

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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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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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”.