



Medicines Amendment Regulations 2015

Rt Hon Dame Sian Elias, Administrator of the Government

Order in Council

At Wellington this 27th day of January 2015

Present:

Her Excellency the Administrator of the Government in Council

Pursuant to sections 96(4), 105(1)(i), and 105(2)(d) of the Medicines Act 1981, Her Excellency the Administrator of the Government makes the following regulations, acting—

- (a) on the advice and with the consent of the Executive Council; and
- (b) on the advice of the Minister of Health tendered after consultation with the organisations or bodies appearing to the Minister to be representative of persons likely to be substantially affected.

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Regulations

- 1 **Title**
These regulations are the Medicines Amendment Regulations 2015.
- 2 **Commencement**
These regulations come into force on the day after the date of their notification in the *Gazette*.
- 3 **Principal regulations**
These regulations amend the Medicines Regulations 1984 (the **principal regulations**).
- 4 **New regulation 58B inserted (Fluoridating agents and fluoridated water not medicines or related products)**
After regulation 58A, insert:
 - “58B **Fluoridating agents and fluoridated water not medicines or related products**
 - “(1) This regulation applies in relation to drinking water in a drinking-water supply.
 - “(2) Fluoridating agents for use in fluoridating drinking water are not medicines or related products for the purposes of the Act.
 - “(3) The addition of 1 or more fluoridating agents to drinking water does not make the drinking water a medicine or related product for the purposes of the Act.
 - “(4) In this regulation,—
 - “**drinking water** and **drinking-water supply** have the same meanings as in section 69G of the Health Act 1956
 - “**fluoridating agent** means—
 - “(a) hydrofluorosilicic acid:
 - “(b) sodium fluoride:
 - “(c) sodium silicofluoride:

“(d) any other substance that releases fluoride when added to water.”

Rachel Hayward,
for Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on the day after the date of their notification in the *Gazette*, amend the Medicines Regulations 1984 by inserting a *new regulation 58B*. *Regulation 58B* declares that neither fluoridating agents for use in fluoridating drinking water nor fluoridated drinking water are medicines or related products for the purposes of the Medicines Act 1981.

These regulations are in response to *New Health New Zealand Inc v Attorney-General* [2014] NZHC 2487, in which the High Court held that hydrofluorosilicic acid and sodium silicofluoride as currently used to fluoridate drinking water are not medicines for the purposes of the Medicines Act 1981. In its judgment, the High Court suggested that the Ministry of Health consider exempting fluoridating agents from the definition of medicine in the Medicines Act 1981.

The *Drinking-water Standards for New Zealand 2005 (Revised 2008)* provide requirements for drinking water safety. Those standards state that the maximum acceptable value for fluoride in drinking water is 1.5 milligrams per litre of water. The standards can be found at www.health.govt.nz/publication/drinking-water-standards-new-zealand-2005-revised-2008

Medicines Amendment Regulations 2015

2015/7

Issued under the authority of the Legislation Act 2012.

Date of notification in *Gazette*: 29 January 2015.

These regulations are administered by the Ministry of Health.
