**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

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

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health (“the Department”).

Section 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, and to certain organisations, bodies or authorities. Subsection 61(1) of the Act provides that therapeutic goods information means, for the purposes of the section, information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department’s functions.

Subsection 61(5AA) provides that the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB) of the Act, therapeutic goods information of a kind specified under subsection 61(5AB) for a purpose specified under that subsection. Subsection 61(5AB) relevantly provides that, for the purposes of subsection 61(5AA), the Minister may, by legislative instrument, specify a person, body or authority, the kinds of therapeutic goods information and the purposes for which the information may be released under such arrangements.

The *Therapeutic Goods (Adverse Events Following Immunisation) (Information) Specification 2021* (“the Specification”) is a legislative instrument made under subsection 61(5AB) of the Act. It specifies the kinds of therapeutic goods information that the Secretary may release to several specified bodies and persons, and the purposes for which that information may be released to those bodies and persons, under subsection 61(5AA) of the Act. The persons and bodies include Jurisdictional Immunisation Coordinators for States and Territories (“JICs”), the National Centre for Immunisation Research and Surveillance (“NCIRS”), and the Surveillance of Adverse Events Following Vaccination In the Community (“SAEFVIC”).

The Specification authorises the release of therapeutic goods information relating to adverse events following immunisation to these bodies and persons, for the purpose of ensuring meaningful and effective participation in meetings on vaccine safety between the TGA, the JICs, NCIRS and SAEFVIC, to support the safety, quality and safe use of vaccines in Australia. The Specification gives effect to existing arrangements to ensure that this essential information can continue to be available to the specified bodies and persons.

**Background**

The TGA meets regularly with the JICs, NCIRS and SAEFVIC to discuss matters such as new safety signals relating to vaccines in Australia. The meeting participants include representatives of the TGA’s Pharmacovigilance and Special Access Branch and the Department’s Immunisation and Communicable Diseases Branch, as well as the JICs and representatives from NCRIS and SAEFVIC.

The meetings are a critical component of the post-market monitoring of vaccines in Australia and of particular importance as part of ensuring the safety of vaccines for use in relation to COVID-19. The meetings provide an open forum for the discussion of adverse events following vaccine immunisation, in order to identify concerns and trends in vaccine safety and to support the effective implementation of vaccine programs.

The JICs are representatives from each State and Territory health department responsible for oversight of vaccine immunisation programs.

The NCIRS is one of Australia’s leading research organisations in vaccine efficacy and safety. Its research and surveillance activities include the monitoring of vaccine coverage, vaccine program evaluation and vaccine safety monitoring. The NCIRS acts as an independent body providing advice to inform policy and planning for vaccine services.

SAEFVIC is a public health partnership initiative of the Victorian Immunisation Program funded by the Department of Health, Victoria. SAEFVIC is currently comprised of two units at the following sites:

* Murdoch Children’s Research Institute (Clinical); and
* Monash Health & University (Epidemiology and Signal Investigation.

As a vaccine safety service and clinical immunisation research team, SAFEVIC focuses on vaccine safety and surveillance. It also acts as the central reporting service in Victoria for adverse events following vaccine immunisation.

The Specification reflects the need for collaboration between the TGA, JICs, NCIRS and SAEFVIC to identify and accurately address safety concerns relating to vaccines as quickly and effectively as possible. It is critical to ensure that these persons and bodies continue to be afforded access to information about adverse events involving vaccine immunisation so that they can participate effectively in the meetings with TGA to contribute to vaccine safety.

The kinds of information specified in the instrument is principally information provided to the TGA by the person reporting the event, such as the patient, carer, medical practitioner, or state or territory health agency, a coroner or a health practitioner. The kinds of information that may be released to JICs, NCIRs and SAEFVIC include: the state or territory in which the adverse event occurred; the name of the relevant vaccine; the duration of the adverse event; the age and gender of the patient; a summary report of the adverse event; and other information that relates to the TGA’s investigation of the event.

**Consultation**

On 25 January 2021, a notice about the nature and purpose of TGA AEFI JIC meetings was published on the TGA’s website (www.tga.gov.au), highlighting the importance of these meetings in relation to vaccine safety and explaining the need for the disclosure of information relating to vaccine immunisation adverse events to support effective post-market monitoring of vaccines in Australia. No stakeholder or public comment was received in relation to the notice. Further consultation was not considered necessary, particularly as the Specification gives effect to existing arrangements, and in light of the need for the Specification to be formalised without delay given the significance of ensuring effective post-market monitoring of the safety of COVID-19 vaccines.

A regulation impact statement was not required in relation to the development of the Specification, as the matter of specifying kinds of therapeutic goods information under section 61 of the Act is the subject of a standing exemption from the regulation impact statement process (OBPR ID15070).

Details of the Specification are set out in **Attachment A**.

The Specification is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Specification is a disallowable legislative instrumentfor the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Adverse Events Following Immunisation) (Information) Specification 2021***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Adverse Events Following Immunisation) (Information) Specification 2021* (“the Specification”).

**Section 2 – Commencement**

This section provides that the Specification commences on the day after it is registered on the Federal Register of Legislation.

**Section 3 – Authority**

This section provides that the legislative authority for making the Specification is subsection 61(5AB) of the *Therapeutic Goods Act 1989* (“the Act”)*.*

**Section 4 – Definitions**

This section notes that the meanings of certain terms used in the Specification, e.g. ‘State’ and ‘therapeutic goods’, are defined in the Act. Other terms have been defined for the purposes of the Specification, including ‘AEFI’, ‘NCIRS’ and ‘SAEFVIC’.

**Section 5 – Release of therapeutic goods information**

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

**Schedule 1 – Therapeutic goods information**

This Schedule specifies that therapeutic goods information relating to adverse events following vaccine immunisation can be released to the JICs, NCIRS and SAEFVIC for the purpose of ensuring meaningful and effective participation in meetings on vaccine safety between the TGA, the JICs, NCIRS and SAEFVIC in order to support the safety, quality and safe use of vaccines in Australia.

The information that may be disclosed may, in some limited circumstances, include information from which it may be possible to identify a particular individual. For example, patients may be identifiable due to the unique adverse reaction or clinical circumstance described in the information. However, such use or disclosure of this information would be consistent with Australian Privacy Principle 6 in the *Privacy Act 1988* as disclosure would occur in a ‘permitted general situation’ where it is impracticable to obtain the individual’s consent to the use or disclosure of the information and the use or disclosure is necessary to lessen or prevent a serious threat to public health or safety.

**Attachment B**

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

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

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of legislative instrument**

The *Therapeutic Goods (Adverse Events Following Immunisation) (Information) Specification 2021* (“the instrument”) is a legislative instrument made under subsection 61(5AB) of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the instrument is to ensure the release of specified therapeutic goods information to Jurisdictional Immunisation Coordinators (“JICs”), the National Centre for Immunisation Research and Surveillance (“NCIRS”) and the Surveillance of Adverse Events Following Vaccination In the Community (“SAEFVIC”) for the purposes of their participation in Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators (“TGA AEFI JIC”) meetings with the TGA. These meetings facilitate discussion of adverse events following vaccine immunisation and are an essential part of responding to adverse events and ensuring vaccine safety more generally.

The instrument reflects the need for collaboration between the TGA, JICs, NCIRS and SAEFVIC to identify and accurately address safety concerns relating to vaccines as quickly and effectively as possible. It is critical to ensure that these persons and bodies are able to access information about adverse events involving vaccine immunisation, so that they can participate effectively in meetings with the TGA to contribute to vaccine safety.

The kinds of information specified by the instrument include, in particular, the state or territory in which the adverse event occurred, the name of the relevant vaccine, the duration of the adverse event, the age and gender of the patient, and a summary report of the adverse event.

The instrument formalises existing arrangements, principally to facilitate meetings between the TGA, JICs, NCIRS and SAEFVIC, and otherwise to support effective post-market monitoring of the safety of COVID-19 vaccines.

**Human rights implications**

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“ICESCR”) and the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the International Covenant on Civil and Political Rights (“ICCPR”).

*Right to health*

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection, which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by ensuring all necessary persons and bodies have access to the information required in order to allow full and effective participation in regular meetings with the TGA on vaccine safety in Australia, supporting the safety of such products and public confidence in vaccines.

*Right to protection against arbitrary and unlawful interferences with privacy*

Article 17 of the ICCPR provides for the right of every person not to be subjected to arbitrary or unlawful interference with privacy. The prohibition on interference with privacy prohibits unlawful or arbitrary interferences with a person’s privacy, family, home and correspondence. It also prohibits unlawful attacks on a person’s reputation. Limitations on the right to privacy must be according to law and not arbitrary, i.e. limitations must be reasonable and necessary in the particular circumstances, as well as proportionate to the objectives the limitations seek to achieve.

The TGA, as part of the Australian Government Department of Health, is an APP entity for the purposes of the *Privacy Act 1988* (“the Privacy Act”) and information that is specified in the instrument will ultimately include health information. It may be possible to identify an individual from that information in limited circumstances due to the unique adverse reaction or clinical circumstance relating to the individual. However, such use or disclosure of this information to JICs, NCIRS and SAEFVIC would be consistent with Australian Privacy Principle 6 in the Privacy Act as such disclosure would occur in a ‘permitted general situation’ where it is impracticable to obtain the individual’s consent to the use or disclosure of the information, and the use or disclosure is necessary to lessen or prevent a serious threat to public health or safety.

The collection and use of the information for this purpose by the TGA, and its disclosure by the TGA to JICs, NCIRS and SAEFVIC for this purpose, is critically important to ensure the safety of vaccines in Australia, particularly the COVID-19 vaccines as less is known about such vaccines than other vaccine products with a longer history of use.

It is also particularly important to note that each of the JICs and persons representing NCIRS and SAEFVIC are required to sign a deed of undertaking in relation to maintaining the confidentiality of information disclosed at TGA AEFI JIC meetings, prior to their initial attendance at those meetings. It would not be practicable to obtain the patient’s consent ahead of a meeting, if the information is not provided by the patient directly, and it is not possible to determine in advance of the disclosure whether the person would be identifiable from the information.

As such, the disclosure of the information would not be an arbitrary or unlawful interference with a person’s privacy under Article 17 of the ICCPR, as the disclosure would be reasonable and targeted through only being to the JICs, NCIRS and SAEFVIC and not more broadly, and the disclosure to those persons and bodies would be necessary and proportionate to the objective of ensuring the safety of vaccines in Australia through essential post-market monitoring activities, including the timely investigation of adverse event signals.

**Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and any engagement with the right to privacy is reasonable, necessary and proportionate.