

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Advisory Committee Meetings) (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 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. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C) of the Act.

The *Therapeutic Goods (Advisory Committee Meetings) (Information) Specification 2022* (“the Specification”) is a legislative instrument made under subsection 61(5D) of the Act. It 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 therapeutic goods information relating to advisory committee meetings to the public, on a range of matters relating to therapeutic goods including the safety and quality or performance of medicines, medical devices and biologicals. The Specification repeals and replaces the *Therapeutic Goods Information (Information about Advisory Committee Meetings) Specification 2014* (“the former Specification”).

### **Background**

A number of important expert advisory committees are established under Part 6 of the *Therapeutic Goods Regulations 1990* (“the Regulations”). These are currently set out in Divisions 1A to 1EB of Part 6. The committees are designed to support the objects and administration of the Act through the provision of critically important expert advice to the Minister and the Secretary about a range of therapeutic goods including medicines, medical devices, complementary medicines, biologicals and vaccines.

For instance, the Advisory Committee on Medicines (“ACM”) provides independent medical and scientific advice to the Minister for Health and Aged Care and the Secretary of the Department of Health on issues relating to the safety, quality and efficacy of medicines supplied in Australia, including issues relating to pre-market and post-market assessment of such products.

Similarly, the Advisory Committee on Vaccines provides independent medical and scientific advice to the Minister and Secretary on issues relating to the safety, quality and efficacy of vaccines supplied in Australia including issues relating to pre-market assessment, post-market monitoring and safe use in national immunisation programmes.

Membership of ACM and the other advisory committees established under Part 6 of the Regulations comprises professionals with specific scientific, medical or clinical expertise, as well as appropriate consumer health issues relating to medicines.

The purpose of the Specification is to authorise the release of therapeutic goods information to the public about the matters considered by the relevant advisory committees, to support transparency and better inform the public about the role and nature of committee advice, and its context in the decision-making process for evaluating new therapeutic goods for marketing approval or for taking regulatory action from a post-market perspective.

The Specification also repeals the former Specification, with the principal update compared to the former Specification being to identify that the Specification relates to those committees established under Part 6 of the Regulations, ensuring that the current suite of advisory committees established in Part 6 are covered as well as any new committees that may be added to Part 6 in the future. Note that although a range of measures are provided for in Part 6 of the Regulations in relation to the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling, the release of therapeutic goods information in connection with these committees is not authorised by the Specification, as those committees are established by sections 52B and 52C of the Act, respectively, rather than Part 6.

The Specification authorises the release of the same kinds of therapeutic goods information as the former Specification, without amendment of this aspect.

## **Consultation**

Specific consultation was not considered necessary, and therefore not undertaken, in relation to the making of the Specification, as it reflects a minor and machinery measure to update the authorisation of the release to the public of therapeutic goods information about advisory committees, without substantially altering existing arrangements. In particular, the instrument does not reflect any changes to the description of the information able to be released, compared to the former Specification.

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 the day after registration on the Federal Register of Legislation.

## **Details of the *Therapeutic Goods (Advisory Committee Meetings) (Information) Specification 2022***

### **Section 1 - Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Advisory Committee Meetings) (Information) Specification 2022* (“the Specification”).

### **Section 2 - Commencement**

This section provides that the Specification commences 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(5D) of the *Therapeutic Goods Act 1989* (“the Act”).

### **Section 4 - Definitions**

This section provides the definitions for certain terms used in the Specification, including ‘committee’, ‘Regulations’ and ‘therapeutic goods information’. The section also notes that a number of terms have the meaning given in subsection 3(1) of the Act, including ‘Secretary’.

### **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 the table in Schedule 1 to the Specification.

### **Section 6 - Repeals**

This section provides that the instruments specified in Schedule 2 are repealed.

### **Schedule 1—Specified kinds of therapeutic goods information**

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

The kinds of information specified includes information about the nature or content of any discussion about matters or items considered by a committee at a committee meeting, or a summary of such a discussion.

### **Schedule 2—Repeals**

This Schedule repeals the *Therapeutic Goods Information (Information about Advisory Committee Meetings) Specification 2014*.

## Statement of Compatibility with Human Rights

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

### *Therapeutic Goods (Advisory Committee Meetings) (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 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”).

The *Therapeutic Goods (Advisory Committee Meetings) (Information) Specification 2022* (“the instrument”) is a legislative instrument made under subsection 61(5D) of the Act. It 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 therapeutic goods information relating to advisory committee meetings to the public, on a range of matters relating to therapeutic goods including the safety and quality or performance of medicines, medical devices and biologicals. The instrument also repeals the *Therapeutic Goods Information (Information about Advisory Committee Meetings) Specification 2014* (“the former instrument”).

A number of important expert advisory committees are established under Divisions 1A to 1EB of Part 6 of the *Therapeutic Goods Regulations 1990* (“the Regulations”). The committees are designed to support the objects and administration of the Act through the provision of critically important expert advice to the Minister and the Secretary about a range of therapeutic goods including medicines, medical devices, complementary medicines, biologicals and vaccines.

For instance, the Advisory Committee on Medicines (“ACM”) provides independent medical and scientific advice to the Minister for Health and Aged Care and the Secretary of the Department of Health on issues relating to the safety, quality and efficacy of medicines supplied in Australia, including issues relating to pre-market and post-market assessment of such products.

Similarly, the Advisory Committee on Vaccines provides independent medical and scientific advice to the Minister and Secretary on issues relating to the safety, quality and efficacy of vaccines supplied in Australia including issues relating to pre-market assessment, post-market monitoring and safe use in national immunisation programmes.

Membership of ACM and the other advisory committees established under Divisions 1A to 1EB of Part 6 of the Regulations comprises professionals with specific scientific, medical or clinical expertise, as well as appropriate consumer health issues relating to medicines.

The purpose of the instrument is to authorise the release of therapeutic goods information to the public about the matters considered by the relevant advisory committees, to support transparency and better inform the public about the role and nature of committee advice, and its context in the decision-

making process for evaluating new therapeutic goods for marketing approval or for taking regulatory action from a post-market perspective.

The instrument also repeals the former instrument, with the principal update compared to the former instrument being to identify that the instrument relates to those committees established under Part 6 of the Regulations, ensuring that the current suite of advisory committees established under Part 6 are covered as well as any new committees that may be added to Part 6 in the future.

### **Human rights implications**

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“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 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 helping to ensure greater transparency and support public awareness about the role and nature of advisory committee advice in informing the regulation of therapeutic goods under the Act, including in relation to significant public health matters.

### **Conclusion**

This instrument is compatible with human rights because it supports the right to health and does not raise any other human rights issues.