EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 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.

Section 42BAA of the Act provides that the Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods, known as the Therapeutic Goods Advertising Code.

The *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* ("the Code") is made under section 42BAA and specifies a range of requirements relating to the advertising of therapeutic goods in Australia. The Code repealed and replaced the *Therapeutic Goods Advertising Code (No.2) 2018* ("the former Code") with effect from 1 January 2022.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* ("the New Permission"), made under section 42DK of the Act, repeals and replaces the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* (which would otherwise cease on 31 December 2022), with effect from 20 December 2022. The New Permission reproduces the earlier permission, and amends the conditions with the effect of providing that an advertisement about COVID-19 vaccines cannot contain a reference to the name of the sponsor or manufacturer of the relevant therapeutic goods (in addition to trade names or active ingredients of the goods) unless the advertisement is made by an approved COVID-19 vaccination provider or, in circumstances where the advertisement is made by the sponsor or the manufacturer, the name of the sponsor or the manufacturer appears in a copyright notice.

The purpose of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 2022* ("the Amendment Instrument") is to include a reference to the New Permission in the Code, and so incorporate the New Permission as in force or existing on 20 December 2022. The reference to the New Permission in the Code has the effect that the Code does not apply to an advertisement that is made in accordance with the New Permission.

Background

The Australian Government's national vaccination program for COVID-19 is widely accepted as being critical to protecting the public health and safety of the Australian population. A public health campaign, within the meaning of the Code, continues to be promoted by the Australian Government to encourage Australians to get vaccinated. A public health campaign means a campaign about a public health matter that is conducted, approved or funded by government from across Australia.

Health professionals and key parts of Australian business have indicated their recognition of the importance of the national vaccination program for COVID-19 for public health and the safety of Australians and their desire to contribute to the national conversation about vaccination. Health professionals carry significant credibility with the public and have the ability to enhance vaccine uptake by making public promotional statements and contributing to the countering of misinformation. In light of that recognition, businesses have expressed a desire to supplement the public health campaign with messages of encouragement and support, including by offering

promotions to inspire Australians to be vaccinated. Examples include offers of food and beverages, and subsidised travel to attend vaccination appointments.

To facilitate this welcome support, a delegate of the Secretary of the Department made a permission under section 42DK of the Act, the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021,* on 4 June 2021, to make specified advertisements in support of the public health campaign containing certain representations lawful. An advertisement was only allowed under this permission if it was consistent with Commonwealth health messaging in relation to the National COVID-19 Vaccination Program; did not contain a reference to trade names or active ingredients of vaccines; made no comparisons or statements that the vaccines cannot cause harm or have no side effects; and were not false or misleading. If the relevant promotion included an offer of valuable consideration (such as a reward for vaccination), it had to contain a statement to the effect that the vaccination must be undertaken on the advice of a health practitioner and not promote any particular vaccine, and alcohol, tobacco or medicines (other than listed medicines) could not be offered as rewards.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021,* which commenced on 10 July 2021, repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021*. This permission was made in the same terms except that alcohol was no longer excluded from the scope of valuable consideration, and so was permitted to be offered to people who have been fully vaccinated under the National COVID-19 Vaccination Program. Such an offer of alcohol is subject to the strict condition that it must not encourage excessive or rapid consumption of alcohol, nor have strong or evident appeal to minors. The offer and supply of alcohol must also be consistent with Commonwealth and state and territory codes and legislation in respect to alcohol advertising, and state and territory codes, guidelines and regulations in respect to the service and consumption of alcohol, including compliance with the Responsible Service of Alcohol requirements.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021*, which commenced on 28 July 2021, repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021.* This permission enabled approved COVID-19 vaccination providers to mention trade names in promotional material, principally to facilitate vaccination bookings and otherwise to provide information relating to their availability.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021*, which commenced on 24 September 2021, repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021*. This permission had the effect of extending the restricted representations that may be made in specified advertisements to include offers of valuable consideration to persons who have been partly (as well as fully) vaccinated in accordance with the National COVID-19 Vaccination Program.

The New Permission repeals and replaces the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021*, with effect from 20 December 2022. The New Permission amends the conditions with the effect of providing that an advertisement cannot contain any reference to the name of the sponsor or manufacturer of the relevant therapeutic goods (in addition to trade names or active ingredients of the goods) unless the advertisement is made by an approved COVID-19 vaccination provider, or is made by the sponsor or the manufacturer and the name of the sponsor or the manufacturer appears only in a copyright notice.

The purpose of the permission is to enable advertisers to disseminate information about the use and availability of COVID-19 vaccines, without allowing for the promotion of specific vaccines. For this reason, the former permissions have permitted only approved COVID-19 vaccination providers to refer to the trade names of COVID-19 vaccines. However, COVID-19 vaccines are more commonly identified by the name of the sponsor or the manufacturer of the vaccine, and consumers generally recognise the vaccines by reference to these names, and so the New Permission makes a

minor amendment to also ensure that only advertisements made by approved COVID-19 vaccination providers can refer to specific COVID-19 vaccines.

Consistent with advertisements that are part of, or otherwise comprise, a public health campaign, it is appropriate that advertisements falling within the terms of the New Permission are excluded from the application of the Code. Key requirements of the Code that are intended to ensure that the promotion of medicines is appropriate, including restrictions on what might be included in relevant advertisements, are replicated in the specific terms on which the New Permission has been made.

Relevantly, an application provision in the New Permission clarifies that the instrument does not apply to an advertisement that is, or forms part of, a Commonwealth, state or territory health campaign that is made in accordance with the *Therapeutic Goods (Restricted Representations—Government Health Campaigns) Permission 2019*.

The Amendment Instrument amends the Code to supplement the kinds of advertisements to which the Code does not apply to include an advertisement that is made in accordance with the New Permission. The former permissions made under section 42DK of the Act mentioned above have been referenced in the Code and former Code for this purpose. The Amendment Instrument therefore amends the Code to exclude advertisements within the terms of the New Permission from the application of the Code. The effect of the Amendment Instrument is that, equivalent to the disapplication of the Code to public health campaigns, the Code does not apply to advertisements to which the New Permission applies.

Incorporation by reference

The Amendment Instrument incorporates by reference the New Permission, which is an administrative instrument made by a delegate of the Secretary under section 42DK of the Act.

The New Permission is not incorporated in the Code dynamically. It is incorporated as in force or existing on a particular date, that being 20 December 2022. The New Permission is published in accordance with the requirements under subsection 42DK(6) of the Act on the Australian Government Department of Health and Aged Care's website. It is freely available at www.tga.gov.au.

Consultation

Targeted consultation in relation to the New Permission was undertaken with Medicines Australia. No objections were raised on the proposal for the New Permission to clarify that only advertisements made by approved vaccination providers can refer to specific COVID-19 vaccines by referencing the trade name, sponsor or manufacturer name, or active ingredient.

The Office of Impact Analysis has advised that the Amendment Instrument is unlikely to have more than a minor regulatory impact, and therefore an Impact Analysis is not required (OBPR22-03782).

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

The Amendment Instrument 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 Amendment Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 20 December 2022.

Attachment A

Details of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 2022* ("the Amendment Instrument").

Section 2 – Commencement

This section provides that the Amendment Instrument commences on 20 December 2022.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument is section 42BAA of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1—Amendments

Schedule 1 amends the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* ("the Code Instrument").

Item 1 repeals and replaces paragraph 6(1)(c) of Schedule 1 to the Code Instrument, to provide that the Therapeutic Goods Advertising Code does not apply to an advertisement made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* made under section 42DK of the Act, as in force or existing on 20December 2022.

Item 1 also substitutes the note at the end of paragraph 6(1)(c) of Schedule 1 to the Code Instrument, and explains that the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* is published on the TGA website.

Item 2 provides for the amendments made by the Amendment Instrument to apply in relation to an advertisement occurring after the commencement of the Amendment Instrument.

Schedule 2—Repeals

Item 1 repeals the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021.*

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 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 (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 2022* ("the instrument") is made under section 42BAA of the *Therapeutic Goods Act 1989* ("the Act"). The purpose of the instrument is to amend the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* ("the Code Instrument") to include a reference to the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* ("the new permission") in the Code Instrument.

The reference to the new permission in the Code Instrument has the effect that the Therapeutic Goods Advertising Code ("the Code") (set out in Schedule 1 to the Code Instrument) does not apply to an advertisement that is made in accordance with the new permission. The new permission has the effect of providing that specified advertisements about COVID-19 vaccines cannot contain any reference to the name of the sponsor or manufacturer of the relevant therapeutic goods (in addition to trade names or active ingredients of the goods) unless the advertisement is made by an approved COVID-19 vaccination provider or is made by the sponsor or the manufacturer and the name of the sponsor or the manufacturer appears only in a copyright notice.

The Australian Government's national vaccination program for COVID-19 is widely accepted as being critical to protecting the public health and safety of the Australian population. A public health campaign, within the meaning of the Code, continues to be promoted by the Australian Government to encourage Australians to get vaccinated. A public health campaign means a campaign about a public health matter that is conducted, approved or funded by government from across Australia.

Health professionals and key parts of Australian business have indicated their recognition of the importance of the national vaccination program for COVID-19 for public health and the safety of Australians and their desire to contribute to the national conversation about vaccination. Health professionals carry significant credibility with the public and have the ability to enhance vaccine uptake by making public promotional statements and contributing to the countering of misinformation. In light of that recognition, businesses have expressed a desire to supplement the public health campaign with messages of encouragement and support, including by offering promotions to inspire Australians to be vaccinated. Examples include offers of food and beverages, and subsidised travel to attend vaccination appointments.

To facilitate this welcome support, a delegate of the Secretary of the Department made a permission under section 42DK of the Act, the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* on 4 June 2021, to make specified advertisements in support of the public health campaign containing certain representations lawful. Consistent with the usual parameters of a public health campaign, advertisements were only allowed if they were consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19; did not contain a reference to trade names or active ingredients of vaccines; made no

comparisons or statements that the vaccines could not cause harm or have no side effects; and were not false or misleading. If the relevant promotion included an offer of valuable consideration (such as a reward for vaccination), it had to contain a statement to the effect that the vaccination must be undertaken on the advice of a health practitioner and not promote any particular vaccine, and alcohol, tobacco or medicines (other than listed medicines) could not be offered as rewards.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021,* which commenced on 10 July 2021, repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021*. This permission was made in the same terms except that alcohol was no longer excluded from the scope of valuable consideration, and so was permitted to be offered to people who have been fully vaccinated under the National COVID-19 Vaccination Program. Such an offer of alcohol is subject to the strict condition that it must not encourage excessive or rapid consumption of alcohol, or have strong or evident appeal to minors. The offer and supply of alcohol must also be consistent with Commonwealth and state and territory codes and legislation in respect to alcohol advertising, and state and territory codes, guidelines and regulations in respect to the service and consumption of alcohol, including compliance with Responsible Service of Alcohol requirements.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021*, which commenced on 28 July 2021, repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021.* This permission was made in the same terms except that it permitted an approved COVID-19 vaccination provider to publicise the trade name of the COVID-19 vaccine available for administration by the provider. This permission enabled approved COVID-19 vaccination providers to mention trade names in promotional material, principally to facilitate vaccination bookings and otherwise to provide information relating to their availability.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021*, which commenced on 24 September 2021, repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021.* This permission had the effect of extending the restricted representations that may be made in specified advertisements to include offers of valuable consideration to persons who have been partly (as well as fully) vaccinated in accordance with the National COVID-19 Vaccination Program.

The new permission, which commenced on 20 December 2022, repeals and replaces the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* (which would otherwise cease on 31 December 2022). The new permission amends the conditions of the permission with the effect that an advertisement cannot contain any reference to the name of the sponsor or manufacturer of the relevant therapeutic goods (in addition to trade names or active ingredients of the goods) unless the advertisement is made by an approved COVID-19 vaccination provider.

The purpose of the permission is to enable advertisers to disseminate information about the use and availability of COVID-19 vaccines, without allowing for the promotion of specific vaccines. For this reason, the former permissions have permitted only approved COVID-19 vaccination providers to refer to the trade names of COVID-19 vaccines. However, COVID-19 vaccines are commonly identified by the name of the sponsor or manufacturer of the vaccine, and consumers generally recognise the vaccines by reference to these names, and so the new permission makes a minor amendment to also ensure that only approved COVID-19 vaccination providers can refer to the sponsor or manufacturer of COVID-19 vaccines.

Consistent with advertisements that are part of, or otherwise comprise, a public health campaign, it is appropriate that advertisements falling within the terms of the new permission are excluded from the application of the Code. Key requirements of the Code that are intended to ensure appropriate promotions of medicines, including restrictions on what might be included in relevant advertisements, are replicated in the specific terms on which the new permission has been made.

Relevantly, an application provision in the new permission clarifies that the instrument does not apply to an advertisement that is, or forms part of, a Commonwealth, state or territory health campaign that is made in accordance with the *Therapeutic Goods (Restricted Representations—Government Health Campaigns) Permission 2019*.

The instrument amends the Code Instrument to supplement the kinds of advertisements to which the Code does not apply to include an advertisement that is made in accordance with the new permission. The former permissions made under section 42DK of the Act mentioned above had been referenced in the Code and former Code for this purpose. The instrument therefore amends the Code Instrument to exclude advertisements within the terms of the new permission from the application of the Code. The effect of the instrument is that, equivalent to the disapplication of the Code to public health campaigns, the Code does not apply to advertisements to which the new permission applies.

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 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 providing for the lawful promotion of advertisements falling within the terms of the new permission, consistent with public health campaigns, which are excluded from the application of the Code. Because the key requirements of the Code that are intended to ensure appropriate promotions of medicines, including the restrictions on what might be included in relevant advertisements, are replicated in the specific terms on which the new permission has been made, the right to health is appropriately protected and promoted.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.