

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021

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.

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 Advertising Code (No.2) 2018* (“the Code”) is made under section 42BAA and commenced on 1 January 2019, with the exception of Part 4 of Schedule 1, which commenced on 1 September 2020. The Code specifies a range of requirements relating to the advertising of therapeutic goods in Australia.

The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* (“the New Permission”) was made under section 42DK of the Act on 23 September 2021. It repeals and replaces the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021* with effect from 24 September 2021. The New Permission reproduces the earlier permission; and extends 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 purpose of the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021* (“the Amendment Instrument”) is to include a reference to the New Permission in the Code, to incorporate the New Permission as in force or existing on 24 September 2021. 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 is presently conducting a national vaccination program for COVID-19, widely accepted as critical to protecting the public health and safety of the Australian population. A public health campaign, within the meaning of the Code, is being 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. There is also clear recognition that the program is also critical to the opening of Australia’s borders and to the health of the Australian economy. 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, on 4 June 2021 a delegate of the Secretary of the Australian Government Department of Health made a permission under section 42DK of the Act, the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* (“the Initial Permission”). An advertisement containing certain representations is only allowed under this permission if it is consistent with Commonwealth health messaging in relation to the National COVID-19 Vaccination Program; does not contain a reference to trade names or active ingredients of vaccines; makes no comparisons or statements that the vaccines cannot cause harm or have no side effects; and is 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* repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* with effect from 10 July 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* repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021* in order to allow 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 New Permission repealed and replaced *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021*. The New Permission extends 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.

Until now, incentives and rewards have only been available to those who have had completed a full course of vaccinations. Full vaccination is particularly important to maximise protection against infection and serious illness from the delta variant of COVID-19. However, as national vaccination rates have significantly increased in the last few weeks, recent data has shown that almost all Australians who receive a first dose of a COVID-19 vaccine will proceed to have their second vaccination within the recommended timeframe.

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 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 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 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.

Notably, the New Permission will cease to have effect on 31 December 2022.

Incorporation by reference

The Amendment Instrument incorporates by reference the New Permission made by a delegate of the Secretary under section 42DK of the Act. The New Permission is an administrative instrument made by a delegate of the Secretary on 23 September 2021 and commences on 24 September 2021.

The New Permission is not incorporated in the Code dynamically. It is incorporated as in force or existing on a particular date, that being 24 September 2021. The New Permission is published in accordance with the requirements under subsection 42DK(6) of the Act on the Australian Government Department of Health's website. It is freely available at www.tga.gov.au.

Consultation

Consultation was undertaken in relation to the former permissions made under section 42DK of the Act with key stakeholders, including Qantas, the Business Council of Australia, the Australian Medical Association and the Royal Australian College of General Practitioners. The question as to whether the terms of a permission should allow the offer of incentives to persons who had only received a single dose of a COVID-19 vaccine was considered during the consultation with these key stakeholders in relation to the Initial Permission. However, at the time the Initial Permission was made (4 June 2021) there were concerns with such an approach, as the public health emphasis was on encouraging people to receive both doses of the vaccine to maximise their protection against COVID-19.

In late September 2021, it became apparent that those who had received their first dose were, overwhelmingly, going on to have their second dose and the public health emphasis turned to addressing vaccine hesitancy. Subsequently, targeted consultations occurred with the National Aboriginal Community Controlled Health Organisation (NACCHO) and the Australian Rugby League Commission, both of which were supportive of an approach to allow incentives for a single dose of the COVID-19 vaccine to assist in addressing vaccine hesitancy. The Queensland Government also asked that incentives be allowed for a single dose.

The New Permission reflects this feedback. In particular, the New Permission has the effect of authorising NACCHO's proposal to address vaccine hesitancy within the indigenous community by offering pre-paid phone cards to indigenous Australians who came forward to receive their first dose of a COVID-19 vaccine, enabling this offer to be made as an incentive for those who are partially or fully vaccinated (or both).

The Prime Minister granted an exemption from the requirement to complete a regulatory impact analysis in the form of a Regulation Impact Statement for all Australian Government measures made in response to COVID-19. The Amendment Instrument is made in response to the public health emergency and relies on this exemption (OBPR ID: 26445).

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 the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021* (“the Amendment Instrument”).

Section 2 – Commencement

This section provides that the Amendment Instrument 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 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 Advertising Code (No.2) 2018* (“the Code”).

Item 1 repeals and replaces paragraph 6(2)(c) of the Code to provide that the Code does not apply to an advertisement made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* made under section 42DK of the Act, as in force or existing on 24 September 2021.

Item 2 substitutes Note 1 at the end of subsection 6(2) of the Code and explains that the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* is published on the TGA website.

Item 3 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. 3) 2021*.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021

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 Amendment (Therapeutic Goods Advertising Code) Instrument (No. 5) 2021* (“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 Advertising Code (No.2) 2018* (“the Code”) to include a reference to the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 4) 2021* (“the new permission”) in the Code.

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. The new permission enables restricted representations that may be made in specified advertisements regarding COVID-19 vaccines 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 Australian Government is presently conducting a national vaccination program for COVID-19, widely accepted as critical to protecting the public health and safety of the Australian population. A public health campaign, within the meaning of the Code, is being 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. There is also clear recognition that the program is also critical to the opening of Australia’s borders and to the health of the Australian economy. 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 Australian Government Department of Health made a permission under section 42DK of the Act, the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 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 are only allowed under this permission if they are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19; do not contain a reference to trade names or active ingredients of vaccines; make no comparisons or statements that the vaccines cannot cause harm or have no side effects; and are 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* repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* with effect from 10 July 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* repealed and replaced the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021* in order to allow 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 new permission repealed and replaced *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021*. The new permission extends 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.

Until now, incentives and rewards have only been available to those who have had completed a full course of vaccinations. Full vaccination is particularly important to maximise protection against infection and serious illness from the delta variant of COVID-19. However, as national vaccination rates have significantly increased in the last few weeks, recent data has shown that almost all Australians who receive a first dose of a COVID-19 vaccine will proceed to have their second vaccination within the recommended timeframe.

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 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.

The 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 for this purpose. The 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 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 current permission, consistent with public health campaigns, which are excluded from the application of the Code. Because the key requirements of the Code 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.