

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination 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 legislative instrument made under section 7AA of the Act is to exclude specified goods from the operation of the Act, including the requirement for those goods to be included in the Australian Register of Therapeutic Goods, or manufactured pursuant to a licence issued under Part 3-3 of the Act.

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. The exclusion is necessary to facilitate the urgent and continued supply of hand sanitisers in Australia during the current outbreak of the disease known as coronavirus disease (COVID-19). The Principal Determination supports the Australian Government’s response to the COVID-19 emergency by ensuring the supply of hand sanitiser in Australia, particularly in medical and health services.

The *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination 2020* (the “Amendment Determination”) is made under section 7AA of the Act. The purpose of the Amendment Determination is to make two minor editorial amendments to the Principal Determination.

The first amendment clarifies that the reference to the “Food Chemicals Codex” in the definition of *food standard grade* in section 4 of the Principal Determination is a reference to that document as in force or existing at the commencement of the Principal Determination. This is consistent with both the nature of the incorporation of the Food Chemicals Codex as described in the explanatory statement to the Principal Determination, and subsection 14(2) of the *Legislation Act 2003*. That subsection relevantly provides that, unless the contrary intention appears, a legislative instrument may not make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

The second amendment addresses an inadvertent error in Schedule 2 to the Principal Determination by repealing and substituting the front label specified in clause 1 of Part 2 of Schedule 2 with an amended label. The purpose of this amendment is simply to ensure that the contact details of the manufacturer or supplier are included on that label, consistent with the front label specified in clause 1 of Part 1 of Schedule 2 to the Principal Determination. Such information is necessary to ensure that manufacturers or suppliers of the specified goods may be readily identified and contacted by consumers. No other information on the front label has been changed.

### **Background**

Subsection 7AA(1) provides that the Minister may determine that specified goods are excluded goods for the purposes of the Act. Further, subsection 7AA(2) provides that the Minister may determine that specified goods are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified way.

A determination made under subsections 7AA(1) or 7AA(2) must be made by legislative instrument; and, in accordance with subsection 13(3) of the *Legislation Act 2003*, that determination may be made with reference to a class or classes of goods.

Before making a determination under section 7AA, the Minister is required to have regard to certain matters specified in subsection 7AA(3). In addition, the Minister may have regard to any other matter that the Minister considers relevant (subsection 7AA(4) refers).

The Principal Determination was made in response to the emergency caused by the coronavirus disease (COVID-19). The effect of the Principal Determination is to exclude specified hand sanitisers from the operation of the Act so that these goods may be manufactured and supplied urgently within Australia to deal with the emergency.

The Amendment Determination supports the Principal Determination by making two minor editorial amendments that are clarifying in nature, and otherwise do not materially affect the terms of the specified goods.

### **Incorporation by reference**

As mentioned above, the Amendment Determination clarifies that the Food Chemicals Codex is incorporated by reference in the Principal Determination as in force or existing at the commencement of that determination. Consistent with the explanatory statement to the Principal Determination, the Food Chemicals Codex is published by the United States Pharmacopeial Convention and available online at [www.foodchemicalscodex.org](http://www.foodchemicalscodex.org). Members of the public may request to view the Food Chemicals Codex without charge at TGA offices in Australia, or local, state and university libraries.

### **Consultation**

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.

OBPR confirmed that, due to the truly urgent and unforeseen events related to the spread of COVID-19, 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 (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.

**Details of the *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination 2020***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Excluded Goods—Hand Sanitisers) Determination 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 Schedule 1 inserts “as in force or existing at the commencement of this instrument” after reference to “Food Chemicals Codex” in the definition of *food standard grade* in section 4 of the Principal Determination. The purpose of this amendment is to clarify the precise nature of the incorporation by reference, as reflected in the explanatory statement to the Principal Determination.

Item 2 of Schedule 1 repeals and substitutes the front label in clause 1 of Part 2 of Schedule 2 to the Principal Determination to ensure that the contact details of the manufacturer or supplier are included on that label, consistent with the front label in clause 1 of Part 1 of Schedule 2 to the Principal Determination.

## 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 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 2020* (the “amendment instrument”) is made under section 7AA of the *Therapeutic Goods Act 1989* (“the Act”). The purpose of the amendment instrument is to make two minor editorial amendments to the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* (“the principal instrument”). That instrument excludes specified hand sanitisers from the operation of the Act.

The principal instrument was made in response to the emergency caused by the coronavirus disease (COVID-19). The effect of the principle instrument is to exclude specified hand sanitisers from the operation of the Act so that these goods may be manufactured and supplied urgently within Australia to deal with the emergency.

The amendment instrument supports the principal instrument by making two minor editorial amendments that are clarifying in nature, and otherwise do not materially affect the terms of the specified goods.

The first amendment clarifies that the reference to the “Food Chemicals Codex” in the definition of *food standard grade* in section 4 of the principal instrument is a reference to that document as in force or existing at the commencement of the principal instrument. This is consistent with both the nature of the incorporation of the Food Chemicals Codex as described in the explanatory statement to the principal instrument, and subsection 14(2) of the *Legislation Act 2003*. That subsection relevantly provides that, unless the contrary intention appears, a legislative instrument may not make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

The second amendment addresses an inadvertent error in Schedule 2 to the principal instrument by repealing and substituting the front label specified in clause 1 of Part 2 of Schedule 2 with an amended label. The purpose of this amendment is simply to ensure that the contact details of the manufacturer or supplier are included on that label, consistent with the front label specified in clause 1 of Part 1 of Schedule 2 to the principal instrument. Such information is necessary to ensure that manufacturers or suppliers of the specified goods may be readily identified and contacted by consumers. No other information on the front label has been changed.

#### 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.

As mentioned above, the amendment instrument supports the principal instrument by making two minor editorial amendments that are clarifying in nature, and otherwise do not materially affect the terms of the specified goods that are the subject of exclusion under the principal instrument.

That exclusion is necessary to ensure the continued supply of specified hand sanitisers in Australia. It accords with the recent policy position taken by 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 allows certain entities, which are not presently regulated by the USFDA, to manufacture and distribute hand sanitisers during the COVID-19 emergency. The policy was informed by the recommendations of the World Health Organisation for local production of hand sanitisers published in April 2020.

The amendment instrument promotes and supports the right to health by clarifying the nature of the incorporation of the Food Chemicals Codex, a document that is referenced in the definition of *food standard grade* in section 4 of the principal instrument for the purpose of adopting international standards as in force or existing at the commencement of the principal instrument. Further, the amendment instrument promotes and supports the right to health by ensuring that the contact details of the manufacturers and suppliers of specified goods containing isopropyl alcohol appear on the labels of those goods, consistent with the labels for specified goods containing ethanol.

## **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.

**Jenny Francis, delegate of the Minister for Health**