



Therapeutic Goods Information 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 31st May 2017

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information Specification 2017*.

2 Commencement

This Specification commences on the day after it is registered.

3 Repeal

This Specification repeals the *Therapeutic Goods Information Specification 2015*.

4 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

Register means the Australian Register of Therapeutic Goods.

Regulations means the Therapeutic Goods Regulations 1990.

TGA means the Therapeutic Goods Administration which is part of the Department of Health.

5 Therapeutic goods information

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

Schedule 1 Specified kinds of therapeutic goods information (section 5)

The following kinds of therapeutic goods information:

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

- 1 Product information approved by the Secretary under subsection 25AA(1) or 25AA(4) of the Act in relation to therapeutic goods.
- 2 Information required by regulation 9A or 9B of the Regulations to be supplied with certain therapeutic goods.
- 3 Information in documents prepared for the purpose of evaluating therapeutic goods under subsection 25(1) or subsection 9D(3) of the Act.
- 4 Information in relation to post-market pharmacovigilance requirements imposed by the Secretary under section 28 of the Act as a condition of registration on therapeutic goods or by a regulation made for the purposes of paragraph 28(5)(e) of the Act.
- 5 Information in documents relating to assessments made of the pharmacovigilance system, quality and non-clinical and clinical data in relation to therapeutic goods for the purpose of evaluating those goods under subsection 25(1) or subsection 9D(3) of the Act.
- 6 Information in documents included in a request of the Secretary to:
 - the Advisory Committee on Medicines (ACM) or its subcommittees or
 - the Advisory Committee on Vaccines (ACV),seeking advice in relation to the evaluation of therapeutic goods under subsection 25(1) of the Act or subsection 9D(3) of the Act, including in relation to post-market pharmacovigilance requirements and the continued suitability for registration of therapeutic goods.
- 7 Information in the minutes or outcomes of ACM or its subcommittees, or ACV, about the evaluation of therapeutic goods under subsection 25(1) or subsection 9D(3) of the Act, including in relation to post-market pharmacovigilance requirements.
- 8 Information in the minutes or outcomes of any other expert committee established by the Regulations about the suitability for inclusion in the Australian Register of Therapeutic Goods of therapeutic goods the subject of an application for approval.
- 9 Information in any written decision made under subsection 25(3) of the Act in relation to the registration of therapeutic goods, including the reasons for the decision.
- 10 Information in any written decision under section 60 of the Act on a review of a decision under subsection 25(3), subsection 9D(3), or subsection 25AA(1) or 25AA(4), of the Act, in relation to therapeutic 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>