

Therapeutic Goods (Prescription Medicines—Transparency Measures) Specification 2020

I, John Skerritt, as delegate of the Minister for Health, make the following specification.

Dated 17 December 2020

Adjunct Professor John Skerritt

Deputy Secretary

Health Products Regulation Group

Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Prescription Medicines—Transparency Measures) 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 | 1 January 2021. | 1 January 2021 |

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 3(1) of the Act, including the following:

(a) indications;

(b) medicine;

(c) passed preliminary assessment;

(d) registered goods;

(e) Secretary; and

(f) therapeutic goods.

In this instrument:

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

***new indications medicine*** has the same meaning as in the Regulations.

***new prescription medicine*** has the same meaning as in the Regulations.

***registered medicine***means a medicine that is a registered good.

***Regulations***means the *Therapeutic Goods Regulations 1990*.

***relevant medicine***means a new prescription medicine or a new indications medicine, which is the subject of an application for registration under section 23 of the Act that has passed preliminary assessment, but does not include a medicine that is a biosimilar in relation to a registered medicine.

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

5 Release of therapeutic goods information

The kinds of therapeutic goods information set out in column 2 of the table in 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.

| Kinds of therapeutic goods information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Item | Information | Description |
| 1 | name | the name of the relevant medicine |
| 2 | applicant | the name of the person who made the application for the registration of the relevant medicine |
| 3 | active ingredients | the active ingredients contained in the relevant medicine |
| 4 | indications | a summary of the proposed indications of the relevant medicine |
| 5 | application type | the type of application that was made in relation to the relevant medicine, as follows:  (a) new chemical entity (type A);  (b) new combination (type B); or  (c) extension of indications (type C) |