Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022

I, Nick Henderson, as delegate of the Secretary of the Department of Health, make the following determination.

Dated 9 June 2022

Nick Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name 1
2 Commencement 1
3 Authority 1
4 Definitions 1
5 Application 3
6 Kind of information 3

Schedule 1—Prescription Medicines 4

1 Name

This instrument is the *Therapeutic Goods (Prescription Medicines—Kind of Information that Must Accompany Application for Registration) Determination 2022*.

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Note: This table relates only to the provisions of this instrument as originally made.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 23B(9) 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) medicine;
(b) Register;
(c) registered goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

biosimilar means a medicine that is a biosimilar in relation to a registered medicine.

extension of indications medicine means a medicine that:
(a) contains the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as another medicine included in the Register; and
(b) has one or more indications in addition to that other medicine.

generic product has the same meaning as in the Regulations.

major variation has the same meaning as in clause 1 of Schedule 9 to the Regulations.

major variation medicine means a medicine that is taken to be separate and distinct from a registered medicine because of a major variation but does not include:

(a) a new chemical entity medicine; or
(b) a new biological entity medicine; or
(c) a new biosimilar medicine; or
(d) a new combination medicine; or
(e) an extension of indications medicine; or
(f) a new generic medicine; or
(g) a new trade name medicine.

new biological entity medicine means a medicine that:

(a) has not previously been included in the Register, and contains a biological substance; or
(b) contains a biological substance mentioned in paragraph (c) of the definition of new chemical entity.

new biosimilar medicine means a medicine that has not previously been included in the Register and is a biosimilar in relation to a registered medicine.

new chemical entity has the same meaning as in clause 1 of Part 1 of Schedule 9 to the Regulations.

new chemical entity medicine means a medicine that contains a new chemical entity as mentioned in paragraphs (a), (b) and (d) of the definition of new chemical entity.

new combination medicine means a medicine that contains a new chemical entity as mentioned in paragraph (e) of the definition of new chemical entity.

new generic medicine means a medicine that has not previously been included in the Register and is a generic product.

new trade name medicine means a medicine that:

(a) has the same active ingredient or active ingredients (or fixed combination of active ingredients) as a registered medicine; and
(b) has the same indications as that other medicine; and
(c) has the same dosage form as that other medicine; and
(d) has been given a different name to that other medicine by the manufacturer, under which the medicine will be supplied.

registered medicine means a medicine that is included in the part of the Register for goods known as registered goods.

Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic Goods Administration has the same meaning as in the Regulations.

5 Application

This instrument applies to medicines of the class specified in paragraph 4(1)(a) of the *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018*, as in force or existing at the commencement of this instrument.

Note: The *Therapeutic Goods (Classes of Therapeutic Goods) Instrument 2018* is a notifiable instrument and is published on the Federal Register of Legislation at www.legislation.gov.au.

6 Kind of information

For the purposes of subparagraph 23B(2)(d)(i) of the Act, an application for the registration of a medicine mentioned in Schedule 1 must be accompanied by information of the following kind:

(a) the information specified for the medicine in the document titled *CTD Module 1: Administrative information and prescribing information for Australia* (Version 4.3, December 2020) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument; and

(b) the information specified for the medicine in the document titled *Mandatory requirements for an effective application* (Version 4.1, June 2022) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The documents mentioned in paragraphs (a) and (b) are published at www.tga.gov.au.

Schedule 1—Prescription Medicines

Note: See section 6.

Prescription medicines	
Column 1	**Column 2**
Item	**Prescription medicines**
1	new chemical entity medicine
2	new biological entity medicine
3	new biosimilar medicine
4	new combination medicine
5	extension of indications medicine
6	major variation medicine
7	new generic medicine