Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019

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

Dated 22 November 2019

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019*.

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Note: This table relates only to the provisions of this instrument as originally made.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) label;
(b) listing number;
(c) manufacture;
(d) medicine;
(e) Register; and
(f) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

compliance review, in relation to a listed medicine, means a post-market review carried out by the Therapeutic Goods Administration for the purpose of determining whether certain requirements of the Act, applicable to the medicine, have been, or are being, complied with.

Note: For example, a compliance review may include verifying the certification made by a relevant sponsor under section 26A or 26AB of the Act in relation to the relevant medicine.

listed medicine means a medicine that is included in the Part of the Register for goods known as listed goods.

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant medicine means the listed medicine that is the subject of a compliance review.

relevant sponsor means the person in whose name the relevant medicine is listed in the Register.

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

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).

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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 of medicine	the name of the relevant medicine
2	listing number	the listing number of the relevant medicine, commonly known as the ARTG ID
3	review outcome	a summary of the outcome of the compliance review in relation to the relevant medicine, including: (a) whether the relevant medicine remains listed on the Register and may continue to be supplied; and (b) the circumstances in which the relevant medicine may continue to be supplied, including in relation to changes that have been made by the relevant sponsor to address issues identified during the compliance review in relation to the medicine
4	consumer advice in relation to continued use	a recommendation as to whether the relevant medicine is considered safe for continued use by consumers, including: (a) the reasons for the recommendation; (b) the circumstances in which the use of the relevant medicine is considered safe
5	consumer advice in relation to required action	a recommendation as to the action a consumer of the relevant medicine should take, for example: (a) no action; (b) reconsidering whether the relevant medicine is right for the consumer; (c) seeking medical advice; (d) disposing of the relevant medicine; (e) contacting the Therapeutic Goods Administration
6	sponsor	the name of the relevant sponsor
7	review type	the type of compliance review carried out in relation to the relevant medicine, as follows: (a) random; or (b) targeted
8	information reviewed	the type of information reviewed during the compliance review of the relevant medicine, for example: (a) the label of the relevant medicine; (b) evidence held by the relevant sponsor in relation to the indications of, and claims made for, the relevant medicine;

Kinds of therapeutic goods information		
Column 1	**Column 2**	**Column 3**
Item	**Information**	**Description**
		(c) documents relating to the manufacture of the relevant medicine; (d) promotional and advertising material in relation to the relevant medicine; (e) information included in the entry in the Register that relates to the relevant medicine
9	issues relating to safety	a summary of any issues identified during the compliance review that relate to the safety of the relevant medicine, including contraventions of the Act
10	issues relating to efficacy	a summary of any issues identified during the compliance review that relate to the efficacy of the relevant medicine, including contraventions of the Act
11	actions taken during the review	a summary of any relevant actions taken by the relevant sponsor or the Therapeutic Goods Administration during the compliance review of the relevant medicine, for example: (a) an update to the listing of the relevant medicine on the Register by the relevant sponsor; (b) an update to the label of the relevant medicine by the relevant sponsor; (c) a request by the relevant sponsor for the cancellation of the listing of the relevant medicine from the Register following notification of issues; (d) a request by the relevant sponsor for the cancellation of the listing of the relevant medicine from the Register following a request for information under section 31 of the Act; (e) the cancellation of the listing of the relevant medicine from the Register by the Secretary, where the cancellation was not at the request of the relevant sponsor
12	grounds for cancellation	where applicable, the grounds for the cancellation of the listing of the relevant medicine from the Register
13	date of cancellation	where applicable, the date that the listing of the relevant medicine was cancelled from the Register by the Secretary, where the cancellation was not at the request of the relevant sponsor
14	date of review outcome	the date that the outcome of the compliance review was notified to the relevant sponsor by the Therapeutic Goods Administration, being the date that the compliance review was concluded
15	date of publication	the date that the information in relation to the compliance review of the relevant medicine was published on the Therapeutic Goods Administration's

Kinds of therapeutic goods information		
Column 1	**Column 2**	**Column 3**
Item	**Information**	**Description**
		website
16	additional information	details of any relevant information, actions taken, or decisions made, in relation to the relevant medicine after the conclusion of the compliance review

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods Information (Outcomes of Compliance Reviews of Listed Complementary Medicines) Specification 2012

1 The whole of the instrument

Repeal the instrument.