Member Alert

Country of Origin Regulations 2020

CMA are pleased to inform members that updated country of origin regulations are now in effect through the passage of the *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020* on 10 December 2020. The passage of these Regulations represents years of work for the Complementary Medicines industry and provides stronger protections for industry by strengthening Country of Origin laws. The Regulations only apply to complementary medicines that are regulated as medicines under the *Therapeutic Goods Regulations 1990* and which are either listed or registered on the Australian Register of Therapeutic Goods. It remains voluntary for the complementary medicines sector to make Australian origin claims under the safe harbour provisions and the above regulations.

The *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020*, available here, amends the Competition and Consumer Regulations 2010 by repealing and substituting regulation 92AA (outlined in Attachment A) to prescribe a process that complementary medicines have undergone in Australia, authorised by a GMP licence, to be substantially transformed for the purposes of paragraph 255(2)(c) of the Australian Consumer Law (ACL).

What has changed?

The Regulations now prescribe, by law, a process of substantial transformation, rather than providing an example of a process that results in substantial transformation. The process prescribed in the Regulations provides circumstances that may be relied upon when assessing substantial transformation for the purposes of making an Australian Made, or Made in Australia or similar, country of origin claim in relation to complementary medicines.

The effect of the amendment will be to ensure that manufacturers of complementary medicines can make representations regarding the country of origin of their products without breaching other provisions of the *Competition and Consumer Regulations 2010*.

Under the Regulations, for a complementary medicine to rely on the safe harbour provisions in section 255 of the ACL, the complementary medicine will need to have undergone the last process in the manufacture of dosage form step of its manufacture in Australia, not including the processes outlined by Subregulation 92AA(4) such as packaging or labelling which do not constitute substantial transformation. In addition, the manufacture must be authorised by a licence to occur at those premises. The manufacture of dosage form step encompasses the key transformative processes regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* .

Key information for members

While the change significantly strengthens the protection afforded to the complementary medicines industry making voluntary made in Australian claims, from a legal and global perspective, it does not at this stage require industry members to undertake any technical change or different approach to that which has been taken under the existing safe harbour laws and the initial introduction of 92AA of the Regulations in December 2019. However, members should note that the progress of other changes to labelling where voluntary country of origin representations are made, including the coupling of any representations with a required information standard or other required labelling rules as previously proposed by the consultation for the Information Standard is still under Government consideration and may result in further changes in 2021.

Background

For more information on the background of the Country of Origin Labelling Regulations please refer to:

- Bills Digest, No. 20, 2020–21: Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Bill 2020
- CMA Member Alert (28 October 2020) Country of Origin Labelling - Progress Update
- CMA Member Alert (31 August 2020) Country of origin labelling for complementary medicines: have your say on the proposed information standard
- CMA Member Alert - (18 December 2019) Competition and Consumer Amendment (Australian made Complementary Medicines) Regulations 2019

Resources:

- *Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020*
- Manufacturing medicines
- Manufacturing principles for medicinal products
- *Therapeutic Goods Act 1989*
- *Competition and Consumer Regulations 2010*

Attachment A: Competition and Consumer Amendment (Australian Consumer Law—Country of Origin Representations) Regulations 2020

New (December 2020) version of the CC Regulations – prescribing a process

92AA Process substantially transforming medicines in Australia

(1) For the purposes of paragraph 255(2)(c) of the Australian Consumer Law, this regulation prescribes a process that medicines have undergone in Australia to be substantially transformed in Australia.

(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 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.

Note: Terms whose meaning is affected include "containers", "dosage form", "labelling", "licence", "listed goods", "manufacture", "medicines", "packaging", "premises", "registered goods", "release for supply", "storage" and "testing".

Previous (Dec 2019) version of the CC Regulations (giving an example)

92AA Processes substantially transforming medicines in Australia

(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.

Note: Terms whose meaning is affected include "containers", "dosage form", "labelling", "licence", "listed goods", "manufacture", "medicines", "packaging", "premises", "registered goods", "release for supply", "storage" and "testing".