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FAIR TRADING ACT 2010

The following instrument is published under the *Fair Trading Act 2010* Section 21

COMMONWEALTH OF AUSTRALIA

COMPETITION AND CONSUMER ACT 2010



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

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 12 December 2019

David Hurley
Governor-General

By His Excellency's Command

Karen Andrews
Minister for Industry, Science and Technology

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Schedule 1—Amendments

Competition and Consumer Regulations 2010

1 Name

This instrument is the *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	18 December 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 139G of the *Competition and Consumer Act 2010*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Competition and Consumer Regulations 2010

1 After regulation 92A

Insert:

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”.
