

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (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 Determination”) is made under section 7AA of the Act. The purpose of the Determination is to exclude specified hand sanitisers from the operation of the Act. The exclusion is specified with reference to the ingredients in the final formulation, the manufacturing practices, advertisement and presentation of the goods for supply.

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

### **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 matters that the Minister must have regard to before making a determination 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 (as mentioned above) 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 World Health Organisation declared the outbreak of COVID-19 to be a Public Health Emergency of International Concern on 30 January 2020, and subsequently characterised the outbreak as a pandemic on 11 March 2020. Since then, the Australian Government has declared a human biosecurity emergency in Australia.

Good hand hygiene is a critical part of Australia's response to the COVID-19 emergency. While washing hands with soap is considered to be the most effective way to practice 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 care settings.

The Determination excludes specified hand sanitisers from the operation of the Act so that these goods may be manufactured and supplied urgently within Australia. The exclusion 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. The policy allows certain entities that are not presently regulated by the USFDA to manufacture and distribute hand sanitisers during the COVID-19 emergency. The policy was informed by recommendations of the World Health Organisation for local production of hand sanitisers published in April 2010.

In accordance with the matters to be taken into account under subsection 7AA(3) of the Act, the goods specified in the Determination are not likely to harm public health when manufactured, advertised or presented for supply in the manner described in the Determination. Further, it is not appropriate to apply the national system of controls established by the Act in the context of a national emergency, where there is an immediate and pressing need for the manufacture and supply of these goods in Australia.

While the goods specified in this Determination are excluded goods for the purposes of the Act, these goods will continue to be regulated as consumer goods by the Australian Competition and Consumer Commission under Australian Consumer Law. The ongoing need for the exclusion may be revisited in the future as circumstances change.

### **Incorporation by reference**

The Determination incorporates by reference the British Pharmacopoeia, the European Pharmacopoeia and the United States Pharmacopoeia-National Formulary. The note in section 4 of the Determination makes it clear that each of these pharmacopoeia are those as defined in subsection 3(1) of the Act.

The definitions of the pharmacopoeia in subsection 3(1) of the Act refer to the publications of each as in effect immediately before the commencement of the relevant definition in the Act, and to any subsequent amendments or editions. The intention in this Determination is therefore to adopt the defined meaning of the pharmacopoeia as set out in subsection 3(1) of the Act (an approach permitted by subsection 10(4) of the Act). Those pharmacopoeias may be accessed from [www.pharmacopoeia.com](http://www.pharmacopoeia.com), [https://www.edqm.eu/en/european\\_pharmacopoeia\\_10th\\_edition](https://www.edqm.eu/en/european_pharmacopoeia_10th_edition) and [www.uspnf.com](http://www.uspnf.com).

The Determination also adopts the Food Chemicals Codex ("the FCC") published by the United States Pharmacopoeial Convention (available at [www.foodchemicalscodex.org](http://www.foodchemicalscodex.org)) as in force as at the commencement of the Determination. Members of the public may request to view the FCC and the pharmacopoeias 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”) was consulted in the preparation of this Determination.

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

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

The 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 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 (Excluded Goods—Hand Sanitisers) Determination 2020***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* (“the Determination”).

### **Section 2 – Commencement**

This section provides that the 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 Determination is section 7AA of the *Therapeutic Goods Act 1989* (“the Act”).

### **Section 4 – Definitions**

This section provides the definitions of certain terms used in the Determination. The section includes a note that a number of expressions used in the Determination are defined in section 3 of the Act.

### **Section 5 – Excluded Goods**

This section is made pursuant to subsection 7AA(2) of the Act and provides that the goods specified in column 2 of an item in Schedule 1, when used, advertised, or presented for supply in a way specified in column 3 of that item, are excluded goods for the purposes of the Act.

### **Schedule 1 – Specified goods used, advertised, or presented for supply in a particular way**

Items 1 and 2 of Schedule 1 specify goods that are excluded goods for the purposes of the Act, when used advertised or presented for supply in a particular way. Specifically, item 1 excludes certain hand sanitisers containing ethanol 80% v/v in the final formulation; and item 2 excludes certain hand sanitisers containing isopropyl alcohol 75% v/v in the final formulation.

### **Schedule 2 – Labels**

Parts 1 and 2 of Schedule 2 specify the labels to be used when advertising or presenting the excluded goods for supply.

## Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### *Therapeutic Goods (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 Act 1989* (“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.

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.

The *Therapeutic Goods (Excluded Goods—Hand Sanitisers) Determination 2020* (“the instrument”) is made under section 7AA of the Act. The purpose of the instrument is to exclude specified hand sanitisers from the operation of the Act. The exclusion is specified with reference to the ingredients in the final formulation, the manufacturing practices, advertisement and presentation of the goods for supply.

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

#### 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 World Health Organisation declared the outbreak of COVID-19 to be a Public Health Emergency of International Concern on 30 January 2020, and subsequently characterised the outbreak as a pandemic on 11 March 2020. Since then, the Australian Government has declared a human biosecurity emergency in Australia.

Good hand hygiene is a critical part of Australia's response to the COVID-19 emergency. While washing hands with soap is considered to be the most effective way to practice 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 care settings.

The instrument excludes specified hand sanitisers from the operation of the Act so that these goods may be manufactured and supplied urgently within Australia. The exclusion 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. The policy allows certain entities that are not presently regulated by the USFDA to manufacture and distribute hand sanitisers during the COVID-19 emergency. The policy was informed by the World Health Organisation recommendations for local production of hand sanitisers published in April 2010.

In accordance with the matters to be taken into account under subsection 7AA(3) of the Act, the goods specified in the instrument are not likely to harm public health when manufactured, advertised or presented for supply in the manner described in the instrument. Further, it is not appropriate to apply the national system of controls established by the Act in the context of a national emergency, where there is an immediate and pressing need for the manufacture and supply of these goods in Australia.

While the goods specified in this instrument are excluded goods for the purposes of the Act, these goods will continue to be regulated as consumer goods by the Australian Competition and Consumer Commission under Australian Consumer Law. The ongoing need for the exclusion may be revisited in the future as circumstances change.

## **Conclusion**

In summary, the instrument promotes and supports the right to health by facilitating access to hand sanitisers. 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.

**Jane Cook, delegate of the Minister for Health**