

## EXPLANATORY STATEMENT

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) 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 *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* (the Amendment Determination) amends the Principal Determination to remove reference to superseded Australian and New Zealand Standards for the evaluation and classification of sunscreens. These references are replaced with references to the new standard – Australian/New Zealand Standard AS/NZS 2604:2021, titled *Sunscreen products - Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand (the 2021 Sunscreen Standard). The effect of this amendment is that for certain secondary sunscreen products to be excluded goods, they will have to comply with the 2021 Sunscreen Standard.

### **Background**

The TGA regulates most sunscreens in Australia as therapeutic goods to ensure the quality, safety and efficacy of such goods. In particular, to ensure that sunscreens adequately protect consumers from the harmful effects of ultraviolet (UV) radiation to reduce the incidence and adverse outcomes of skin cancer.

Sunscreen preparations fall into two categories, ‘primary sunscreens’ and ‘secondary sunscreens’. Primary sunscreens are those products that are represented as being primarily to protect the skin from UV radiation. Secondary sunscreens are products that are represented as having a primary function other than sun protection (for example, moisturisers, foundations, lip balms) that also provide some protection of the skin from UV radiation.

All primary sunscreens, and some secondary sunscreens (depending on their presentation and Sun Protection Factor (SPF)) are regulated by the TGA as therapeutic goods and, unless exempt or the subject of an approval or authority under the Act, must be included in the Australian Register of Therapeutic Goods (Register) before they can be lawfully imported into, supplied within, or exported from Australia.

Some secondary sunscreen products are excluded goods for the purposes of the Act and therefore do not need to comply with the requirements of the Act. These are low risk cosmetic products, which are excluded if they meet the requirements set out in the Principal Determination.

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, the secondary sunscreen products 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;
- 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 certain sunscreen standards. Preparations that contain a suncreening substance but make no reference to sun protection, and make no other therapeutic claims, are also excluded goods.

The Principal Determination incorporates two outdated standards - *AS/NZS 2604:1998 Sunscreen products – Evaluation and classification* (“the 1998 Sunscreen Standard”), and *AS/NZS 2604:2012 Sunscreen products – Evaluation and classification* (“the 2012 Sunscreen Standard”).

On 25 June 2021, Standards Australia published the 2021 Sunscreen Standard, which was updated in 2022. The 2021 Sunscreen Standard specifies the current testing and labelling requirements for sunscreens and incorporates compliance with the latest International Organization for Standardization (ISO) standards for testing. The 2021 Sunscreen Standard replaced the 2012 Sunscreen Standard, principally to:

- align Australian and New Zealand test methods for determining the SPF, broad spectrum, and water resistance of sunscreen preparations with internationally adopted ISO standards; and
- introduce labelling requirements that require sunscreen preparations that are supplied as sunscreen aerosols or in spray pump packs to contain instructions in relation to dosage, optimum conditions for application, and the avoidance of inhalation.

## **Purpose**

The Amendment Determination 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.

The effect of this amendment is that in order for the secondary sunscreen products specified in the Principal Determination to be excluded goods, they will be required to comply with the 2021 Sunscreen Standard. It is considered appropriate for these excluded goods to meet the updated requirements in the 2021 Sunscreen Standard.

The amendments in the Amendment Determination provide for a 5-year transitional arrangement for goods that were excluded goods immediately prior to the amendments made by the Amendment Determination. During this period, secondary sunscreen products that were excluded goods prior to these amendments may continue to be excluded goods until 1 July 2029 if they comply with the specified requirements of the 2012 Sunscreen Standard or the 2021 Sunscreen Standard. Secondary sunscreen products that only comply with the 1998 Sunscreen Standard will no longer be excluded goods, as it is considered that sunscreen products need to comply with a more recent standard. After 1 July 2024, new secondary sunscreen products will need to comply with the 2021 Sunscreen Standard. All secondary sunscreen products that are imported, manufactured or supplied from 1 July 2029 must comply with the 2021 Sunscreen Standard.

## 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. In summary, the amendments are made on the basis that compliance with the 2021 Sunscreen Standard will maintain continuity of quality standards for these low-risk cosmetic therapeutic goods.

## Documents incorporated by reference

The Amendment Determination incorporates the 2021 Sunscreen Standard. The manner of incorporation is as the 2021 Sunscreen Standard is in force or existing on 1 July 2024. This is in accordance with subsection 14(2) of the *Legislation Act 2003*.

The 2021 Sunscreen Standard may be purchased from [www.saiglobal.com](http://www.saiglobal.com). It is not freely available, as it is subject to copyright. However, it is anticipated that the persons who are most affected by the adoption of the 2021 Sunscreen Standard in the Principal Determination are likely to possess the publication. As important benchmarks for the quality, safety, and efficacy of sunscreen preparations, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publication is not freely available. Alternatively, by prior written arrangement where possible, and without charge, the 2021 Sunscreen Standard can be viewed by members of the public at the TGA office in Fairbairn, ACT.

## Consultation

In 2022 and 2023, the TGA conducted a targeted consultation with a number of industry groups to advise them of the TGA's intention to adopt the 2021 Sunscreen Standard. This included bilateral meetings with Accord Australasia and Consumer Healthcare Products Australia (CHP Australia), as well as the Complementary and OTC Medicines Regulatory and Technical Consultative Forum (ComTech). ComTech is a forum that facilitates consultation between the TGA and representatives from the complementary and over-the-counter medicines industry.

In addition, TGA conducted a public consultation from 24 April 2023 to 31 May 2023. Nineteen submissions were received from a broad range of stakeholders including: sponsors, manufacturers, regulatory affairs associates and consultants, industry groups, government agencies and organisations, consumers and consumer representative bodies, and a not-for-profit organisation.

All stakeholders were supportive of adopting the 2021 Sunscreen Standard as it would ensure alignment with international sunscreen testing methodology. The majority of respondents agreed that all new sunscreens should be required to comply with the 2021 Standard. Industry requested a longer transition period than the 3-year period proposed in the consultation to comply with the new testing requirements, so the Amendment Determination provides a 5-year transition period.

## Other details

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

An impact analysis (IA) was prepared on the proposed reforms relating to the adoption of the 2021 Sunscreen Standard, taking into account the feedback received from stakeholders throughout the consultations. The Office of Impact Analysis (OIA) determined that the IA was adequate (OIA23-05253). The IA has been published prior to commencement of the Amendment Determination on the OIA website at: [oia.pmc.gov.au/](http://oia.pmc.gov.au/).

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 1 July 2024.

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

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024* (“the Amendment Determination”).

### **Section 2 – Commencement**

This section provides that the Amendment Determination commences 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 4 (definition of AS/NZS 2604:1998)**

This item repeals the definition of the 1998 Sunscreen Standard.

##### **Item 2– Section 4 (definition of AS/NZS 2604:2012)**

This item repeals the definition of the 2012 Sunscreen Standard.

##### **Item 3– Section 4**

This item introduces a definition for ‘AS/NZS 2604:2021’, which is the 2021 Sunscreen Standard, and ‘secondary sunscreen product’ which has the same meaning as in the 2021 Sunscreen Standard.

##### **Item 4 – Section 7 (heading)**

This item replaces the heading for section 7 as a consequential amendment to other amendments in this Schedule.

##### **Item 5 – Section 7**

This item makes an editorial amendment to provide for subsections in section 7 of the Principal Determination.

#### **Item 6 – At the end of section 7**

This item introduces a new subsection to section 7 of the Principal Determination, which sets out transitional arrangements for the amendments made by items 7 to 10 in this Schedule.

Items 14 and 15 of the table in Schedule 1 to the Principal Determination, and items 5 and 10 of the table in Schedule 2 to the Principal Determination, as in force immediately before the commencement of the Amendment Determination, continue to apply to goods covered by the relevant item that comply with the 2012 Sunscreen Standard, were excluded goods under those items immediately before commencement of the Amendment Determination (i.e. on 30 June 2024), and are imported, manufactured or supplied before 1 July 2029.

The effect of this amendment is that secondary sunscreen products imported, manufactured or supplied before 1 July 2029 will continue to be excluded if such goods were excluded under item 14 or 15 of the table in Schedule 1 to the Principal Determination, or item 5 or 10 of the table in Schedule 2 to the Principal Determination, prior to the amendment of those items by the Amendment Determination and they comply with the 2012 Sunscreen Standard. Therefore, goods that are excluded under those items on 30 June 2024 will have until 1 July 2029 to comply with the 2021 Sunscreen Standard.

Secondary sunscreen preparations that only comply with the 1998 Sunscreen Standard will no longer be excluded goods from 1 July 2024. Also from 1 July 2024, new secondary sunscreen products (i.e. those that did not exist on 30 June 2024) will need to comply with the updated 2021 Sunscreen Standard. From 1 July 2029, all secondary sunscreen products that are excluded goods will need to comply with the 2021 Sunscreen Standard.

#### **Item 7 – Schedule 1 (table item 14)**

This item replaces item 14 in Schedule 1 to the Principal Determination, relating to products intended for application to the lips that contain sunscreen. New item 14 is amended to refer to the 2021 Sunscreen Standard, with references to the 1998 Sunscreen Standard and 2012 Sunscreen Standard removed.

The effect of this amendment is that for these goods to be excluded goods for the purposes of the Act, they must comply with relevant requirements of the 2021 Sunscreen Standard. The item otherwise remains unchanged in its effect. Goods covered by item 14 must not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, must meet the definition of secondary sunscreen product in the 2021 Sunscreen Standard, and must comply with the 2021 Sunscreen Standard in relation to the description of the protection factor or any equivalent description, labelling and performance requirements .

#### **Item 8 – Schedule 1 (table item 15)**

This item replaces item 15 in Schedule 1 to the Principal Determination, relating to tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen. New item 15 refers only to the 2021 Sunscreen Standard, with references to the 1998 Sunscreen Standard and 2012 Sunscreen Standard removed.

The effect of this amendment is that for these goods to be excluded goods for the purposes of the Act, they must comply with relevant requirements of the 2021 Sunscreen Standard. The item otherwise remains unchanged in its effect. Goods covered by item 15 must not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, must meet the definition of secondary sunscreen product in the 2021 Sunscreen Standard and must comply with the 2021 Sunscreen Standard in relation to the description of the protection factor or any equivalent description, labelling and performance requirements .

**Item 9 – Schedule 2 (table item 5)**

This item replaces item 5 in Schedule 2 to the Principal Determination, which specifies moisturising skin care products that contain sunscreen. New item 5 refers only to the 2021 Sunscreen Standard, with references to the 1998 Sunscreen Standard and 2012 Sunscreen Standard removed.

The effect of this amendment is that for these goods to be excluded goods for the purposes of the Act, they must comply with relevant requirements of the 2021 Sunscreen Standard. The item otherwise remains unchanged in its effect. Goods covered by item 5 must not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard, must meet the definition of secondary sunscreen product in the 2021 Sunscreen Standard, and must comply with the 2021 Sunscreen Standard in relation to the description of the protection factor or any equivalent description, labelling and performance requirements .

**Item 10 – Schedule 2 (table item 10)**

This item replaces item 10 in Schedule 2 to the Principal Determination, which specifies sunbathing skin care products that contain sunscreen with a sun protection factor of at least 4 and not more than 15. New item 10 refers only to the 2021 Sunscreen Standard, with references to the 1998 Sunscreen Standard and 2012 Sunscreen Standard removed.

The effect of this amendment is that for these goods to be excluded goods for the purposes of the Act, they must comply with relevant requirements of the 2021 Sunscreen Standard. The item otherwise remains unchanged in its effect. Goods covered by item 10 must not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard, must meet the definition of secondary sunscreen product in the 2021 Sunscreen Standard, and must comply with the 2021 Sunscreen Standard in relation to the description of the protection factor or any equivalent description, labelling and performance requirements.

## 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 (Sunscreen) 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**

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.

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#### **Background**

The TGA regulates most sunscreens in Australia as therapeutic goods to ensure the quality, safety and efficacy of such goods. In particular, to ensure that sunscreens adequately protect consumers from the harmful effects of ultraviolet (UV) radiation to reduce the incidence and adverse outcomes of skin cancer.

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All primary sunscreens, and some secondary sunscreens (depending on their presentation and Sun Protection Factor (SPF)) are regulated by the TGA as therapeutic goods and, unless exempt or the subject of an approval or authority under the Act, must be included in the Australian Register of Therapeutic Goods (Register) before they can be lawfully imported into, supplied within, or exported from Australia.

Some secondary sunscreen products are excluded goods for the purposes of the Act and therefore do not need to comply with the requirements of the Act. These are low risk cosmetic products, which are excluded if they meet the requirements set out in the Principal Determination.

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, the secondary sunscreen products 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;
- 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 certain sunscreen standards. Preparations that contain a suncreening substance but make no reference to sun protection, and make no other therapeutic claims, are also excluded goods.

The Principal Determination incorporates two outdated standards - *AS/NZS 2604:1998 Sunscreen products – Evaluation and classification* (“the 1998 Sunscreen Standard”), and *AS/NZS 2604:2012 Sunscreen products – Evaluation and classification* (“the 2012 Sunscreen Standard”).

On 25 June 2021, Standards Australia published the 2021 Sunscreen Standard, which was updated in 2022. The 2021 Sunscreen Standard specifies the current testing and labelling requirements for sunscreens and incorporates compliance with the latest International Organization for Standardization (ISO) standards for testing. The 2021 Sunscreen Standard replaced the 2012 Sunscreen Standard, principally to:

- align Australian and New Zealand test methods for determining the SPF, broad spectrum, and water resistance of sunscreen preparations with internationally adopted ISO standards; and
- introduce labelling requirements that require sunscreen preparations that are supplied as sunscreen aerosols or in spray pump packs to contain instructions in relation to dosage, optimum conditions for application, and the avoidance of inhalation.

### ***Purpose***

The Amendment Determination 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.

The effect of this amendment is that in order for the secondary sunscreen products specified in the Principal Determination to be excluded goods, they will be required to comply with the 2021 Sunscreen Standard. It is considered appropriate for these excluded goods to meet the updated requirements in the 2021 Sunscreen Standard.

The amendments in the Amendment Determination provide for a 5-year transitional arrangement for goods that were excluded goods immediately prior to the amendments made by the Amendment Determination. During this period, secondary sunscreen products that were excluded goods prior to these amendments may continue to be excluded goods until 1 July 2029 if they comply with the specified requirements of the 2012 Sunscreen Standard or the 2021 Sunscreen Standard. Secondary sunscreen products that only comply with the 1998 Sunscreen Standard will no longer be excluded goods, as it is considered that sunscreen products need to comply with a more recent standard. After 1 July 2024, new secondary sunscreen products will need to comply with the 2021 Sunscreen Standard.

All secondary sunscreen products that are imported, manufactured or supplied from 1 July 2029 must comply with the 2021 Sunscreen Standard.

### **Human rights implications**

The Amendment Determination engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 Determination supports the right to health by ensuring that low-risk cosmetic preparations that contain sunscreen meet minimum safety and quality standards, even though they are excluded from the therapeutic goods regulatory scheme. It is considered appropriate for these goods to comply with the more recent 2021 Sunscreen Standard as the minimum benchmark, specifically in relation to the description of the protection factor or any equivalent description, labelling and performance requirements.

### **Conclusion**

The Amendment Determination 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.