



Therapeutic Goods (Medicines and Biologicals—Ingredients and Components Information) Specification 2020

I, Jane Cook, as delegate of the Minister for Health, make the following specification.

Dated 7 February 2020

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
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Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Medicines and Biologicals—Ingredients and Components Information) Specification 2020*.

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Note: This table relates only to the provisions of this instrument as originally made.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

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) biological;
- (b) included in the Register;
- (c) medicine;
- (d) Register; and
- (e) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active component, in relation to a biological, means a therapeutically active component in the final formulation of the biological that is responsible for its physiological action.

active ingredient has the same meaning as in the Regulations.

other component, in relation to a relevant biological, means a component of the biological other than:

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- (a) an active component;
 - (b) a proprietary colour;
 - (c) a proprietary flavour; or
 - (d) a proprietary fragrance.

other ingredient, in relation to a relevant medicine, means an ingredient in the medicine other than:

- (a) an active ingredient;
- (b) a proprietary colour;
- (c) a proprietary flavour; or
- (d) a proprietary fragrance.

proprietary colour means a formulation that is identified as a proprietary ingredient in TGA Business Services for the purpose of providing colour to a therapeutic good, or part of a therapeutic good.

proprietary flavour means a formulation that is identified as a proprietary ingredient in TGA Business Services for the purpose of providing flavour to a therapeutic good, or part of a therapeutic good.

proprietary fragrance means a formulation that is identified as a proprietary ingredient in TGA Business Services for the purpose of providing fragrance to a therapeutic good, or part of a therapeutic good.

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant biological means a biological included in the Register.

relevant medicine means a medicine included in:

- (a) the part of the Register for goods known as registered goods; or
- (b) the part of the Register for goods known as listed goods.

TGA Business Services means TGA Business Services on the Therapeutic Goods Administration website that may be accessed on the internet at <https://business.tga.gov.au>.

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

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

5 Therapeutic goods information

- (1) In relation to a relevant medicine, the kinds of therapeutic goods information mentioned in column 2 of the table in Part 1 of Schedule 1, as described in column 3 of the corresponding item, are specified for the purpose of subsection 61(5C) of the Act.
- (2) In relation to a relevant biological, the kinds of therapeutic goods information mentioned in column 2 of the table in Part 2 of Schedule 1, as described in

column 3 of the corresponding item, are specified for the purpose of subsection 61(5C) of the Act.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C).

Schedule 1—Specified kinds of therapeutic goods information

Note: See section 5.

Part 1—Medicines

Kinds of therapeutic goods information in relation to a relevant medicine		
Column 1	Column 2	Column 3
Item	Information	Description
1	active ingredients	the name and amount of each active ingredient
2	other ingredients	the name of each other ingredient
3	the presence of a proprietary colour	where the relevant medicine contains a proprietary colour—the word “colour”
4	the presence of a proprietary flavour	where the relevant medicine contains a proprietary flavour—the word “flavour”
5	the presence of a proprietary fragrance	where the relevant medicine contains a proprietary fragrance—the word “fragrance”

Part 2—Biologicals

Kinds of therapeutic goods information in relation to a relevant biological

Column 1	Column 2	Column 3
Item	Information	Description
1	active components	the name and amount of each active component
2	other components	the name of each other component
3	the presence of a proprietary colour	where the relevant biological contains a proprietary colour—the word “colour”
4	the presence of a proprietary flavour	where the relevant biological contains a proprietary flavour—the word “flavour”
5	the presence of a proprietary fragrance	where the relevant biological contains a proprietary fragrance—the word “fragrance”