



## **Therapeutic Goods (Things that are Biologicals) Specification 2019**

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I, Jane Cook, as delegate of the Secretary of the Department of Health, make the following specification.

Dated 13 December 2019

Dr Jane Cook  
First Assistant Secretary  
Medicines Regulation Division  
Health Products Regulation Group  
Department of Health

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## 1 Name

This instrument is the *Therapeutic Goods (Things that are Biologicals) 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	1 January 2020.	1 January 2020

Note: This table relates only to the provisions of this instrument as originally made.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 32A(2) 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) biological.

In this instrument:

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

*faecal microbiota transplant product* has the same meaning as in the *Therapeutic Goods Regulations 1990*.

## 5 Things that are biologicals

The things mentioned in Schedule 1 are specified to be biologicals for the purposes of subparagraph 32A(1)(a)(ii) of the Act.

Note: The meaning of *biological* in section 32A of the Act includes a thing that is specified under subsection 32A(1)(a)(ii).

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## **6 Repeals**

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

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## Schedule 1—Things that are biologicals

Note: See section 5.

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### Things that are biologicals

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Column 1	Column 2
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Item	Specified things
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1	a thing that comprises or contains live animal cells, tissues or organs
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2	a thing that is a faecal microbiota transplant product
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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods (Things that are Biologicals) Specification 2017 (No.1)***

#### **1 The whole of the instrument**

Repeal the instrument