

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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 and Aged Care (“the Department”).

Section 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, as well as 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.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. The *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023* (“the Instrument”) is a legislative instrument made under subsection 61(5D) of the Act and specifies kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The Instrument authorises the release of specified kinds of therapeutic goods information, relating to adverse events involving medicines and biologicals, from the Database of Adverse Event Notifications – Medicines (“DAEN – Medicines”). The Instrument also authorises the release of specified kinds of therapeutic goods information, relating to adverse events involving, and defects of, medical devices and other therapeutic goods (“OTGs”), from the Database of Adverse Event Notifications – Medical Devices (“DAEN – Medical Devices”).

The DAEN – Medicines and DAEN – Medical Devices are publicly available databases maintained by the TGA. The public release of information from both the DAEN – Medicines and DAEN – Medical Devices benefits a range of key external stakeholders including consumers, patients and healthcare professionals, by providing access to information about adverse events involving therapeutic goods in Australia.

The Instrument repeals the following two instruments (collectively known as “the former Specifications”) and replaces them with a single instrument dealing with adverse event notifications for all therapeutic goods:

- the *Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) Specification 2013* (“the former DAEN – Medical Devices Specification”), which would otherwise sunset on 1 October 2023; and
- the *Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022* (“the former DAEN – Medicines Specification”).

The Instrument also repeals the *Therapeutic Goods Information (Joint Recalls Portal) Specification 2013*, which is due to sunset on 1 October 2023, as that instrument is no longer required.

Background

Adverse events

Adverse events are, in practice, principally unintended and sometimes harmful occurrences associated with the administration or use of therapeutic goods. In some instances, the therapeutic good may have caused the event, and there may be other instances where the use of the therapeutic good may have been a coincidence rather than a cause of the adverse event. Adverse events in this context may range in severity from mild, expected reactions (such as headache, nausea and body aches) to more severe events, including death. The TGA uses reports of adverse events to monitor the safety of therapeutic goods and, where possible, to identify safety signals that may be investigated and used to alert patients, health practitioners and the public about particular risks.

An adverse event in the context of a medical device or OTG is an event that has led, or might have led, to the death of, serious injury to, or serious deterioration in the health of, a person, following the use of a medical device or OTG. This may include a life-threatening illness or injury, permanent impairment of a body function, permanent damage to a body structure or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

In relation to adverse events that might have led to death, serious injury or serious deterioration in the health of a person, it may be that, due to the timely intervention of a healthcare practitioner, none of these outcomes eventuated. In addition, a defect in a medical device or OTG might have led to death, serious injury or serious deterioration in the health of a person. A defect is any malfunction or deterioration in the characteristics or performance of the medical device or OTG, or any inadequacy in the design, production, labelling, instructions for use or advertising materials of the medical device or OTG, that might lead, or might have led, to the death of, a serious injury to, or serious deterioration in, the health of a person.

The DAEN – Medical Devices and DAEN – Medicines

The DAEN – Medicines and DAEN – Medical Devices are an essential component of the TGA's work to maintain the transparency of adverse event and defect information relating to the administration or use of therapeutic goods in Australia. These databases are accessed daily by the public and there is a high level of community interest and focus on adverse event information, and importance in ensuring public access to it. These databases also support research and analysis relating to therapeutic goods adverse events, which may in turn inform and provide insights to improve future regulation to prevent and better address such events.

Members of the public including, in particular, consumers, health practitioners, sponsors and manufacturers can search the DAEN – Medicines and view data about adverse event reports relating to medicines and biologicals. This includes, for example, the name of the medicine or biological, de-identified patient details (age and gender) and scientific terms that describe the event. The search results also include summaries of the total number of cases in relation to a medicine or biological, the number of cases where death was a reported outcome, and the number of cases where the medicine or biological was the only therapeutic good suspected of being related to the adverse event.

Similarly, members of the public can search the DAEN – Medical Devices to view information about adverse events and defects relating to medical devices and OTGs. This includes details about the device or OTG such as the trade name, ARTG number, GMDN term, device classification, model number, software version, whether the device or OTG is supplied in a sterile state, and whether the device or OTG is single use. In addition, details of the name of the sponsor or manufacturer, a description of the event and the outcome, the category of reporter (e.g. consumer, health professional, etc.) and details of any other medical devices or OTGs involved in the event are also reported in the DAEN – Medical Devices.

The former Specifications

The former DAEN – Medicines Specification came into force in 2022 and specified, under subsection 61(5D) of the Act, kinds of adverse event information relating to both medicines and biologicals contained in the DAEN – Medicines. That information could be released by the Secretary to the public under subsection 61(5C) of the Act. The former DAEN – Medicines Specification enabled the TGA to publicly display de-identified data about reports of adverse events that the TGA had received in relation to medicines, including vaccines, and biologicals in Australia.

The former DAEN – Medical Devices Specification came into force in 2013 and specified, under subsection 61(5D) of the Act, kinds of adverse event and near adverse event information relating to medical devices contained in the DAEN – Medical Devices. That information could be released by the Secretary to the public under subsection 61(5C) of the Act. The former DAEN – Medical Devices Specification also specified information relating to adverse events, or near adverse events, in New Zealand. This was for the purpose of supporting a single, publicly accessible database of adverse event notifications in Australia and New Zealand that was to be administered by the joint regulatory agency that was proposed at the time. The joint regulatory agency did not proceed and the DAEN – Medical Devices does not contain any information relating to adverse events in New Zealand.

Purpose

The Instrument authorises the release of information about adverse events in relation to therapeutic goods and provides a legal basis under the Act to support the release of this information to the public in the DAEN – Medicines and DAEN – Medical Devices.

The Instrument repeals and replaces the former DAEN – Medical Devices Specification, which would otherwise sunset on 1 October 2023, to ensure the continued release of information from the DAEN – Medical Devices beyond that date. The Instrument replaces the former DAEN – Medical Devices Specification without changing its effect, other than to omit the content dealing with adverse events in New Zealand as the DAEN – Medical Devices is no longer proposed to include New Zealand adverse event notifications.

The Instrument also repeals and replaces the DAEN – Medicines Specification, without substantive change, for the principal purpose of consolidating the two former Specifications into a single legislative instrument.

Schedule 1 to the Instrument sets out in detail the kinds of therapeutic goods information that the Secretary may release through the DAEN – Medical Devices and the DAEN – Medicines. The information that is specified in Schedule 1 is the same as the information specified in the former Specifications.

Incorporation by reference

Subsection 61(9) of the Act relevantly provides that, despite subsection 14(2) of the *Legislation Act 2003* (“Legislation Act”), an instrument under subsection (5D) may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

The MedDRA

The Instrument incorporates by reference the *Medical Dictionary for Regulatory Activities* (“the MedDRA”), which contains internationally recognised, standardised medical terminology developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (“ICH”), and which relates to such matters as medical conditions,

medicines, biologicals and medical devices. The MedDRA is maintained and distributed by the MedDRA Maintenance and Support Services Organization (“MSSO”).

The MedDRA is used by regulators, industry, academics and health professionals, and facilitates the sharing of information internationally. The MedDRA is a subscription-based product and may be accessed from the ICH MedDRA website (www.meddra.org). While the MedDRA is not available for free, it is anticipated that sponsors and manufacturers of medicines and biologicals would have access to it, through an annual paid subscription for commercial users. Health practitioners and academics are also able to access the MedDRA at no cost from the MSSO. By prior written arrangement with the TGA, members of the public may also request to view the MedDRA without charge at the TGA office in Fairbairn, ACT.

Pursuant to subsection 61(9) of the Act, the MedDRA is incorporated as in force or existing from time to time.

The IMDRF Terminology Document

The Instrument also incorporates by reference the *Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes* (“the IMDRF Terminology Document”), which is an international guidance document published by the International Medical Device Regulators Forum (“IMDRF”). The IMDRF Terminology Document was prepared by the IMDRF Adverse Event Working Group, being a group within the IMDRF charged with developing harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics (IVDs).

The IMDRF Terminology Document is freely available from the IMDRF website (www.imdrf.org/).

Pursuant to subsection 61(9), the IMDRF Terminology Document is incorporated as in force or existing from time to time.

Consultation

On 11 May 2023, the TGA consulted with industry members through an out of session update with the Regulatory and Technical Consultative Forum for medical devices (“RegTech”) on the proposal to remake the former DAEN – Medical Devices Specification without significant change. RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry. RegTech was supportive of the proposal and did not raise any concerns.

Consultation was not undertaken in relation to the DAEN – Medicines because consultation was undertaken in 2022 when the former DAEN – Medicines Specification was made, and no substantive changes have been made to the content of the former DAEN – Medicines Specification.

The Office of Impact Analysis (OIA) advised that the making of the Instrument is unlikely to have more than a minor regulatory impact, therefore the preparation of an Impact Analysis is not required (OIA23-04525).

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

The Instrument is compatible with the 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 Instrument is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 30 September 2023.

Details of the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023* (“the Instrument”).

Section 2 – Commencement

This section provides that the Instrument commences on 30 September 2023.

Section 3 – Authority

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

Section 4 – Definitions

This section provides the definitions of key terms used in the Instrument, including ‘adverse event’, ‘DAEN – Medical Devices’, ‘DAEN – Medicines’, ‘defect’, ‘IMDRF Terminology Document’, ‘MedDRA’ and ‘therapeutic goods information’. This section also notes that a number of terms used in the Instrument have the meaning given in subsection 3(1) of the Act, including for instance ‘biological’, ‘medical device’, and ‘medicine’.

Importantly, the Instrument combines the definitions of ‘near adverse event’ and ‘adverse event’, which were both defined in the former DAEN – Medical Devices Specification, into a single definition for ‘adverse event’. Under the former DAEN – Medical Devices Specification, a separate definition for ‘near adverse event’ was included to distinguish between events that led to the death of, or to a serious injury or serious deterioration to, a person (i.e. an ‘adverse event’), and those that *might* have led to these outcomes (i.e. a ‘near adverse event’).

The Instrument also introduces a new definition for ‘defect’ to more clearly include reports that the TGA receives and publishes in the DAEN – Medical Devices about problems with devices, such as a malfunction or issue with the design or instructions for use.

Section 5 – Release of therapeutic goods information

This section provides that the kinds of therapeutic goods information set out in an item in the tables in Parts 1 and 2 of Schedule 1 are specified for the purpose of subsection 61(5C) of the Act. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in Schedule 1 to the Instrument.

Schedule 1 to the Instrument sets out in detail the kinds of therapeutic goods information that the Secretary may release through the DAEN – Medical Devices and DAEN – Medicines.

Section 6 – Repeals

This section provides that each instrument in Schedule 2 to the Instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1 – Therapeutic goods information

This Schedule specifies, for the purposes of section 5 of the Instrument, the kinds of therapeutic goods information which the Secretary may release to the public under subsection 61(5C) of the Act.

The kinds of therapeutic goods information specified in column 2 of the table in Part 1 to this Schedule relates to an adverse event involving a medical device or other therapeutic good (“OTG”) that has been reported to the Therapeutic Goods Administration (“the TGA”). This includes details of the medical device or OTG, such as the trade name, ARTG number, GMDN term, device classification, model number, software version, whether the device or OTG is supplied in a sterile state and whether the device or OTG is single use. In addition, this includes details of the name of the sponsor or manufacturer, a description of the event, event type and outcome, the category of reporter (e.g. consumer, health professional, etc.) and details of any other medical devices or OTGs involved in the event are also reported in the DAEN – Medical Devices.

The kinds of therapeutic goods information specified in item 1 of the table in Part 2 to this Schedule relates to an adverse event involving a medicine or biological that has been reported to the TGA. This includes, for instance, details of the relevant medicine or biological, details of any OTGs administered to the person who is reported to have suffered the adverse event and the age and gender of the relevant person.

The kinds of therapeutic goods information specified in item 2 of the table in Part 2 to this Schedule is collated by the TGA from adverse events that have been reported to the TGA in relation to the medicine or biological and recorded in the DAEN – Medicines, including, for instance (for a medicine or biological), the number of relevant cases and the number of relevant cases that have resulted in death.

The information specified in the Instrument that may contain personal information would possibly include:

- (a) the name of the sponsor of a therapeutic good, which is the person who imports the goods into Australia, exports the goods from Australia, or manufactures the goods in Australia;
- (b) the name of the manufacturer of the therapeutic good, if different to the sponsor; or
- (c) the trade name of a medicine or biological, as the name of the sponsor or manufacturer may also be part of the trade name of the medicine or biological.

Although the sponsor or manufacturer is most often a company, the sponsor or manufacturer may be an individual, so it may be possible to identify an individual from that information published in the DAEN – Medicines or DAEN – Medical Devices. However, the name of the sponsor for, and the trade name of, a medicine or biological that is in the Australian Register of Therapeutic Goods (“the Register”) would already be publicly available in the Register.

The TGA, as part of the Australian Government Department of Health and Aged Care, is an APP entity for the purposes of the *Privacy Act 1988* (“the Privacy Act”). Any use or disclosure of personal information would be consistent with the Privacy Act. The collection and use of the information specified in the Instrument by the TGA, and its disclosure, is critically important to promote transparency and the safety of patients, users and the public. It is important that the public knows the sponsor or manufacturer that supplied the goods in Australia, even if it is an individual.

Other information released in the DAEN – Medicines and DAEN – Medical Devices is de-identified and is not considered sufficient to identify an individual. It may only be possible to identify an individual where that individual chooses to release additional, personal information publicly or to the media which specifically identifies that individual. For example, where an individual is interviewed by the media about an adverse event associated with a vaccine. In this case, the details of the individual would already be public.

Schedule 2 – Repeals

This Schedule provides that the *Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022*, the *Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) Specification 2013* and the *Therapeutic Goods Information (Joint Recalls Portal) Specification 2013* are repealed.

The Instrument replaces the *Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022* and the *Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) Specification 2013*, combining them into one consolidated instrument.

The Instrument repeals the *Therapeutic Goods Information (Joint Recalls Portal) Specification 2013*, which is due to sunset on 1 October 2023, as that instrument is no longer required. It was made to support the establishment of a single portal containing information relating to recalls in Australia and New Zealand, to be administered by the joint regulatory agency that was proposed at the time. The joint regulatory agency did not proceed, and the joint recalls portal was never established.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023

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 Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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 and Aged Care (“the Department”).

The *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023* (“the Instrument”) is made under subsection 61(5D) of the Act for the purpose of specifying kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act. The Instrument authorises the release of specified kinds of therapeutic goods information, relating to adverse events involving medicines and biologicals, from the Database of Adverse Event Notifications – Medicines (“DAEN – Medicines”). The Instrument also authorises the release of specified kinds of therapeutic goods information, relating to adverse events involving, and defects of, medical devices and other therapeutic goods (“OTGs”), from the Database of Adverse Event Notifications – Medical Devices (“DAEN – Medical Devices”). The DAEN – Medicines and DAEN – Medical Devices are publicly available databases, maintained by the TGA.

The Instrument repeals the following two instruments (collectively known as “the former Specifications”) and replaces them with a single instrument dealing with adverse event notifications for all therapeutic goods:

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- the *Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022* (“the former DAEN – Medicines Specification”).

Background

Adverse events

Adverse events are, in practice, principally unintended and sometimes harmful occurrences associated with the administration or use of therapeutic goods. In some instances, the therapeutic good may have caused the event, and there may be other instances where the use of the therapeutic good may have been a coincidence rather than a cause of the adverse event. Adverse events in this context may range in severity from mild, expected reactions (such as headache, nausea and body aches) to more severe events, including death. The TGA uses reports of adverse events to monitor the safety of therapeutic goods and, where possible, to identify safety signals that may be investigated and used to alert patients, health practitioners and the public about particular risks.

An adverse event in the context of a medical device or OTG is an event that has led, or might have led, to the death of, serious injury to, or serious deterioration in the health of, a person, following the use of a medical device or OTG. This may include a life-threatening illness or injury, permanent impairment of a body function, permanent damage to a body structure or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

In relation to adverse events that might have led to death, serious injury or serious deterioration in the health of a person, it may be that, due to the timely intervention of a healthcare practitioner, none of these outcomes eventuated. In addition, a defect in a medical device or OTG might have led to death, serious injury or serious deterioration in the health of a person. A defect is any malfunction or deterioration in the characteristics or performance of the medical device or OTG, or any inadequacy in the design, production, labelling, instructions for use or advertising materials of the medical device or OTG, that might lead, or might have led, to the death of, a serious injury to, or serious deterioration in, the health of a person.

The DAEN – Medical Devices and DAEN – Medicines

The DAEN – Medicines and DAEN – Medical Devices are an essential component of the TGA's work to maintain the transparency of adverse event and defect information relating to the administration or use of therapeutic goods in Australia. These databases are accessed daily by the public and there is a high level of community interest and focus on adverse event information, and importance in ensuring public access to it. These databases also support research and analysis relating to therapeutic goods adverse events, which may in turn inform and provide insights to improve future regulation to prevent and better address such events.

Members of the public including, in particular, consumers, health practitioners, sponsors and manufacturers can search the DAEN – Medicines and view data about adverse event reports relating to medicines and biologicals. This includes, for example, the name of the medicine or biological, de-identified patient details (age and gender) and scientific terms that describe the event. The search results also include summaries of the total number of cases in relation to a medicine or biological, the number of cases where death was a reported outcome, and the number of cases where the medicine or biological was the only therapeutic good suspected of being related to the adverse event.

Similarly, members of the public can search the DAEN – Medical Devices to view information about adverse events and defects relating to medical devices and OTGs. This includes details about the device or OTG such as the trade name, ARTG number, GMDN term, device classification, model number, software version, whether the device or OTG is supplied in a sterile state and whether the device or OTG is single use. In addition, details of the name of the sponsor or manufacturer, a description of the event and the outcome, the category of reporter (e.g. consumer, health professional, etc.) and details of any other medical devices or OTGs involved in the event are also reported in the DAEN – Medical Devices.

The former Specifications

The former DAEN – Medicines Specification came into force in 2022 and specified, under subsection 61(5D) of the Act, kinds of adverse event information relating to both medicines and biologicals contained in the DAEN – Medicines. That information could be released by the Secretary to the public under subsection 61(5C) of the Act. The former DAEN – Medicines Specification enabled the TGA to publicly display de-identified data about reports of adverse events that the TGA had received in relation to medicines, including vaccines, and biologicals in Australia.

The former DAEN – Medical Devices Specification came into force in 2013 and specified, under subsection 61(5D) of the Act, kinds of adverse event and near adverse event information relating to medical devices contained in the DAEN – Medical Devices. That information could be released by

the Secretary to the public under subsection 61(5C) of the Act. The former DAEN – Medical Devices Specification also specified information relating to adverse events, or near adverse events, in New Zealand. This was for the purpose of supporting a single, publicly accessible database of adverse event notifications in Australia and New Zealand that was to be administered by the joint regulatory agency that was proposed at the time. The joint regulatory agency did not proceed and the DAEN – Medical Devices does not contain any information relating to adverse events in New Zealand.

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 facilitating the public release of therapeutic goods information relating to adverse events involving therapeutic goods, as well as defects concerning medical devices and OTGs. The Instrument promotes transparency and public awareness of therapeutic goods adverse events reported to the TGA. The publication of this information enables the Australian public to be better informed about the safety of therapeutic goods, as well as supporting research and analysis relating to therapeutic goods adverse events and the insights that such research and analysis may generate to help improve the safety of therapeutic goods for Australians.

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 specified in the Instrument that may contain personal information would possibly include:

- (a) the name of the sponsor of a therapeutic good, which is the person who imports the goods into Australia, exports the goods from Australia, or manufactures the goods in Australia;
- (b) the name of the manufacturer of the therapeutic good, if different to the sponsor; or
- (c) the trade name of a medicine or biological, as the name of the sponsor or manufacturer may also be part of the trade name of the medicine or biological.

Although the sponsor or manufacturer is most often a company, the sponsor or manufacturer may be an individual, so it may be possible to identify an individual from that information published in the DAEN – Medicines or DAEN – Medical Devices. However, the name of the sponsor for, and the

trade name of, a medicine or biological that is in the Australian Register of Therapeutic Goods (“the Register”) would already be publicly available in the Register.

The TGA, as part of the Australian Government Department of Health and Aged Care, is an APP entity for the purposes of the *Privacy Act 1988* (“the Privacy Act”). Any use or disclosure of personal information would be consistent with the Privacy Act. The collection and use of the information specified in the Instrument by the TGA, and its disclosure, is critically important to promote transparency and the safety of patients, users and the public. It is important that the public knows the sponsor or manufacturer that supplied the goods in Australia, even if it is an individual.

Other information released in the DAEN – Medicines and DAEN – Medical Devices is de-identified and is not considered sufficient to identify an individual. It may only be possible to identify an individual where that individual chooses to release additional, personal information publicly or to the media which specifically identifies that individual. For example, where an individual is interviewed by the media about an adverse event associated with a vaccine. In this case, the details of the individual would already be public.

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 given it is appropriate and justified for the public to know who the sponsor or manufacturer is (even if it is an individual), and the disclosure would be necessary and proportionate to the objective of promoting the safety of therapeutic goods in Australia.

Conclusion

The 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 in Article 17 of ICCPR is reasonable, necessary and proportionate.