers. Industry representatives say that if a significant reduction in sales occurs in export markets, impacts could include reduced employment and growth in the Sector.

The AMAG logo is licensed to industry by Australian Made Campaign Limited (AMCL) in accordance with the Deed of Assignment between the Commonwealth of Australia and AMCL and the AMAG Logo Code of Practice (certified trade mark rules). The AMAG logo can only be licensed for products that are consistent with Australian Consumer Law (ACL) safe harbour defences.

The February 2017 changes to the substantial transformation test under the ACL, meant for claims of 'Made in Australia' to qualify for the relevant ACL safe harbour defences, a new product with imported ingredients needs to be fundamentally different in identity, nature or essential character from the imported ingredients.

The Australian Competition and Consumer Commission's (ACCC) guide to the Sector in March 2018 outlined a number of production scenarios that the ACCC considers likely to either meet or not meet safe harbour defences. The Sector is concerned that many of its products will not meet the ACCC's interpretation of substantial transformation and therefore will not be allowed to use the AMAG logo.

2. Purpose

The Taskforce will investigate and assess claims made by the Complementary Medicines Sector regarding the effect the changes to the ACL substantial transformation test will have on the Sector's ability to utilise the AMAG logo, or make a 'Made in Australia' claim; and the effect upon Australian manufacturing jobs. Both industry and consumer interests will be considered in this process and will be presented in the report.

3. Scope

The Taskforce shall:

1. Assess how the current CoOL policy framework, including ACCC guidance regarding the substantial transformation test, interacts with the complementary healthcare sector. This

shall include reporting on industry concerns about how this policy and guidance may be impacting upon business decisions within both the Sector, and AMCL in licensing use of the AMAG logo.

2. Assess the commercial impacts of the current substantial transformation test under the ACL on the complementary healthcare sector regarding products generally referred to as vitamins, minerals and supplements.
3. Assess Australian consumer understanding and expectations relating to suggested changes by the Sector regarding rules governing the use of the AMAG logo. This will include consideration of impacts on consumer choices in purchasing products, and the need to protect and ensure the integrity of 'Australian made' claims and the AMAG logo.
4. Give consideration to broader market or industry impacts regarding CoOL and AMAG logo use beyond the complementary healthcare sector. Identify appropriate next steps for responding to the Sector's concerns.

4. Membership

The Taskforce will comprise representatives from the:

1. Department of Industry, Innovation and Science;
2. Department of the Prime Minister and Cabinet;
3. Treasury;
4. Department of Foreign Affairs and Trade/ Austrade;
5. Department of Agriculture and Water Resources;
6. Australian Competition and Consumer Commission; and
7. Department of Health.

In conducting its activities the Taskforce will consult with:

- Relevant State Government agencies;
- Complementary Medicines Australia;
- Manufacturers within the complementary healthcare sector;
- Other industry stakeholders with an interest in 'Made in Australia' claims
- Consumer organisations;
- Australia Made Campaign Ltd; and
- Other agencies and/or stakeholders as required.

5. Operations

The Taskforce:

1. Will meet as required. If required, members can ask the chair to hold additional meetings, providing at least two weeks' notice is given.
2. Will meet via teleconference with the option to meet in person if appropriate. Members may (on agreement with the Chair) undertake work out-of-session to inform and support the deliberations of the Taskforce.

- The Department of Industry will provide the Chair and Secretariat for the Taskforce.
- Members will contribute professional knowledge and expertise to discussions of the Taskforce.
- Members may be requested to contribute data to establish an evidence base for the Taskforce to consider options.

- Some sales, employment or marketing data (or other commercial information) relevant to Taskforce deliberations may be commercial-in-confidence. The Taskforce will seek advice as appropriate to manage the confidentiality of data provided to the group.
- The Taskforce may draw upon the expertise of non-members to inform the discussions of the group on an ad-hoc basis. The Chair will consider and approve such requests.
- The Chair will consider for approval requests for the attendance of non-members (outside of the Secretariat) at Taskforce meetings.

6. Deliverables

The Taskforce shall provide Government with a report addressing each of the issues identified for examination within scope for the Taskforce.
The Taskforce will provide advice to Government by the end February 2019.

7. Review and reporting

Members of the Taskforce will have scope to review and comment on the final report. The final report will be delivered to the Minister for the Department of Industry, Innovation and Science and the Assistant Treasurer.

Appendix B – Therapeutic Goods Administration

Good Manufacturing Practice / Strict Manufacturing Standards

In Australia, the Therapeutic Goods Act 1989 requires, with certain exceptions, that manufacturers of therapeutic goods hold a licence (for medicines) or a conformity assessment certificate (medical certificate). It is an offence, carrying heavy penalties, to manufacture therapeutic goods for human use without a licence or a conformity - assessment certificate unless the manufacturer or goods are exempt from this requirement.

TGA GMP Certification and Clearance process for overseas manufacturers

There are two ways overseas manufacturers receive TGA GMP approval - TGA GMP certification and TGA GMP Clearance. The main difference between the two is GMP Certification requires a physical on-site inspection by the TGA while a GMP Clearance is provided on the basis of an on-site inspection of the overseas manufacturing facility by an accepted comparable overseas regulator and a TGA desk-top review of documentation.

There are no differences between the domestic and overseas inspection procedures.

GMP requirements for Australian complementary medicines (listed medicines)

Overview

- In Australia, the Therapeutic Goods Act 1989 requires, with certain exceptions, that manufacturers of medicines (a type of therapeutic goods) hold a licence. It is an offence, carrying heavy penalties, to manufacture medicines for human use without a licence unless the manufacturer or goods are exempt from this requirement.
- Only Australian manufacturing sites can obtain a manufacturing licence. If any of the manufacturing steps are performed in Australia, each nominated manufacturer of that manufacturing step is required to obtain a TGA manufacturing 'licence'. A TGA licence is required regardless of whether the medicine ingredients are sourced internationally or locally.
- To obtain a licence, an Australian manufacturer must demonstrate compliance with the relevant code of Good Manufacturing Practice (GMP). This is usually, but not always, done through an on-site inspection.
- Overseas manufacturers can instead obtain GMP Certification following a successful on-site inspection by the TGA.
- GMP certification applications are required to be submitted by the Australian sponsor or an agent acting on the Australian sponsor's behalf. On successful close out of an on-site inspection, the Australian sponsor is issued a 'GMP Clearance' for the purposes of registration or listing.
- Alternatively, sponsors may apply for a GMP Clearance via a Desk-Top Assessment (DTA) pathway. This process has two further pathways determined by the agreements and arrangements in place between the TGA and other comparable overseas regulators, provided that the products are also regulated as medicines in the other country.
- The two pathways for GMP Clearance are the Mutual Recognition Agreement (MRA) pathway and the Compliance Verification (CV) pathway.
- The TGA uses internationally harmonised manufacturing standards to allow manufacturers to operate in an international environment. All manufacturers of medicines, including complementary medicines, are required to comply with the GMP Principles set out in the

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products.

- PIC/S presently comprises 52 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia). However, not all Participating Authorities require products regulated as 'listed medicines' in Australia to comply with these GMP principles34.
- No batch of product (including validation batches) manufactured prior to licensing or certification can be sold or supplied within Australia, or exported from Australia, unless prior approval has been obtained.

Manufacturing steps required to be GMP compliant

- It is an offence in Australia to manufacture complementary medicines without appropriate evidence of GMP compliance, unless the manufacturer is exempt from this requirement under the Act.
- The sections of the PIC/S Guide that apply to a product are determined by the nature of the manufacturers operations and the types of products or dosage forms being manufactured.
- There are a number of manufacturing steps broadly referred to as below each of which have specific steps/requirements referenced in GMP guidance. Some manufacturing steps are mandatory and required to be recorded in the ARTG. Others are non-mandatory:
    - Manufacture of dosage form – is the process of formulating the active ingredient(s), usually in combination with excipients, into the form in which they are marketed for administration to the patient/consumer, e.g. tablet, cream either ready for assembly into final containers or in individual containers ready for assembly to final packs.
    - Labelling & packaging – is the process in which a bulk product (e.g. tablet, cream) is included in its primary container (e.g. blister packs, bottles etc.) for release for supply to the market, excluding any outer packaging used for transportation or shipment.
    - Testing microbial and Testing chemical & physical is any activity concerned with sampling and testing of all materials used throughout the manufacturing process to established specifications, including starting materials, intermediates, excipients, preservatives, and final bulks or products, to ensure quality before release for further processing or supply.
        - Microbial testing includes testing for contamination of the product by microorganisms such bacteria, fungi etc.
        - Chemical and physical testing includes testing of the composition, strength, potency, stability and purity
            - For example - stability testing for listed and complementary medicines is mandatory. All responsibilities related to ongoing stability testing should be defined in a GMP agreement (unless the sponsor, manufacturer and authorised person conducting release for supply are all from the same entity).
- Release for supply is the process where the last manufacturer in the supply chain certifies that each production batch has been produced and controlled in accordance with the requirements of the marketing authorisation and any other relevant regulations, before the product is released to the Australian market

[34] For example many products considered as complementary medicines in Australia are considered in other countries as food supplements and regulated according to food regulations

- Secondary packaging - Any packaging or labelling process (including repackaging and labelling, over-labelling and supplementary labelling) where the medicine is already in the primary container, and that primary container is not opened, breached or modified in the secondary packaging process.
- For 'listed' complementary medicines, the following (mandatory) steps are required to be entered on the ARTG (evidence of GMP compliance is required for) manufacture of the finished dosage form, labelling/packaging, microbial and chemical testing, and release for supply.
    - A manufacturer can perform one step (e.g. packaging and labelling only) or all steps.
    - Multiple manufacturers can perform the same step(s), provided evidence of GMP compliance is provided for each manufacturer.
- All manufacturing steps are required to be GMP compliant unless they are exempt. However, evidence of GMP compliance is only required if the manufacturing step is recorded in the ARTG.
- If the step is not recorded on the ARTG (and evidence of GMP is not required), it is the responsibility of the manufacturer of the first step that is recorded on the ARTG to verify ongoing GMP compliance. For example, for listed medicines the dosage form manufacturer is required to verify manufacture of the active ingredients.

Demonstrating compliance with manufacturing principles

- Manufacture of a complementary medicine could be covered by a number of Australian and overseas based manufacturers provided valid evidence of GMP compliance is provided for the mandatory steps (see overview above).
    - For example, manufacture of dosage form could be covered by sites in both Australia and overseas and it would be acceptable for the Australian sponsor to source products from these sites interchangeably.

GMP Certification process summary

1. Australian Sponsor (Marketing Authorisation holder) submits a Certification (CE) Application for an onsite TGA inspection of an overseas manufacturer.
2. CE application is reviewed to ensure that an onsite inspection is warranted and that there is no alternative evidence from a comparable overseas regulator available to utilise the GMP Clearance pathway.
3. Onsite inspection is scheduled within a 6 month parcel and specific dates are agreed between the assigned TGA GMP lead Inspector and the overseas manufacturing site.
4. Preparation work is undertaken by the inspection team prior to undertaking the onsite inspection (review of certain site documentation and development of Inspection Plan).
5. Inspection team travel to the site and holds and opening meeting and confirms the scope of the inspection and details the Inspection Plan.
6. GMP inspection is conducted which includes a physical inspection of the facility and a review of the relevant manufacturing and quality documentation used on-site.
7. At the end of an inspection a closing meeting is held where the inspection team provide an overview of the inspection and its outcome. The inspection team provides the manufacturer with a list of issues identified during the inspection which may or may not be raised as an official deficiency in the final report.

8. A Post Inspection Letter (PIL) is prepared on return to Australia that records any deficiencies identified during the inspection. These deficiencies reference specific clauses in the GMP code. The purpose of the PIL is to formally notify the manufacturer of the deficiencies identified.
9. Deficiencies are classified as critical, major or other and the manufacturer must provide as response to all deficiencies listed in the PIL. A site may be found unacceptable at this point if they are significantly non-compliant and there is concern for public health.
10. The manufacturer is provided four weeks to respond and identify corrective actions, which are reviewed by the lead inspector. Objective evidence may be requested depending on classification of the deficiency and/or the response provided.
11. Where a suitable response and corrective actions have been provided the inspection may be closed out and a Final Inspection Report and GMP certificate issued to the manufacturer with an expiry date determined by the compliance rating received.
12. Compliance rating can be between A1 (good), A2 (satisfactory), A3 (basic) or unacceptable.
13. The Australian sponsor is issued with an active GMP Clearance for the purposes of their registration or listing with the same scope and expiry date as identified on the manufacturer's certificate.

TGA GMP Clearance process summary

1. Australian Sponsor (Marketing Authorisation holder) submits a GMP Clearance (CL) Application for a desk-top assessment of an overseas manufacturer that has been inspected by a comparable overseas regulator with whom the TGA has an agreement or arrangement with.
2. CL application is receipted to ensure the correct pathway is selected and all the required documentary evidence for that pathway has been provided.
3. The application and relevant GMP documentation (such as the inspection report, Site Master File, Product Quality Review and Validation Master Plan etc.) is then assessed against the GMP code to ensure the acceptability of the evidence for the Australian market.
4. Deficiencies identified are communicated to the Australian Sponsor to address within specific timeframes. Deficiencies reference specific clauses in the GMP code where applicable but are not classified like on inspections.
5. A determination is then made to issue, issue with a condition, or not issue the GMP Clearance application.
6. GMP Clearances are issued for a specific time period only. Not issued GMP Clearances may result in a Certification (CE) applications being required to be submitted by the Australian Sponsor.

Advertising therapeutic goods

- The TGA is also responsible for ensuring that medicine labels and advertising in Australia support the safe and effective use of medicines.

- Therapeutic goods are not usual items of commerce as consumers rely on them to manage their health.

- There is specific legislation that applies to the advertising of therapeutic goods to consumers (over and above Australian Consumer Law, which regulates advertising generally) through the requirements under the *Therapeutic Goods Act 1989*, the Therapeutic Goods Regulations 1990 and the Therapeutic Goods Advertising Code (No 2) 2018 (the Code). The therapeutic goods advertising requirements aims to ensure that consumers are properly informed so that they can select appropriate treatment options and that advertising materials are truthful, balanced and not misleading.

- It is an offence under section 42DL of the *Therapeutic Goods Act* for an advertisement (which includes the product label) to suggest or imply that a medicine has been approved or recommended by a government body (including a foreign government agency) unless authorised or required to do so by law.

- Under this provision, sponsors would not be permitted to refer to the TGA, use a TGA logo, to indicate that the goods are manufactured or approved in Australia as this may imply endorsement by the TGA. This is to ensure that consumers are not unduly influenced to purchase a therapeutic good by the weight they may give to statements made by the TGA (or other government agency) about a particular product.

- The Code also provides a range of other advertising requirements. These include prohibitions on advertising that is false, misleading, or uses inappropriate or complex scientific terminology.

- The Act provides a range of other sanctions that can be used to address non-compliant advertising, including directions, infringement notices, and cancelling the therapeutic good from the ARTG.

- In the event that TGA considered a complaint about country of origin claims in advertising, it would likely be treated as a 'low' category matter (provided there were no public health and safety issues) under the advertising complaints framework. Low category complaints are generally actioned with an obligations notice to alert the advertiser to their obligations under the therapeutic goods advertising legislation. Further complaints that indicate an advertiser has not acted to address their obligations may be allocated a higher category and the TGA may consider applying the sanctions available under the Act.

- There are likely to be a range of additional issues with the Advertising Code in relation claims that the 'manufacture of dosage form' and 'packaging and labelling', when performed in accordance with prescribed Manufacturing Principles within the Therapeutic Goods Act satisfy 'Australian Made' criteria because of the potential for advertisements containing claims to be misleading, including:

    - consumers are unlikely to know what GMP or other licensing requirements mean,

    - GMP compliance is a requirement for all therapeutic goods, whether manufactured in Australia or overseas.

Appendix C – AMAG logo types

There is a series of AMAG logo certification trademark subtypes, each of which accompany of the following descriptors:

Logo	Type	Description
	Australian Made	The product has undergone its last substantial transformation in Australia.
	Australian Grown	All of the product's significant ingredients have been grown in Australia; and all or nearly all of the processing has been carried out in Australia.
	Product of Australia	All of the product's significant ingredients come from Australia; and all, or nearly all of the manufacturing or processing has been carried out in Australia.
	Australian Seafood	The product is a seafood product; and all of the product's significant ingredients have been grown or harvested in Australia; and all, or nearly all, of the processing has been carried out in Australia.
	Australian	Can only be used in export markets; and The product must satisfy the criteria for at least one of the four preceding claims, and not be misleading.

	Australian Food Labelling	From July 1, 2016, the Australian Government incorporated the Australia Made Campaign Ltd.'s (AMCL) Australian Made, Australian Grown (AMAG) kangaroo logo into a new country of origin label, which, on July 1, 2018, became mandatory for most Australian food products sold in Australia.
AUSTRALIAN MADE AND OWNED	Australian Made & Owned | Australian Grown & Owned	Ownership is important to many Australians and for that reason a number of businesses choose to include '& owned' with the relevant country of origin claim for their products. The AMAG logo cannot be used on products which do not meet the criteria in the Code of Practice, irrespective of whether the company is Australian owned or not.

Source: https://www.australianmade.com.au/why-buy-australian-made/about-the-logo/

Appendix D – History and use of the 'Australian Made, Australian Grown' logo

Use of the logo, officially called the Australian Made, Australian Grown Certified Trademark, is governed by the Australian Made Code of Practice.

The code of practice aims to:

- provide information to licensees of the 'Australian Made, Australian Grown' logo on their rights and obligations to ensure the consistent, correct usage of the 'Australian Made, Australian Grown' logo;
- build consumer confidence that goods promoted in association with the 'Australian Made, Australian Grown' logo comply with established legislative consumer information and country of origin labelling standards, promote the benefits of buying Australian goods; and
- raise the domestic and international profile of goods that are produced in Australia. .

As the then owner of the logo, the Commonwealth licensed its use to AMCL in 1999. In 2002, the Commonwealth transferred ownership of the logo to AMCL via a Deed of Assignment and Management, which set out strict conditions under which AMCL may administer the logo. In 2007, the logo coverage was expanded and it became the 'Australian Made, Australian Grown' (AMAG) logo. Immediately prior to the 2016 Country of Origin labelling reforms, the AMAG logo was owned and managed by AMCL under deeds with the Commonwealth in accordance with the Code of Practice.

On 1 July 2016, the Country of Origin Food Labelling Information Standard 2016 (the Information Standard) came into effect. The Information Standard sets out mandatory country of origin labelling requirements for food products sold in Australia. A key feature of the new labels is the inclusion of the logo as part of the country of origin label for foods grown, produced or made in Australia. As a consequence of this, the Deed of Management between AMCL and the Government was amended in January 2017. Under the amended deeds, use of the AMAG logo on food products sold domestically is free of charge to the producer but must be used under the terms of the Information Standard published by the Australian Government. AMCL retains responsibility for licensing use of the logo on other Australian products sold in Australia and overseas, and on Australian foods products sold overseas.

Recognised and trusted by consumers

The AMAG logo was chosen by the Commonwealth as the key visual marker to represent country of origin in food because the logo has a strong presence with consumers. AMCL commissioned research supports this position with a series of studies undertaken since 2002. Roy Morgan's 2012 study found that approximately 99 per cent of Australian consumers recognised the logo. That same research found that over 88 per cent of consumers considered that the logo indicated the product to which it was affixed was of Australian origin.

Key findings of the 2012 Roy Morgan research as reported by AMCL[35] was that:

- 99 per cent of consumers recognise the AMAG logo;

[35] https://www.australianmade.com.au/media/35435/2012-Research-summary.pdf

- 88 per cent of consumers trust the AMAG logo as a country-of-origin identifier;
- 68 per cent of consumers purchase products grown in Australia based on country-of-origin claims;
- 58 per cent of consumers purchase products made in Australia based on country-of-origin claims; and
- 40 per cent of consumers find it difficult to identify Australian products.

Other Sector's use of the logo

The AMAG logo is used across a wide variety of sectors. The industrial sector has the greatest usage of the logo at 20 per cent. Beauty, skin care and cosmetics represents 15 per cent of total logo usage with food and beverage (12 per cent) clothing and footwear (8 per cent), pharmaceutical and medical (6 per cent) and furniture (5 per cent) sectors representing the next largest users of the logo. Around 31 per cent of logo usage falls into the broad 'other consumer' category.[36]

Complementary healthcare products in the vitamins, minerals and supplements category generally fall within the pharmaceutical and medical sector.

Timeline of key recent studies, investigations and reviews leading to CoOL reforms

2009 - Australian and New Zealand Food regulation ministers	Agreed to a comprehensive independent review of food labelling law and policy
January 2011 - Labelling Logic Report	The Australian and New Zealand Food panel's final report, 'Labelling Logic', was publicly released on 28 January 2011. **The report noted:** *The report found general **confusion** among consumers regarding commonly-used origin labelling terms. In particular, the report identified the 'Made in Australia' claim as a source of '**extraordinary public confusion**'.*
2012 Senate Select Committee Report	Senate Select Committee Inquiry into Australia's Food Processing Sector, which stated: *The operation of these safe haven provisions attracted significant criticism from witnesses throughout the inquiry. ….Much of the criticism centred around the two tests for whether something can be said to have been 'made in' a country, being:* *a. the requirement that the goods be 'substantially transformed' in that country; and* *b. the requirement that 50 per cent or more of the total cost of producing or manufacturing the goods (including expenditure on materials, labour and overheads) is attributable to production or manufacturing processes that occurred in that country.*

[36] Australian Made Campaign Limited 2018 Annual report to the Department of Industry, Innovation and Science.

	Recommendation: *that the government reform country of origin labelling requirements for food so that these requirements are clearer, more transparent and focus on the consumer's understanding.'*
2012 - Food Processing Industry Strategy Group Non-Government Members Report42	To address confusion around country of origin labelling, the Group recommended regulatory clarification of 'substantial transformation', taking into consideration consumer perceptions of 'made in' and international trade obligations. It also suggested an education campaign for businesses and consumers once regulatory changes were made.
2012 - CHOICE Survey	A country of origin labelling survey undertaken by CHOICE found that around 80 per cent of respondents said that it was either crucial or very important to know if food was grown or manufactured in Australia. These survey results also revealed a wide gap between consumer understanding of origin claims and their technical definitions, further demonstrating the confusion highlighted in other reports.
2013 - Senate Rural and Regional Affairs Legislation Committee Report – Competition and Consumer Amendment (Australian Food Labelling) Bill 2012 (No. 2)	The Australian Greens tabled a Bill seeking changes to country of origin labelling rules through amendments to the Competition and Consumer Act 2010 and the Imported Food Control Act 1992. The Explanatory Memorandum raises the problem of consumer confusion. The Committee recommended that the Bill not be passed. While it found support for improving country of origin labelling rules, there was no substantial stakeholder support for the substance of the amendments. The Committee instead recommended that governments consider developing a more effective country of origin labelling framework that better balanced the interests of consumers, primary producers and manufacturers (including a more effective definition of 'substantially transformed', which included a 'negative list' of processes that did not meet that definition). The Committee also recommended that an effective education campaign be undertaken following the implementation of any changes. The inquiry received 32 submissions.
October 2014 - House of Representatives Standing Committee on Agriculture and Industry	'A clearer message for consumers report' recommending changes to Australia's Country of Origin Labelling system
June 2015 - DIIS Discussion Paper	**'Australian Consumer Law possible changes to country of origin safe harbour defences' discussion paper released to businesses by Department of Industry** This flagged proposals to remove the production cost test and clarify the definition of substantial transformation. The revised definition of ST was not circulated at this point.

December 2015-February 2016 – Consultation RIS	Consultation RIS package released **This included an exposure draft of changes to safe harbour defences and substantial transformation definition, and an explanatory discussion paper of the changes.** The terms fundamentally different from inputs, in **identity** or **essential character** were introduced. This differs from the existing wording at that time with substantial transformation defined as "…undergo a fundamental change in that country in **form**, **appearance** or **nature**." Nb: A significant change from the draft ACL ST test to final test which appears in ACL now, was the addition of the word **nature** which increases the scope, potentially allowing more products to meet the criteria. During this period a cross-agency team conducted information sessions in every capital city and some regional centres and held one-on-one meetings with 58 businesses. The Taskforce received 240 written submissions and comments over the consultation period.
March 2016 – Decision RIS	Decision RIS released: this RIS does not note the definitional change to substantial transformation but does link to the consultation process and the draft language changes for the substantial transformation test.
March 2016 - COAG	Reform package was agreed by Legislative and Governance Forum on Consumer Affairs (Commonwealth, State and Territory Consumer Affairs Ministers) including amendments to **safe harbour defences** and new definition of **substantial transformation** in consumer law.
February 2017 – ACL Law	**Bill amending ACL Safe Harbour Defences came into force** Royal assent to Competition and Consumer Amendment (Country of Origin) Act 2017 (Changed definition of substantial transformation as it applies to the safe harbour provisions of the Australian Consumer Law)
March 2018 – ACCC guide for the Complementary Healthcare sector	The ACCC provided guidance of what it considered qualified for the **safe harbour defence provisions and met the substantial** transformation test under the ACL by publishing its guidance document Country of origin labelling for complementary healthcare products: a guide for business. The guide is intended to assist businesses to understand the application of the Australian Consumer Law (ACL) in relation to

	country of origin claims and in particular, when businesses can safely make a 'made in' claim about their products.
May 2018 – AMCL advice on which Complementary Healthcare product processes could meet safe harbour defences	AMCL issued a Compliance Policy for Pharmaceutical and Complementary Healthcare Products. Reflective of the ACCC's guidance and changes to **safe harbours and substantial transformation**.

Appendix E – Market Share by Company

Registered Australian Company (National Brand Owner in Australia)	2018 market share (percentage of total VMS retail sales)	AMAG licensee (As of June 2018)
Swisse Wellness Pty Ltd	19.9	NO
Blackmores Ltd	18.9	NO
Sanofi-Aventis Australia Pty Ltd (Cenovis, Nature's Own, Ostelin and Bio-Organics brands)	10.6	YES
Pharmacare Laboratories Pty Ltd (Nature's Way and Bioglan brands)	9.5	NO
Nature's Care Pty Ltd (HealthyCare, VitAustralia and Vitamore brands)	7.9	YES
Health World Ltd (InnerHealth and Ethical Nutrients brands)	3.6	NO
Bayer Australia Pty Ltd (Berocca, Elevit, Redoxon, Supradyn brands)	2.9	NO
Pfizer Australia Pty Ltd (Caltrate and Centrum brands)	2.6	YES
Life-Space Group Pty Ltd	1.9	NO
Herbalife Australasia Pty Ltd	1.4	NO
USANA Australia Pty Ltd	1.2	NO
Vitaco Health Australia Pty Ltd	1.2	NO
Caruso's Natural Health	1.1	NO
Vita Life Sciences Ltd	1.0	NO
Martin & Pleasance Pty Ltd	0.8	YES
Synergy Natural Products Pty Ltd	0.6	NO
Perrigo Australia	0.6	NO
Sigma Healthcare Ltd	0.5	NO
Integria Healthcare Pty Ltd	0.5	NO
Amway Australia Ltd (Nutriway)	0.5	NO
Comvita Ltd	0.4	NO
Mannatech Australia Pty Ltd	0.3	NO
Australian Pharmaceutical Industries Ltd (BioSource)	0.3	NO
Melaleuca of Australia & New Zealand Pty Ltd	0.3	NO
Nu Skin Enterprises Australia Inc	0.2	NO
DJ Health Group (Blossom)	0.2	YES
Actavis Australia Pty Ltd (Voost)	0.2	NO
Aldi Stores Supermarkets Pty Ltd	0.2	YES
Pro-Ma Systems (Australia) Pty Ltd	0.2	NO
Lateral Food Corp Australia Pty Ltd	0.1	YES
Modere Australia Pty Ltd	0.1	NO
Vitaminhaus Pty Ltd	0.1	NO
GNC Livewell Australia	0.1	NO
Bausch & Lomb (Australia) Pty Ltd	0.1	NO
Felton Grimwade & Bickford Pty Ltd	0.1	NO
*Others	9.8	N/A
Sources:		
Euromonitor 2019, Passport database, Consumer Health in Australia		
Australian Made Campaign Limited licensee registration database July 2018		

Appendix F – Consultation Process for CoOL Reforms

Industry and Consumers

In an effort to gauge the impact of proposals to amend the safe harbour defences on the non-food sector, in June 2015, the department wrote to 23 peak industry bodies representing non-food businesses (including the complementary healthcare sector), seeking responses to an issues paper containing a number of proposals. The issues paper was also placed on the department's country of origin labelling website in June 2015, with an invitation to respond by the end of June 2015.

The Department received 13 responses to the issues paper, nine in response to letters and four in response to the website (two of which solely represented businesses in the food sector). Respondents included generic industry representatives and representatives of specific sectors, such as medicines, textiles, clothing and footwear and non-food groceries. No responses were received from consumer representatives. As the issues sought feedback on costs and savings associated with the possible changes, the Department undertook to keep submissions confidential. Given that undertaking, the submissions remain confidential, even though none provided information on costs and savings.

Following this early targeted consultation the department released the Consultation Regulation Impact Statement (RIS) for CoOL in December 2015 as part of a broader consultation package. During the consultation period 240 written submissions were received, including 130 comments in response to the Consultation package, 56 comments were received from six trading partners in response to formal notification, information sessions were held across ten locations with around 380 participants in total and 58 one-on-one meetings were held with businesses, industry associations and consumer groups. Extensive feedback was received throughout the consultation period. Stakeholders provided comments on the overall intent of the proposed reforms as well as on specific policy issues.

The Complementary Healthcare Sector contributed to the CoOL reform consultation process. Both ASMI and CMA provided comments on the proposed substantial transformation test. Only one company from the Sector provided input to the consultation process. Views on changing the substantial transformation test were not consistent across the three submissions, however for the two submissions that did support a change in the test, those responses were consistent with broader, non-Sector specific, views that the new substantial transformation test need to be cleared defined.

The importance of easy to find labels was also indicated in the Colmar Brunton research by the clear preference of participants for the labels which included visual elements, particularly the label that combined text statements with visual representations via the kangaroo logo and bar chart. While it is difficulty to accurately assess and quantify the benefits that consumers obtain from increased information and reduced confusion from clearer origin information, visual elements enable consumers to find the origin information more quickly and result in time savings. The Decision Regulatory Impact Statement (RIS) estimates that if each consumer saves just 11 seconds each weekly shopping trip, the benefits to consumers from the time savings will outweigh the cost to industry of providing the information.

The reforms are not intended to influence consumer preferences. Rather, they aim to ensure businesses provide consumers with the information they need at the purchasing point to make decisions reflecting their preferences.

It was broadly acknowledged that consumers found existing country of origin labelling confusing, and that improvements needed to be made. In general, participants in the consultation agreed with the objective to revise the current framework to meet consumer demand for more information on origin while keeping the cost to business as low as possible.

Industry and consumer consultation revealed that consumers most wanted to know the amount of Australian content in the food they bought, and that knowing the country of origin became more important the less processed a product was. Consumer research also indicated that labels featuring the AMAG logo, a bar chart and a statement indicating the proportion of Australian ingredients best conveyed this information.

Key industry groups in June 2015 noted that the heart of the issue is the 'substantial transformation' test. If a product is substantially transformed here, it's safe to make the claim it is 'Made in Australia' under the 'safe harbour' defences of the ACL.

State and Territory Consultations

Enhancing the country of origin for labelling framework required a range of legislative and administrative changes needing state and territory agreement. These included:

- Removing the CoOL rules from the Food Standards Code Australia New Zealand (the Code);
- Creating an Information Standard for CoOL for food under the ACL, which differed from the current CoOL requirements in the Code only as far as was necessary to give effect to the desired changes;
- Revision of the safe harbour defences under the ACL, including clarifying and tightening the definition of substantial transformation for origin claims like 'made in';
- Amending the Commerce (Import) Regulations 1940 to reflect the new rules for CoOL;
- Redrawing the Deed of Agreement between the Commonwealth and AMCL to make the AMAG logo free to use for the purposes of labelling under the Standard;

To secure state and territory agreement, a consultation Regulation Impact Statement (RIS) and other documents (including the draft Information Standard and amended safe harbour defences) were released for comment in December 2015, with consultation closing in January 2015. Trading partners were notified in December 2015 and given until February 2016 to comment.

In general, state and territory officials were comfortable with the Commonwealth's proposal. While concerned about potential costs to business, they understood that impacts on the food industry were being assessed and that the proposal sought to limit any cost imposts, e.g. through reasonable transition arrangements.

Some jurisdictions raised the prospect of unforeseen effects on business behaviour - e.g. businesses choosing to source only imported ingredients so as to avoid the extra labelling impost. New Zealand raised the potential for the opposite effect on ingredient sourcing. It was noted that the consultation would seek to examine this issue.

No alternative proposals or significant amendments to the Commonwealth's proposal were advanced when officials were asked to suggest other ways to address the problem. It was widely accepted that the proposal had the balance about right between the provision of extra information for the benefit of consumers and keeping the impact on businesses low.

CoOL Reform Background

The increasing internationalisation of food supply chains has brought many products to Australian shelves that were not substantially sourced domestically. Labelling regulations did not require businesses to provide the proportion of Australian ingredients and only a small proportion of businesses opted to do so.

Consumers found terms like 'made in' and 'product of' particularly confusing. Almost 60 per cent of consumers mistakenly believed a 'Made in Australia' claim indicated that the product was entirely processed in Australia, rather than that it complied with the 50 per cent production cost test. The 50 per cent production cost test for most country of origin claims was found to be a burden to business and meant little to consumers. Only 44 per cent understood that a 'Product of Australia' claim carried that message. Information was not adequately communicated to consumers even where products carried clear or unambiguous origin claims.

Consumer preferences to be better informed as to the origin of the products consumed has been a clear message heard by numerous enquiries and studies for more than a decade. For instance, in 2009, Australian and New Zealand Food regulation Ministers agreed to a comprehensive independent review of food labelling law and policy. The final report released early in 2011 noted:

*'The report found general **confusion** among consumers regarding commonly-used origin labelling terms. In particular, the report identified the 'Made in Australia' claim as a source of '**extraordinary public confusion**'.*

This report built momentum for other research and reviews that lead to the inquiry conducted by the House of Representatives Standing Committee on Agriculture and Industry on the subject, which reported in October 2014. The subject was also touched on in the Senate Standing Committee on Rural and Regional Affairs and Transport enquiry into the labelling of seafood and seafood products, which reported in December 2014. In both instances it was clear that consumers did not understand current origin statements, and felt they did not provide the kind of information they most wanted to know. A timeline of recent studies, reports and investigations can be found at Appendix E.

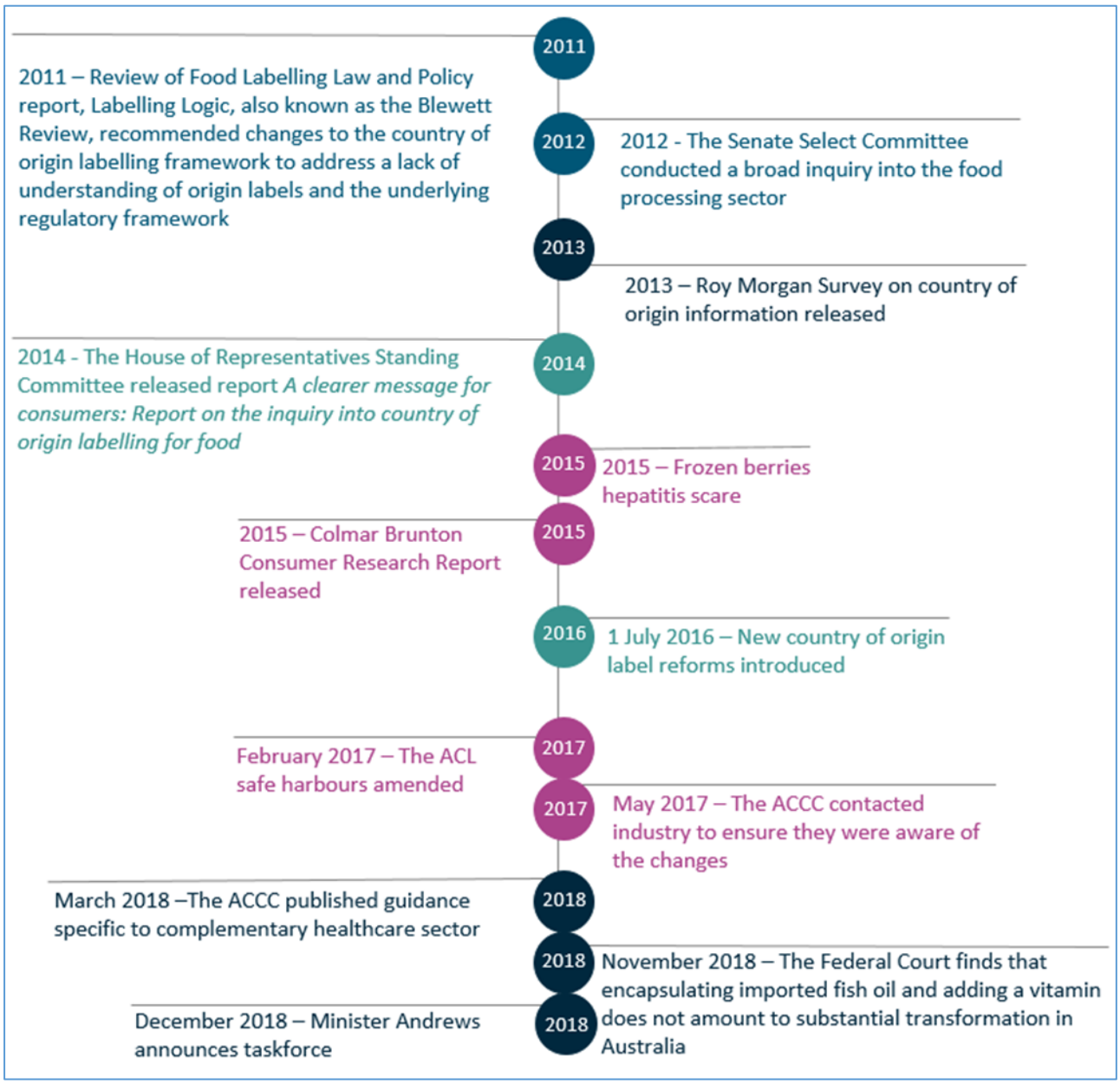
The frozen berries hepatitis scare of early 2015 brought the issue to a head and the department was directed to explore options for reform.

The Reform process

The intention of the reforms was to meet consumer demand for better information on the origin of food products. This was based on research commissioned by the Commonwealth Department of Industry, Innovation and Science (the Department) in 2015 with Colmar Brunton to investigate the value Australian consumers place on country of origin information when purchasing food. It found that being able to identify the country of origin of food is either important or very important to 74 per cent of consumers surveyed. The research found that consumers driven by different objectives when purchasing food. For example, convenience, price, quality, local manufacturing, origin of ingredients or health and safety. Some or any combination of the above drivers, including country of origin information, can influence consumer decisions. The research also highlighted that the value consumers place on origin information can vary between food types, depending on the level of processing. Country of origin information is valued more for fresh and less processed food. This finding is supported by an international literature review of country of origin food labelling which cited different studies in which country of origin was shown to be one of the most important cues demanded by consumers on meat products. The research undertaken by Colmar Brunton provided

valuable insights regarding consumer preferences as part of the CoOL consultation process. Further information on the Consultation Process is at Appendix F.

Figure 14: Timeline of Australia's Country of Origin Labelling System



Safe Harbour Defences

The ACL prohibits false or misleading origin representations. The safe harbour defences under section 255 of the ACL (Appendix F) provide businesses with automatic protections against allegations that country of origin representations are false or misleading, provided certain requirements are met. These defences provide businesses selling goods in Australia with an assurance that they can safely make certain origin claims, without fear of retribution, where the relevant requirements are met.

- The safe harbours provide protection for goods:
  - **Grown in** a particular country

- Are the **product of** a particular country
- Were **made or manufactured in** a particular country

In order for a company to benefit from using a safe harbour defence, a set of criteria needs to be met. To make a 'grown in' claim, the significant ingredients or components of a product needs to have been 'grown' in that country and all, or virtually all, of the processes involved in the production or manufacture of the goods needs to have occurred there too. To make a 'product of' claim, all the significant ingredients or components of a product needs to have originated there and all, or virtually all, of the processes involved in the production or manufacture of the goods needs to have occurred there too. To make a 'made in' claim, the product needs to have underwent its last substantial transformation in the country named, as defined by section 255 of the ACL.[37] Goods that meet the safe harbour defences, qualify for using the AMAG logo.

Substantial transformation as defined by law

Reforms to the *Competition and Consumer Act 2010* in 2017 amended the definition of substantial transformation as part of the CoOL reforms. Of relevance to the complementary healthcare sector, the new definition, found at section 255 states that:

(2) Goods were substantially transformed in a country if:

> *(b) 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.*

The changes to the safe harbour defences in the ACL included clarification of the definition of substantial transformation. The changes eliminated reference to form or appearance being sufficient grounds to claim substantial transformation, in addition to the 50 per cent production cost test. This change aligns the definition with international practice and consumer expectations.

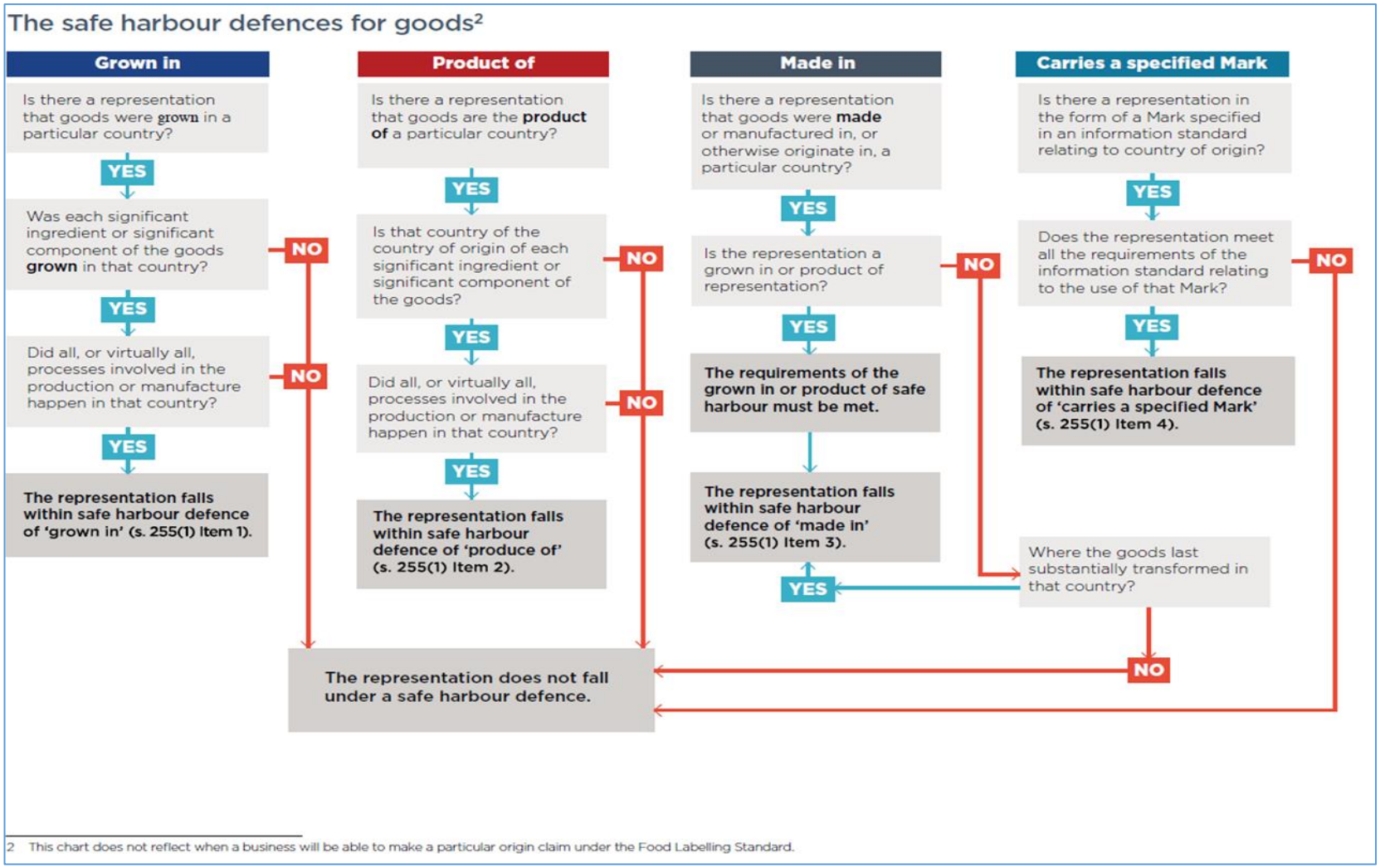
Specifically, for a new product with imported ingredients to claim to be 'Made in Australia' it needs to be fundamentally different in:

- Identity: the condition, character or identifying features of a thing.
- Nature: the particular combination of qualities belonging to a thing by birth or constitution, native or inherent character.
- Essential character: the necessary or indispensable qualities that distinguish something from others.

The change to the definition of substantial transformation makes it clearer that substantial transformation requires a final product to be materially different to its imported ingredients. The reforms were agreed by all state and territory governments through the Legislative and Governance Forum on Consumers Affairs in March 2016. They received bipartisan support in the Federal Parliament on 23 February 2017, contained in the *Competition and Consumer Amendment (Country of Origin) Act 2017*.

[37] ACCC Country of Origin Labelling for Complementary Healthcare Products: A guide for business. March 2018.

Figure 15: Representations that fall within a Safe Harbour Defence



Source: ACCC. Country of Origin Claims and the Australian Consumer Law. March 2017.

Appendix G - The Role of the Australian Competition and Consumer Commission (ACCC): Compliance and Enforcement Approach to Country of Origin Food Labelling

The ACCC is an independent Commonwealth statutory body that is responsible for administering the ACL, the Information Standard and the Competition and Consumer Act 2010. The ACCC promotes compliance with these laws and, where appropriate, takes enforcement action against businesses that breach them. The ACCC's role complements that of state and territory consumer affairs agencies who also share responsibility for enforcing the Standard as well as the ACL.

During the two year transition period, which ended on 30 June 2018, the ACCC engaged extensively with businesses and industry/peak body associations to make them aware of the new food labelling requirements under the Standard. As part of this engagement, the ACCC delivered guidance and targeted assistance to businesses throughout the supply chain to pre-empt risk and encourage compliance. This included providing specific guidance for the complementary healthcare sector (see ACCC Guidance for the Complementary Healthcare Sector at Section 4.9 below).

From 1 July 2018, when the new labels became mandatory, the ACCC, in conjunction with the National Measurement Institute, commenced market surveillance checks to ensure businesses are correctly displaying the new labels under the Standard. The ACCC is also conducting compliance checks relying upon information gathering powers in the Standard in order to test the accuracy of claims being made.

To provide some certainty to industry, the ACCC published an outline of its compliance and enforcement approach to country of origin labelling laws on its Country of Origin food labelling webpage. The webpage clarifies that while it is not possible for the ACCC to provide exemptions from the law, the ACCC has discretion about the matters it investigates and how we resolve concerns where issues are identified. Where the ACCC identifies non-compliance, it will take into account the surrounding circumstances. For example, the ACCC will generally distinguish between businesses that have made a genuine effort to label their products correctly and a business that makes false or misleading origin claims.

The ACCC can issue infringement notices or take court action seeking financial penalties where it identifies non-compliance.

A review of the effectiveness of the appropriateness of the ACCC's compliance and enforcement approach to country of origin food labelling will take place in 2020-21 as part of the broader evaluation of the enhanced country of origin labelling framework. This timing will allow consideration of two full years of the compliance and enforcement strategy, post-transition. The review will be conducted by the Department of Industry, Innovation and Science in consultation with the ACCC and other relevant Commonwealth agencies.

Appendix H – Australian Consumer Law

255 Country of origin representations do not contravene certain provisions

(1) A person does not contravene section 18, 29(1)(a) or (k) or 151(1)(a) or (k) only by making a representation of a kind referred to in an item in the first column of this table, if the requirements of the corresponding item in the second column are met.

Country of origin representations

Item	Representation	Requirements to be met
1	A representation that goods were grown in a particular country	(a) each significant ingredient or significant component of the goods was grown in that country; and (b) all, or virtually all, processes involved in the production or manufacture of the goods happened in that country.
2	A representation that goods are the produce of a particular country	(a) the country was the country of origin of each significant ingredient or significant component of the goods; and (b) all, or virtually all, processes involved in the production or manufacture of the goods happened in that country.
3	A representation that goods were made or manufactured in, or otherwise originate in, a particular country	(a) the goods were last substantially transformed in that country; and (b) the representation is not a representation to which item 1 or 2 of this table applies.
4	A representation in the form of a mark specified in an information standard relating to country of origin labelling of goods	the requirements under the information standard relating to the use of that mark.

(2) Goods were ***substantially transformed*** in a country if:

(a) the goods met, in relation to that country, the requirements of item 1 or 2 in the second column of the table in subsection (1); or

(b) 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.

(3) Without limiting subsection (2), the regulations:

(a) may prescribe (in relation to particular classes of goods or otherwise) processes or combinations of processes that, for the purposes of that subsection, do not have the result described in subsection (2)(b); and

(b) may include examples (in relation to particular classes of goods or otherwise) of processes or combinations of processes that, for the purposes of that subsection, have the result described in subsection (2)(b).

(5) Item 2 of the table in subsection (1) applies to a representation that goods are the produce of a particular country whether the representation uses the words “product of”, “produce of” or any other grammatical variation of the word “produce”.

(7) Goods, or ingredients or components of goods, are ***grown*** in a country if they:

(a) are materially increased in size or materially altered in substance in that country by natural development; or

(b) germinated or otherwise arose in, or issued in, that country; or

(c) are harvested, extracted or otherwise derived from an organism that has been materially increased in size, or materially altered in substance, in that country by natural development.

(8) For the purposes of item 1 of the table in subsection (1) in relation to particular goods, packaging materials are not treated as ingredients or components of the goods.

(9) For the purposes of item 1 of the table in subsection (1) in relation to an ingredient or component, water added to the ingredient or component is treated as having the same origin as the ingredient or component, regardless of its actual origin, if:

(a) the ingredient or component has been dried or concentrated by the evaporation of water; and

(b) the added water returns the water content of the ingredient or component to no more than its natural level.

Appendix I – Nature's Care vs AMCL Case Note

Nature's Care Manufacture Pty Ltd v Australian Made Campaign Limited [2018] FCA 1936

Parties

Applicant	Nature's Care Manufacture Pty Ltd ('Nature's Care')	Nature's Care is a manufacturer of complimentary medicines. Since 2012 they have been licensed by the AMCL to use the 'Australian made and owned' logo ('AMAG Logo') on a number of their products.
Respondent	Australian Made Campaign Limited ('AMCL')	The Australian Made Campaign Limited ('AMCL') is the owner and licensor of the AMAG Logo.
Intervener	Australian Competition and Consumer Commission ('ACCC')	The ACCC intervened as AMLC's position was significantly influenced by ACCC publications regarding when a product manufactured in Australia can be classified as 'Australian made'.

Court: Federal Court of Australia Judge: Perram J Date of Decision: 3 December 2018

Outcome of Proceeding

Nature's Care application was dismissed. The Court held that 'substantial transformation' requires a 'fundamental change in the essential characteristics of the imported ingredients collectively when compared to the manufactured goods'[38].

Background

Nature's Care sought declaratory relief that their 'Fish Oil + Vitamin D' capsules (capsules) were made in Australia. Nature's Care sought relief from the Court following AMCL's decision not to extend Nature's Care licence to use the AMAG Logo, as AMCL were not satisfied that the capsules were 'Made in Australia'. AMCL's decision was influenced by the ACCC's guidelines about when a product manufactured in Australia can be classified as Australian made.

At issue in the proceeding was whether the capsules were 'substantially transformed' in Australia.

Relevant law

The Australian Consumer Law ('ACL') prohibits those engaged in trade or commerce from engaging in misleading or deceptive conduct.[39] The ACL contains a number of rules about specific conduct which is taken not to be a breach of s 18, these are known as safe harbor provisions. Relevantly is s 255[40] of the ACL, which provides when a person does not contravene s 18 in relation to country of origin representations.

Arguments

Nature's Care argued that they should continue to be licensed to use the AMAG Logo, as the manufacturing process of the capsules satisfied the 'substantially transformed' requirement of the ACL. It was implied

[38] Nature's Care v AMCL, at [52].
[39] ACL s 18.
[40] See Attachment F for an extract of s 255 of the ACL.

throughout Nature's Care submissions that the manufacturing process of the capsules went beyond minor processes such as canning or dicing[41].

AMCL did not accept that the capsules were substantially transformed[42]. AMCL believed that the fish oil and vitamin D were not substantially transformed by the encapsulation process. This position was based on the ACCC position that encapsulation of imported substances does not satisfy the 'substantially transformed' requirement. This argument was ultimately successful.

Reasons for Outcome

The Court held that:

- section 255(2)(b) requires a comparison between the 'ingredients' which were imported and the goods which were produced as a result of the 'process undertaken'
- this comparison requires one to ask whether the manufactured goods differ 'fundamentally' from the imported ingredients 'in identity, nature or essential character'[43]
- section 255(2)(b) only requires that a fundamental change in at least one of identity, nature or essential character. It would not be appropriate to "blur them together… no doubt these three words have a very considerable overlap but they are not identical"[44]
- it is "permissible to consider the role of form and appearance in asking what a fundamental difference between the manufactured goods and the imported ingredients might be"[45]
- **what s 255(2)(b) requires is a "fundamental change in the essential characteristics of the imported ingredients collectively when compared to the manufactured goods'**[46]
- "what is required by s 255(2)(b) is an overall assessment: the manufactured goods must be compared to the imported ingredients collectively and an overall opinion formed as to whether they are fundamentally different in nature, identity or essential character"[47]

As a result of the Court's reasoning it held that:

- The fish oil and vitamin D3 ingredients as they exist in the capsules were 'identical' to when they were imported. As such, they were not substantially transformed.
- In particular, the fish oil in the capsules underwent no fundamental chemical or molecular transformation.
- The initial glycerol ingredient was substantially transformed from a liquid to a gel. However, when the capsules were viewed collectively rather than in isolation this was not sufficient to overcome the lack of transformation to the fish oil and vitamin D3.

[41] Nature's Care v AMCL, at [26]-[30].
[42] Nature's Care v AMCL, at [3] and [15].
[43] Nature's Care v AMCL, at [16]-[24].
[44] Nature's Care v AMCL, at [32].
[45] Nature's Care v AMCL, at [39].
[46] Nature's Care v AMCL, at [52].
[47] Ibid [52].

Appendix J – Commerce (Trade Descriptions) Act 1905

Commerce (Trade Descriptions) Act 1905

Section 13 (in part): Penalty for applying false trade description to exports

Penalty for applying false **trade description** to exports

(1) No person shall:

(a) intentionally apply any false trade description to any goods intended or entered for export or put on any ship or boat for export, or brought to any wharf or place for the purpose of export; or

(b) intentionally export or enter for export or put on any ship or boat for export any goods to which a false trade description is applied.

Trade description, in relation to any goods, means any description, statement, indication, or suggestion, direct or indirect:

(a) as to the nature, number, quantity, quality, purity, class, grade, measure, gauge, size, or weight of the goods; or

(b) as to the country or place in or at which the goods were made or produced; or

(c) as to the manufacturer or producer of the goods or the person by whom they were selected, packed, or in any way prepared for the market; or

(d) as to the mode of manufacturing, producing, selecting, packing, or otherwise preparing the goods; or

(e) as to the material or ingredients of which the goods are composed, or from which they are derived; or

(f) as to the goods being the subject of an existing patent, privilege, or copyright; and includes an import entry relating to goods; and any mark which according to the custom of the trade or common repute is commonly taken to be an indication of any of the above matters shall be deemed to be a trade description within the meaning of this Act.

Appendix K – HS codes used for official trade statistics as nominated by CMA and Austrade

HS Code	Definition
2101	Green tea extract
2922	Oxygen-function amino-compounds
293610	Provitamins (Unmixed)
293621	Vitamins and Their Derivatives
293622	Vitamin B1 and Its Derivatives
293623	Vitamin B2 and Its Derivatives
293624	D or Dl-pantothenic Acid (Vitamin B3 or Vitamin B5)and Its Derivatives
293625	Vitamin B6 and Its Derivatives
293626	Vitamin B12 and Its Derivatives
293627	Vitamin C and Its Derivatives
293628	Vitamin E and Its Derivatives
293629	Other Vitamins and Their Derivatives (Unmixed)
293690	Intermixtures of Provitamins, Vitamins, Derivatives Thereof
2940	sugar/maltodextrin for sports nutrition
300450	Medicaments Containing Vitamins or Other Products(Put up in Packings) -- fuller definition from ABS is “Medicaments (excluding goods of 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale”

Appendix L – Colemar Brunton Consumer Research Report

Consumer Preferences for Country of Origin Labelling:

Vitamins, Minerals and Supplements.

DRAFT Research Report.

Prepared for: Department of Industry, Innovation & Science
Prepared by: Sarah Zanker, Colmar Brunton
Date issued: 15 February 2019

Background and Methodology.

Background.

The Country of Origin Food Labelling Information Standard 2016 (Standard) commenced on 1 July 2016 and from 1 July 2018, food to be sold in Australia must be labelled according to the requirements of the Standard. While complementary healthcare products sold in Australia are not required by law to carry country of origin labelling (CoOL), if they do so, they must avoid false, misleading or deceptive claims and comply with CoOL requirements.

In March 2018, the ACCC communicated with the complementary healthcare sector to assist them to understand and comply with CoOL requirements in the new Standard. This publication advised industry that under the new Standard some complementary healthcare products which were previously able to use the Australian Made Australian Grown (AMAG) logo, would no longer be able to do so. The ACCC's interpretation of the Standard regarding requirements for a Made In Australia claim was supported by the Federal Court in late 2018 when the court ruled that the encapsulation in Australia of imported fish oil and Vitamin D by Nature's Care Manufacture Pty Ltd (Nature's Care) would not permit the capsules to be labelled 'Made in Australia'

This decision is only one example of the impact of the changes to CoOL requirements but it is a crucial example which has the potential to have a significant impact in an industry which relies heavily on imported ingredients. For example, Blackmores, a major player in the industry has been quoted as saying that the global food and nutritional supplements industries are heavily reliant on China as the source of almost all of the worlds vitamin C and that Australia does not grow or make most of the ingredients for other supplements.

The importance of CoO claims for complementary healthcare products is further highlighted by instances of contamination of some traditional medicines for example traditional Burmese medicines for digestion and strength in babies being found to contain arsenic in NSW.

Research objectives.

The aim of the research was to gather information that provides an accurate, representative and defensible view of the importance of the AMAG logo on purchasing decisions and consumer expectations on the application of the logo to vitamins, minerals and supplements.

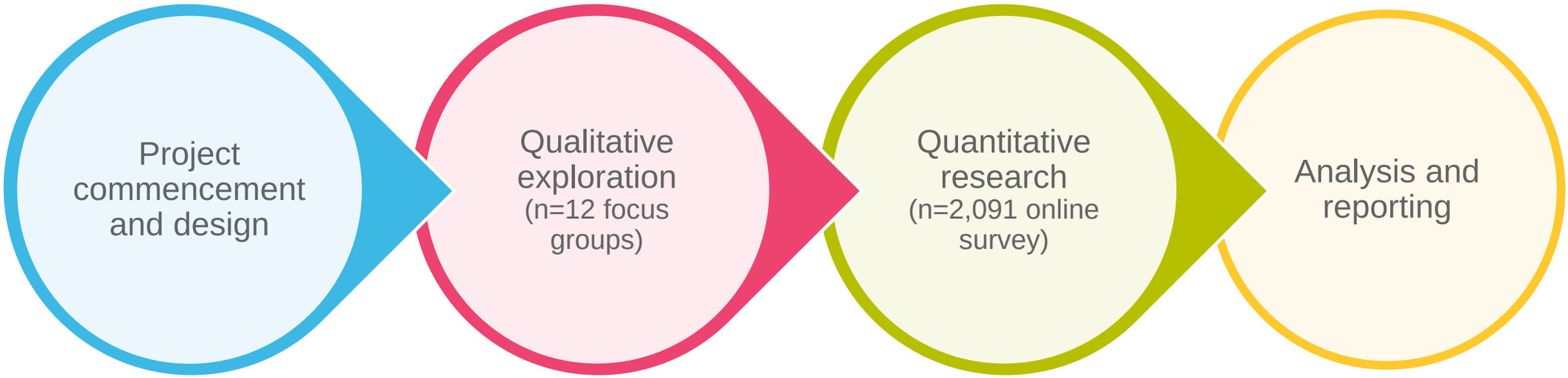
The specific objectives of the research included understanding:

- The importance of the AMAG logo to the complementary healthcare consumer; and
- Consumer preferences for the use of the AMAG logo on a range of complementary healthcare products including:
    - When should the logo be used; and
    - Under what circumstances would logo use be an inappropriate designation of “made in Australia”.

Findings from this research will form part of a broader review which is being undertaken by the taskforce which in addition to findings from this research will consider information from stakeholders and representations already made by industry. Based on the range of information gathered, a recommendation will be made regarding whether or not changes should be made to CoOL laws as they apply to complementary healthcare products.

Research approach.

The overarching approach to this research can be summarised through the diagram below.



Initially, a formal project commencement meeting was held to agree on the methodology, sampling, timeframes and reporting outputs. Following this meeting, a series of consumer focus groups were conducted. Four of these were mini-groups made up of 4-5 CALD consumers per group, with two of these conducted in Brisbane and two in Sydney. The remaining 8 focus groups ensured an even mix of Australian consumers aged under and over 45 years with 7-8 people attending per group. Two sessions were held per evening (29, 30 ad 31 January) in Sydney, Brisbane, Wagga Wagga and Bendigo.

To quantify these results, a 10 minute online survey was designed, launched and completed by 2,091 Australians. The survey was representative of Australian consumers in terms of age, gender and geography, and provides a robust sample by which to make inferences of the wider Australian consumer population.

Research findings.

Interpreting the data in this report.

- All sample sizes can be found in the footer of each slide.
- Percentages are generally rounded to whole numbers. Some percentages may not add to 100 percent due to rounding.
- Where appropriate, rows in tables and charts are sorted from most frequent response to least.
- Some acronyms are used – CoO refers to ‘Country of Origin’, CoOL refers to ‘Country of Origin Labelling’, MIA refers to ‘Made in Australia’ and AM refers to ‘Australian Made’.
- This report summarises the research findings in a thematic way, integrating the qualitative (focus group) findings and quantitative (online survey) findings throughout the report. At the top of each page, the following symbols have been used to highlight which research source the findings come from.

FG **Focus Groups**

OS **Online Survey**

OS FG **Online Survey and Focus Groups**

Who we spoke to.

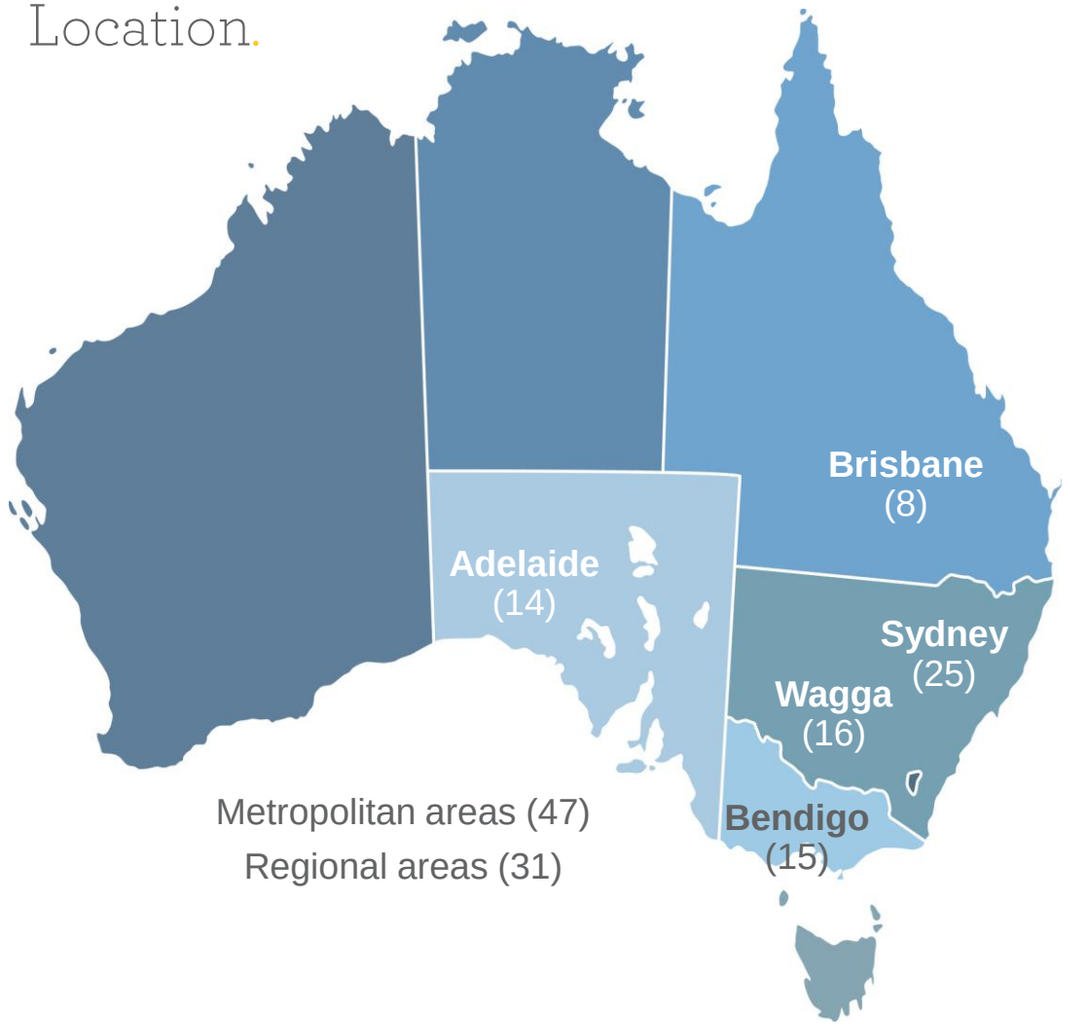
Focus Group Demographics.

Total number of participants.

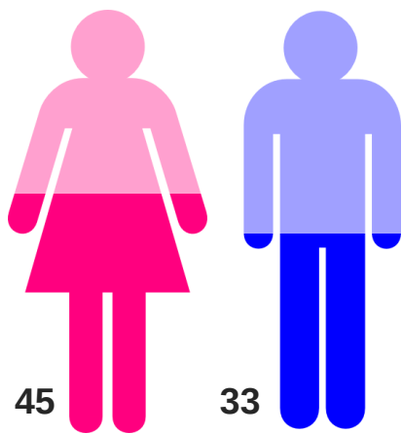
78

Age.

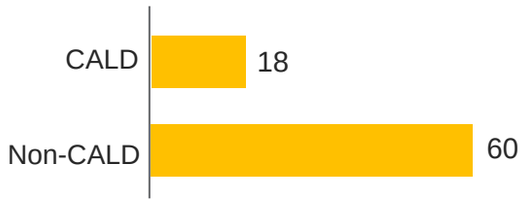
Location.



Gender.

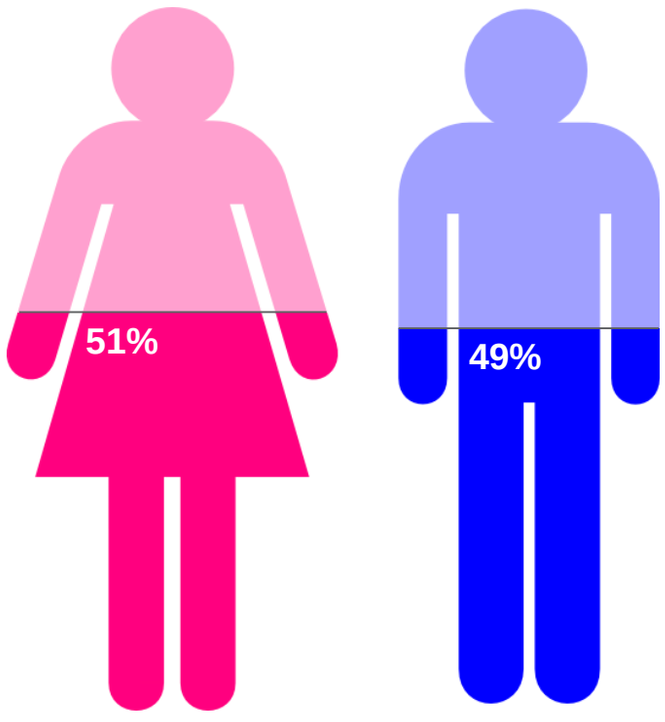


CALD.

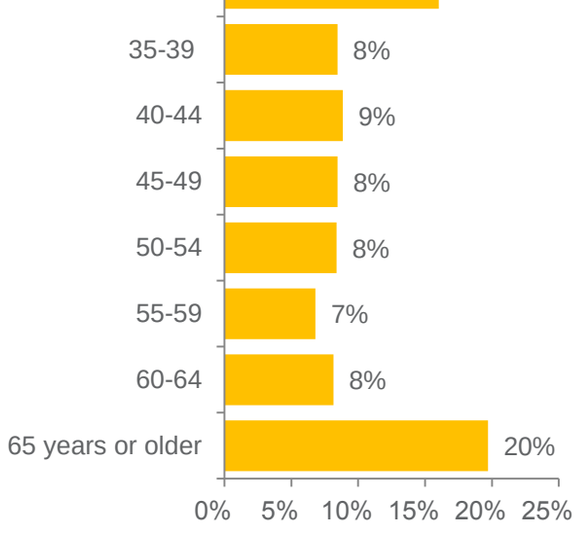


Online Survey Demographics.

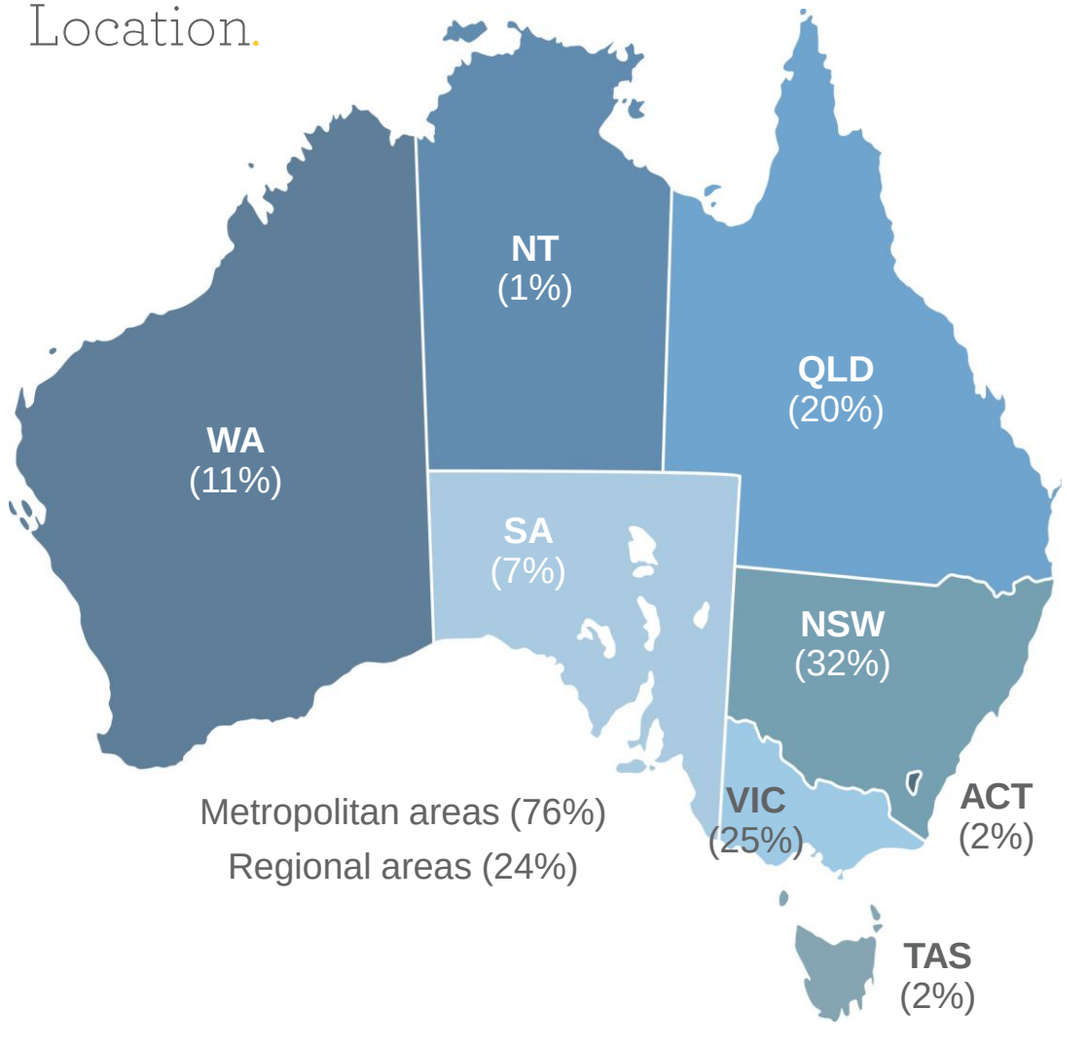
Gender.



Age.



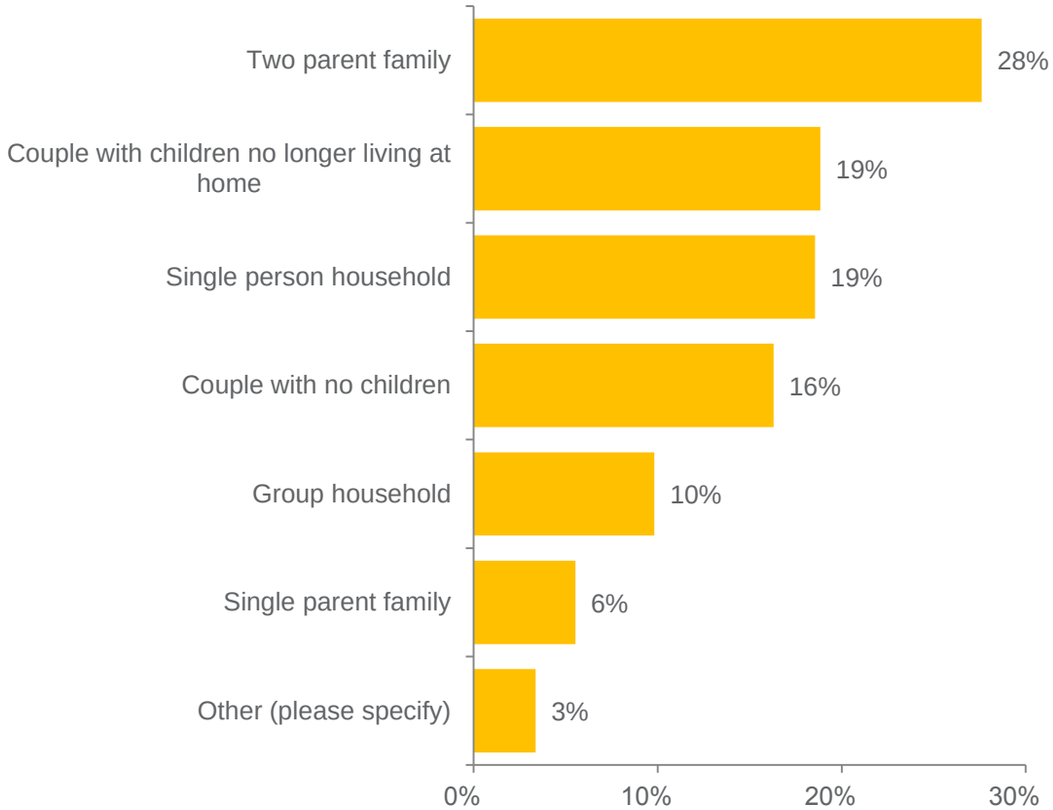
Location.



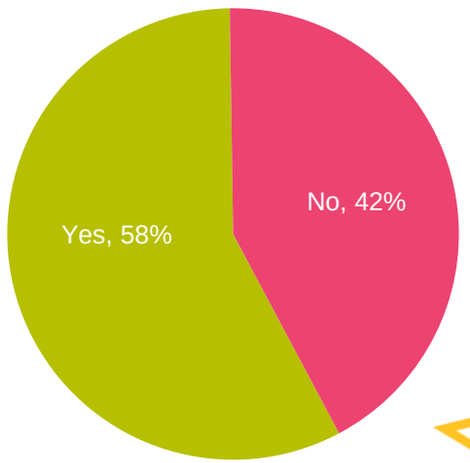
Base: All respondents (n=2091)

Online Survey Demographics.

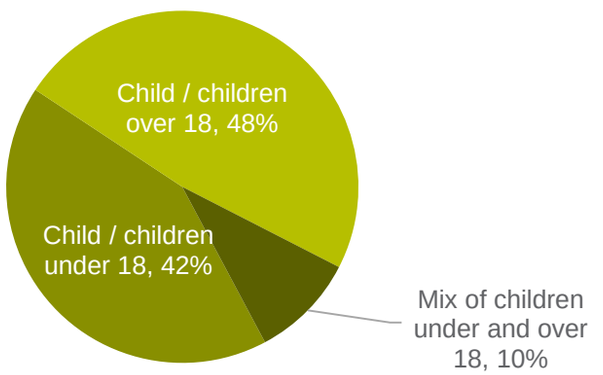
Household composititon



Parents



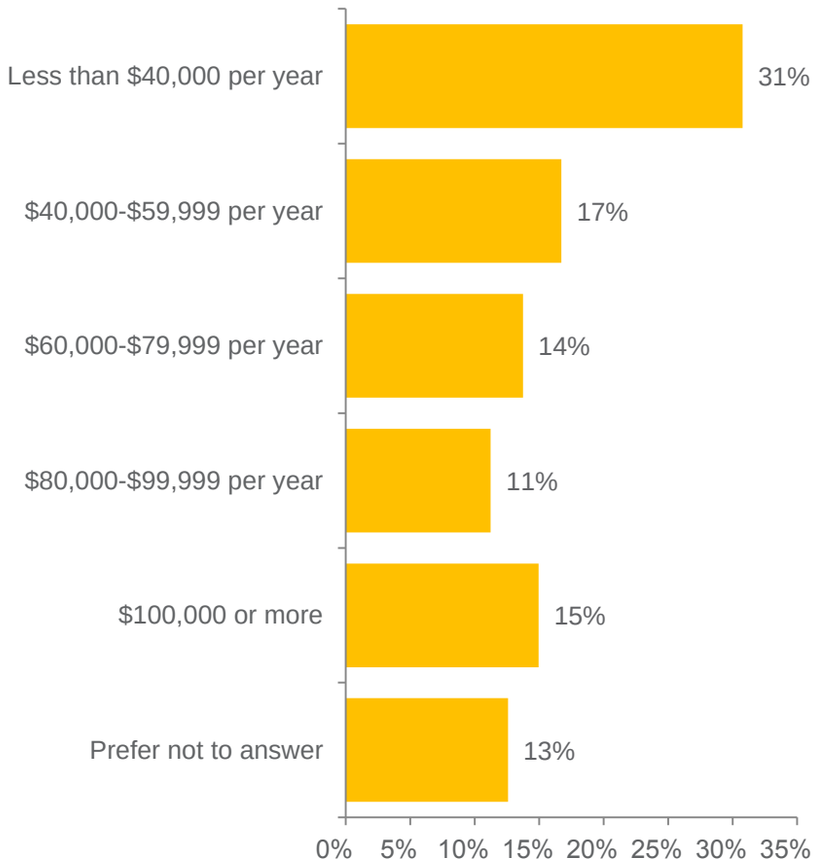
Age of children



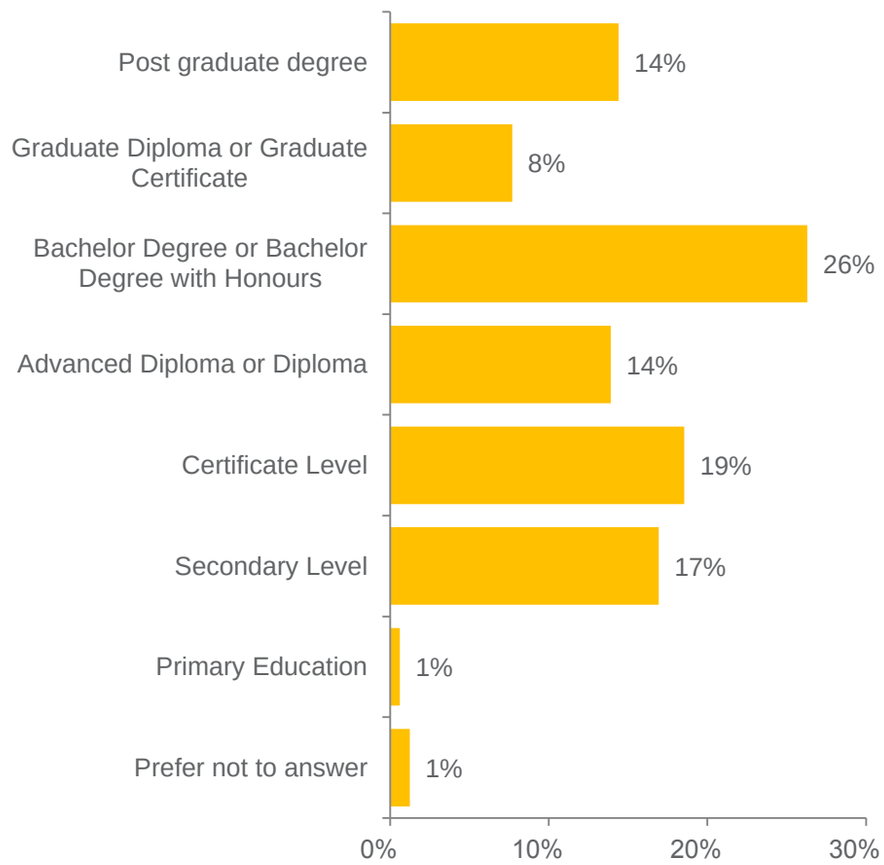
Base: All respondents (n=2091)

Online Survey Demographics.

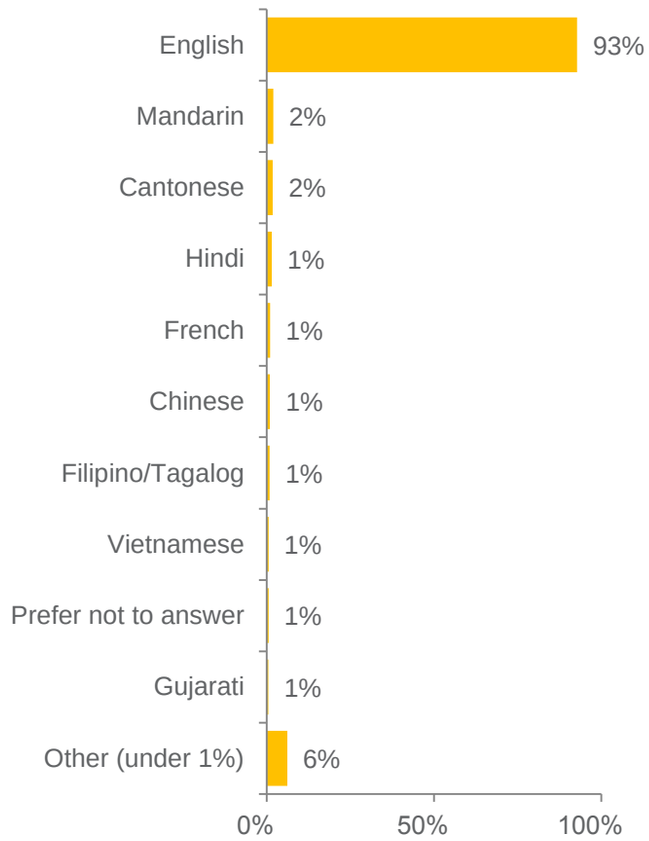
Personal gross income



Education level



Languages spoken at home



Base: All respondents (n=2091)

Consumers and complementary health products.

Vitamins, minerals & supplements.

Based on the learnings from focus group participants, people buy different complementary health products for varying reasons. For some, it's for general health and wellbeing, for others it is to enhance their performance at the gym and for others it's on recommendation from a GP or other health professional.

The most common complementary health products consumed by younger people involved in the focus groups included Vitamin C, D, Fish oil, Hair Skin Nail formulas, Iron, Folic Acid (particularly through pregnancy), hemp oil, chondroitin, calcium Magnesium and multivitamins. Those with an active lifestyle also take food supplements such as protein powders or energy drinks like Powerade.

In addition to the above, older Australians who took part in the focus groups also mentioned taking glucosamine, echinacea, garlic, macuvision, turmeric, probiotics, Vitamin B cranberry, acidophilus, yeast, chia powder, gingko balboa, melatonin and many more.

Based on the focus groups, it is quite common for consumers to be taking multiple products at the same time, in addition to the catch all, multi-vitamin. Rarely was one person on just one pill.

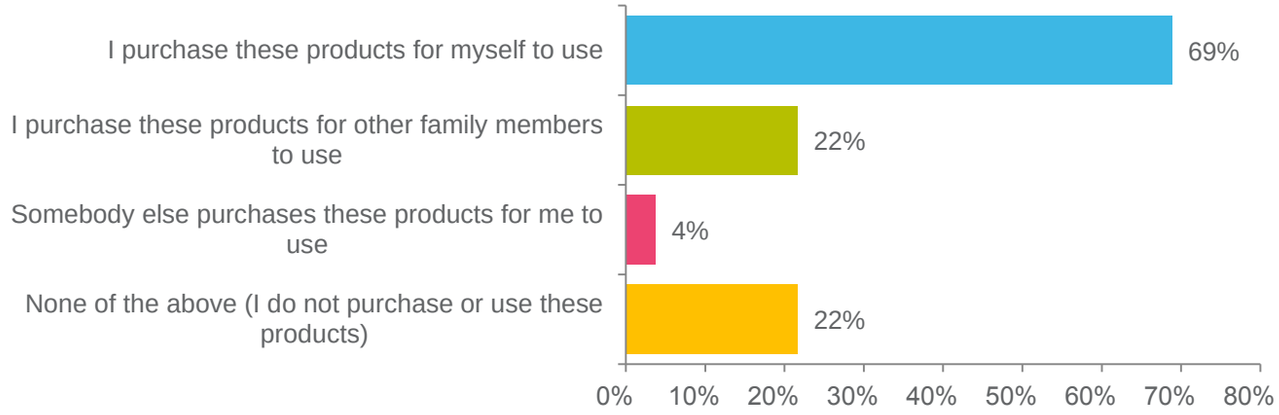
Use of complementary healthcare products.

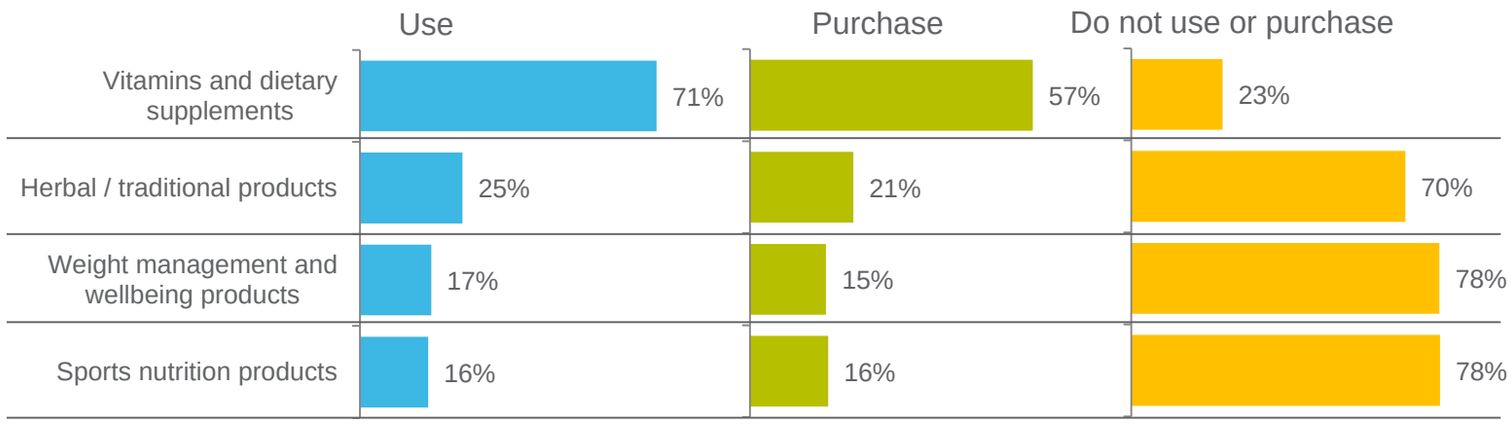
Which of the following describes your purchase and use of vitamins, minerals or other supplements?

78% of Australian consumers surveyed either purchase or use complementary health products. Most (69%) are purchasing these products for themselves to use, with 22% purchasing for family members and 4% stating these products are purchased for them by someone else. 22% do not purchase or use complementary health products at all.

Consumption of Vitamins and dietary supplements was highest, with 71% of Australians using them and 57% purchasing them.

Herbal or traditional products were the second most consumed category with a quarter (25%) of Australians using these products and 21% purchasing them.





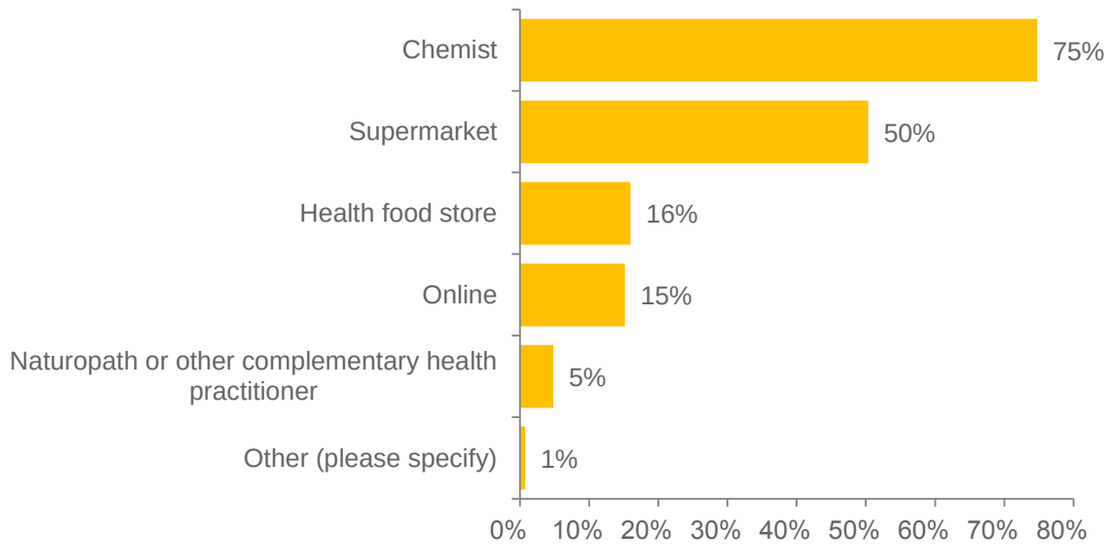
Q1. Which of the following describes your purchase and use of vitamins, minerals or other supplements?
Base: All respondents (n=2091)
Q2. Which of the following product categories do you personally regularly USE or PURCHASE for your own or your families consumption? (MR)
Base: All respondents (n=2091)

Purchase location.

Based on the online survey results, complementary health products are most often purchased at chemists (75%), followed by supermarkets (50%) and health food stores (16%).

This aligned with findings from focus group participants, who mentioned Chemist Warehouse, other pharmacies and supermarkets as the most common places of purchase for their complementary health products.

The focus group participants also mentioned that for fitness and workout supplements, advice is sought from friends, online (e.g. health forums) or from a specialist store, however products are often bought online for a reduced price or when they can't be sourced within Australia.



Q1b. Where do you purchase vitamins, minerals and other supplements?
Base: All respondents who use or purchase complementary healthcare products for themselves or others (n=1578)

Brand is a key driver of choice.

CoO is not something Australians look for or notice in complementary health products. It was not spontaneously mentioned as a driver for product choice, or a factor of consideration. Upon probing most said they'd prefer Australian made, yet very few mentioned looking for this actively. The most common drivers for choice in this category were brand and price.

Brand is based predominantly on a perceived faith or trust in that brand, based on its reputation, prominence, familiarity and perception of quality. Some focus group consumers admitted that they would preference a known brand that wasn't Australian Made over an unknown brand that was Australian made if the quality and value for money was perceived to be higher. There was a perception that known and familiar brands such as Swisse, Blackmores, Nature's Way, Centrum and Cenovis were Australian brands, and with this comes great trust and as mentioned by one person, 'Blind faith' in these brands and products.

"Consistency in brand is important to me, I don't swap brands when it comes to vitamins." 45+ year old from Adelaide

Pricing also drives choice.

Price is also a considerable factor or driver in consumers choice of vitamins, minerals and supplements. Given how expensive these products can be, looking for items on special is something consumers regularly do and often their selection comes down to which product within their known and trusted brands is available for a cheaper price. However, it is important to note that price is not the sole motivator as it is seen as an indicator of quality.

The strength of the ingredients (levels of concentration and required daily dosage) is also considered by many, as is the format of the vitamins (tablets vs chewables), the size, odour and flavour of the tablet, the number of pills in a bottle, and as a result of a recommendation by friends, family or health professionals such as a GP or Pharmacist.

Past experience was also important for some who had trialled and experimented with different brands and products. If they felt that the product was working or they were healthier than before they started using the product, then they continued to buy it.

"If the brand I buy is on special I'll stock up for sure." 45+ year old from Bendigo

"The higher the price, the higher the quality. However, I only buy on special." 45+ year old from Adelaide

Drivers of choice.

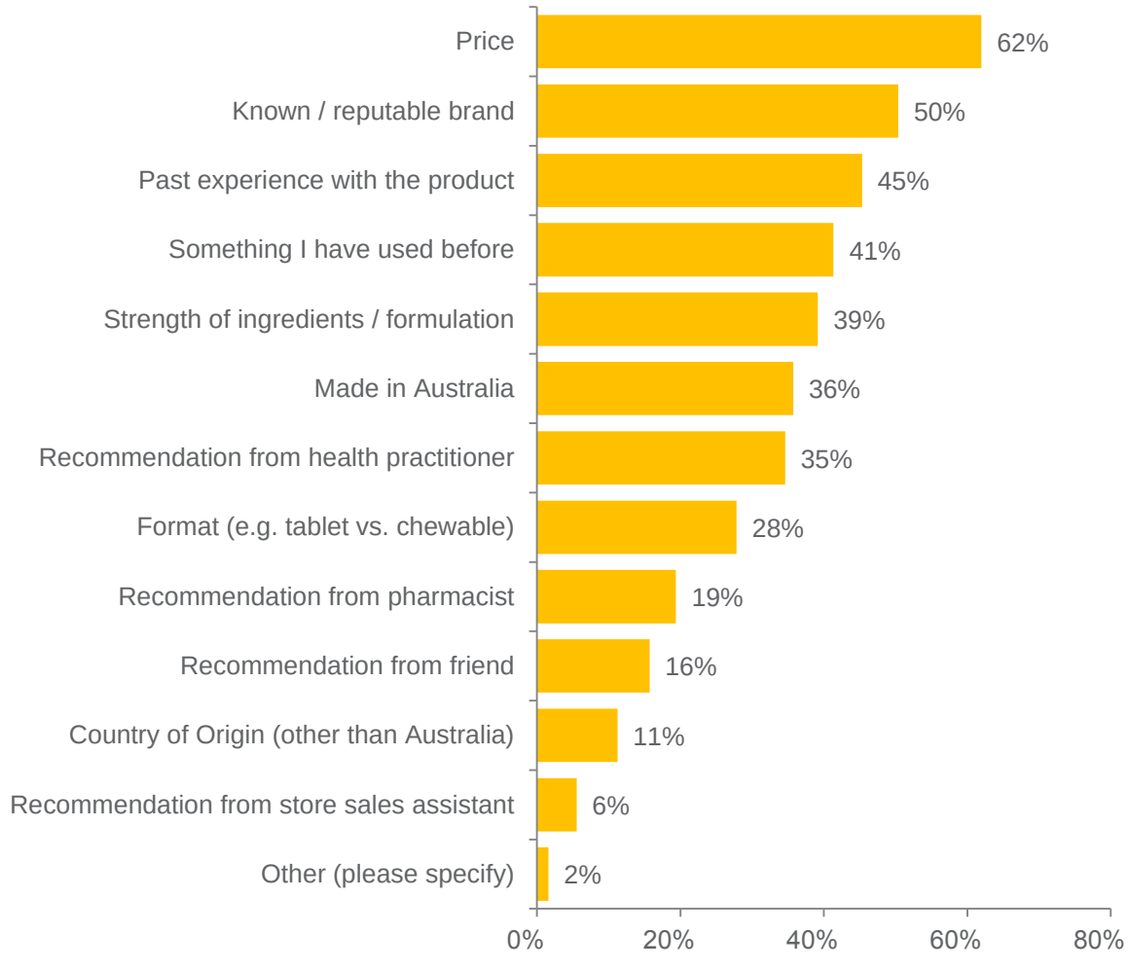
Which of the following do you take into account when purchasing vitamins, minerals and/or supplements?

Based on the findings from the online survey of Australian consumers, the factor most take into account when purchasing complementary health products is price (62%), followed by known or reputable brand (50%).

These findings are consistent with the focus groups findings which also identified the key factors driving decision making around complementary health products as being price and a known or reputable brand.

With regards to CoO, 36% mentioned 'Made in Australia' as being a factor they consider in the purchase of complementary health product, ranked lower than past experience with a product (45%), something they'd used before (41%) and the strength of ingredients (39%).

A small proportion (11%) mentioned Country of Origin (other than Australia) as being a factor influencing their purchase decision.



Q3. Which of the following do you take into account when purchasing vitamins, minerals and/or supplements?
Base: All respondents who purchase any category of healthcare products (n=1409)

Evaluating quality.

For the most part, the quality of vitamins, minerals and supplements is evaluated on the physiological changes or improvements noticed by consumers. Most looked for more energy, reduced pain or stronger hair and nails, whereas others relied on more measurable evidence e.g. through blood or urine tests. For many, the perceived changes to overall health and sense of wellbeing was a way of measuring the quality of complementary health products.

Some saw the distribution options as a way of evaluating quality with supermarket access indicating a lower quality.

Natural products were also seen as being higher quality than synthetic products.

Recommendations from Doctors or naturopaths and word of mouth from friends and family were also used to assess the quality of a particular product or brand.

Despite these perceived indicators of quality, there is a view amongst consumers that there may be a ‘placebo effect’ in some of these products.

“Where you can buy it. If you can buy it in a supermarket, I won’t touch it.” 18-44 year old from Adelaide

“I prefer natural rather than synthetic vitamins. Natural is the more high-end option.” 45+ year old from Adelaide

Salience of CoOL in complementary health products.

'MIA' important, but seeking CoOL is rare.

There was a distinct knowledge gap across the focus groups when it came to where the vitamins, minerals and supplements they consume come from. Many admitted to never having checked where the products they consume were made or ingredients were sourced from.

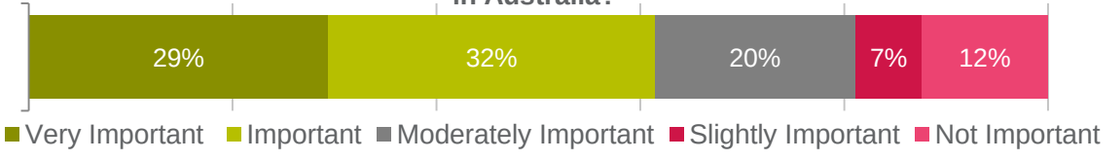
"I've never checked. I don't know." 18-44 year old from Adelaide

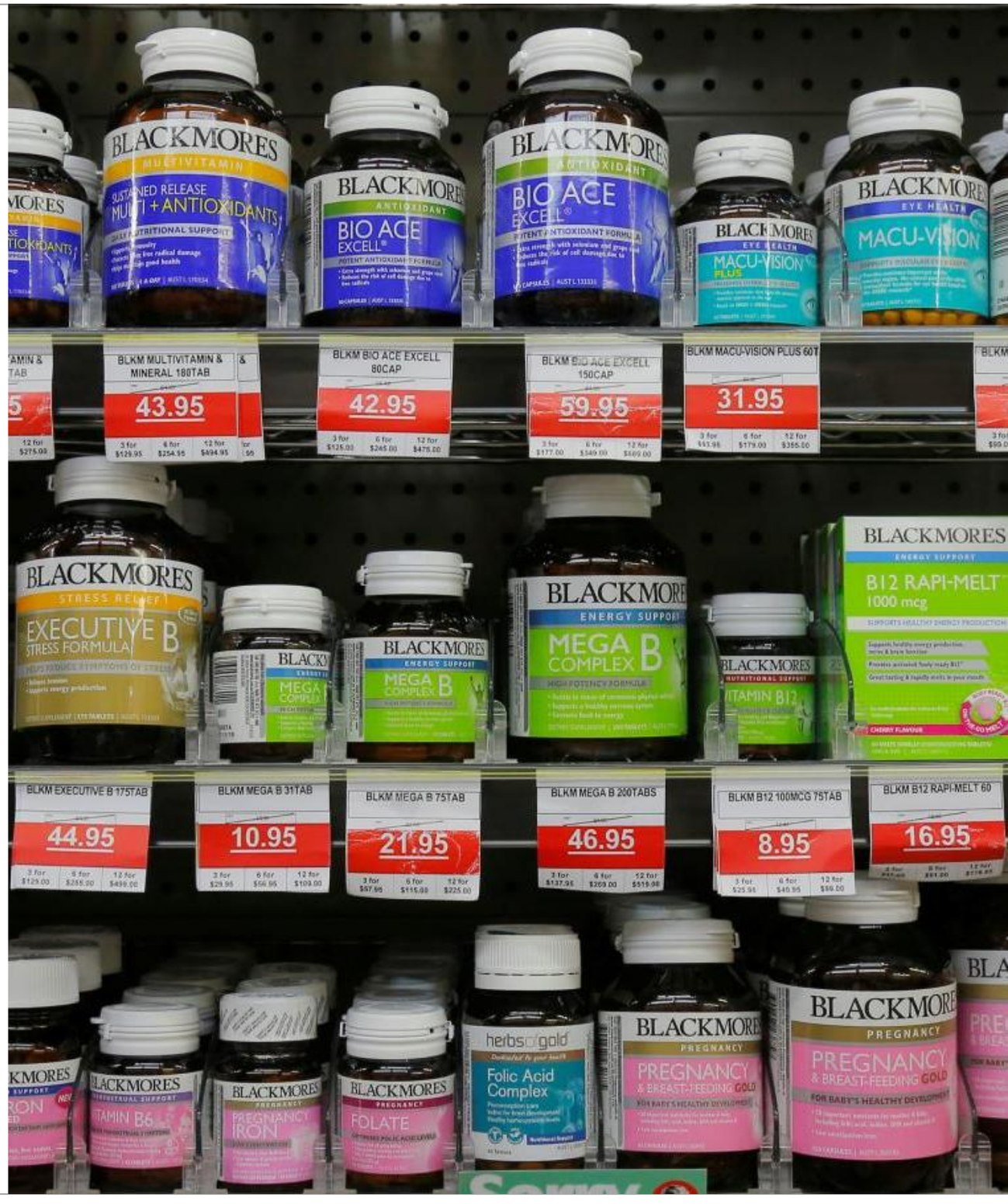
Despite not knowing where their supplements had actually come from or been made in, focus group participants assumed that products sold in Australia would have undergone strict quality testing.

"To be sold here it has to be approved by the TGA." 18-44 year old from Adelaide

Although consumers (through both the focus group and online survey) felt that other factors were more important in a purchasing decision, many agreed that it is important that complementary healthcare products are Made in Australia (51% of online survey participants).

How important is it that vitamins, minerals and supplement products are Made in Australia?





Q4. How important is it to you that vitamins, minerals and supplement products are Made in Australia?
Base: All respondents (n=2091)

Trust in some countries more than others.

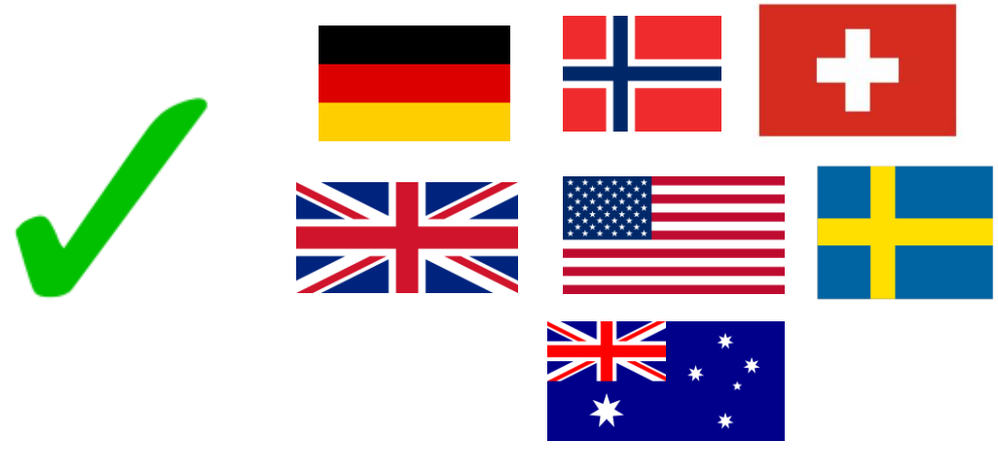
The lack of attention (identified in the focus groups) towards CoOL was backed up by the suggestion that as long as products are 'made in' a country perceived to be quality, trustworthy and with rigorous quality control processes in place, consumers don't immediately mind where these products are made, or where the ingredients sourced.

"It doesn't need to be made here to be quality" CALD, 45+ year old from Brisbane

For example, vitamins, minerals and supplements from the US, the UK and Europe (e.g. Sweden, Switzerland, Norway, Germany) were perceived to be trustworthy and accepted across the board, and in some cases more desirable. Countries such as China or India were seen to be less trustworthy or appealing as Countries of origin.

"You can't guarantee that a product that comes from China is quality" CALD, 45+ year old from Brisbane

"The medical standards in Europe are much higher …medications are much superior to what we have here" CALD, 45+ year old from Brisbane



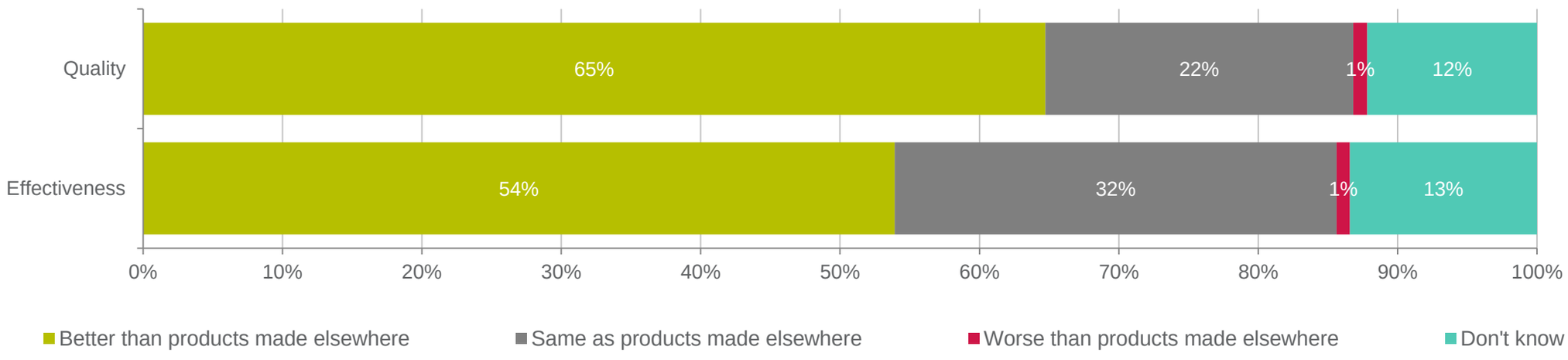
Perceived difference between Made in Australia and made elsewhere.

Would you expect the quality / effectiveness of vitamins, minerals and supplements made in Australia to be...

Through the online survey, Australian consumers were asked to rate their perception of the quality of complementary health products that were made in Australia versus being made elsewhere in terms of their quality and effectiveness.

In terms of **Quality**, based on the results from the online survey, 65% of Australians expect the quality of complementary healthcare products made in Australia to be better than products made elsewhere, while 22% felt they'd be the same and just 1% felt that products made in Australia would be worse than complementary health products made elsewhere.

Similarly, 54% of Australians felt that the **Effectiveness** of complementary health products made in Australia would be better than those made elsewhere, while 32% felt it would be comparable and just 1% felt that products made in Australia would be worse than complementary health products made elsewhere.



Q5 & Q5a. Would you expect the quality / effectiveness of vitamins, minerals and supplements made in Australia to be...
Base: All respondents (n=2091)

There is an element of 'blind faith'.

Generally, consumers don't mind where these products come from, as long as it is a country with a perceived level of trust and regulations.

There was a perception that brands such as Blackmores and Swisse were Australian Made and an expectation that all products that are sold in Australia have already been screened and tested before even being made available for purchase by Australian consumers.

"I've never really looked, isn't it terrible how much trust we place in it?" Bendigo, 45+

A small proportion of people would like to see these products being Made in Australia to support jobs and the economy, however many realised that it may not be feasible to source all ingredients locally.

Many assumed that the products they purchased in this category were made in Australia from local ingredients and were surprised when they heard others saying this was not necessarily the case.

"I like to think that the brands I am using are Australian, but I don't know." 45+ year old from Adelaide

"They wouldn't sell it in Australia if it wasn't of a high enough quality." CALD person from Sydney

Comparison to food.

There were mixed views about the relative importance of CoO when comparing food to vitamins, minerals and supplements. Some felt that CoO was equally important as all these products are being consumed or “put into our bodies”.

Others felt that CoO was less important for vitamins, minerals and supplements because these tended to be processed, stored and ‘long-life’, whereas food needed to be fresh. Even though both are ingested, it seems that these products are scrutinised differently to food. This was suggested because vitamins, supplements and minerals are not typically fresh produce or an essential product. Similarly, others felt that CoO was less important for vitamins, minerals and supplements as people felt that ‘you don’t consume them as often’, despite some people taking as many as six different vitamins/supplements per day. This category was also referred to as being closer to medicine than food, which brought with it a much lower concern for CoO and an increased reliance on manufacturer and Government regulation, scrutiny and testing.

Why CoOL is important.

Those that felt CoOL was important, did so because…

- Consumers need to be aware of where ingredients are from and where products are made (especially if the two are different), some countries are trusted more so than others and the perception of standards and quality is different across countries;
- The distance travelled matters, particularly if the product requires refrigeration, or is perishable. Consumers want to know that it hasn't had to travel too far and therefore risk losing strength or the key properties; and
- To allow consumers to support Australian made products, as they would with food.

"In Australia the rules are different to other countries" 45+ year old from Wagga Wagga

I assume it would have better quality control if it has a "made in Australia" label" 45+ year old from Wagga Wagga

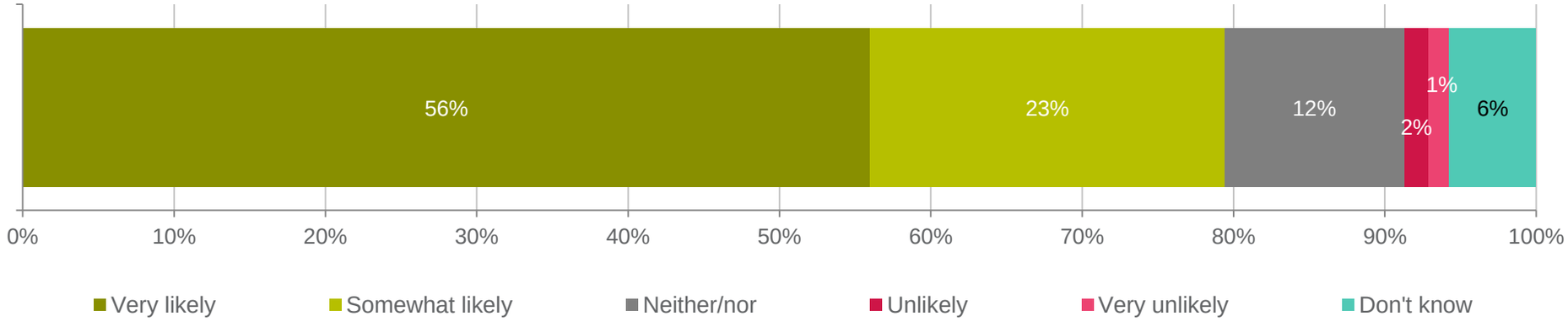
"For food it is more important, I like knowing I support Aussie farmers" 18-44 year old from Wagga Wagga

OS

Consumer preference for made in Australia versus made elsewhere.

If pricing is comparable, how likely would you be to choose the complementary healthcare product made in Australia?

If given the choice between a comparably priced product made elsewhere, 79% of consumers from the online survey would purchase the product that is made in Australia (56% very likely, 25% somewhat likely) over one made elsewhere.



Q6. If you had a choice between a vitamin, mineral or supplement product made in Australia and one made elsewhere for a comparable price, how likely would you be to choose the product made in Australia?
Base: All respondents (n=2091)

colmar brunton.

Sources of ingredients.

Regarding the ingredients in vitamins, minerals and supplements, most were unaware where the ingredients in their vitamins, minerals and supplements come from, and also felt that it wasn't necessarily important that ingredients are from Australia, as long as the source (brand, country of origin) is reputable. There were examples of people undertaking extensive online research and reading reviews, online forums, and investigating the CoO, although this was the exception rather than the norm.

When comparing vitamins, minerals and supplements that are 'Made in Australia', versus made elsewhere, most felt that the quality should be mostly similar; however, some potential differences were identified as follows:

- Some expected Australian made to be a higher quality, based on higher and stricter standards;
- Australian made may be more expensive;
- Higher prices could be observed if from a country like Germany; and
- The quality of products from Asian countries, particularly China and Vietnam were seen to be lower.

Awareness of changes to CoOL.

People are largely unaware.

None were aware of any recent media, focus or attention being placed on CoOL in this category.

"I haven't noticed it, and quite frankly it's not advertised" CALD person from Brisbane

"I've never done research into this" CALD person from Brisbane

"It's displayed more on food products" CALD person from Brisbane

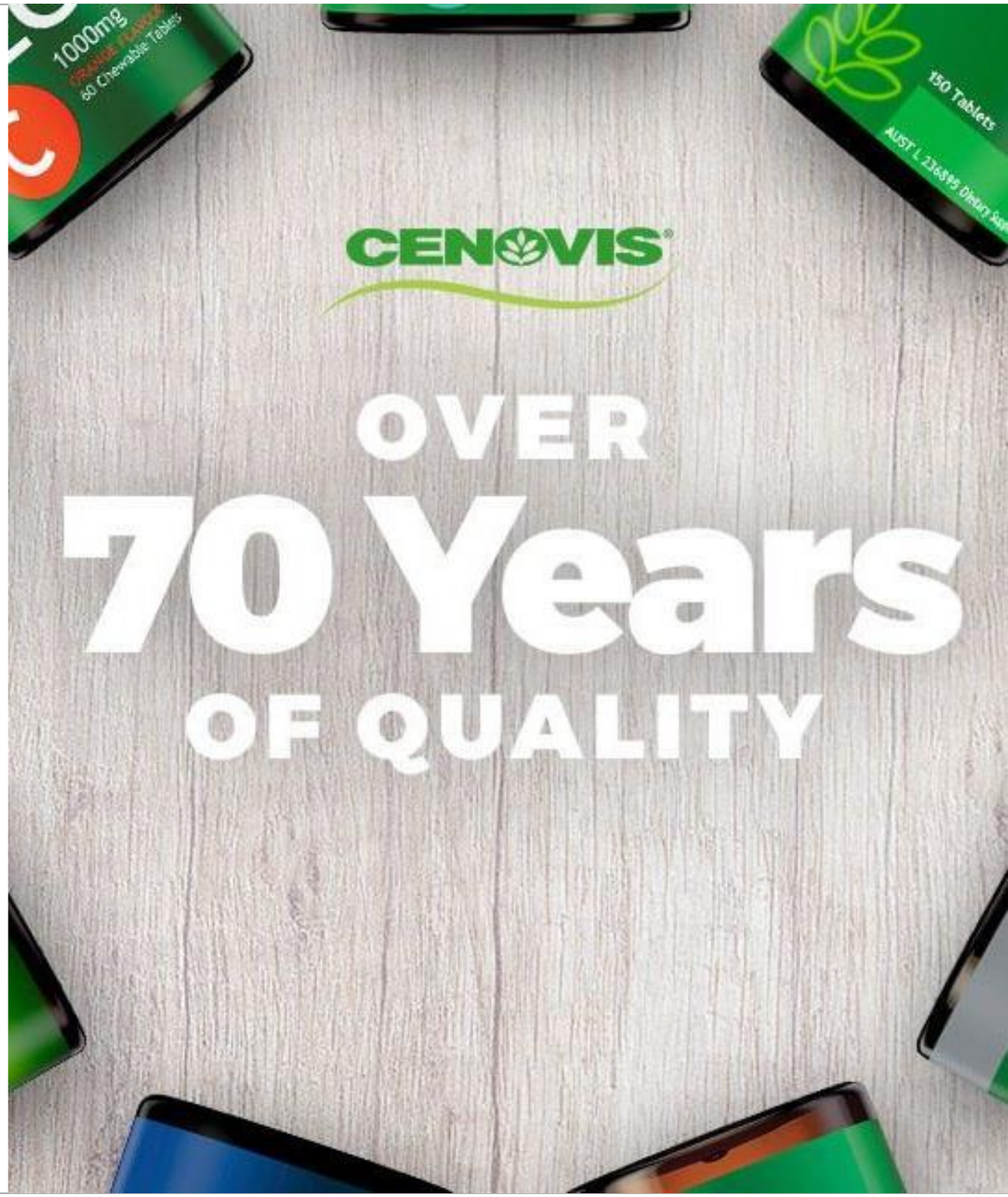
Understanding of CoOL.

Confusion in the definition of CoOL.

There was some debate around the definition of ‘Country of origin labelling’, with some understanding it as referring to where ingredients are sourced, others felt that it represented where products were manufactured, and others thought it was a combination of both.

Despite this, very few could recall seeing CoO labelling on vitamin, mineral and supplement products.

“You just as assume that the reputable brands are using ingredients from somewhere you trust” 45+ year old from Sydney



CoOL not noticed in this category.

The majority of focus group participants do not pay attention to CoO labelling on vitamins, minerals and supplements because:

- They feel as though other factors are more important (brand, price, strength, effectiveness)
- They are more focussed on the claims around benefits received rather than CoO
- They assume the products are of a high enough quality given that they are available for purchase from a reputable or well-known retailer (a large retailer such as a major supermarket or pharmacy)
- They've never noticed it

For the small proportion who do pay attention to CoO labelling, it was typically due to health conditions (like Cancer) which required them to do so.

"I look for it on everything I buy, it takes me hours to shop. I look at every ingredient on everything." 18-44 year old from Adelaide

Multi-Vitamin & Mineral Program

Supplement Facts

Serving Size 3 Energy Support Tablets/3 Bone Support Tablets
Servings Per Container 30 Energy Support/30 Bone Support

Amount Per Serving	Energy Support % Daily Value	Bone Support % Daily Value
Citrus Fruit Peel Bioflavonoids Complex	105 mg †	
Inositol	75 mg †	15 mg †
Choline (from Choline Bitartrate)	60 mg †	12 mg †
Tocotrienols (TOCOBEADS®)	4.5 mg †	4.5 mg †
Boron (from Boron Glycinate)		1.5 mg †

*Percent Daily Value are based on a 2,000 calorie diet.
†Daily Value not established.

"Country of Origin labelling is the last thing you think about." 18-44 year old from Sydney

"You assume a good level of quality if it's sold in Australia." 18-44 year old from Sydney

"We have an unconscious incompetence… we don't know what we don't know." 45+ year old from Sydney

"Country of Origin is lower down the list." 45+ year old from Sydney

"90% of the commodities are imported into Australia, we have no manufacturing here" CALD, 45+ year old from Brisbane

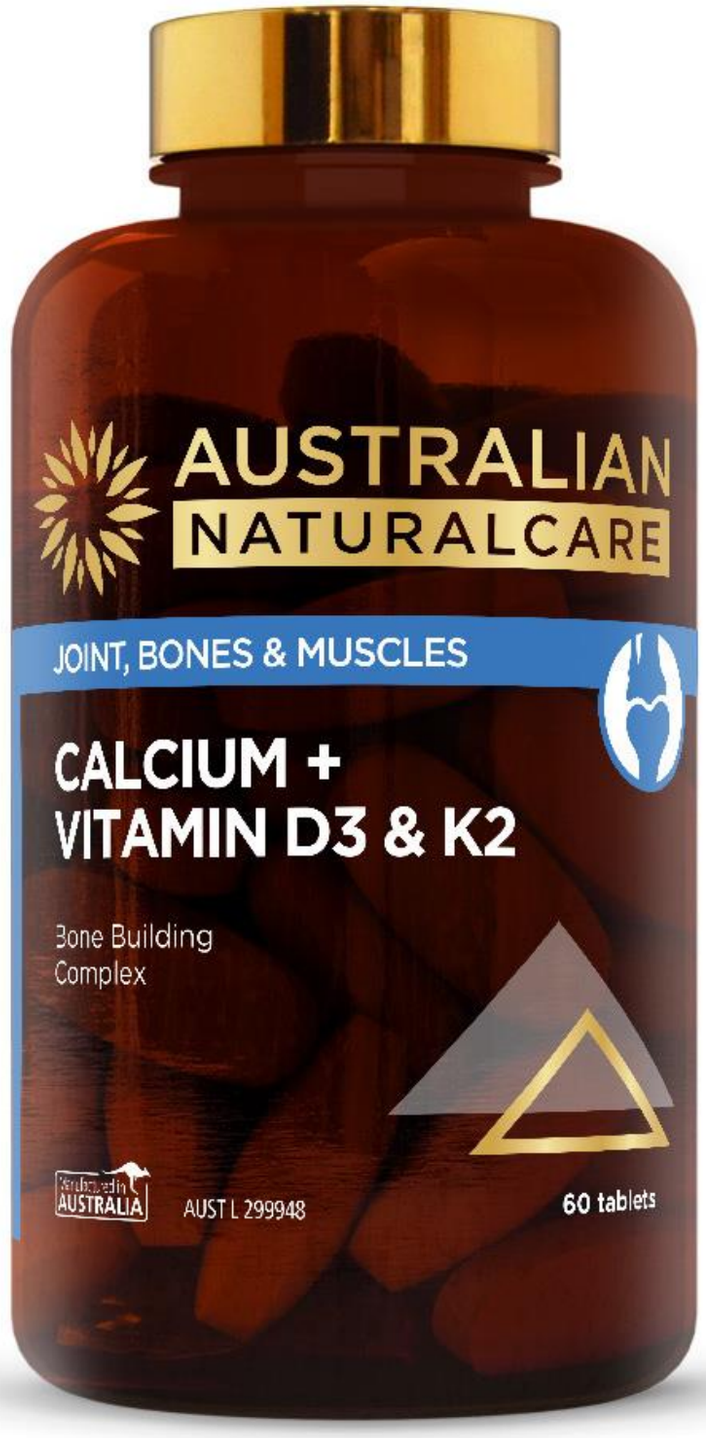
A note on CoOL terminology overall.

Overall, most focus group participants agreed that the CoO terminology (including both 'Made in Australia' and 'Australian Made'), despite being simple, created confusion as consumers identify three key elements in the overarching process – sourcing ingredients, manufacture and packaging. By having a catch all 'Made in Australia' meant that consumers would expect all stages of this process to occur in Australia without the claim appearing misleading.

"I think about the end products being made in Australia… packaging, pills, labels, but may doubt that the ingredients are Australian." 45+ year old from Sydney

"You assume that 'made in' means that all of it was Australian." 18-44 year old form Sydney

"The label with the kangaroo gives you a feeling of comfort and it is more recognisable" 45+ year old from Wagga Wagga



Knowledge of 'Made in Australia' requisites.

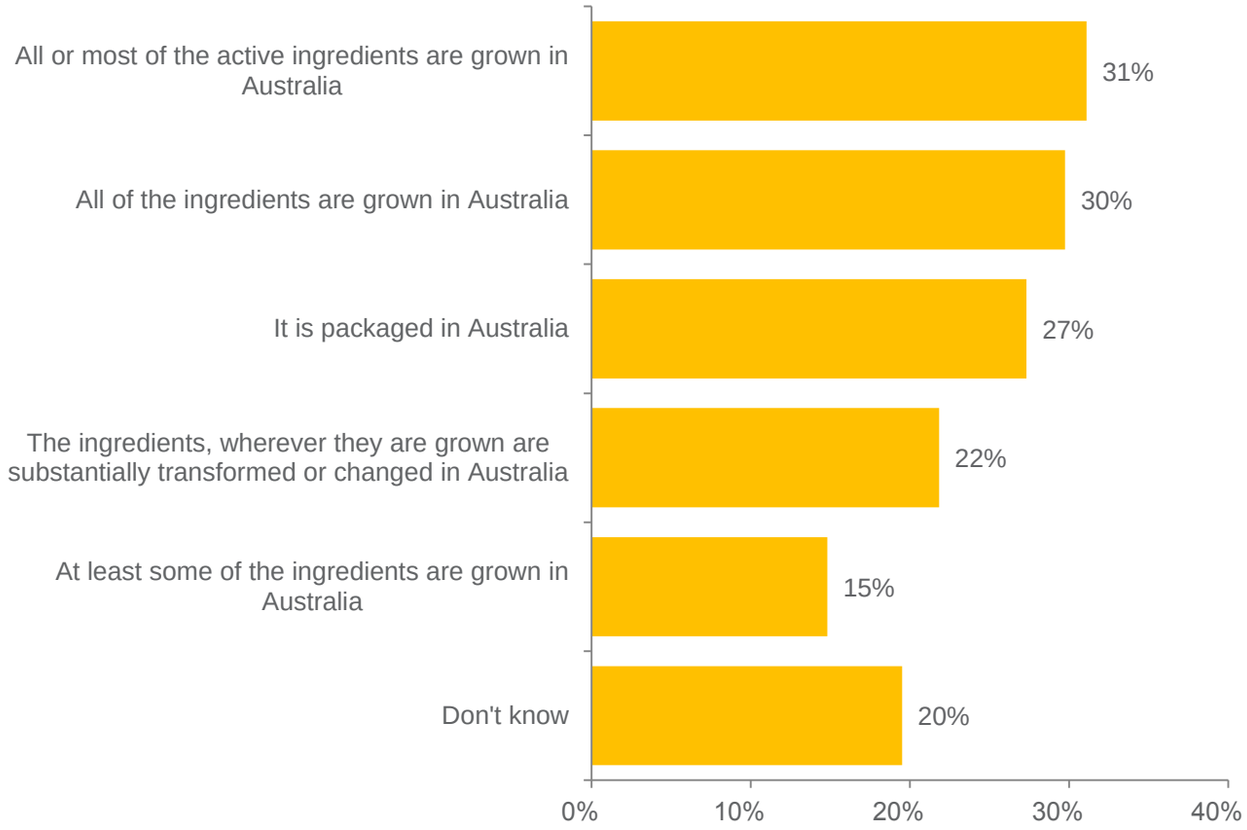
Which of the following must happen for vitamin, mineral or supplement products to be labelled 'Made in Australia'?

Based on the consumer confusion revealed in the focus groups, online survey respondents were asked to identify what features they felt a product must have before being able to use the 'Made in Australia claim'.

The most common requisite (31% mentioned) of Australians believe all or most of the active ingredients need to be grown in Australia in order to receive the label. A similar proportion (30%) believe all of the ingredients need to be grown in Australia.

27% of respondents were of the belief that products packaged in Australia could be labelled 'Made in Australia'.

22% felt that a product could claim to be 'Made in Australia' if the ingredients, wherever they are grown are substantially transformed or changed in Australia.



'Q7. As far as you know, which of the following must happen for vitamin, mineral or supplement products to be labelled 'Made in Australia'?
Base: All respondents (n=2091)

Made in Australia (MIA) text.

The MIA logo was met with mixed reactions. Initially participants felt this would be used on a product that is made in Australia from Australian ingredients, however scepticism quickly crept in and participants then questioned whether or not a product with this logo would in fact be made from Australian ingredients.

Once this scepticism was in place, consumers were concerned about the MIA message being misleading as although made in Australia, it may in fact be from imported ingredients. Without expressing the source of the ingredients in the logo, consumers may become confused and believe the product is wholly Australian, when it isn't. Participants agreed that CoOL need to specifically state (alongside MIA) that there are imported ingredients if this is the case.

"It is made in Australia but the ingredients aren't necessarily Australian." 18-44 year old from Sydney

"If I saw this I wouldn't assume that the ingredients are from Australia." 45+ year old from Sydney

"If it's brought in it can't be made in Australia" CALD person from Brisbane

The term 'Packed in Australia' was viewed suspiciously as many felt that although bottled or packed here, there was ambiguity about where the products were actually from.

'Australian Made' logo with the kangaroo.

When shown the AM logo with the kangaroo, focus group participants responded positively to this labelling, trusting it almost immediately, as they feel it guarantees them a wholly Australian product – from the sourcing of ingredients through to the manufacture and packaging.

"This logo shows that something is tried and tested… it's trustworthy and familiar." 45+ year old from Sydney

"This has rules and quality control around it." 18-44 year old from Sydney

In addition, Australian consumers who participated in the online survey had high levels of awareness – with 95% aware of the logo.

The AM logo with the kangaroo was perceived to be more official / had to be earned / was a marker of trust or a trademark of quality assurance, only available to those who earn it. This logo brought with it a perception of credibility and a sense of security that there are authorities regulating which products receive this stamp of 'top notch', 'gold standard', 100% Australian recognition.

"It gives me more confidence" CALD person from Brisbane

"It has gone through all the checks and balances" CALD person from Brisbane

Q10. Before participating in this survey, were you aware of the Australian Made Logo?
Base: All respondents (n=2091)

AM logo risks being seen as deceptive.

Realising, based on the current and previous rules, that organisations that import ingredients (despite still making the products in Australia) could still use this logo, created anger amongst consumers and risked tarnishing the credibility of this logo.

It was likened to the 'Heart Foundation tick' that was later known to be unreliable based on organisations' ability to purchase this logo rather than earn it.

Packed in Australia was seen to be self-explanatory, with most concluding that although packed in Australia, it's unlikely that the ingredients are Australian nor was it made in Australia. This logo instilled scepticism, with most thinking that product would not contain any Australian ingredients, and might not even be manufactured here. They felt it would be better to not have the label on a product, if this was the case.

"The ingredients are definitely from somewhere else" CALD person from Brisbane

A small proportion valued the honesty associated with this label, however it still resulted in more questions being raised about the place of manufacturing and where ingredients were sourced from.

Consumers demand honesty, simply.

Through a set of scenarios, consumers in the focus groups concluded that products that are 100% Australian (including ingredients, manufacture and packaging) have earned the right to use the AM logo with the Kangaroo.

Also, products that are Made in Australia and incorporate imported ingredients should be able to use the MIA logo however must (like food) specify that some ingredients are imported (and what proportion this is) and where they have come from.

Demonstrating just how important honest and complete information is in CoOL, consumers agreed that it is more misleading to claim MIA and exclude the fact that some ingredients are imported, than to not provide CoOL labelling at all.

The rules.

Both tests were seen as too relaxed.

Participants across the country agreed that both the current and previous rules were too relaxed. Although the new rules were seen to be a slight improvement by some, they were still perceived as not strict enough, particularly for removing the production cost criteria and through the scenario of the vitamin company – this example was still not acceptably AM because ingredients were imported.

"It would pass, but whether I like it is a different thing" CALD person from Brisbane

"Under the laws they can, but they shouldn't, it isn't ethical" 18-44 year old from Adelaide

The wording in both versions of the rules was confusing and subjective, but overall consumers felt that even if something is fundamentally changed but the ingredients are from overseas then it shouldn't be able to make an AM claim.

Previous test

Up until a few years ago, the 'test' for using the Australian Made logo was that it could be used if the product had 50% of its production costs occurring in Australia, or undergoes a **fundamental change in form, appearance or nature** such that the goods after the change are new and different good from those existing before the change.

Current test

Recently, the 'test' changed and removed the 50% production cost test. This was because it was hard to calculate, and could change depending on the source of some ingredients (e.g. low cost labour markets) or if exchange rates fluctuated. The new rules say that the Australian Made logo can be used if the goods are **fundamentally different in identity**, nature or essential character from all of their ingredients or components that were imported.

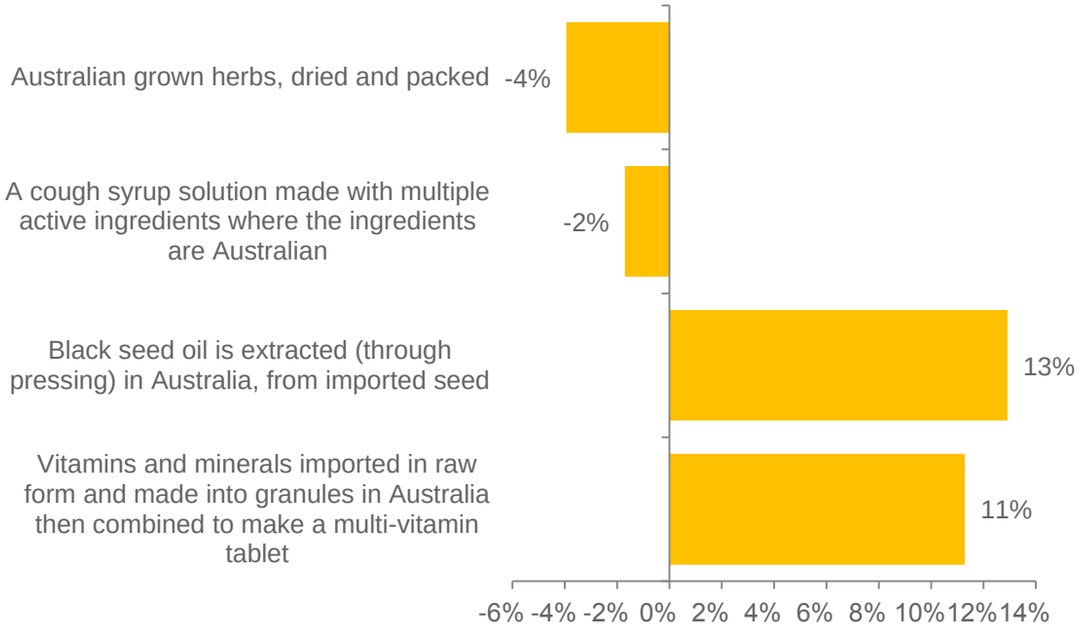
Knowledge of 'Made in Australia' requisites.

Would the following be able to claim 'Made in Australia'? (Green shading represents a 'Yes' to passing the test)

Example	Would it pass the test?			
	Pre-informed		Post-informed	
	% yes	% no	% yes	% no
A cough syrup solution made with multiple active ingredients where the ingredients are Australian	79%	8%	77%	9%
Imported Vitamin C powder, made into tablets and packed into sachets in Australia	22%	62%	21%	63%
Australian grown herbs, dried and packed	85%	5%	81%	7%
Imported bulk cod liver oil bottled in Australia with added orange flavour	20%	64%	20%	64%
Imported herbs dried and packed in Australia	21%	65%	23%	63%
Raw materials imported to Australia and manufactured into a cream	32%	50%	53%	32%
Liquid vitamin B capsules, encapsulated in Australia using imported Vitamin B	24%	57%	22%	61%
Vitamins and minerals imported in granules combined (blended) in Australia to make a multi-vitamin tablet	28%	53%	35%	48%
Vitamins and minerals imported in raw form and made into granules in Australia then combined to make a multi-vitamin tablet	36%	47%	47%	37%
Black seed oil is extracted (through pressing) in Australia, from imported seed	35%	46%	48%	36%
A cough syrup solution made with multiple active ingredients where the ingredients are Australian	79%	8%	77%	9%

Impact of explanation.

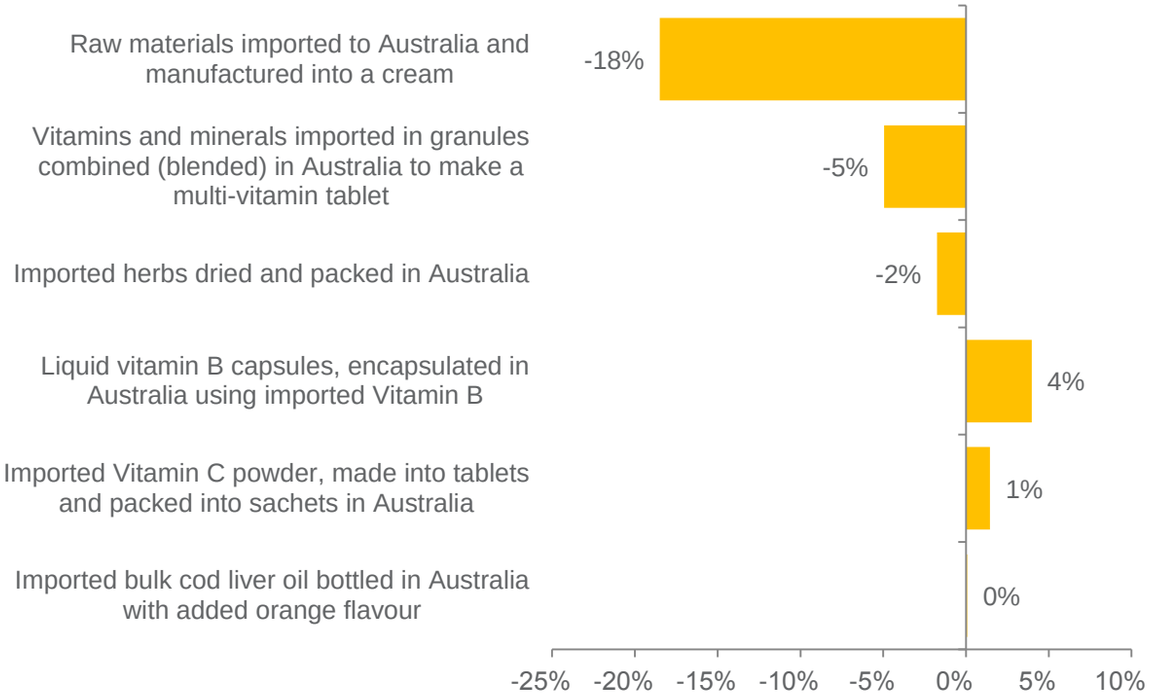
Change in Yes response



The above chart shows the percentage change in the scenarios where the correct answer was yes. The positive numbers show an increase in correct answers, while negative proportions show a decrease in the correct answers.

In other words, more people correctly interpreted the black seed oil and vitamins and minerals scenarios after being shown the explanation. Fewer people correctly interpreted the Australian herbs and cough syrup scenarios after the explanation.

Change in No response



Again, the above chart shows the percentage change in the scenarios where the correct answer was no. The positive numbers show an increase in correct answers, while negative proportions show a decrease in the correct answers.

After the explanation, a total of 18% of Australians incorrectly changed their answer to yes in regard to the raw materials being manufactured into a cream.

Q8. Which of the following examples would you consider to be ‘Made in Australia’?
Q9. Based on this definition and examples, which of the following examples would you consider to be ‘Made in Australia’?
Base: All respondents (n=2091)

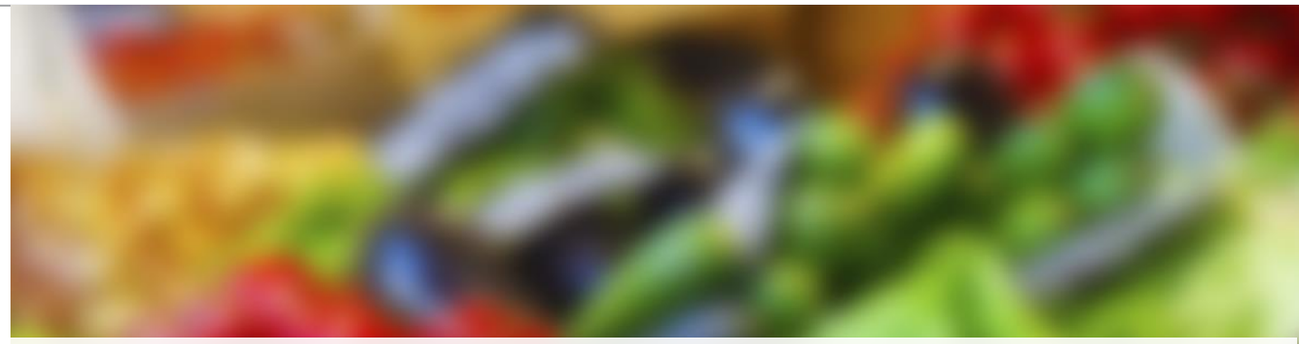
Ingredients and manufacture CoO matters most.

The most important point was for participants to know what proportion of the product was made of Australian ingredients and where ingredients were sourced from overseas. Many felt that this didn't necessarily need to be on shown on the label, and that a supporting website could be used to provide this additional information.

Where the product was manufactured and packaged was seen as less important in CoOL.

Consumers agreed that using this subjective and easily manipulated wording could mean that organisations and their lawyers could easily argue themselves out of a wrongful claim.

They felt that incorporating some clear and measurable test (based on ingredient source rather than production costs) would enhance community faith in this test and the overall CoOL of complementary healthcare products.



"They've thrown away the 'hard and fast' test. This is the opposite of what would reassure me." 18-44 year old from Sydney

"it's misleading… organisations are trying to find a way to say Australian Made without being fully Australian made, hoping that people are fooled." 45+ year old from Sydney

"Fundamentally different? Well it's still the basis of the product" CALD person from Brisbane

"it is too lenient… as long as you change 'something' about it you can use the label?" 45+ year old from Wagga Wagga

"It all comes down to what 'fundamental' means…" 45+ year old from Wagga Wagga

"'100% made in Australia', if that definition applied then nothing will be made in Australia" CALD person from Brisbane

"Producers could manipulate the wording just to get the label" 18-44 year old from Wagga Wagga

"Why bother with a logo if it is so easy. Quite deceptive." 18-44 year old from Adelaide

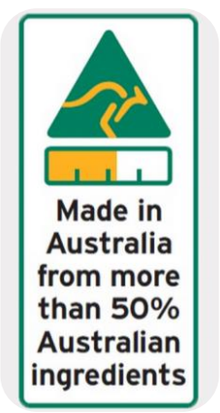
The consumer verdict.

Across the board, consumers preferred the AM logo, provided it would be something that was an official label enforced by government. It was easy to recognise and stood out more due to the icon.

The following shows how consumers would like to see CoOL apply to vitamins, minerals and supplements.

If product is made in Australia, from 100% Australian ingredients:

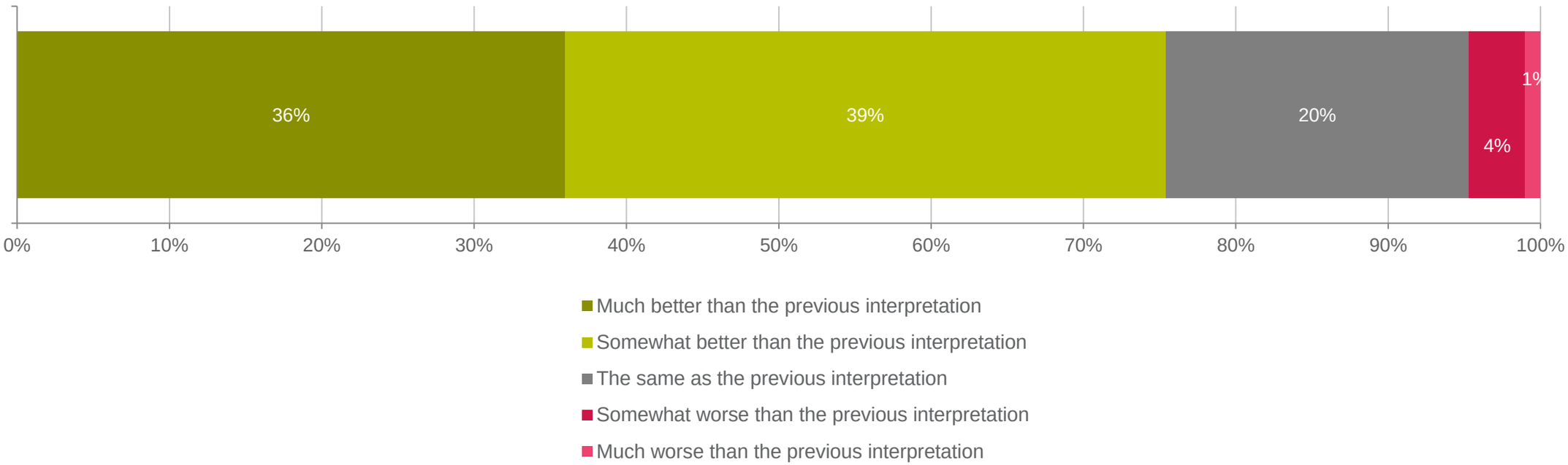
If product is made in Australia, from a mix of local and imported ingredients:



If product is not made in Australia:

Feedback on new interpretation.

Do you feel that this new, stricter interpretation of ‘Made in Australia’ is...



Three quarters (75%) of Australian consumers surveyed felt that the new interpretation is better (36% much better, 39% somewhat better).

Q11. Do you feel that this new, stricter interpretation of ‘Made in Australia’ is...
Base: All respondents (n=2091)

A note on the focus groups overall.

Consumer attitudes changed.

Having awareness of CoOL made consumers concerned and more vigilant. There was a strong support and preference for Australian made, but until the group was prompted, this was not something they noticed or looked for when buying vitamins.

People expect complementary health products available in Australia to be made in Australia, from Australian ingredients, to be of a high quality and heavily regulated. Hearing these rules contradicted this belief and filled consumers with scepticism around just how high the standards are in Australia given what can be claimed as Made in Australia and will now start taking a closer look.

Participants called for greater clarity around what proportion of ingredients are from Australia, similar to food, in order to make more informed decisions.

"I'd call this 'unconscious incompetence'." 45+ year old from Sydney

"I thought the standards would be higher, I'm disappointed to hear that to be honest." 18-44 year old from Adelaide

Implications and next steps.

Overall observations and next steps.

Based on the research, and in particular the reaction to the MIA and AM wording, any changes in this industry that are communicated to the consumer will need to be done in plain English, and incredibly clearly and simply. Given the many different interpretations of the claims, and in particular, the expectation that the AM Kangaroo logo represents a product that is wholly Australian made and from Australian products, it will be important for the Department to communicate the meaning of this logo and what it represents, to Australian consumers. Consumers have become aware of and familiar with the CoOL for food, and have suggested a similar approach is adopted for complementary health products, where the place of manufacture and proportion of Australian ingredients is provided.

There is a preference among Australian consumers for the Australian Made logo, as long as that term is easily understood and not deceptively used by organisations and corporations who may use it to 'fool' consumers in order to increase sales. The research has revealed that consumers believe that this mark should not be able to be bought and must be earned, monitored and regularly assessed in terms of their permissions to use it. Communicating that this assurance sits behind the use of the logo will help build credibility in the logo and its use.

Given the consumer scrutiny on the wording of the previous and current tests, there is scepticism in the ambiguity of the wording and the focus groups revealed a need to further tighten up the definition to clarify what could or could not use the MIA or AM claim. This includes using hard and quantifiable measures which would prevent organisations from being able to 'argue' their way out of any false claims.

There is an assumption made by Australian consumers that because they are buying brands that are perceived to be reputable (due to their familiarity), such as Blackmores, Swisse Nature's own and Cenovis, they believe that they are buying high quality products that are subject to Australian standards and rigour. The industry is aligned more closely with medicines rather than food and with this comes a 'blind faith' in the quality of complementary healthcare products. Becoming more aware of this throughout the research increased the level of scrutiny consumers place on this industry and created a desire for more information about where products are made, and where their ingredients are sourced.

Qualitative research instrument.

PROJECT AND PARTICIPANT INTRODUCTIONS (10 MINS)

- Introduction to the research including who the client is, nature of the study.
- Cover length of session, one to speak at a time, all to have say, confidentiality and the opportunity to ask questions, group recording, clients viewing if applicable.
- Emergency procedures, toilets, mobile phones to silent.
- Participant introductions including background, family and a good movie/TV show seen recently.

UNDERSTAND PRODUCTS PURCHASED, FREQUENCY, KEY PURCHASE DECISION FACTORS (20 MINS)

- The session tonight is about vitamins, minerals and supplements that we consume.
- What vitamins, minerals and supplements do we personally purchase and who are we purchasing them for (i.e. self or other family member)?
- What are the key things we look for when purchasing vitamins, minerals and supplements? IF NOT MENTIONED PROMPT: Price, brand, Country of Origin, formulation, past experience, recommendation from friend/shop assistant/pharmacist/doctor/other health practitioner
- How do we evaluate the quality of vitamins, minerals and supplements that we purchase? IF NOT MENTIONED PROMPT: Price, brand, Country of Origin, formulation, past experience, recommendation from friend/shop assistant/pharmacist/doctor/other health practitioner
- Is it important that vitamins, mineral and supplements are made in Australia? How come?
- Is it more important, less important or the same importance as food? How come?
- Where are the vitamins, minerals and supplements we purchase made?
- Is it important that the ingredients in vitamins, minerals and supplements are from Australia? How come?
- Is it more important, less important or the same importance as food? How come?
- Where do the ingredients for the vitamins, minerals and supplements that we purchase come from?
- Would we expect a vitamin, mineral or supplement that is made in Australia to be different to one not made in Australia? How would they be different?

UNDERSTANDING OF COUNTRY OF ORIGIN LABELLING FOR COMPLEMENTARY HEALTHCARE PRODUCTS (20 MINS)

- What do you understand the phrase 'Country of Origin Labelling' to mean in the context of vitamins, minerals and supplements?
  IF NECESSARY, PROBE FOR: Ingredients, Made in…, Packaged in…
  IF CONCEPT NOT UNDERSTOOD: We are talking about statements about where food has been made or where ingredients are from on product labels, packaging or in advertising. Common claims include 'product of…', 'grown in…' and 'made in…'
- Where have we seen Country of Origin Labelling for vitamins, minerals and supplements? *PROBE: On labels, on stands, in other places?*
- Do we pay attention to Country of Origin Labelling when we are shopping for vitamins, minerals and supplements?
- Do we do this – all, some, none of the time?
  - What are the reasons we pay attention to Country of Origin Labelling for vitamins, minerals and supplements?
  - What are the reasons we do not pay attention?
- How do we obtain information about Country of Origin Labelling? *PROBE: Read labels, notice signs, research online or other sources?*

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- Is Country of Origin Labelling more important for some types of vitamins, minerals and supplements than others?
  - *PROBE:* Vitamins vs. herbs vs supplements or tablets vs drinks vs powders?
  - *PROBE:* Vitamins, minerals and supplements that are known to be grown/made in Australia?
  - *PROBE:* Higher risk products vs lower risk?
- What impact does Country of Origin Labelling have on the vitamins, minerals and supplements we purchase?
- What is happening to Country of Origin Labelling for vitamins, minerals and supplements in Australia at the moment?
  - What have we heard?
  - How do we know this?
  - Where do we get our information from?

REACTION TO THE CHANGES TO THE COUNTRY OF ORIGIN LABELLING FOR COMPLEMENTARY HEALTHCARE PRODUCTS (30 MINS)

- Imagine we were in a supermarket and picked up a pack of vitamin C tablets that said 'Made in Australia' on the packaging. What do we think that means? SHOW MADE IN AUSTRALIA (NO KANGAROO).
- Now imagine we picked up a pack of vitamin C tablets that said 'Made in Australia' on the packaging and the kangaroo was displayed. What do we think that means? SHOW MADE IN AUSTRALIA (WITH KANGAROO).
- Is the meaning of the two labels different? In what way?
- Now, imagine we're in a supermarket and picked up a pack of liquid vitamin B capsules that said 'Packed in Australia' on the packaging. What do we think that means?
  - How is it different to packaging that says 'Made in Australia'?
- Imagine a scenario where a company imports a range of different vitamin powders into Australia and turns them into a multi-vitamin tablet. None of the ingredients are from Australia but the tablets are manufactured and packaged here.
  - Should this company be able to say the product is 'Made in Australia'? How come?
  - Should this company be able to use the Australian Made logo? How come?
- Imagine a scenario where a company imports a huge container of fish oil into Australia and puts the fish oil into capsules. None of the fish oil is from Australia but the fish oil is put into capsules and packaged here.
  - Should this company be able to say the product is 'Made in Australia'? How come?
  - Should this company be able to use the Australian Made logo? How come?
- Up until a few years ago, the 'test' for using the Australian Made logo was that it could be used if the product had 50% of its production costs occurring in Australia, or undergoes a **fundamental change in form, appearance or nature** such that the goods after the change are new and different good from those existing before the change.
  - Do we agree or disagree that this is the test that should be applied to determine whether the Australian Made logo can be used? How come?
  - Is the 'test' too strict, too relaxed, or about right? How come?
  - Using this 'test' on the multi-vitamin example we discussed earlier, do we think these multi-vitamins pass or fail? How come?

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- Using this 'test' on the fish oil capsule example we discussed earlier, do we think these multi-vitamins pass or fail? How come?

- Recently, the 'test' changed and removed the 50% production cost test. This was because it was hard to calculate, and could change depending on the source of some ingredients (e.g. low cost labour markets) or if exchange rates fluctuated. The new rules say that the Australian Made logo can be used if the goods are **fundamentally different in identity**, nature or essential character from all of their ingredients or components that were imported.
  - What do we think of the 'new test'?
  - Is it stricter, more relaxed or the same as the 'old test'? How come?

- Under the 'old test', the company that made the multi-vitamins could use the Australian Made logo. How do we feel about this?
- Under the 'old test', the company that made the fish oil capsules could use the Australian Made logo. How do we feel about this?
- Under the 'new test', the company that made the multi-vitamins can still use the Australian Made logo. How do we feel about this?
- Under the 'new test', the company that made the fish oil capsules can no longer use the Australian Made logo. How do we feel about this?

CONCLUSION (5 MINS)

- Finalisation of group including reminder of privacy / confidentiality and the provision of incentives.

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Made in Australia

AUSTRALIAN MADE

Packed in Australia

QMS ONLINE QUESTIONNAIRE

NOTE TO PROGRAMMER:
TEXT IN CAPITALS ARE INSTRUCTIONS
TEXT IN SENTENCE CASE IS THE SCRIPT, WHICH SHOULD BE READ EXACTLY AS WRITTEN

INTRODUCTION

We are conducting some research on behalf of the Australian government. In this research, we ask about your product labelling preferences, your understanding of current laws and any areas of confusion.
The survey will take around 10 minutes of your time.

SCREENER

We want to get feedback from a broad range of people. Firstly, a few questions about you…

S2 AGE
S2 Which one of the following age groups do you fall into? (SR)

01	Under 18 years
02	18-24
03	25-29
04	30-34
05	35-39
06	40-44
07	45-49
08	50-54
09	55-59
10	60-64
11	65 years or older
99	I prefer not to answer

IF 1 OR 99 IN S2, TERMINATE

S3 GENDER
S3 What is your gender? (SR)

01	Male
02	Female
03	Other
99	Prefer not to answer

CHECK QUOTAS
IF 99 TERMINATE

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S4 LOCATION
S4 In which area do you live?

01	Sydney
02	Regional NSW
03	Melbourne
04	Regional Victoria
05	Brisbane
06	Regional Queensland
07	Adelaide
08	Regional South Australia
09	Darwin
10	Regional NT
11	Perth
12	Regional WA
13	Hobart
14	Regional Tasmania
15	ACT
99	I prefer not to answer/none of these

CHECK QUOTAS
IF 99 TERMINATE

IF SUCCESSFUL CONTINUE

MAIN QUESTIONNAIRE

Q1 PURCHASE CATEGORY
Q1 Which of the following describes your purchase and use of vitamins, minerals or other supplements? (MR)

01	I purchase these products for myself to use
02	I purchase these products for other family members to use
03	Somebody else purchases these products for me to use
99	None of the above (I do not purchase or use these products) [SR]

IF 01, 02, 03 IN CODE AS COMPLEMENTARY HEALTHCARE PURCHASER OR USER
IF 04 IN CODE AS NON COMPLEMENTARY HEALTHCARE PURCHASER OR USER

ASK Q1B IF A COMPLEMENTATY HEALTHCARE CONSUMER

Q1B PURCHASE CATEGORY
Q1B Where do you purchase vitamins, minerals and other supplements? (RANDOMISE) (MR)

01	Chemist
02	Supermarket
03	Online
04	Health food store
05	Naturopath or other complementary health practitioner
96	Other (specify)
99	None of these (I do not purchase or use complementary healthcare products) [SR]

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Q2 USAGE

Q2 Which of the following product categories do you personally regularly USE or PURCHASE for your own or your families consumption? (MR)

		Use	Purchase	Do not use or purchase
01	Vitamins and dietary supplements			
02	Sports nutrition products			
03	Herbal/traditional products			
04	Weight management and wellbeing products			
05	Other (specify)			

ASK Q3 IF PURCHASE SELECTED AT Q2

Q3 PURCHASE CONSIDERATIONS

Q3 Which of the following do you take into account when purchasing vitamins, minerals and/or supplements? (MR) [RANDOMISE]

01	Price
02	Made in Australia
03	Known / reputable brand
04	Country of Origin (other than Australia)
05	Strength of ingredients / formulation
06	Past experience with the product
07	Recommendation from friend
08	Recommendation from pharmacist
09	Recommendation from health practitioner
10	Recommendation from store sales assistant
11	Something I have used before
12	Format (e.g. tablet vs. chewable)
96	Other (specify)

Q4 MADE IN AUSTRALIA

Q4 How important is it to you that vitamins, minerals and supplement products are Made in Australia? (MR)

01	Very Important
02	Important
03	Moderately Important
04	Slightly Important
05	Not Important

Q5 QUALITY

Q5 Would you expect the **quality** of vitamins, minerals and supplements made in Australia to be…

01	Same as products made elsewhere
02	Better than products made elsewhere
03	Worse than products made elsewhere
98	Don't know

Q5A EFFECTIVENESS

Q5A Would you expect the **effectiveness** of vitamins, minerals and supplements made in Australia to be…

01	Same as products made elsewhere
02	Better than products made elsewhere
03	Worse than products made elsewhere
98	Don't know

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Q6 LIKELIHOOD

Q6 If you had a choice between a vitamin, mineral or supplement product made in Australia and one made elsewhere for a comparable price, how likely would you be to choose the product made in Australia?

01	Very likely
02	Somewhat likely
03	Neither/nor
04	Unlikely
05	Very unlikely
98	Don't know

Q7 KNOWLEDGE

Q7 As far as you know, which of the following must happen for vitamin, mineral or supplement products to be labelled 'Made in Australia'? [RANDOMISE] [MR]

01	It is packaged in Australia
02	At least some of the ingredients are grown in Australia
03	All of the ingredients are grown in Australia
04	All or most of the active ingredients are grown in Australia
05	The ingredients, wherever they are grown are substantially transformed or changed in Australia
96	Other (specify)
98	Don't know

Q8 EXAMPLES

Q8 Which of the following examples would you consider to be 'Made in Australia'? [RANDOMISE] [SR PER ROW]

		Yes	No	Don't Know	Correct response (DO NOT DISPLAY)
01	A cough syrup solution made with multiple active ingredients where the ingredients are Australian				Yes
02	Imported Vitamin C powder, made into tablets and packed into sachets in australia				No
03	Australian grown herbs, dried and packed				Yes
04	Imported bulk cod liver oil bottled in Australia with added orange flavour				No
05	Imported herbs dried and packed in Australia				No
06	Raw materials imported to Australia and manufactured into a cream				No
07	Liquid vitamin B capsules, encapsulated in Australia using imported Vitamin B				No
08	Vitamins and minerals imported in granules combined (blended) in Australia to make a multi-vitamin tablet				No
09	Vitamins and minerals imported in raw form and made into granules in Australia then combined to make a multi-vitamin tablet				Yes
10	Black seed oil is extracted (through pressing) in Australia, from imported seed				Yes

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Q9 SUBSTANTIAL TRANSFORMATION

Q9 To be labelled 'Made in Australia', vitamin, mineral and supplement products must be substantially transformed in Australia so that after being transformed, the goods are fundamentally different in identity, nature or essential character from all of their ingredients or components that were imported into Australia.

Example 1: Glucosamine granules are imported and compressed into a tablet. Because the glucosamine tablets are not fundamentally different in identity, nature or essential character from the imported glucosamine granules, this is not substantially different/transformed and therefore cannot claim to be 'Made in Australia'.

Example 2: Imported arnica herb undergoes processing in Australia to extract the active ingredient and is then combined with raw, local and imported ingredients to form a cream that claims to assist with pain and swelling. The extraction of the herb and its dilution into a topical cream is classed as a substantial transformation and can likely support a 'Made in Australia' claim.

Based on this definition and examples, which of the following examples would you consider to be 'Made in Australia'? [RANDOMISE] [SR PER ROW]

		Yes	No	Don't Know	Correct response (DO NOT DISPLAY)
01	A cough syrup solution made with multiple active ingredients where the ingredients are Australian				Yes
02	Imported Vitamin C powder, made into tablets and packed into sachets				No
03	Australian grown herbs, dried and packed				Yes
04	Imported bulk cod liver oil bottled in Australia with added orange flavour				No
05	Imported herbs dried and packed in Australia				No
06	Raw materials imported to Australia and manufactured into a cream				No
07	Liquid vitamin B capsules, encapsulated in Australia using imported Vitamin B				No
08	Vitamins and minerals imported in granules combined (blended) in Australia to make a multi-vitamin tablet				No
09	Vitamins and minerals imported in raw form and made into granules in Australia then combined to make a multi-vitamin tablet				Yes
10	Black seed oil is extracted (through pressing) in Australia, from imported seed				Yes

Q10 AUSTRALIAN MADE LOGO

Q10 Before participating in this survey, were you aware of the Australian Made Logo? (SR)

01	Yes
02	No
98	Don't know

AUSTRALIAN MADE

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Q11 LOGO CHANGES

Q11 Changes made in 2017 to Australia's country of origin labelling laws mean that some vitamin, mineral and supplement products that were previously able to be labelled 'Made in Australia' and use the kangaroo logo are now no longer able to do so because they are not considered to have been 'substantially transformed' in Australia.

Up until recently, the 'test' for using the Australian Made logo was that it could be used if the product had 50% of its production costs occurring in Australia, or undergoes a fundamental change in form, appearance or nature such that the goods after the change are new and different good from those existing before the change.

Recently, the 'test' changed and removed the 50% production cost test. This was because it was hard to calculate, and could change depending on the source of some ingredients (e.g. low cost labour markets) or if exchange rates fluctuated. The new rules say that the Australian Made logo can be used if the goods are fundamentally different in identity, nature or essential character from all of their ingredients or components that were imported.

For example, recently the Federal Court ruled that imported fish oil plus Vitamin D made into capsules in Australia could not be labelled 'Made in Australia', as the process of encapsulation does not represent a 'significant transformation'.

Do you feel that this new, stricter interpretation of 'Made in Australia' is…

01	Much better than the previous interpretation
02	Somewhat better than the previous interpretation
03	The same as the previous interpretation
04	Somewhat worse than the previous interpretation
05	Much worse than the previous interpretation

Q12 LOGO CHANGES CONTINUED

Q12 How much do you agree or disagree that…

		Strongly agree	Agree	Neither	Disagree	Strongly disagree	Not sure
01	…the revised Country of Origin Labelling will enable consumers to make informed complementary healthcare product purchasing decisions						
02	…the revised Country of Origin Labelling will help to identify whether the complementary healthcare product was grown or made in Australia						
03	…the revised Country of Origin Labelling will help to identify what country the complementary healthcare product was packed in						

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FINAL DEMOGRAPHICS

Finally a few questions about you to make sure we survey a cross-section of respondents.

The answers you give will remain completely confidential.

D1 POSTCODE
D1 What is the postcode of the area in which you live? _____

D2 INCOME
D2 Which of the following best describes your personal, yearly income before tax? (SR). REQUIRED.

01	<$40,000 per year
02	$40,000-$59,999 per year
03	$60,000-$79,999 per year
04	$80,000-$99,999 per year
05	$100,000+
06	Prefer not to answer

D3A CHILDREN.
D3A Do you have any children?

01	Yes
02	No

IF 2 IN D3A GO TO D3B

D3B NO OF CHILDREN
D3B How many children do you have under 18? How many do you have that are 18+

01	<18
02	18+

D4 EDUCATION
D4. Which of the following best describes the highest level of education you have completed to date?

01	Post graduate degree
02	Graduate Diploma or Graduate Certificate
03	Bachelor Degree or Bachelor Degree with Honours
04	Advanced Diploma or Diploma
05	Certificate Level
06	Secondary Level
07	Primary Education
96	Other (Specify)
98	Prefer not to answer

D5 HOUSEHOLD
D5. Which of the following best describes your household? SHOWCARD 7

01	Couple with no children
02	Two parent family
03	Couple with children no longer living at home
04	Single parent family
05	Single person household
96	Group household
96	Other (Specify)

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D6 LANGUAGE
D6 What languages do you speak at home? (MR)

01	English
02	Mandarin
03	French
04	Korean
05	Chinese
06	German
07	Cantonese
08	Spanish
09	Nepali
10	Vietnamese
11	Indonesian
12	Hindi
13	Gujarati
14	Telega
15	Filipino/Tagalog
96	Other (Specify _____)
99	Prefer not to answer

CLOSING

Thank you very much for participating in this research today.

That's the end of the survey. As this is market research, it is carried out in compliance with the Privacy Act and the information you provided will be used only for research purposes. Your answers will be combined with those of other participants to help our client in their decision making.

For your information, this survey was conducted on behalf of The Department of Industry, Innovation and Science.

colmar brunton.

Appendix M – Submission: Dr Ken Harvey

Submission to the Complementary Health Care Taskforce

By

Assoc Prof Ken Harvey MB BS, FRCPA, AM

On behalf of

Choice (Australian Consumers' Association)

Public Health Association Australia (PHAA)

Health Action International Asia Pacific (HAIAP)

Friends of Science in Medicine (FSM)

Submission to Complementary Health Care Taskforce

Background

The Australian Therapeutic Goods Administration (TGA) defines 'complementary medicines' (known as supplements in other countries) as vitamins and minerals, fish oil, Western herbal medicine, Chinese traditional medicines, Ayurveda (Indian) medicines, indigenous medicines, homeopathic medicines, probiotics and aromatherapy products.

A recent Federal court case[1] ruled that encapsulation in Australia of imported fish oil (from Chile) and Vitamin D (from China) did not qualify for the 'Made in Australia' logo as mere encapsulation did not represent 'substantial transformation' of a product as required under Australian Competition and Consumer (ACCC) Guidelines.[2]

Complementary Medicines Australia (CMA) argued that this decision will have significant detrimental impacts on the industry's $1.2 billion export market and threaten a work force supporting a 4.9-billion-dollar industry.

They noted that many consumers, especially those in the Asia-Pacific region, look for the 'Made in Australia' logo as proof of high quality, trusted, products synonymous with Australian complementary medicines.

CMA argued that the ACCC criteria for 'substantial transformation' should be watered-down such that all finished medicinal products manufactured in Australia under GMP meet the definition.[3]

Four perspectives

1. Consumers

Choice

Set up by consumers for consumers, **Choice** provides Australians with information and advice, free from commercial bias.[4] Choice fights to hold industry and government accountable and achieve real change on the issues that matter most.

I have represented Choice on many government inquiries and consultations, I'm a past Board Member and I've been awarded Life Membership for services to the consumer movement.

Country of Origin Labelling (CoOL) is a priority issue for Choice. In addition, Australian Consumer Law[5] and the Therapeutic Goods Advertising Code[6] both state that representations must be truthful, accurate and not misleading.

Choice supports the ACCC CoOL guideline for complementary healthcare products.

TGA Consumer survey

During June and July 2018, the TGA conducted a **survey of consumer opinion about complementary medicines**.[7] It employed a dual sampling methodology: a quota driven population-based sample (Panel) and an Opt-in sample sourced through known TGA contacts, networks and consumer stakeholders.

[1] http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2018/2018fca1936
[2] https://www.accc.gov.au/publications/country-of-origin-labelling-for-complementary-healthcare-products-a-guide-for-business
[3] http://www.cmaustralia.org.au/Australian-Made-Issues
[4] https://www.choice.com.au/
[5] https://www.legislation.gov.au/Details/C2015C00327
[6] https://www.tga.gov.au/publication/therapeutic-goods-advertising-code
[7] https://www.tga.gov.au/tga-consumer-survey-2018

There was a considerable gender and age difference between the two groups: females; Panel, 50% compared to Opt-in, 66% and age over 55: Panel, 33% compared to Opt-in, 50%. However, the groups did not differ in complementary use, around half of each sample reported they used these medicines.

Across the range of measures relating to complementary medicines, 18-34-year olds consistently showed the highest level of nett agreement with the above statements and those in the 55-plus group show the lowest levels of nett agreement.

The results for other medicines showed higher positive responses to the same questions reflecting the difference between the "light-touch" regulatory standards for complementary medicines compared to the higher standards applied for other medicines.

Overall, the responses below showed considerable concerns by survey participants relating to statements about complementary medicines.

Agreed with statement:	Panel (n=1,045)	Opt-in (n=684)
Complementary medicines are safe	38.5%	25.8%
Appropriately regulated	32.2%	14.5%
Manufactured to high standard	38.4%	20.6%
Trusted	37.6%	23.9%
Government monitors safety	41.8%	18.2%
Overall	37.7%	20.6%

An ongoing focus on addressing and responding to consumer concerns about complementary medicines was recommended.

This survey also casts doubt on the assumption by CMA that Australian complementary medicines are regarded as high quality, trusted products.

2. Public Health Association of Australia (PHAA)

PHAA is the principal Australian public health NGO working to promote the health and well-being of all Australians.[8] Its mission is to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health. I'm a member of PHAA and active in their complementary medicine special interest group.

The PHAA has the following position statement. Food labelling is needed to assist consumers to make healthy food choices and promote public health including, ingredient labelling and nutrition information panels (including added sugar), and interpretive front-of-pack-labelling (adopted 26 September 2018).

The same "truth-in-labelling" principles should apply to complementary medicines. A draft policy on this topic is currently undergoing consideration (including CoOL).

[8] https://www.phaa.net.au/

3. Health Action International Asia Pacific (HAIAP)

HAIAP is part of an independent global network, working to increase access to essential medicines and improve their rational use through research excellence, evidence-based policy advocacy, and strengthening the capacity and involvement of civil society in government decision making.

It has been my privilege to work with many health activists in our region, learn of their struggles and share their expertise and solidarity.

HAIAP want medicines to be evidence-based, address real health needs, affordable and promoted ethically, by both local and international companies.

Regrettably, as shown in the appended presentation, very few Australian complementary medicines fit these criteria.

4. Friends of Science in Medicine (FSM)

FSM as formed in 2011 to emphasise the importance of basing Australian health care on evidence, scientifically sound research and established scientific knowledge published in peer-reviewed journals of accepted standing. Valuing scientific rigor is especially important in an age where unsubstantiated health claims are rampant and scientific consensus is 'imbalanced' by the views of extremists. As of February 2019, FSM has more than 1200 leading scientists, clinicians, lawyers and consumer advocates as supporters. I am currently the President of FSM.[9]

We campaign against the unethical promotion of therapeutic goods and services to consumers. The former includes many complementary medicines, diagnostic tests and medical devices. The latter includes services offered by both registered and unregistered health professionals.

We welcome and support well-conducted research into complementary medicines. Some traditional medicines have been found to contain valuable medicinal ingredients, which have subsequently been isolated, purified and used effectively to treat disease. Examples include salicylates and aspirin from willow bark, digitalis from foxglove, paclitaxel from the bark of the Pacific yew tree and artemisinin compounds used for drug-resistant malaria isolated from Traditional Chinese Medicine made from sweet wormwood.

However, FSM deplores the current TGA "light-touch" CM policy settings: no pre-market assessment of most complementary medicines; sponsors trusted to: select ingredients from the TGA's low-risk list; manufacture under GMP, and hold evidence for claims made and no timely or effective penalties for regulatory breaches.

The inevitable result is that around 80% of the TGA's limited post-marketing reviews show regulatory violations (mainly no evidence to support claims made). Around 98% of published advertising complaint outcomes are upheld; many more complaints have no published outcomes. In addition, research is discouraged; a better return on investment comes from industry spending money on promotional hype and celebrities. This makes it hard for consumers (and health professionals) to separate the evidence-based wheat from the hype-driven chaff.

[9] https://www.scienceinmedicine.org.au/welcome-message/

FSM believes upholding the CoOL, thus encouraging 'substantial transformation', will stimulate the complementary medicines industry to produce more research-based products which, ultimately, is their only long-term future.

Conclusion

Consumers and health professionals in Australia and overseas want complementary medicines to be evidence-based, address real health needs, be affordable, and promoted ethically.

CMA are essentially saying they will lose money if they stop misleading consumers about their CoOL and obey Australian Consumer Law.

I reiterate that upholding the CoOL, thus encouraging 'substantial transformation', will stimulate the CM industry to produce more research-based products which, ultimately, is their only long-term future.

I urge the Taskforce to report to government that watering-down the ACCC CoOL guidelines would not be in the interests of consumers, the industry's future or the reputation of the Australia Made logo.

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Associate Professor

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22 February 2019

AUSTRALIAN MADE

Complementary Healthcare Taskforce Presentation

Dr Ken Harvey MB BS, FRCPA, AM
Associate Professor, School of Public Health and Preventive Medicine
http://www.medreach.com.au/

Department of Industry, Innovation and Science, Canberra, 31 January 2019

MONASH University

1

AUSTRALIAN MADE

What are complementary medicines?

Vitamins and minerals, fish oil, Western herbal medicine, Chinese traditional medicines, Ayurveda (Indian) medicines, indigenous medicines, homeopathic medicines, probiotics and aromatherapy products.

2

Complementary Medicines Australia concerns:

- The revised ACCC Country of Origin Labelling (CoOL) Guidelines means over 200 licensees to the Australian Made logo are in danger of being revoked.
- This will have significant detrimental impacts on the industry's $1.2 billion export market and threaten a work force supporting a 4.9 billion dollar industry.

http://www.cmaustralia.org.au/Australian-Made-Issues

3

The Issue: Substantial transformation

- ACCC Guidelines:
  - 'Substantially transformed' means a finished product that's **fundamentally different** from the imported ingredients that went into it.
- Federal Court ruled (03/12/2018):
  - Encapsulation in Australia of imported fish oil (from Chile) and Vitamin D (from China) was **NOT** substantial transformation.

4

Complementary Medicines Australia concerns:

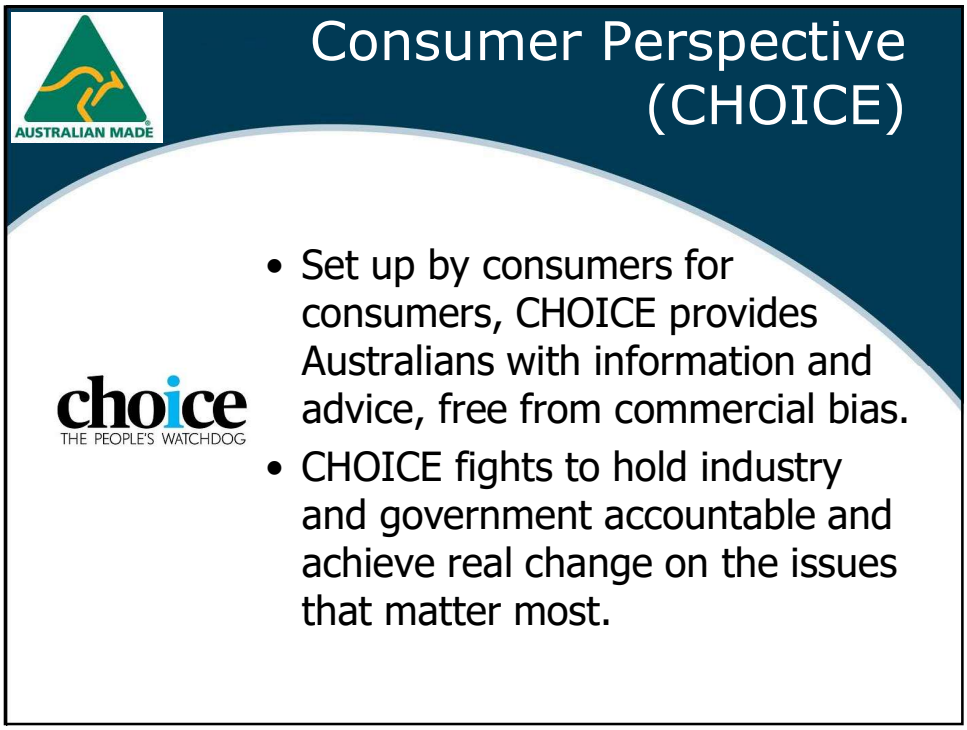
- Many consumers, especially those in the Asia-Pacific region, look for the 'Made in Australia' logo as proof of high quality, trusted, products synonymous with Australian complementary medicines
- The ACCC criteria for substantial transformation should be watered-down such that all finished medicinal products manufactured in Australia under GMP meet the definition.

5

Four perspectives

- Consumers (Choice, TGA survey)
- Public Health (PHAA)
- South East Asian Region (Health Action International Asia Pacific)
- Friends of Science in Medicine

6



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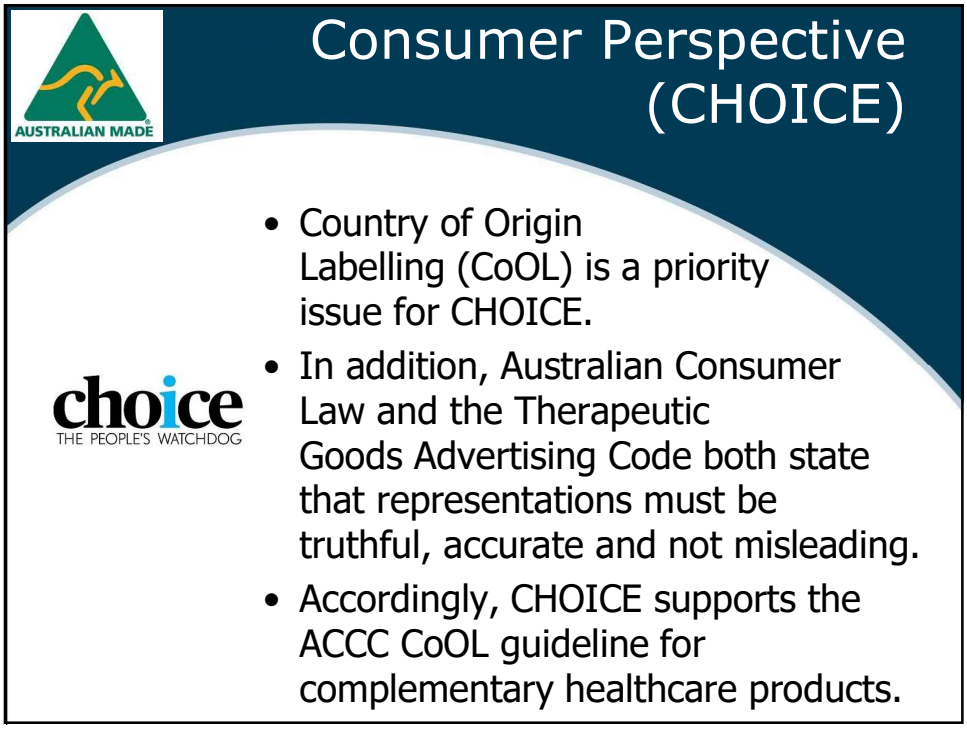

8

Consumer Perspective (TGA survey)

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Overall, the responses showed considerable concerns by survey participants relating to statements about complementary medicines

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Overall	37.7%	20.6%

https://www.tga.gov.au/tga-consumer-survey-2018

9

Public Health Perspective (PHAA)

Public Health Association AUSTRALIA

- The PHAA is the principal Australian public health NGO working to promote the health and well-being of all Australians.
- Its mission is to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

10

Public Health Perspective (PHAA)

- Position Statement
  - Food labelling is needed to assist consumers to make healthy food choices and promote public health including: ingredient labelling and nutrition information panels (including added sugar) and interpretive front-of-pack-labelling (adopted 26 September 2018).
  - Complementary medicine. Draft policy currently undergoing consideration (including CoOL).

11

SE Asian Perspective (HAIAP)

- HAIAP is part of an independent global network, working to increase access to essential medicines and improve their rational use through:
  - research excellence;
  - evidence-based policy advocacy, and
  - strengthening the capacity and involvement of civil society in government decision making.

12

SE Asian Perspective (HAIAP)

13

SE Asian Perspective (HAIAP)

HAIAP want medicines to be:

- evidence-based,
- address real health needs,
- affordable, and
- promoted ethically, by both local and international companies.

14

Does this product fit HAIAP requirements?

- Swisse Wellness, which launched in China in 2016, offers Lung Health Support with ingredients from traditional Chinese medicine.
- With the world's highest smoking rate and some of the world's most polluted cities, the Chinese market offers unrivalled opportunity for such products.

https://assets.kpmg/content/dam/kpmg/au/pdf/2018/demystifying-chinese-investment-in-australian-healthcare-january-2018.pdf

15

CRP Complaint: Swisse Lung Health Support

- Complaint: 2018/02/006
- Claim: "Swisse Ultiboost Lung Health Support has been formulated based on scientific and traditional evidence to provide a comprehensive formula that helps protect lungs from modern environmental influences".
- I alleged that this claim breached the *Therapeutic Goods Act* 1989 s.22(5) as it refers to therapeutic uses not included on the Australian Register of Therapeutic Goods.
- It also breached the *Therapeutic Goods Advertising Code 2015,* s4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) as no scientific evidence could be found supporting the claims made.
- TGACRP outcome (27/03/2018) "better dealt with by another authority (referred to TGA)". To-date, no outcome from TGA.

16

How many Australian CMs fit HAIAP requirements?

17

Friends of Science in Medicine Perspective

- We welcome and support well-conducted research into complementary medicines (CM).
- Some traditional medicines have been found to contain valuable medicinal ingredients, which have subsequently been isolated, purified and used effectively to treat disease.

18

Friends of Science in Medicine Perspective

- However, FoSM deplores the current TGA "light-touch" CM policy settings:
  - No pre-market assessment of most CM.
  - Sponsors trusted to: select ingredients from the TGA's low-risk list; manufacture under GMP, and hold evidence for claims made.
  - No timely or effective penalties for regulatory breaches.
- The inevitable result:
  - Around 80% of the TGA's limited post-marketing reviews show regulatory violations (mainly no evidence to support claims made).
  - Around 98% of published advertising complaint outcomes are upheld; many more complaints have no published outcomes.
  - Research discouraged; a better return on investment comes from industry spending money on promotional hype and celebrities.
  - CM only trusted by 24% of knowledgeable consumers.

19

Perverse outcomes of CM Policy

http://www.youtube.com/watch?v=12ww26sQF7E&feature=youtu.be

20

Rules under review: What did we want?

- A regulatory system with teeth;
- That supports research;
- That provides evidence-based products that meet real health needs at an affordable price;
- Ethically promoted.

21

What did we get?

During 2018-19

A flurry of activity:

- The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017.
- The Therapeutic Goods (Permissible Indications) Determination No.1 of 2018.
- The Therapeutic Goods Advertising Code Council and Complaint Resolution Panel (CRP) were abolished, the TGA took over the advertising complaint system and a TGA Advertising Consultative Committee replaced the Code Council.
- The Therapeutic Goods Advertising Code 2015 remained operational until 1 January 2019 when it was replaced by the 2018 (No 2) Code.

22

Health Minister Hunt said:

Jan 2018

Current Federal Health Minister Hon Greg Hunt MP

These measures:

> "Will enable potential harms from inappropriate advertising to be comprehensively prevented but at the same time make it clear to industry that they have the responsibility to produce compliant advertisements in the first place."

The accompanying paper (in confidence until publication), and surveyed consumer's lack of trust in the TGA, suggests the Minister's hopes have not been realised.

23

Conclusion

- Consumers and health professionals in Australia and overseas want CM to be evidence-based, address real health needs, be affordable, and promoted ethically.
- CMA are essentially saying they will lose money if they stop misleading consumers about their CoOL and obey Australian Consumer Law.
- I put to the Taskforce that upholding the CoOL, thus encouraging substantial transformation, will stimulate the CM industry to produce more research-based products which, ultimately, is their only long-term future.
- I urge the Taskforce to report to government that watering-down the ACCC CoOL guidelines would not be in the interests of consumers, the industry's future or the reputation of the Australia Made logo.

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