EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

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 (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022* ("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 persons, bodies or authorities, and the purposes for which that information may be released to those persons, bodies and authorities, under subsection 61(5AA) of the Act. The persons and bodies specified in the Specification are the National Centre for Immunisation Research and Surveillance ("the NCIRS"), and Surveillance of Adverse Events Following Vaccination In the Community ("SAEFVIC").

The Specification authorises the release of certain therapeutic goods information relating to adverse events following immunisation to these bodies and persons, for the purpose of facilitating appropriate and effective analysis of data relating to safety signals associated with vaccines.

Background

The TGA collaborates with a range of organisations as part of working constantly to improve and enhance safety responses to adverse event information involving vaccines and other therapeutic goods.

The Specification supports two such activities, involving the NCIRS and SAEFVIC. In relation to each activity, the Specification provides for therapeutic goods information held by the TGA to be shared with these two bodies in order to support their functions of analysing adverse events following immunisation.

In relation to NCIRS, this is intended to include in particular working together on the analysis of certain kinds of data relating to adverse events involving vaccines in Australia, including for example the aggregate numbers of adverse event reports in the Adverse Event Management System ("AEMS") relating to vaccines, the number of doses of a vaccine administered in Australia (as identified in the Australian Immunisation Register), the TGA's analysis of data provided by NCIRS or drawn from AEMS or the Australian Immunisation Register ("AIR") and methodologies and

results of analysis pertaining to the risk of adverse events following immunisation with vaccines, to better identify vaccine safety trends and issues.

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.

Working together with NCIRS in this way, and sharing such information with NCIRS, will harness NCIRS' expertise and capacity and allow NCIRS to conduct sophisticated and large-scale observed versus expected analyses utilising adverse event data from the AEMS and the TGA's initial analysis of such data. This is designed to ensure rapid and accurate detection and validation of post-market safety signals for vaccines in Australia, including COVID-19 vaccines.

In relation to SAEFVIC, this is intended to include in particular working together to improve the monitoring of vaccine safety and enhancing the effectiveness of analysis of vaccine safety data through the provision of information to SAEFVIC in relation to case details for adverse event reports recorded in AEMS.

This information is already provided by the TGA, under subsection 61(3) of the Act, to Jurisdictional Immunisation Coordinators in the states and territories to support their vaccine safety monitoring. Currently, this information cannot be provided directly to SAEFVIC which leads to a delay in the information being received by SAEFVIC (through the Victorian Department of Health). This can impair the efficiency of information-sharing and the timely following-up of patients who have suffered serious adverse events following immunisation, as well as the effective management of vaccine safety signals in Victoria. Such delays can also prevent the TGA from being able to identify the whole picture of national vaccine safety signals.

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, SAEFVIC focuses on vaccine safety and surveillance. It also acts as the central reporting service in Victoria for adverse events following immunisation.

Reflecting SAEFVIC's critical role in undertaking regional pharmacovigilance in Victoria, it is important that the TGA is able to provide this information directly to SAEFVIC, reducing delays in identifying and addressing concerns and trends in vaccine safety.

Consultation

SAEFVIC and the Victorian Department of Health raised the matter of the direct provision of case details of adverse event reports in AEMS multiple times with the TGA, and the Specification is designed to address those concerns.

NCIRS was also consulted on the proposed making of the Specification in September 2021, with no objections to the proposed approach.

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 ID 15070).

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 instrument for 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 (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022* ("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. 'Secretary', are defined in the Act. Other terms have been defined for the purposes of the Specification, including 'AEMS', '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 in the tables in Part 1 and 2 of Schedule 1 to the Specification, the kinds of therapeutic goods information specified in column 2 may be released to the persons, bodies or authorities specified in column 3, for the purposes specified in column 4 of that table.

Schedule 1 – Therapeutic goods information

Part 1 of this Schedule specifies that therapeutic goods information relating to adverse events following immunisation with vaccines can be released to the NCIRS for the purpose of facilitating appropriate and effective analysis of data relating to safety signals associated with vaccines. It specifies that the kinds of therapeutic goods information that may be shared for this purpose is information that relates to one or more of the following: the aggregate numbers of AEMS reports, the number of doses administered as included in the AIR, case narratives of individual AEMS reports, case-line listed data, the TGA's analysis of data provided by the NCIRS or drawn from the AEMS and AIR databases and methodologies and results of analysis pertaining to risk of adverse events following immunisation with vaccines.

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.

Part 2 of this Schedule specifies that therapeutic goods information relating to adverse events following immunisation with vaccines can be released to SAEFVIC for the purpose of facilitating appropriate and effective analysis of data relating to safety signals associated with vaccines. It

specifies that the kind of therapeutic goods information that may be shared for this purpose is information that is case details in relation to individual AEMS reports.

The information that may be disclosed includes identifying personal information to enable follow up of patients by SAEFVIC to learn as much as possible about their adverse event. Information of this nature is already received by SAEFVIC, following release of the information from the TGA to the Victorian Department of Health, who then provide the information to SAEFVIC. 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 (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022

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 (Analysis of Adverse Events Following Immunisation) (Information) Specification 2022* ("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 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 facilitating appropriate and effective analysis of data relating to safety signals associated with vaccines.

The instrument reflects the need for collaboration between the Therapeutic Goods Administration ("TGA"), 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 be afforded access to information about adverse events involving immunisation with vaccines so that they can work effectively with the TGA to contribute to vaccine safety.

The kinds of information specified by the instrument that may be released to NCIRS is information about adverse events following immunisation with vaccines, that relates to one or more of the following: the aggregate numbers of Adverse Event Management System ("AEMS") reports, the number of doses administered as identified in the AIR, case narratives of individual AEMS reports, case-line listed data, the TGA's analysis of data provided by the NCIRS or drawn from the AEMS and AIR databases, and methodologies and results of analysis pertaining to risk of adverse events following immunisation with vaccines.

In relation to SAEFVIC, the instrument specifies the kinds of information that may be released as information about adverse events following immunisation with vaccines that is case details relating to individual adverse event reports recorded in AEMS.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the 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 ("the 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 to facilitate appropriate and effective analysis of data relating to safety signals associated with 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 information that may be disclosed in particular to SAEFVIC under the instrument includes identifying personal information to enable follow up of patients by SAEFVIC to learn as much as possible about their adverse event. Information of this nature is already received by SAEFVIC, following release of the information from the TGA to the Victorian Department of Health, who then provide the information to SAEFVIC.

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 released to NCIRS in limited circumstances due to the unique adverse reaction or clinical circumstance relating to the individual. Information released to SAEFVIC will identify individuals, which is necessary to enable follow up of patients by SAEFVIC to learn as much as possible about their adverse event. However, such use or disclosure of this information to 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 NCIRS and SAEFVIC for this purpose, is critically important to ensure the safety of vaccines in Australia, including in particular the COVID-19 vaccines as less is known about such vaccines than other vaccine products with a longer history of use.

It would not be practicable to obtain the patient's consent ahead of a release of therapeutic goods information, 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.

Personal information that is released by the TGA to NCIRS and SAEFVIC in accordance with the instrument would be protected by Commonwealth and state legislation that is applicable to those bodies, including the *Privacy Act 1988* (Cth), *Privacy and Data Protection Act 2014* (Vic), and the *Health Records Act 2001* (Vic), as relevant.

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 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.