

MCC 63: Harmonisation of the New Zealand and Australian schedules

8 Harmonisation of the New Zealand and Australian schedules

8.1

out of
scope

[Redacted]

[Redacted]

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[Redacted]

8.1.1

out of
scope

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8.1.2

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out of scope
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8.1.3

out of scope
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8.1.4

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8.1.5

out of scope
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8.1.6

out of scope
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8.1.7

out of scope [Redacted]

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8.1.8

out of scope [Redacted]

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8.2 Decisions by the Secretary to the Department of Health and Aging in Australia (or the Secretary's Delegate)

8.2.1 Decisions by the Delegate – 6 June 2019

TGA extract



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8.2.1.a Alkyl nitrites

A new group entry for alkyl nitrites was created in Schedule 4 (prescription) except when specified elsewhere in the schedules.

The Schedule 4 (prescription) entry for amyl nitrite was down-scheduled to Schedule 3 (Restricted) when in preparations for human therapeutic use and packaged in containers with child-resistant closures.

The Schedule 4 (prescription) entries for isoamyl nitrite, butyl nitrite, isobutyl nitrite and octyl nitrite remained unchanged.

New Schedule 10 (prohibited) entries were created for isopropyl nitrite and n-propyl nitrite.

The implementation date for the delegate's decision is 1 February 2020, in view of the fact that there are new Schedule 10 entries and the incorporation of a group alkyl nitrite entry in Schedule 4 which captures previously unscheduled substances.

Schedule 1 of the Medicines Regulations currently does not contain a group entry for alkyl nitrites.

Amyl nitrite is currently classified as a prescription medicine except when sold to a person who holds a controlled substances licence (issued under section 95B of the Hazardous Substances and New Organisms Act 1996) authorising the person to possess cyanide; except when sold to an exempt laboratory covered by a Hazardous Substances and New Organisms Act 1996 approved code of practice.

Isoamyl nitrite, butyl nitrite, isobutyl nitrite and octyl nitrite are currently classified as prescription medicines.

Potential impact on products in the New Zealand market:

There are no products currently approved or pending containing these specified substances.