Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health, make this specification under subsection 61(5D) of the *Therapeutic Goods Act 1989*.

Dated 15 December 2017

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

1 Name of specification

This specification is the *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification2017*.

2 Commencement

(1) Each provision of this specification 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 specification	The day after this specification is registered.	19 December 2017

Note: This table relates only to the provisions of this specification as originally made. It will not be amended to deal with any later amendments of this specification.

(2) Any information in column 3 of the table is not part of this specification. Information may be inserted in this column, or information in it may be edited, in any published version of this specification.

3 Authority

This specification is made under subsection 61(5D) of the *Therapeutic Goods Act 1989.*

4 Definitions

In this specification:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the meaning as in section 2 of the *Therapeutic Goods Regulations 1990.*

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

(a) included in the Register;

(b) indications;

(c) Register;

(d) registered goods;

(e) registration number;

(f) sponsor;

(g) therapeutic goods;

(h) therapeutic goods information; and

(i) therapeutic use.

5 Therapeutic goods information

The kinds of therapeutic goods information mentioned in Schedule 1 are specified under subsection 61(5D) of the Act for the purposes 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

(section 5)

For each item in column 1 of the following table, the kind of therapeutic goods information specified in column 2 has the description given in column 3.

Kinds of therapeutic goods information		
Column 1	**Column 2**	**Column 3**
Item	**Information**	**Description**
1	name of active ingredient of registered goods	the name of one or more active ingredients of the registered goods described in column 3 of item 3
2	particulars of specified therapeutic goods approved under section 19A	the name of specified therapeutic goods approved under section 19A of the Act for which the registered goods described in column 3 of item 3 may be substituted, comprising the trade name, active ingredient name, strength and dosage form
3	particulars of registered goods	the name of one or more therapeutic goods included in the Register that are unavailable or in short supply in Australia comprising the trade name, active ingredient name, strength, dosage form and registration number
4	name of person to whom approval is granted under section 19A	the name, contact telephone number and Australian Business Number of the person to whom an approval for importation into Australia, or the supply in Australia, of specified therapeutic goods is granted under section 19A of the Act
5	image of specified therapeutic goods packaging	one or more photographic or pictorial images of the packaging of the specified therapeutic goods approved under section 19A of the Act, as supplied in one or more foreign countries, displaying in relation to the goods: (a) the name and address of the person in whose name the goods are registered or approved for general marketing; (b) the name of one or more active ingredients; (c) the strength, dosage form and pack size; (d) the name of the manufacturer;

Kinds of therapeutic goods information		
Column 1 **Item**	**Column 2** **Information**	**Column 3** **Description**
		(e) the name of the distributor, if different from the person in whose name the goods are registered or approved for general marketing; (f) the reference number of the goods registered or approved for general marketing in one or more foreign countries; (g) the storage conditions; (h) the batch number and expiry date; and (i) any other packaging information including additional administration instructions
6	indications of specified therapeutic goods	the therapeutic uses of the specified therapeutic goods specified in the relevant notice of approval as a condition of that approval under section 19A of the Act
7	expiry date of approval	the date on which the approval under paragraph 19A(8)(a) of the Act expires, as specified in the relevant notice of approval
8	information relating to the lapsing of any approval under section 19A for the specified therapeutic goods	the date on which any previous approval under section 19A was granted in relation to the specified therapeutic goods, the period for which it was granted as specified in the relevant notice of approval, the date on which the approval lapsed, and the reason for such lapsing in accordance with paragraph 19A(8)(b) and subsection 19A(9) of the Act
9	medicine shortages information	a hyperlink to information relating to the active ingredient described in column 3 of item 1 that is publicly available, by reason other than this specification, on the Medicine Shortages Information Initiative database on the Therapeutic Goods Administration website; or, in the event that there is no such information, confirmation that no information is publicly available on the Medicines Shortages Information Initiative database in relation to that ingredient
10	supply information	information relating to the availability of the specified therapeutic goods during the period of approval under section 19A of the Act

11	pharmaceutical benefits scheme information	a hyperlink to information relating to the specified therapeutic goods, that is publicly available, by reason other than this specification, on the Pharmaceutical Benefits Scheme website; or, in the event that there is no such information, confirmation that no information is publicly available on the Pharmaceutical Benefits Scheme website in relation to those goods

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation kept under the *Legislation Act 2003.* See http://www.legislation.gov.au.