AUSTRALIAN SENATE

**Senate Standing Committee for the Scrutiny of Delegated Legislation**
Parliament House, Canberra ACT 2600
02 6277 3066 | sdlc.sen@aph.gov.au
www.aph.gov.au/senate_sdlc

13 February 2020

The Hon Karen Andrews MP
Minister for Industry, Science and Technology
Parliament House
CANBERRA ACT 2600

Via email: Karen.Andrews.MP@aph.gov.au

CC: industrydlo@industry.gov.au; CommitteeScrutiny@treasury.gov.au

Karen

Dear Minister,

**Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019 [F2019L01627]**

The Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee) assesses all legislative instruments subject to disallowance, disapproval or affirmative resolution by the Senate against the scrutiny principles outlined in Senate standing order 23. The committee has identified scrutiny concerns in relation to the above instrument, and the committee seeks your advice about this matter.

***Matters more appropriate for parliamentary enactment***

Senate standing order 23(3)(j) requires the committee to consider whether an instrument contains matters more appropriate for parliamentary enactment (that is, matters that should be included in primary, rather than delegated, legislation).

Section 255 of the Australian Consumer Law (the ACL) allows country of origin representations to be made if the representation satisfies certain requirements. This provision is commonly referred to as the 'safe harbour provision'. Under this provision a representation that goods were made in a particular country may be made if 'the goods were last substantially transformed in that country'.

The regulations provide that complementary medicines, such as vitamins, herbal medicines, and sports supplements, may rely on the safe harbour provision and therefore make 'made in Australia' claims if they undergo the 'last step in the manufacture of the dosage form' in Australia. It therefore appears that the effect of the regulations is to allow manufacturers of complementary medicines to make 'made in Australia' claims even where there is no 'substantial transformation' of the relevant goods in Australia as required by the ACL.

In this regard, the committee notes that in December 2018, the Federal Court held that the encapsulation of imported fish oil (from Chile) and Vitamin D (from China) in Australia did not qualify for the 'Made in Australia' logo, as the mere encapsulation of these ingredients did not represent 'substantial transformation' of a product as required by the ACL (see *Nature's Care Manufacture Pty Ltd v Australian Made Campaign Limited* [2018] FCA 1936 (3 December 2018).

The committee further notes that your media release of 18 December 2019 indicates that amendments will be proposed to the ACL this year to provide that 'made in Australia' claims based on the lower threshold will be required to display a bar chart showing the proportion of Australian ingredients.

The committee appreciates the significant complexities and history associated with the subject matter of this instrument. Nevertheless, as a matter of technical scrutiny, the committee is required to scrutinise each legislative instrument as to whether it contains matters more appropriate for parliamentary enactment.

**In this regard, the committee requests your advice as to why it is considered necessary and appropriate to use delegated legislation, rather than primary legislation, to lower the threshold for manufacturers of complementary medicines to make 'made in Australia' claims, noting that associated changes to the primary legislation are currently being formulated.**

The committee's expectation is to receive a response in time for it to consider and report on the instrument while it is still subject to disallowance. If the committee has not concluded its consideration of an instrument before the expiry of the 15th sitting day after the instrument has been tabled in the Senate, the committee may give notice of a motion to disallow the instrument as a precautionary measure to allow additional time for the committee to consider information received.

Noting this, and to facilitate the committee's consideration of the matters above, the committee would appreciate your response by **27 February 2020**.

Finally, please note that, in the interests of transparency, this correspondence and your response will be published on the committee's website.

If you have any questions or concerns, please contact the committee's secretariat on (02) 6277 3066, or by email to sdlc.sen@aph.gov.au.

Thank you for your assistance with this matter.

Yours sincerely,

[redacted]

**Senator the Hon Concetta Fierravanti-Wells**
**Chair**
**Senate Standing Committee for the Scrutiny of Delegated Legislation**

**The Hon Karen Andrews MP**

**Minister for Industry, Science and Technology**

COPY

POSTED

MC20-001430

Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation
Parliament House
CANBERRA ACT 2600

Dear Senator

Thank you for your letter of 13 February 2020 concerning the *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019*.

**Reasons for use of Delegated Legislation – an interim first step**

The *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019* have improved the ability for Australian made complementary medicines to make 'made in Australia' claims. The *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019* were necessary as the 2017 changes to the Country of Origin Labelling laws in the *Competition and Consumer Act 2010* resulted in unintended consequences impacting upon particular businesses ability to make Australian origin claims. The intent of section 255 of the Australian Consumer Law was to allow for examples of processes that meet the definition of substantial transformation.

My department and I have engaged with representatives of the $5 billion complementary medicines sector industry over many months. I have taken on board the advice received that a lack of clarity on Country of Origin Labelling requirements was having a deleterious effect on exports and employment in the sector. The sector reported that without clear and immediate action by government there was a high likelihood of business closures, a significant risk to domestic investment in complementary medicine manufacturing and the loss of jobs.

Following consultation with the Hon Michael Sukkar MP, Assistant Treasurer, and the Hon Scott Morrison MP, Prime Minister, and agreement through the Legislative & Governance Forum on Consumer Affairs, I considered it necessary and appropriate to use delegated legislation as an interim step towards achieving our policy objective of alleviating the imminent risks to the sector.

**Background**

In December 2018 my department initiated a multi-agency taskforce to review the effects of the 2017 Country of Origin Labelling changes on the sector. The taskforce reported in February 2019. The Taskforce noted increasing concerns the sector had regarding the effects of the Country of Origin Labelling changes on domestic and export sales and the potential loss of businesses and jobs. Noting the concerns, the Australian Government decided to engage the states and territories on possible changes to the Australian Consumer Law through changes to the *Competition and Consumer Act 2010* and the *Competitions and Consumer Regulations 2010*.

On 12 December 2019, the states and territories through the Legislative & Governance Forum on Consumer Affairs decided on a two-step action plan to alleviate the risks faced by the sector.

As a first step, the Legislative & Governance Forum on Consumer Affairs agreed to seek an interim regulatory change to provide certainty about the circumstances in which complementary medicines manufacturers can claim Australian origin if at least the last activity in the 'manufacture of dosage form step' of their manufacture occurs in a Therapeutic Goods Administration licensed Australian facility. This first step commenced on 18 December 2019 when the *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019* came into force.

**Proposed changes to Primary Legislation – the second and final step**

The second step, agreed by the Legislative & Governance Forum on Consumer Affairs, will require amendments to the *Competition and Consumer Act 2010* allowing regulations to prescribe processes that satisfy the definition of substantial transformation for complementary medicines. Under this second step, consumers will gain additional support as new regulations will be made requiring labels of complementary medicines to display the proportion of Australian ingredients if an Australian origin claim is made under the proposed new laws.

I intend to present to the Parliament later this year the necessary amendments to the Australian Consumer Law and subsequent regulations.

Consumer protection will be further strengthened when proposed changes to the *Competition and Consumer Act 2010* are made and new regulations are passed requiring greater disclosure of the proportion of domestic ingredients in complementary medicine products.

Yours sincerely

Karen Andrews

27/2 /2020

AUSTRALIAN SENATE

**Senate Standing Committee for the Scrutiny of Delegated Legislation**
Parliament House, Canberra ACT 2600
02 6277 3066 | sdlc.sen@aph.gov.au
www.aph.gov.au/senate_sdlc

3 April 2020

The Hon Karen Andrews MP
Minister for Industry, Science and Technology
Parliament House
CANBERRA ACT 2600

Via email: Karen.Andrews.MP@aph.gov.au

CC: industrydlo@industry.gov.au; CommitteeScrutiny@treasury.gov.au

Dear Minister,

**Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019 [F2019L01627]**

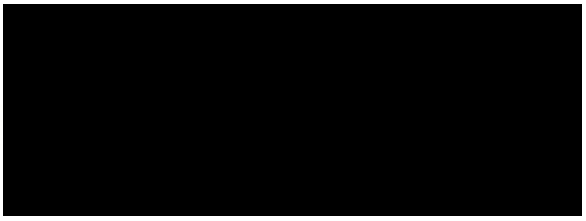
Thank you for your response of 27 February 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation, in relation to the above instrument.

The committee considered your response at its private meeting on 1 April 2020. On the basis of your advice, the committee has concluded its examination of the instrument.

In the interests of transparency, I note that this correspondence will be published on the committee's website and recorded in the *Delegated Legislation Monitor.*

Thank you for your assistance with this matter.

Yours sincerely,



**Senator the Hon Concetta Fierravanti-Wells**
**Chair**
**Senate Standing Committee for the Scrutiny of Delegated Legislation**