

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 2) 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 of the Act and commenced on 1 January 2019 (except for 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 Amendment (Therapeutic Goods Advertising Code) Instrument 2021* (“the Former Amendment Instrument”) amended 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 *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* (“the Former Permission”). The Former Permission was identified as being made under section 42DK of the Act, as in force or existing on 5 June 2021. The effect of the Former Amendment Instrument was that, equivalent to the disapplication of the Code to public health campaigns, the Code did not apply to advertisements to which the Former Permission applied. On 9 July 2021, the Former Permission was repealed and replaced by the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021* (“the Current Permission”).

The purpose of the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 2) 2021* (“the Amendment Instrument”) is to replace references to the Former Permission in the Code with references to the Current Permission, and so incorporate the Current Permission as in force or existing on 10 July 2021.

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 represented to the Australian Government their recognition of the importance of the national vaccination program for COVID-19 for the public health and 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 offers of practical support including by promotions and offers intended to encourage 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 an instrument under section 42DK of the Act (that being, the Former Permission) to lawfully enable advertisements of this nature. The effect of the Former Permission was 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, the Former Permission only allowed advertisements that are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19; advertisements that do not contain a reference to trade names or active ingredients of vaccines; advertisements that make no comparisons or statements that the vaccines cannot cause harm or have no side effects; and advertisements that 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. The Former Permission did not allow for alcohol, tobacco or medicines (other than listed medicines) to be offered as rewards.

On 9 July 2021, the Former Permission was repealed and replaced by the Current Permission. The Current Permission is made in the same terms as the Former Permission, except for the scope of valuable consideration (as defined in section 4 of the Current Permission). Under the Current Permission, alcohol is no longer excluded from the scope of valuable consideration, and so may be offered to people who have been fully vaccinated under the Government's 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.

Having regard to its support for the Australian Government's own health messaging for the national vaccination program for COVID-19, it is appropriate that advertisements falling within the terms of the Current Permission are, like public health campaigns, 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 Current Permission has been made.

The Amendment Instrument therefore amends the Code to exclude advertisements within the terms of the Current Permission from the application of the Code.

Incorporation by reference

The Amendment Instrument incorporates by reference the Current Permission made by a delegate of the Secretary under section 42DK of the Act. The Current Permission is an administrative instrument that was made on 9 July 2021 and commenced on 10 July 2021. The Current Permission is not incorporated in the Code dynamically. It is incorporated as in force or existing on a particular date, that being 10 July 2021. The Current 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

The Amendment Instrument replaces references to the Former Permission in the Code with references to the Current Permission, and so incorporate the Current Permission as in force or existing on 10 July 2021. Consultation was undertaken in relation to the Former Permission and the Former Amendment Instrument with key stakeholders, including Qantas and the Business Council of Australia, offering support for the Australian Government's health messaging for the national vaccination program for COVID-19.

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. 2) 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 2) 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 that is covered by the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021* made under section 42DK of the Act, as in force or existing on 10 July 2021.

Item 2 substitutes the note at the end of subsection 6(2) of the Code and explains that the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 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 that Instrument.

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. 2) 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. 2) 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”).

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 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 represented to the Australian Government their recognition of the importance of the national vaccination program for COVID-19 for the public health and 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 offers of practical support including by promotions and offers intended to encourage 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 the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* (“the former permission”) under section 42DK of the Act on 4 June 2021 to lawfully enable advertisements of this nature. The effect of the former permission was 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, the former permission only allowed: advertisements that are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19; advertisements that do not contain reference to trade names or active ingredients of vaccines; advertisements that make no comparisons or statements that the vaccines cannot cause harm or have no side effects; and advertisements that 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. The former permission did not allow for alcohol, tobacco or medicines (other than listed medicines) to be offered as rewards.

On 9 July 2021, the former permission was repealed and replaced by the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 2) 2021* (“the current permission”). The current permission is made in the same terms as the former permission, except

for the scope of valuable consideration (as defined in section 4 of the current permission). Under the current permission, alcohol is no longer excluded from the scope of valuable consideration, and so may 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.

Having regard to its support for the Australian Government's own health messaging for the national vaccination program for COVID-19, it is appropriate that advertisements falling within the terms of the current permission are, like public health campaigns, excluded from the application of the Code. 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 current permission has been made.

The instrument therefore amends the Code to exclude advertisements within the terms of the current permission from the application of the Code.

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, like 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 current permission has been made, the right to health is appropriately protected and promoted. Further, the inclusion of alcohol within the scope of valuable consideration that is permitted to be offered to people who are fully vaccinated is, consistent with the usual public health measures associated with the service and consumption of alcohol, subject to the strict conditions that the advertising must not encourage excessive or rapid consumption of alcohol, or have strong or evident appeal to minors. The offer and supply of alcohol will need to comply with Commonwealth and state and territory regulation including Responsible Service of Alcohol requirements.

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.