

Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018

I, Larry Kelly, Acting Deputy Secretary, Health Products Regulation Group, a delegate of the Minister for Health for the purposes of section 32EC of the *Therapeutic Goods Act 1989*, make the following Determination under subsection 32EC(2) of that Act.

Dated 29 March 2018

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

1 Name

This instrument is the *Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018*.

2 Commencement

This instrument commences on the day after it is registered.

3 Definitions

In this instrument:

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

4 Conditions of inclusion in Register—reporting and record-keeping

For the purposes of paragraphs 32EC(2)(c) and (ca) of the Act, a person in relation to whom a biological is included in the Register must:

(a) in relation to each distribution of the biologicals—keep a record of the distribution at least until the end of the period of 10 years after the distribution; and

(b) comply with the record-keeping requirements and the reporting requirements set out in the document titled *Biovigilance Responsibilities of Sponsors of Biologicals – Australian requirements and recommendations*, version 1.0, published by the Therapeutic Goods Administration in December 2017.

Note: A copy of the document mentioned in paragraph 4(b) is available on the Therapeutic Goods Administration website (www.tga.gov.au).

5 Conditions of inclusion in Register—variations

For the purposes of paragraph 32EC(2)(e), a person in relation to whom a biological is included in the Register must not implement a variation to, or in relation to, the biological before the Secretary approves the variation by varying the entry in the Register that relates to the biological under section 9D of the Act.