

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 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 (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 Amendment Instrument”) amends the Code to supplement the kinds of advertisements in which it does not apply to include an advertisement which is made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* (“the Permission”) made under section 42DK of the Act, as in force or existing on 5 June 2021. The effect is that, equivalent to the disapplication of the Code to a public health campaign, the Code does not apply to advertisements to which the Permission applies.

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 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 has therefore made an instrument under section 42DK of the Act (the Permission mentioned above) to lawfully enable advertisements of this nature. The effect of the Permission is to make specified advertisements in support of the public health campaign lawful containing certain representations. Consistent with the usual parameters of a public health campaign, the Permission only allows advertisements which are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19; those which do not

contain a reference to trade names or active ingredients of vaccines; advertisements which 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 includes an offer of valuable consideration, such as a reward for vaccination, it must 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 permission does not allow for alcohol, tobacco or medicines (other than listed medicines) to be offered as rewards.

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 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 Permission has been made.

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

Incorporation by reference

The Amendment Instrument incorporates by reference the Permission made by a delegate of the Secretary under section 42DK of the Act. That Permission is an administrative instrument that was made on 4 June 2021 and commences on 5 June 2021. The Permission is not incorporated in the Amendment Instrument dynamically. It is incorporated as in force or existing on a particular date, that being, 5 June 2021. The Permission is published in accordance with the requirements under section 42DK(6) of the Act on the Australian Government Department of Health's website. It may be found at www.tga.gov.au.

Consultation

The amendments made by the Amendment Instrument were consulted on with key stakeholders, including Qantas and the Business Council of Australia, offering to support the Australian Government's health messaging for the national vaccination program for COVID-19.

Consistent with the Prime Minister's exemption from the requirement to complete 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 (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 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 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 inserts a new paragraph (c) at the end of paragraph 6(2)(b) 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 2021* made under section 42DK of the Act, as in force or existing on 5 June 2021.

Item 2 provides for the application of 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 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 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 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 has therefore made a permission under section 42DK of the Act to lawfully enable advertisements of this nature. The effect of that permission is to make specified advertisements in support of the public health campaign lawful. Consistent with the usual parameters of a public health campaign the permission only allows advertisements which are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19; those which do not contain reference to trade names or active ingredients of vaccines; advertisements which 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 includes an offer of valuable consideration, such as a reward for vaccination, it must 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 permission does not allow for alcohol, tobacco or medicines (other than listed medicines) to be offered as rewards.

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 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 permission has been made.

The instrument therefore amends the Code to exclude advertisements within the terms of the 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 (“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 permission, like public health campaigns, 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 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.