



Therapeutic Goods (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022

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

Dated 24 February 2022

Nick Henderson
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 (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022*.

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Note: This table relates only to the provisions of this instrument as originally made.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) Secretary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

AEMS means the Adverse Event Management System maintained by the Therapeutic Goods Administration.

AIR means the Australian Immunisation Register established and kept under the *Australian Immunisation Register Act 2015*.

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

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).

Therapeutic Goods Administration, or ***TGA***, means that part of the Department known as the Therapeutic Goods Administration.

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 in the tables in Part 1 and 2 of Schedule 1, the kinds of therapeutic goods information specified in column 2 may be released to a person, body or authority (or kinds of persons, bodies or authorities) specified in column 3, for the purposes specified in column 4.

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

Schedule 1—Therapeutic goods information

Note: See section 5.

Part 1—NCIRS

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 about adverse events following immunisation with vaccines that relates to one or more of the following: (a) the aggregate numbers of AEMS reports; (b) the number of doses administered, as included in the AIR; (c) case narratives of individual AEMS reports; (d) case-line listed data, including (but not limited to) the: (i) number allocated to the adverse event by the TGA; (ii) date the adverse event was reported to the TGA; (iii) date of the onset of symptoms; (iv) sex of the patient; (v) age of the patient; (vi) reaction outcome; (vii) vaccine; (e) the TGA's analysis of data provided by NCIRS or drawn from the AEMS and AIR databases; (f) methodologies and results of analysis pertaining to risk of adverse events following immunisation with vaccines	the NCIRS	to facilitate appropriate and effective analysis of data relating to safety signals associated with vaccines

Part 2—SAEFVIC

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 about adverse events following immunisation with vaccines that is: (a) case details in relation to individual AEMS reports	SAEFVIC	to improve the monitoring of vaccine safety and facilitate appropriate and effective analysis of data relating to safety signals associated with vaccines
