

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment Determination 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 (the Department).

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.

The *Therapeutic Goods (Excluded Goods) Amendment Determination 2024* (the Amendment Determination) amends the Principal Determination to correct a reference in new subsection 7(2), which is introduced by the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*. New subsection 7(2) refers to “items 5 and 9” of the table in Schedule 2 in error, and should instead refer to items 5 and 10 of the table in Schedule 2 to the Principal Determination – the Amendment Determination makes this correction.

Background

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 way, to be excluded goods for the purposes of the Act.

Under items 14 and 15 in Schedule 1 to the Principal Determination, and items 5 and 10 in Schedule 2 to the Principal Determination, a number of secondary sunscreen products are excluded goods. Secondary sunscreens are products that are represented as having a primary function other than sun protection, that also provide some protection of the skin from ultraviolet radiation (UV) radiation. The secondary sunscreens that are excluded goods include:

- products applied to the lips that contain sunscreen;
- tinted bases and foundations that contain sunscreen;
- moisturisers that contain sunscreen with SPF of up to 15 in a pack size no larger than 300 mL or 300 g, that do not make any therapeutic claims other than reducing premature ageing from sun exposure; and
- sunbathing products (e.g. products for tanning without sun, and after-sun skin care products) with an SPF of between 4 and 15 in a pack size no larger than 300mL or 300g, that do not make any therapeutic claims other than those relating to premature ageing from sun exposure.

These goods are exempt provided they do not contain ingredients in Schedule 2, 3, 4 or 8 to the Poisons Standard and they meet relevant sunscreen standards.

The *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*, which commences on 1 July 2024, amends items 14 and 15 in Schedule 1 to the Principal Determination, and items 5 and 10 in Schedule 2 to the Principal Determination, to remove reference to the 1998

Sunscreen Standard and the 2012 Sunscreen Standard, and to require compliance with the 2021 Sunscreen Standard for specified sunscreen preparations that are excluded goods.

These amendments also included a 5-year transitional arrangement for goods that were excluded goods immediately prior to these amendments. These goods can comply with either the 2021 Sunscreen Standard, or the 2012 Sunscreen Standard until 1 July 2029. Subsection 7(2) was introduced by the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*, and provides that secondary sunscreen products that were excluded goods prior to these amendments and meet the requirements of the 2012 Sunscreen Standard continue to be excluded goods until 1 July 2029.

Purpose

Subsection 7(2), as introduced by the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*, contains an incorrect reference to item 9 of the table in Schedule 2 to the Principal Determination. This provision should instead refer to item 10 of the table in Schedule 2 to the Principal Determination as the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* replaces item 10 of Schedule 2, not item 9.

The Amendment Determination amends subsection 7(2) of the Principal Determination to correct this error and replace the reference to item 9 with a reference to item 10 of the table in Schedule 2 to the Principal Determination.

The Amendment Determination commences immediately after the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* to affect an immediate correction to subsection 7(2).

Statutory pre-conditions

Subsection 7AA(3) 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* and commences immediately after the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* on 1 July 2024.

Details of the *Therapeutic Goods (Excluded Goods) Amendment Determination 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment Determination 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 (Sunscreen) Determination 2024* 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– Subsection 7(2)

This item replaces the incorrect reference to item 9 in subsection 7(2) with a reference to item 10 of the table in Schedule 2 to the Principal Determination. Subsection 7(2) should refer to item 10 instead, as the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* replaced item 10 with an updated reference to the 2021 Sunscreen Standard.

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 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

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Human rights implications

As the Amendment Determination simply corrects an erroneous reference in subsection 7(2) of the Principal Determination, 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.