
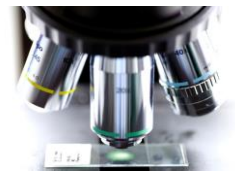


Member Alert

Competition and Consumer Amendment (Australian made Complementary Medicines) Regulations 2019

Complementary Medicines Australia (CMA) are pleased to announce that after our advocacy and submissions to the Country of Origin taskforce, the Government has enshrined in legislation new protections for the complementary medicine industry. Applicable immediately, the amendment to the regulations, originally proposed by CMA, ensures access to Australian origin claims and the Australian Made logo for all complementary medicines meeting the newly legislated example.

The *Competition and Consumer Amendment (Australian made Complementary Medicines) Regulations 2019* ('the Regulation') has now been registered on the Federal Register of Legislation, and includes an example of a process undertaken in Australia for complementary medicines that meet the substantial transformation test under the Australian Consumer Law (ACL). It is effective from **18 December 2019**.

The example in the Regulation (Subregulation 92AA(3)) provides greater detail on circumstances that can be relied upon when assessing substantial transformation for the purposes of making an Australian Made or similar country of origin claim in relation to complementary medicines.

Government Media Release announcing changes

A joint media release 'Claiming back Australian Made for complementary medicines' by the Hon Karen Andrews MP, Minister for Industry, Science and Technology, and Assistant Treasurer the Hon Michael Sukkar MP, has formally announced this measure. Minister Andrews:

"The Morrison Government is a strong supporter of local business and manufacturing, that's why we acted as quickly as possible to resolve the unintended consequences of country of origin labelling laws."

"We listened to the sector and the public to understand what would be best for all stakeholders and that's seen us bring in this interim measure.

"This will allow the local industry to continue to expand our $1 billion plus export market for complementary medicines, securing jobs into the future."

Minister Sukkar:

"Sensible refining of our country of origin labelling framework will allow the Australian public to continue to have confidence in supporting local businesses and allow those businesses to grow their exports overseas."

How it will work

The Regulations clarify complementary medicines that complete the last step in the manufacture of dosage form step in Australia, in compliance with TGA regulatory requirements, would meet the safe harbour defences to make Australian country of origin claims under Australian Consumer Law.

The Regulations only apply to complementary medicines that are regulated as medicines by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act* 1989, and which are either listed or registered on the Australian Register of Therapeutic Goods (ARTG).

Under the Regulations, for a complementary medicine to rely on the safe harbour provision in section 255 of the Act, the complementary medicine will need to have undergone the last process in the manufacture of dosage form step in Australia. The last step of the process is required to occur at premises in Australia that hold a valid manufacturing licence issued by the TGA for that step.

Certain manufacturing processes not included

The new Regulation also specifies steps in subregulation (4) that are **not** considered to be the last step in the manufacture of the dosage form of complementary medicines – these steps are not considered transformative manufacturing steps that would have the result of substantial transformation for the purposes of a country of origin claim under Australian Consumer Law. These steps are: the covering of the dosage form in containers; packaging; labelling; storage (whether in packaging or not); testing; or release for supply. A full description is included on page 3 of this alert.

Other considerations

A country of origin claim remains voluntary. The Regulations will not make it mandatory to claim Australian origin if a product satisfies the new example and they do not affect any existing or future claims under the substantial transformation test as it exists now.

This measure is an interim measure by the Government. Additional measures may be considered in 2020 in respect of country of origin labelling, including considerations around substance origin.

As members would be aware, CMA has continued its strong advocacy for the complementary health sectors continued access to make an 'Australian Made' claim. With our members' support we have worked collaboratively with stakeholders and government, aiming to provide Australian manufacturers of complementary medicines with a practical resolution and way forward. Business certainty has been provided in the form of these regulation changes.

Resources

Media Release - Claiming back Australian Made for complementary medicines
Technical Alert – Country of Origin 16 December 2019
Member Alert - Australian Made Country of Origin Claims 26 August 2019
Decision Regulatory Impact Statement
Country of origin food labels
Complementary Medicine Country of Origin Labelling survey

Legislative outline – Processes substantially transforming medicines in Australia

Paragraph 255(2)(b) and 255(3)(b) of Australian Consumer Law provide 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.

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

(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).

Section 92AA – (updated) Competition and Consumer Regulations 2019

(1) For the purposes of paragraph 255(3)(b) of the Australian Consumer Law, this regulation includes an example of a process undertaken in Australia in relation to medicines that has the result described in paragraph 255(2)(b) of that Law.

(2) This regulation applies to medicines that are complementary medicines (within the meaning of the *Therapeutic Goods Regulations 1990*) and are either:

(a) listed goods; or

(b) registered goods.

(3) The example of the process is the carrying out of the last step (**except one** covered by subregulation (4)) in the manufacture of the dosage form of medicines that:

(a) occurs at premises in Australia; and

(b) is authorised by a licence to occur in relation to those medicines at those premises.

(4) This subregulation covers the following steps:

(a) covering of the dosage form of medicines in containers;

(b) packaging of the dosage form of medicines;

(c) labelling of the dosage form of medicines;

(d) storage of the dosage form of medicines (whether in packaging or not);

(e) testing of the dosage form of medicines;

(f) release for supply of the dosage form of medicines.

(5) A term (except "process") used in this regulation and the Therapeutic Goods Act 1989 has the same meaning in this regulation as it has in that Act.

For further questions, please contact us at: technical@cmaustralia.org.au

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