EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020

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 Department of Health.

Section 7AA of the Act provides that the Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. The effect of a determination made under section 7AA is to exclude specified goods from the operation of the Act, including from the requirement for those goods to be included in the Australian Register of Therapeutic Goods ("the Register"), or manufactured pursuant to a licence issued under Part 3-3 of the Act.

Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3), and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act. The matters the Minister must have regard to are:

(a) whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act;

(b) whether it is appropriate in all the circumstances to apply the national system of controls established by the Act to regulate the specified goods; and

(c) whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

The *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* ("the Principal Determination") is made under section 7AA of the Act. The Principal Determination excludes specified hand sanitisers from the operation of the Act with reference to a number of matters including the final formulation, manufacturing practices, and presentation for supply of the goods.

The exclusion is necessary to facilitate the continued supply of hand sanitisers in Australia during the ongoing public health emergency caused by the outbreak of the disease known as coronavirus disease ("COVID-19"). The approach taken in the Principal Determination accords with the policy position of the United States Food and Drug Administration ("USFDA"), communicated in the *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* published March 2020. That policy position was informed by the World Health Organisation ("WHO") recommendations for the local production of hand sanitisers published in April 2010.

The *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020* ("the Amendment Determination") is made under section 7AA of the Act. The Amendment Determination amends the Principal Determination to clarify certain matters relating to the specification of hand sanitisers that are excluded goods for the purposes of the Act, and to introduce minor safety measures relating to presentation for supply. Moreover, following updates to the USFDA policy for hand sanitisers (revised 15 April 2020), the Amendment Determination aligns the TGA's approach with the USFDA, particularly with respect to the use of purified water in the manufacture of specified hand sanitisers. Accordingly, the Amendment Determination provides for the safety, quality and continued availability of specified hand sanitisers in Australia

during the COVID-19 public health emergency by ensuring that hand sanitisers, which are excluded from the operation of the Act, are manufactured and supplied in accordance with certain matters relating to the formulation and presentation for supply of those goods.

The amendments introduced by the Amendment Determination can be broadly categorised as those relating to the ingredients used in the manufacture of specified hand sanitisers, and those relating to the advertising and presentation for supply of those goods. The effect and operation of the Amendment Determination is detailed below accordingly. The Amendment Determination also contains transitional arrangements, which provide that the Principal Determination as it was in force before the commencement of the Amendment Determination continues to apply for the transition period ending on 30 June 2020 in relation to the manufacture and supply of goods as specified by the Principal Determination prior to the commencement of the Amendment Determination.

Amendments relating to ingredients

The Principal Determination provides that the water used in the manufacture of specified hand sanitisers must be distilled water or boiled cold water. In addition to boiling or distillation, the Amendment Determination introduces a definition for *other purification process*, which provides manufacturers with the option of undertaking an alternative purification process for water (such as reverse osmosis) provided that the process meets specified requirements.

Those requirements include that the purification process is validated to produce and distribute water that is of both acceptable microbiological quality (where the microbial count of the water is less than 100 colony forming units per millilitre) and acceptable chemical quality. Regular microbiological testing must be undertaken, including sampling at the point of use, by filtration of a suitable sample size through a membrane of nominal pore size not greater than 0.45 µm, using R2A agar and incubating on a single plate at 30-35°C, or on separate plates at 35-37°C and 20-22°C, for not less than 5 days. These test methods reflect the methods described in the current monograph relating to purified water in the British Pharmacopoeia and the European Pharmacopoeia, and the Australian and New Zealand Standard 4276.3.2:2003 *Water Microbiology – Method 3.2: Heterotrophic colony count methods – Plate count of water containing biocides*, respectively.

Moreover, the Principal Determination provides that the glycerol used in the manufacture of specified hand sanitisers must comply with an applicable standard in the British Pharmacopoeia, European Pharmacopoeia, or United States Pharmacopoeia-National Formulary (*pharmacopoeial grade*). The Amendment Determination relaxes this requirement for glycerol by specifying that glycerol may be manufactured in accordance with an applicable standard in the Food Chemicals Codex (*food standard grade*) as an alternative to the pharmacopoeial grade.

Finally, the Amendment Determination clarifies that a specified hand sanitiser made with ethanol may contain a denaturant such as denatonium benzoate (NLT 5ppm), sucrose octaacetate (0.12%w/v), or tertiary butyl alcohol (0.25%v/v).

Amendments relating to advertising and presentation for supply

In addition to the above, the Amendment Determination amends the matters relating to the advertising and presentation for supply of specified hand sanitisers specified in column 3 of the table in Schedule 1 to the Principal Determination. Most importantly among those amendments is the introduction of a safety measure providing that specified hand sanitisers must not be presented for supply in a way that is likely to result in the goods being mistaken for or confused with food or beverages. This amendment addresses concerns raised with the TGA about the inadvertent use of hand sanitisers supplied in inappropriate containers, such as those with a pop top lid, or in foil sachets or pouches with a spout. In addition, the Amendment Determination makes consequential

amendments to the labels specified in Schedule 2 to the Principal Determination to include a warning statement and contact details for the Poisons Information Centre.

Further, the Amendment Determination amends the labelling matters specified in column 3 of the table in Schedule 1 to the Principal Determination to permit (among other things) a batch number and expiry date to be included on labels for specified hand sanitisers, in addition to a statement that the formulation of the goods is based on the handrub formulation of the World Health Organization; and any caution, warning or other marking that relates to the safe use, transportation or storage of the goods.

Finally, the Amendment Determination permits advertising that is consistent with the information contained on the labels for specified hand sanitisers, and that includes information about where the goods may be purchased, and the associated price.

In accordance with the matters to be taken into account under subsection 7AA(3) of the Act, the amendments introduced by the Amendment Determination principally safeguard public health by ensuring ingredients used in the manufacture of specified hand sanitisers are of an acceptable quality and the presentation for supply of those goods would not lead to unsafe use. Further, it would not be appropriate to apply the national system of controls established by the Act, in circumstances where the benefits associated with the timely availability of the goods significantly outweighs the negligible risks associated with excluding the goods from regulation under the Act. Importantly, the goods would continue to be regulated, as those goods presently are, under consumer protection legislation and work place health and safety laws.

Background

On 11 March 2020, the World Health Organization ("WHO") declared the outbreak of COVID-19 caused by the pathogen virus known as severe acute respiratory syndrome coronavirus ("SARS-CoV-2") a pandemic. On 18 March 2020, the Governor-General made a declaration, acting with the advice of the Federal Executive Council, that a human biosecurity emergency exists in Australia.

COVID-19 represents a severe and immediate threat to public health, both in Australia and globally, placing significant pressure on health care systems and causing economic disruption. In order to respond to the COVID-19 outbreak effectively, appropriate clinical management and infection control in conjunction with implementation of community mitigation measures are necessary. Good hand hygiene is a critical part of Australia's response to the COVID-19 emergency. While washing hands with soap is considered the most effective way of practising good hand hygiene, hand sanitisers also play an important role in attempting to reduce the spread of microorganisms. This has led to increased demand for hand sanitisers in Australia and subsequent shortages in medical and health services.

Consultation

The Amendment Determination is made following considerable feedback received by the TGA in relation to the Principal Determination from members of the public, businesses, and industry representative bodies. The Australia Competition and Consumer Commission ("ACCC"), the National Industrial Chemicals Notification and Assessment Scheme ("NICNAS") and the Office of Best Practice Regulation ("OBPR") were consulted in the preparation of the Principal Determination.

Given the Amendment Determination specifies minor safety measures, clarifies certain matters in the Principal Determination, and otherwise relaxes the regulatory arrangements for specified hand sanitisers, the rule-maker considers that, in accordance with section 17 of the Legislation Act, public consultation was not necessary or appropriate in the circumstances.

Moreover, the Prime Minister has 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 (OBPR reference: 26445). The Amendment Determination is similarly made in response to the public health emergency.

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

The Amendment Determination 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 Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination 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 Determination is section 7AA 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 Determination 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 instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* ("the Principal Determination").

Item 1 of this Schedule inserts a new heading "Part 1—Preliminary" before section 1 of the Principal Determination.

Item 2 of this Schedule substitutes the note at the beginning of section 4 to also include a reference to 'batch'.

Item 3 of this Schedule inserts definitions for "acceptable microbiological quality" and "other purification process" in section 4 of the Principal Determination.

Item 4 of this Schedule inserts a new heading "Part 2—Excluded Goods" before section 5 of the Principal Determination.

Item 5 of this Schedule inserts a new Part 3, which deals with application, saving and transitional provisions. Specifically, this item inserts a new section 6, which provides that the Principal Determination as it was in force before the commencement of the Amendment Determination continues to apply for the duration of the transition period in relation to the manufacture and supply of goods as specified by the Principal Determination before the commencement of the Amendment

Determination. The transition period is defined in new subsection 6(1) as the period beginning on the day on which the Amendment Determination commences and ending on 30 June 2020.

Item 6 of this Schedule amends subparagraph (a)(i) in column 2 of table item 1 in Schedule 1 to the Principal Determination to allow specified hand sanitiser made with ethanol to contain a denaturant such as denatonium benzoate (NLT 5ppm), sucrose octaacetate (0.12%w/v) or tertiary butyl alcohol (0.25%v/v).

Item 7 of this Schedule repeals and replaces subparagraph (a)(ii) in column 2 of table item 1 in Schedule 1 to the Principal Determination to clarify that the water to be used in the formulation is purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process (which is defined in section 4 of the Principal Determination).

Item 8 of this Schedule amends subparagraph (a)(iii) in column 2 of table item 1 in Schedule 1 to the Principal Determination to provide that the glycerol specified in that subparagraph may be pharmacopoeial grade or food standard grade.

Item 9 of this Schedule inserts a new paragraph (ba) in column 2 of table item 1 in Schedule 1 to the Principal Determination. This paragraph requires the purified water specified in subparagraph (a)(ii) to be used as soon as practicable following purification to maintain the acceptable chemical quality, and the acceptable microbiological quality, of the water.

Item 10 of this Schedule inserts a reference to paragraph (ba) in paragraph (d) in column 2 of table item 1 in Schedule 1 to the Principal Determination, as a consequence of the amendment made by item 9.

Item 11 of this Schedule repeals and replaces the matters specified in column 3 of table item 1 in Schedule 1 to the Principal Determination, which relate to the advertising and presentation for supply of the specified goods. In particular, the amendments made by this item include the introduction of safety measures, and allow additional matters to be included on the labels of the goods, such as the batch number, expiry date, and specified warning statements.

Item 12 of this Schedule repeals and replaces subparagraph (a)(ii) in column 2 of table item 2 in Schedule 1 to the Principal Determination to clarify that the water to be used in the formulation is purified water derived from potable water that has been rendered sterile or otherwise purified by boiling, distillation or other purification process (which is defined in section 4 of the Principal Determination).

Item 13 of this Schedule amends subparagraph (a)(iii) in column 2 of table item 2 in Schedule 1 to the Principal Determination to provide that the glycerol specified in that subparagraph may be pharmacopoeial grade or food standard grade.

Item 14 of this Schedule inserts a new paragraph (ba) in column 2 of table item 2 in Schedule 1 to the Principal Determination. This paragraph requires the purified water specified in subparagraph (a)(ii) to be used as soon as practicable following purification to maintain the acceptable chemical quality, and the acceptable microbiological quality, of the water.

Item 15 of this Schedule inserts a reference to paragraph (ba) in paragraph (d) in column 2 of table item 2 in Schedule 1 to the Principal Determination, as a consequence of the amendment made by item 14.

Item 16 of this Schedule repeals and replaces the matters specified in column 3 of table item 2 in Schedule 1 to the Principal Determination, which relate to the advertising and presentation for supply of the specified goods. In particular, the amendments made by this item include the

introduction of safety measures, and allow additional matters to be included on the labels of the goods, such as the batch number, expiry date, and specified warning statements.

Item 17 of this Schedule repeals and replaces Schedule 2 to the Principal Determination, in order to make consequential amendments to the labels specified in that Schedule. These amendments amend the labels principally to include a warning statement and contact details for the Poisons Information Centre.

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 (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020

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 (Excluded Goods—Hand Sanitisers) Determination (No. 2) 2020* (the "amendment instrument") is made under section 7AA of the *Therapeutic Goods Act 1989* ("the Act"). The amendment instrument amends the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* ("the principal instrument"). The purpose of the amendment instrument is to amend the principal instrument to clarify certain matters relating to the specification of hand sanitisers that are excluded goods for the purposes of the Act, and to introduce minor safety measures relating to presentation for supply.

Moreover, following updates to the United States Food and Drug Administration ("USFDA") policy for hand sanitisers (revised 15 April 2020), the amendment instrument aligns the TGA's approach with the USFDA, particularly with respect to the use of purified water in the manufacture of specified hand sanitisers. Accordingly, the amendment instrument provides for the safety, quality and continued availability of specified hand sanitisers in Australia during the COVID-19 public health emergency by ensuring that hand sanitisers, which are excluded from the operation of the Act, are manufactured and supplied in accordance with certain matters relating to the formulation and presentation for supply of those goods.

Principally, the amendments introduced by the amendment instrument can be broadly categorised as those relating to the ingredients used in the manufacture of specified hand sanitisers, and those relating to the advertising and presentation for supply of those goods. The amendment instrument also contains transitional arrangements, which provide that the principal instrument as it was in force before the commencement of the amendment instrument continues to apply for the transition period ending on 30 June 2020 in relation to the manufacture and supply of goods as specified by the principal instrument prior to the commencement of the amendment instrument.

In accordance with the matters to be taken into account under subsection 7AA(3) of the Act, the amendments introduced by the amendment instrument principally safeguard public health by ensuring ingredients used in the manufacture of specified hand sanitisers are of an acceptable quality and the presentation for supply of those goods would not lead to unsafe use. Further, it would not be appropriate to apply the national system of controls established by the Act, in circumstances where the benefits associated with the timely availability of the goods significantly outweighs the negligible risks associated with excluding the goods from regulation under the Act. Importantly, the goods would continue to be regulated, as those goods presently are, under consumer protection legislation and work place health and safety laws.

Human rights implications

The amendment 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 amendment instrument promotes and supports the right to health by providing minor safety measures, as well as greater clarity in relation to the requirements for specified hand sanitisers that are excluded from the operation of the Act by virtue of the principal instrument. Good hand hygiene is a critical part of Australia's response to the public health emergency caused by the outbreak of COVID-19, and this includes appropriate use of hand sanitisers. The increased demand for hand sanitisers in light of the outbreak of COVID-19 has led to subsequent shortages in Australia. The principal instrument and the amendment instrument thereby support the Australian Government's response to the COVID-19 emergency by ensuring the continued supply of hand sanitisers in Australia, including in the context of medical and health services.

By specifying minor safety measures, more clearly and accurately reflecting matters for the specification of hand sanitisers, and otherwise relaxing the regulatory arrangements for these goods, the amendment instrument supports manufacturers to meet increased demand during the COVID-19 emergency; and therefore ensure the timely availability of hand sanitisers in Australia.

Conclusion

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