



Therapeutic Goods (Biologicals—Information that Must Accompany Application for Inclusion in Register) Determination July 2018

I, Jane Cook, a delegate of the Secretary of the Department of Health for the purposes of section 32DDA of the *Therapeutic Goods Act 1989*, make the following Determination under subsections 32DDA(9) and (10) of that Act.

Dated 27 July 2018

(Signed by)

JANE COOK

Delegate of the Secretary of the Department of Health

1 Name

This instrument is the *Therapeutic Goods (Biologicals—Information that Must Accompany Application for Inclusion in Register) Determination July 2018*.

2 Commencement

This instrument commences on the day after it is registered.

3 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

4 Definitions

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

Class 2 biological has the meaning given by regulation 2 of the *Therapeutic Goods Regulations 1990*.

Class 3 biological has the meaning given by regulation 2 of the *Therapeutic Goods Regulations 1990*.

Class 4 biological has the meaning given by regulation 2 of the *Therapeutic Goods Regulations 1990*.

TGA means the part of the Department of Health known as the Therapeutic Goods Administration.

5 Applications to which this instrument applies

This instrument applies to an application under section 32DD of the Act to include a Class 2 biological, Class 3 biological or Class 4 biological in the Australian Register of Therapeutic Goods.

6 Kind of information

For the purposes of subsection 32DDA(9) of the Act, an application relating to a Class 2,3 or 4 biological must be accompanied by the information required by the Technical Requirements section of the document titled Dossier requirements for Class 2, 3 and 4 biologicals, Australian Regulatory Guidelines for Biologicals (ARGB) version 1.0, published by the TGA in July 2018.

Note: The document mentioned in section 6 is available on the TGA website (www.tga.gov.au).

7 Form of information

For the purposes of subsection 32DDA (10) of the Act, the information must be:

- (a) contained in an application dossier; and
- (b) in a form consistent with the document titled *General dossier requirements*, version 1.4, published by the TGA in July 2018.

Note: The document mentioned in paragraph 7(b) is available on the TGA website (www.tga.gov.au).

Schedule 1—Repeals

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1 The whole of the instrument

Repeal the instrument.