Therapeutic Goods (Adverse Events Following Immunisation) (Information) Specification 2021

I, Jane Cook, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 12 March 2021

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 (Adverse Events Following Immunisation) (Information) Specification 2021*.

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	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 61(5AB) 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) health practitioner;
(b) Secretary;
(c) State; and
(d) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

AEFI means an adverse event that occurs in relation to a person in Australia following immunisation with a vaccine.

JIC means a Jurisdictional Immunisation Coordinator for a State.

Note: ***State*** is defined in section 3 of the Act as including the Australian Capital Territory and the Northern Territory.

NCIRS means the National Centre for Immunisation Research and Surveillance (ABN 53 188 579 090).

Regulations means the *Therapeutic Goods Regulations 1990*.

SAEFVIC means the Surveillance of Adverse Events Following Vaccination In the Community, funded by the Department of Health, Victoria.

Note: SAEFVIC is comprised of two units at the following sites:
(a) Murdoch Children's Research Institute (Clinical); and
(b) Monash Health & University (Epidemiology and Signal Investigation).

TGA ADR report means an adverse drug reaction report made to the Therapeutic Goods Administration in relation to an adverse event associated with a vaccine.

TGA means Therapeutic Goods Administration.

Therapeutic Goods Administration has the same meaning as in the Regulations.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

5 Release of therapeutic goods information

For subsection 61(5AA) of the Act, in relation to each item, the kinds of therapeutic goods information specified in column 2 of the table in Schedule 1, may be released to the persons or bodies specified in column 3, for the purposes specified in column 4 of the table.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person or body that is specified under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

Schedule 1—Therapeutic goods information

Note: See section 5.

Therapeutic goods information that may be released			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of information**	**Persons or bodies**	**Purposes**
1	information relating to an AEFI, including the following: (a) the State in which the AEFI occurred; (b) the number allocated to the TGA ADR report for the AEFI by the TGA; (c) the name of the relevant vaccine; (d) the duration of the AEFI; (e) the age and gender of the relevant person; (f) a description of the AEFI; (g) a summary report of the AEFI; (h) other information, including clinical and non-clinical information, about the AEFI that is provided to the TGA by the person reporting the AEFI, a coroner or a health practitioner, and that relates to the TGA's investigation of the AEFI	the following persons or bodies: (a) JICs; (b) NCIRS; (c) SAEFVIC	to ensure meaningful and effective participation in meetings on vaccine safety between the TGA, JICs, NCIRS and SAEFVIC to support the safety, quality and safe use of vaccines in Australia