

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment Determination (No. 2) 2024

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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 and Aged Care.

Section 7AA of the Act relevantly provides that the Minister may, by legislative instrument, determine that specified goods are excluded goods for the purposes of the Act. The effect of a determination under section 7AA is to exclude the specified goods from the operation of the Act.

The *Therapeutic Goods (Excluded Goods) Determination 2018* (the Principal Determination) is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act. The effect of the Principal Determination is that the goods that are determined to be excluded goods are not subject to the Act.

A number of amendments to the Principal Determination commenced on 1 July 2024, principally as a result of the following instruments:

- the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* (the Sunscreen Determination); and
- the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024* (the Vaping Determination).

The effect of the Sunscreen Determination was to update certain regulatory requirements that secondary sunscreen products must comply with to be excluded goods. Relevantly, the Sunscreen Determination amended section 7 of the Principal Determination to provide for a transitional arrangement for secondary sunscreen products that were excluded goods immediately before 1 July 2024. However, this transitional arrangement was inadvertently repealed by the Vaping Determination.

The *Therapeutic Goods (Excluded Goods) Amendment Determination (No. 2) 2024* (the Amendment Determination) amends the Principal Determination to correct this unintended repeal of the transitional arrangements relating to secondary sunscreens. The Amendment Determination does so by introducing new section 7 to the Principal Determination, which implements the 5-year transitional arrangement for secondary sunscreen products that was intended under the Sunscreen Determination. This amendment applies retrospectively from 1 July 2024, which is the date the transitional provisions were intended to commence under the Sunscreen Determination.

Background

The Principal Determination, which is made under section 7AA of the Act, determines specified goods, including specified goods when used, advertised, or presented for supply in a specified way, to be excluded goods for the purposes of the Act.

Some secondary sunscreen products are excluded goods for the purposes of the Act if they comply with certain conditions specified in the Principal Determination (table items 14 and 15 in Schedule 1, and table items 5 and 10 in Schedule 2, to the Principal Determination refer). Secondary sunscreens are products that are represented as having a primary function other than sun protection (e.g.,

moisturisers, foundations, and lip balms) that also provide some protection of the skin from ultraviolet (UV) radiation.

On 1 July 2024, the Sunscreen Determination amended the Principal Determination to, in effect, update the testing and (certain) labelling requirements that secondary sunscreen products must comply with to be excluded goods.

Relevantly, the Sunscreen Standard amended section 7 of the Principal Determination to provide for a 5-year transitional arrangement for secondary sunscreen products that were excluded goods immediately before 1 July 2024 (the sunscreen transitional arrangement). The effect of this arrangement is that secondary sunscreen products would continue to be excluded goods until 1 July 2029, provided they comply with the testing and labelling requirements in either the 2012 Standard or the 2021 Standard.

Prior to this amendment in the Sunscreen Determination, section 7 of the Principal Determination provided a transitional arrangement for certain vaping devices (the vaping devices transitional arrangement). The vaping devices transitional arrangement was repealed on 1 July 2024 by the Vaping Determination. However, the Vaping Determination erroneously repealed section 7 of the Principal Determination in its entirety and, in doing so, inadvertently also repealed the sunscreen transitional arrangement.

Purpose

The Amendment Determination amends the Principal Determination to introduce new section 7, which makes provision for the sunscreen transitional arrangement that was inadvertently repealed by the Vaping Determination. The effect of new section 7 is exactly the same as the transitional arrangement set out in the Sunscreen Determination.

That is, new section 7 of the Principal Determination provides that items 14 and 15 of the table in Schedule 1 and items 5 and 10 of the table in Schedule 2, as in force immediately before the commencement of the Sunscreen Determination, continue to apply to goods covered by those items if:

- the goods were excluded goods under those items on 30 June 2024; and
- paragraph (b) in column 2 of each of those items, as in force immediately before the commencement of the Sunscreen Determination, applies to the goods; and
- the goods are imported, manufactured or supplied before 1 July 2029.

In effect, new section 7 provides for a 5-year transitional arrangement for secondary sunscreen products that were excluded goods under the Principal Determination immediately before 1 July 2024. During this period, such products can continue to be excluded goods if they comply with the specified requirements of either the 2012 Standard or the 2021 Standard.

After 1 July 2024, new secondary sunscreen products will need to comply with the 2021 Standard. All secondary sunscreen products that are imported, manufactured, or supplied from 1 July 2029 must comply with the 2021 Standard.

Importantly, the sunscreen transitional arrangement does not apply to secondary sunscreen products that comply with the *AS/NZS 2604:1998 Sunscreen products – Evaluation and classification* (the 2018 Standard). Consequently, secondary sunscreen products that comply with the 2018 Standard are no longer excluded goods for the purposes of the Act.

Statutory pre-conditions

Subsection 7AA(3) of the Act provides that, before making a determination under section 7AA, the Minister must have regard to the following matters:

- (a) whether it is likely that the specified goods, if not regulated under the Act, might harm the health of members of the public;
- (b) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by the Act to regulate the specified goods;
- (c) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

These matters have been considered by the rule-maker in making the Amendment Determination. However, the purpose of the Amendment Determination is simply to correct an inadvertent error.

Consultation

Consultation was not undertaken because the purpose of the Amendment Determination is simply to correct an inadvertent error. Consultation was separately undertaken in relation to the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*.

Other details

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

An impact analysis was not prepared in relation to the Amendment Determination as the amendment is minor and machinery in nature.

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*. The Amendment Determination commences immediately after the Vaping Determination and therefore has a retrospective commencement date of 1 July 2024.

This retrospective commencement date is necessary to give effect to the sunscreen transitional arrangement that was intended under the Sunscreen Determination, and to ensure that the inadvertent repeal of the transitional arrangement on 1 July 2024 by the Vaping Determination does not result in any unintended or adverse consequences for industry participants. This retrospective commencement is intended to have the effect that the sunscreen transitional arrangement applies as if it had not been inadvertently repealed on 1 July 2024.

Details of the *Therapeutic Goods (Excluded Goods) Amendment Determination (No. 2) 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment Determination (No. 2) 2024* (the Amendment Determination).

Section 2 – Commencement

This section provides that the Amendment Determination commences immediately after the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024*, and therefore commence retrospectively on 1 July 2024.

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. The Amendment Determination 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 as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Excluded Goods) Determination 2018* (the Principal Determination).

Item 1 – Section 7

This item introduces new section 7 to the Principal Determination to provide a 5-year transitional arrangement with respect to amendments made by the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* (the Sunscreen Determination). The effect of new section 7 is exactly the same as the transitional arrangement that was introduced by the Sunscreen Determination but inadvertently repealed on 1 July 2024 by the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2024*.

New section 7 of the Principal Determination provides that items 14 and 15 of the table in Schedule 1 and items 5 and 10 of the table in Schedule 2, as in force immediately before the commencement of the Sunscreen Determination, continue to apply to goods covered by those items only where:

- the goods were excluded goods under those items on 30 June 2024; and
- paragraph (b) in column 2 of each of those items, as in force immediately before the commencement of the Sunscreen Determination, applies to the goods; and
- the goods are imported, manufactured or supplied before 1 July 2029.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Excluded Goods) Amendment Determination (No. 2) 2024

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

Section 7AA of the *Therapeutic Goods Act 1989* (the Act) provides that the Minister may, by legislative instrument, determine that specified goods are excluded goods for the purposes of the Act. The effect of a determination under section 7AA is to exclude the specified goods from the operation of the Act.

The *Therapeutic Goods (Excluded Goods) Determination 2018* (the Principal Determination) is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act. The effect of the Principal Determination is that the goods that are determined to be excluded goods are not subject to the Act.

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On 1 July 2024, the Sunscreen Determination amended the Principal Determination to, in effect, update the testing and (certain) labelling requirements that secondary sunscreen products must comply with to be excluded goods.

Relevantly, the Sunscreen Standard amended section 7 of the Principal Determination to provide for a 5-year transitional arrangement for secondary sunscreen products that were excluded goods immediately before 1 July 2024 (the sunscreen transitional arrangement). The effect of this arrangement is that secondary sunscreen products would continue to be excluded goods until 1 July 2029, provided they comply with the testing and labelling requirements in either the 2012 Standard or the 2021 Standard.

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In effect, new section 7 provides for a 5-year transitional arrangement for secondary sunscreen products that were excluded goods under the Principal Determination immediately before 1 July 2024. During this period, such products can continue to be excluded goods if they comply with the specified requirements of either the 2012 Standard or the 2021 Standard.

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Importantly, the sunscreen transitional arrangement does not apply to secondary sunscreen products that comply with the *AS/NZS 2604:1998 Sunscreen products – Evaluation and classification* (the 2018 Standard). Consequently, secondary sunscreen products that comply with the 2018 Standard are no longer excluded goods for the purposes of the Act.

Human rights implications

As the Amendment Determination simply re-introduces a provision in the Principal Determination that was inadvertently repealed by a separate legislative instrument, the Amendment Determination does not engage any applicable rights or freedoms.

Conclusion

The Amendment Determination is compatible with human rights because it does not raise any human rights issues.