**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Database of Adverse Event Notifications) (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 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 (Database of Adverse Event Notifications) (Information) Specification 2022* (“the Specification”) 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 Specification authorises the release of specified kinds of therapeutic goods information relating to adverse events involving medicines and biologicals, which is contained in the Database of Adverse Event Notifications (“DAEN”), maintained by the TGA. The Specification repeals and replaces the *Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012* (“the former Specification”), which would otherwise sunset on 1 October 2022.

**Background**

The former Specification came into force in 2012 and specified, under subsection 61(5D) of the Act, kinds of adverse event information relating to medicines contained in the DAEN, that the Secretary could release to the public under subsection 61(5C) of the Act. The former 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, in Australia.

Adverse events are, in practice, principally unintended and sometimes harmful occurrences associated with the use of a therapeutic good, for example, a vaccine. 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 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.

The DAEN is an essential component of the TGA’s work to maintain the transparency of adverse event information relating to the use of medicines and biologicals in Australia, and is accessed daily by the public. Consumers, health practitioners, sponsors and manufacturers can search the DAEN and view data about medicine and biological adverse event reports, including 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.

The DAEN also supports 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. In the 12 months from 1 May 2021 to 30 April 2022, information about adverse events relating to medicines and biologicals contained in the DAEN was accessed on more than 680,000 occasions, demonstrating both the level of community interest and focus on adverse event information, and the importance of ensuring public access to it.

The Specification authorises the release of adverse event information relating to both medicines and biologicals. Since the making of the former Specification, and the commencement on 31 May 2011 of amendments made to the Act by Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2009* (which introduced a new regulatory framework for biologicals), biologicals have transitioned to the new framework that commenced in May 2011 and include a range of products including for instance faecal microbiota transplants, skin grafts and products made from genetically modified cells (CAR-T cells). Prior to the commencement of the new regulatory framework for biologicals in May 2011 biologicals were regulated as either medicines or medical devices, depending on the type of product and its manufacture. Identifying biologicals separately in the Specification better reflects the regulation of this class of product in its own right and clarifies that adverse events associated with biologicals may also be published in the DAEN.

As with the former Specification, the kinds of therapeutic goods information specified by the Specification may be grouped into two broadly different categories:

* information relating to an adverse event that has been reported to the TGA in relation to a medicine or biological, including for instance the details of the medicine or biological and the adverse event description term, as described in the Medical Dictionary for Regulatory Activities published by the MedDRA Maintenance and Support Services Organization; and
* a summary of information relating to adverse events that (as at the time a person accesses the DAEN) are reported as having occurred in relation to a medicine or biological.

Schedule 1 to the Specification sets out in detail the kinds of therapeutic goods information that the Secretary may release through the DAEN.

**Consultation**

Between March and April 2022, the TGA invited 24 consumer, industry and health professional organisations to provide feedback on the proposal to remake the former Specification without significant change. The TGA received 23 responses (from three consumer groups, 11 health professional and medical bodies, a government body, five medicine sponsor groups and companies and three individual or anonymous respondents) supporting the need for continued transparency and reporting of medicine adverse event data in Australia. There was almost unanimous support for remaking the instrument without change, noting an intention to consult further on a potential future expansion of data published in the DAEN. The one respondent who did not support the remaking of the instrument was an individual who raised concerns about a perceived culture among health professionals of limited reporting of adverse events.

In August 2022 the TGA undertook a further targeted round of consultation, specifically in relation to the publication of information about adverse events reported in relation to biologicals. The TGA invited sponsors of biologicals to comment on this continued publication of adverse event information in the DAEN. Six responses were received, with all either supporting the proposal or not objecting to it. Several responses noted that the DAEN was a good resource for the tissue banking sector, with access to the data provided by the DAEN being both useful and valuable for health practitioners. In particular, there was strong support for the transparency of this important safety data.

OBPR advised that a Regulation Impact Statement is not required in relation to the making of the Specification (OBPR22-01957).

**Incorporation by reference**

The Specification incorporates by reference the *Medical Dictionary for Regulatory Activities* (“the MedDRA”), which is an 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 at https://www.meddra.org. While unfortunately 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 MedDRA without charge at the TGA office in Fairbairn, ACT.

In accordance with section 14 of the *Legislation Act 2003* (“Legislation Act”), the MedDRA is incorporated as in force or existing immediately before the commencement of the Specification.

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

The Specification 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 Specification is a disallowable legislative instrument for the purposes of theLegislation Actand commences on 30 September 2022.

**Attachment A**

**Details of the** ***Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022* (“the Specification”).

**Section 2 – Commencement**

This section provides that the Specification commences on 30 September 2022.

**Section 3 – Authority**

This section provides that the legislative authority for making the Specification 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 Specification, including ‘adverse event’, ‘DAEN’ and ‘MedDRA’. This section also notes that a number of terms used in the Specification have the meaning given in subsection 3(1) of the Act, including for instance ’biological’ and ‘medicine’.

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

This section provides that the kinds of therapeutic goods information set out in the table in 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 Specification.

**Section 6 – Repeals**

This section provides that each instrument in Schedule 2 to the Specification 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 Specification, 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 item 1 of the table in this Schedule relate to an adverse event involving a medicine or biological that has been reported to the Therapeutic Goods Administration (“the TGA”), including for instance details of the relevant medicine or biological, details of any other therapeutic goods 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 this Schedule relates to a medicine or biological that 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, including for instance (for a medicine or biological) the number of relevant cases and the number of relevant cases that have resulted in death.

**Schedule 2 – Repeals**

This Schedule provides that the *Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012* is repealed.

**Attachment B**

**Statement of Compatibility with Human Rights**

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

***Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022***

This disallowable legislative instrumentis 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 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 (Database of Adverse Event Notifications) (Information) Specification 2022*(“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 to the public of specified kinds of therapeutic goods information relating to adverse events involving medicines and biologicals, from the Database of Adverse Event Notifications (“the DAEN”), a database of such information that is maintained by the TGA on the TGA website. The instrument also repeals and replaces the *Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012* (“the former instrument”)*,* which would otherwise sunset on 1 October 2022.

The former instrument, made under subsection 61(5D) of the Act, came into force in 2012 and facilitated the release to the public of certain adverse event information relating to medicines contained in the DAEN. The former Specification enabled the TGA to publicly display data about reports of adverse events that the TGA has received in relation to medicines, including vaccines, in Australia.

Adverse events are, in practice, principally unintended and sometimes harmful occurrences associated with the use of a therapeutic good, for example, a vaccine. 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 event. Adverse events 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.

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**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”). 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 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 continuing to promote transparency and public awareness in relation to adverse events reported to the TGA in relation to medicines and biologicals. The publication of such information enables the Australian public to be better informed about the safety of medicines and biologicals, 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 such products for Australians.

**Conclusion**

The instrument is compatible with human rights because it maintains and supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.