



# **Therapeutic Goods (Prescription Medicines— Sharing of AusPARs) (Information) Specification 2023**

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I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 20 July 2023

Nicholas Henderson  
Acting First Assistant Secretary  
Medicines Regulation Division  
Health Products Regulation Group  
Department of Health and Aged Care

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## 1 Name

This instrument is the *Therapeutic Goods (Prescription Medicines—Sharing of AusPARs) (Information) Specification 2023*.

## 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) health practitioner;
- (b) medicine;
- (c) product information;
- (d) Register;
- (e) registered goods;
- (f) Secretary.

In this instrument:

*Act* means the *Therapeutic Goods Act 1989*.

**approved product information** means the product information approved by the Secretary under section 25AA of the Act.

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**AusPAR** means the Australian Public Assessment Report for a prescription medicine, including the attached approved product information, that is published by the TGA.

Note: AusPARs may also include the Clinical Evaluation Report, or an extract of the Clinical Evaluation Report, as an attachment. AusPARs are published on the TGA website at [www.tga.gov.au](http://www.tga.gov.au).

**Australian Prescriber** means the journal published by Therapeutic Guidelines.

**registered prescription medicine** means a medicine that:

- (a) is included in the part of the Register for goods known as registered goods; and
- (b) would require a prescription from a health practitioner who is authorised to prescribe medicine under a law of a State or Territory.

**Therapeutic Goods Administration**, or **TGA**, means the part of the Department known as the Therapeutic Goods Administration.

**therapeutic goods information** has the meaning given by subsection 61(1) of the Act.

**Therapeutic Guidelines** means Therapeutic Guidelines Ltd (ABN 45 074 766 224).

## 5 Release of therapeutic goods information

For subsection 61(5AA) of the Act, in relation to each item in the table in Schedule 1, the kinds of therapeutic goods information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

## 6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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## Schedule 1—Therapeutic goods information

Note: See section 5.

Therapeutic goods information that may be released			
Column 1	Column 2	Column 3	Column 4
Item	Kinds of information	Persons or bodies	Purposes
1	information about a registered prescription medicine that is contained in the AusPAR for the medicine	Therapeutic Guidelines	to facilitate the publication of the information specified in column 2 in Australian Prescriber soon after the publication of the AusPAR on the TGA website

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## Schedule 2—Repeals

Note: See section 6.

### *Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015*

#### **1 The whole of the instrument**

Repeal the instrument.