# Poisons Standard Amendment (Ivermectin) Instrument 2021

I, Tony Gill, as delegate of the Secretary of the Department of Health, make the following instrument.

Dated 10 September 2021

Tony Gill
Principal Medical Adviser
Health Products Regulation Group
Department of Health

# Contents

## 1 Name

This instrument is the *Poisons Standard Amendment (Ivermectin) Instrument 2021*.

## 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. | |

Note: This table relates only to the provisions of this instrument as originally made.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 paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989*.

## 4 Schedules

Each instrument that is specified in Schedule 1 is amended or repealed as set out in the applicable items in that Schedule, and any other item has effect according to its terms.

# Schedule 1—Amendments

## *Poisons Standard June 2021*

### 1 Schedule 4 of Part 4 of Schedule 1 (entry for ivermectin)

Repeal the entry, substitute:

# IVERMECTIN:

a) for human use; or

b) for the treatment of mange in dogs.

### 2 At the end of Appendix D of Part 5 of Schedule 1

Add:

| | | |
|---|---|---|
| **10.** | **Poisons available only when prescribed or authorised for:** | |
| | (1) | an indication that is accepted by the Secretary of the Australian Government Department of Health in relation to the inclusion of ivermectin in tablet dosage form in the Australian Register of Therapeutic Goods (an ***approved indication***); or<br><br>Note: Approved indications are shown in the public summary of the Australian Register of Therapeutic Goods on the Therapeutic Goods Administration website at www.tga.gov.au. |
| | (2) | an indication that is not an approved indication, when the preparation is prescribed or authorised by a medical practitioner registered under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in any of the following specialties or fields of specialty practices:<br><br>(a) dermatology;<br><br>(b) gastroenterology and hepatology;<br><br>(c) infectious diseases;<br><br>(d) paediatric gastroenterology and hepatology;<br><br>(e) paediatric infectious diseases; or |
| | (3) | use in a clinical trial that is approved by, or notified to, the Secretary of the Australian Government Department of Health under the *Therapeutic Goods Act 1989*. |

| | |
|---|---|
| | IVERMECTIN in preparations for oral administration for human use. |

## 3 Schedule 1 (index)

Omit the entry for ivermectin, substitute:

**IVERMECTIN**

Schedule 7
Schedule 5
Schedule 4
Appendix D, Item 10