EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 4) 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 purpose of the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 4) 2021* ("the Amendment Instrument") is to add a reference to the *Therapeutic Goods (Restricted Representations—HHD Group Pty Limited) (AZ) Permission 2021* ("the Permission") to subsection 6(2) of the Code. By adding a reference to the Permission in this provision, the Amendment Instrument has the effect that the Code does not apply to an advertisement that is made in accordance with the 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.

HHD Group Pty Limited (ACN 119920204) has communicated to the Australian Government its wish to support the national vaccination program for COVID-19 for the public health and safety of Australians. The @TheFactsination campaign, initiated by a group of advertising bodies led by HHD Group Pty Limited, launched on Instagram on 9 August 2021 in support of an open letter from prominent health experts urging Australians to 'get jabbed with whatever TGA-approved vaccine was available to them, including the AstraZeneca vaccine.'

@TheFactsination campaign uses the alphabet to illustrate activities which, by reference to sourced facts, present greater risks of death than the use of Vaxzevria (previously COVID-19 Vaccine AstraZeneca, and commonly known as AZ). From launch, the campaign has been more successful than anticipated, reaching hundreds of thousands of people through social media with promotions by print and paid television. An option presents for further and deeper penetration by prominent media platforms at no charge. The @TheFactsination campaign, with no connections with the pharmaceutical industry, is consistent with Commonwealth health messaging in relation to the National COVID-19 Vaccination Program, noting in particular the present and clear threat to public health presented by the highly contagious delta variant of COVID-19 and its penetration across Eastern Australia.

Taking account of these considerations, a delegate of the Secretary of the Australian Government Department of Health has made an instrument under section 42DK of the Act to lawfully enable

advertisements by HHD Group Pty Limited within certain conditions. The permission restricts advertisements to those which are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19 and consistently with the general obligations imposed by the Code, those which do not contain any comparisons with other COVID-19 vaccines, make no comparisons or statements that the vaccines cannot cause harm or have no side effects; and advertisements that are not inaccurate, false or misleading. There is also a requirement that the source of any claim relating to adverse events or mortality rates that are used in the advertisements are reviewed and agreed to by the Therapeutic Goods Administration prior to the advertisements being published or broadcast.

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. The permission is an administrative instrument that was made on 23 August 2021 and commences on 24 August 2021.

The permission is not incorporated in the Code dynamically. It is incorporated as in force or existing on a particular date, that being 24 August 2021. The 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 *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2021* 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 amendments made by the Amendment Instrument are consistent with the consultations on the basis of which the previous permission was made.

The Prime Minister granted an 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 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.

Attachment A

Details of the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 4) 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 4) 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 adds a new paragraph (d) at the end of paragraph 6(2)(c) of the Code to provide that the Code does not apply to an advertisement that is made in accordance with the *Therapeutic Goods (Restricted Representations—HHD Group Pty Limited) (AZ) Permission 2021* made under section 42DK of the Act, as in force or existing on 24 August 2021.

Item 2 makes a consequential amendment to the existing note at the end of subsection 6(2).

Item 3 adds a second note at the end of subsection 6(2) of the Code, which explains that the *Therapeutic Goods (Restricted Representations—HHD Group Pty Limited) (AZ) Permission 2021* is published on the TGA website.

Item 4 provides that the amendments made by the Amendment Instrument apply in relation to an advertisement occurring after the commencement of the Amendment Instrument.

Attachment B

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. 4) 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. 4) 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 instrument adds a reference to the *Therapeutic Goods (Restricted Representations—HHD Group Pty Limited) (AZ) Permission 2021* ("the permission") to subsection 6(2) of the Code, with the effect that the Code does not apply to an advertisement that is made in accordance with the permission.

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.

HHD Group Pty Limited (ACN 119920204) has communicated to the Australian Government its wish to support the national vaccination program for COVID-19 for the public health and safety of Australians. The @TheFactsination campaign, initiated by a group of advertising bodies led by HHD Group Pty Limited, launched on Instagram on 9 August 2021 in response to an open letter from prominent health experts urging Australians to 'get jabbed with whatever TGA-approved vaccine was available to them, including the AstraZeneca vaccine.'

@TheFactsination campaign uses the alphabet to illustrate activities which, by reference to sourced facts, present greater risks of death than the use of Vaxzevria (previously COVID-19 Vaccine AstraZeneca, and commonly known as AZ). From launch, the campaign has been more successful than anticipated, reaching hundreds of thousands of people through social media with promotions by print and paid television. An option presents for further and deeper penetration by prominent media platforms at no charge. The @TheFactsination campaign, with no connections with the pharmaceutical industry, is consistent with Commonwealth health messaging in relation to the National COVID-19 Vaccination Program, noting in particular the present and clear threat to public health presented by the highly contagious delta variant of COVID-19 and its penetration across Eastern Australia.

Taking account of these considerations, a delegate of the Secretary of the Australian Government Department of Health has made an instrument under section 42DK of the Act to lawfully enable advertisements by HHD Group Pty Limited within certain conditions. The permission restricts advertisements to those which are consistent with Commonwealth messaging in relation to the national vaccination program for COVID-19 and consistently with the general obligations imposed by the Code, those which do not contain any comparisons with other COVID-19 vaccines, make no comparisons or statements that the vaccines cannot cause harm or have no side effects; and advertisements that are not inaccurate, false or misleading. There is also a requirement that the source of any claim relating to adverse events or mortality rates that are used in the advertisements

are reviewed and agreed to by the Therapeutic Goods Administration prior to the advertisements being published or broadcast.

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 ("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, 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 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.