Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

# Consultation: Seeking feedback on improvements to the regulation of sunscreens in Australia

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# Contents

# Overview

## What we are proposing to do

The primary objective of the regulation of sunscreens is to ensure their quality, safety and efficacy to protect consumers from the sun's harmful ultraviolet (UV) radiation, to reduce the incidence and impact of skin cancer.

The current regulatory framework for sunscreens has been in place for some years, and the regulatory landscape has changed over this time. Recent international and domestic developments have highlighted a number of matters in relation to the current regulation of sunscreens, such as the variability of sunscreen sun protection factor (SPF) claims, the reproducibility of current SPF testing methods, the level of oversight of laboratories performing SPF testing, and the understanding of sponsors (product owners) and manufacturers of their regulatory obligations.

The Therapeutic Goods Administration (TGA) is seeking feedback on proposed changes to improve the regulation of therapeutic sunscreens in Australia.

## What is covered in this consultation paper

### Matters in scope

The following issues are in scope:

- Matters related to SPF testing.
- Potential quality or efficacy concerns with specific formulations and ingredients.
- SPF labelling.
- Excluded (cosmetic) sunscreens that make high SPF claims.
- Sunscreen manufacturing guidance.

### Matters not in scope

While the following are discussed in this paper to provide context, they are being considered as part of other TGA consultative processes or reviews and are therefore out of scope for this consultation:

- Safety of sunscreen ingredients.
- Consideration of sunscreens specifically marketed to children.
- The Regulatory Environment for sunscreens in Australia.
- Labelling instructions for novel dosage forms.

A number of options are presented to address the matters in scope. These proposals are intended to strengthen confidence in sunscreen performance. If accepted, options presented in this paper would be implemented in a proportionate and targeted manner.

This consultation paper is presented in 2 parts:

1. Part 1 sets out the background to the current regulatory framework.
2. Part 2 outlines the key matters raised with the current framework.

# How to respond

We have posed questions within this consultation paper to help guide feedback. We also welcome any additional comments, via a separate response document if you wish.

You do not have to answer all the questions, and none are mandatory.

You can submit your views by clicking the link and answering the questions from the consultation paper.

You can also upload your own response document on the final page of the link above.

# Executive summary

Sunscreens are critical in protecting Australians from the harmful effects of ultraviolet (UV) radiation and in reducing the incidence and impact of skin cancer. In Australia, therapeutic sunscreens are regulated as listed medicines, and are thus subject to post-market monitoring rather than pre-market evaluation. While this framework has supported timely market access to sunscreens, recent domestic and international developments have highlighted potential areas for improvement with the current framework.

We have been monitoring international developments relating to sunscreens:

- In 2019, the United States Food and Drug Administration (FDA) published an interim notification that certain sunscreen ingredients may no longer be considered Generally Recognized as Safe and Effective (GRASE)[1].
- In 2024, the International Organization for Standardization (ISO) published new SPF *in vitro* testing methods.

We have also been investigating domestic developments and media reports:

- The Australian consumer advocacy group, CHOICE, published a report[2] on 12 June 2025 that found that 18 out of 20 sunscreens failed to meet their claimed Sun Protection Factor (SPF) 50 or 50+ ratings, based on independent testing, with one product testing as low as SPF 4.
- An ABC investigation revealed that a number of different products marketed in Australia were being supplied under the one Australian Register of Therapeutic Goods identification number, as well as raising concerns relating to a number of sunscreen products not meeting their claimed SPF rating.

These developments, alongside our own internal reviews and investigations, have prompted the TGA to review aspects of the current regulatory framework for sunscreens. This paper identifies several key matters with the current framework.

Matters being considered by the TGA:

- There are potential quality, safety or efficacy concerns related to specific formulations or specific ingredients.
- There is recognised variability with the current SPF *in vivo* testing method.
- SPF testing data from certain laboratories appear to be unreliable.
- There is evidence of a lack of understanding by some sponsors (product owners) and some manufacturers of their legal obligations under the regulatory framework.
- Current understanding of SPF values, combined with the variability of test results, highlights the need for clearer SPF labelling to ensure that consumers can make informed decisions about their sun protection, and provide sponsors greater certainty of regulatory compliance.
- Therapeutic goods exemption provisions that enable certain cosmetic sunscreens to make very high SPF claims are overly complex and potentially confusing for consumers, retailers and health professionals.
- Sunscreens are regulated differently across different international jurisdictions, and regulatory requirements do not always align, which can be a source of confusion when comparing international and the Australian regulator's actions.

[1] www.fda.gov/media/124655/download

[2] www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/sunscreen-test

- New novel dosage forms for sunscreens (e.g. foam) have been brought to market, for which there are no specific labelling requirements.
- The current framework is based on sponsor certifications that are monitored in the post market environment with heavy reliance on individual product investigations which are resource intensive and time consuming. As a result, this can lead to the Australian public questioning the response time of the regulator when issues arise.

We are already addressing some of the above matters under the provisions of the current framework, such as the safety of sunscreen ingredients, labelling for novel dosage forms and improving sponsor's and manufacturer's understanding of their regulatory obligations. While briefly discussed in this paper, they are considered out of scope of this consultation.

Other matters are complex and will take time to resolve, such as:

- improving reliability and transparency of SPF testing
- enabling new testing technologies to be adopted in a more timely manner
- strengthening oversight of testing laboratories
- enhancing lifecycle quality assurance (periodic testing, ingredient standards)
- simplifying and clarifying SPF labelling
- providing greater consistency with the indications that therapeutic and cosmetic sunscreens can make, and
- updating GMP guidance to improve manufacturing quality.

For each matter above, this paper presents a range of options, including the status quo, targeted enhancements or more substantial reforms.

Without effective resolution of these complex issues, concerns regarding sunscreen SPF accuracy are likely to persist. For consumers, this causes uncertainty regarding the effectiveness and safety of sunscreens currently available on the market. If the SPF claims on product labels cannot be confidently verified due to variable or inconsistent laboratory testing, individuals may unknowingly use sunscreens that offer less protection than advertised, potentially increasing their risk of sunburn and long-term skin damage.

The lack of robust oversight and standardisation in SPF testing can undermine public trust in sunscreen products and in the regulatory system responsible for their approval, highlighting the importance of transparent and credible testing to ensure consumers can make informed decisions about their sun protection.

Continuing to conduct post-market compliance investigations and reviews of individual sunscreen products, without regulatory change, is not considered to be a viable long-term solution to the issues outlined in this consultation document. Individual investigations/reviews into each sponsor/product are approaches that are both resource intensive and complicated by the existing vulnerabilities within the sunscreen regulatory framework. Challenges with scrutinising sponsor compliance further complicates investigations.

Rather than relying solely on case-by-case investigations, a more sustainable strategy would be to systematically close regulatory loopholes over time. This strengthens overall compliance, limits the need for frequent enforcement actions, reduces the potential risk of sunscreen shortages, and ultimately provides greater assurance of product safety and integrity.

# Part 1: Background - current regulatory framework

## Importance of sunscreens in Australia

UV radiation from the sun is divided into different categories based on wavelength, with ultraviolet A (UVA) and ultraviolet B (UVB) rays being the most significant for human health.

UVA rays have longer wavelengths and account for approximately 95% of the UV radiation reaching the Earth's surface. They penetrate the skin more deeply, contributing to premature ageing, wrinkling, and long-term skin damage. UVB rays have shorter wavelengths and are primarily responsible for causing sunburn and direct Deoxyribonucleic Acid (DNA) damage in skin cells, which can lead to skin cancers such as melanoma.

Sunscreens are one of the defences against UV radiation, with broad spectrum sunscreens protecting against both UVA and UVB rays.

Protection against UV radiation is achieved through the use of protective measures such as wearing hats, sunglasses and long-sleeved clothing, seeking shade during peak sunlight hours, and appropriately applying sunscreen.

## How sunscreens are currently regulated in Australia

In Australia, sunscreens are regulated as either cosmetics or therapeutic goods depending on factors including their ingredients, therapeutic claims and claimed SPF.

Sunscreen products are categorised as ‘primary’ or ‘secondary’ in the Australian/New Zealand standard AS/NZS 2604:2021 *Sunscreen products – Evaluation and classification* (AS/NZS 2604) (the 2021 Sunscreen Standard):

- **Primary sunscreen product:** represented as being primarily to protect the skin from UV radiation.
- **Secondary sunscreen product:** represented as having a primary function other than sun protection whilst providing some protection of the skin from UV radiation.

### Excluded sunscreens

Many secondary sunscreen products with a primary purpose other than sun protection are not considered to be therapeutic goods, so are excluded from the application of therapeutic goods legislation. These product types are outlined under the Therapeutic Goods (Excluded Goods) Determination 2018 (Excluded Goods Determination). To be eligible for exclusion, these products must meet certain criteria, such as not containing ingredients included in a schedule to the Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons), and being compliant with the applicable clauses of the AS/NZS 2604 adopted by the TGA. Examples include moisturisers with an SPF of 15 or less and tinted foundations and lip products with an SPF up to 50+.

The Australian Industrial Chemicals Introduction Scheme (AICIS) assesses the safety of ingredients used in sunscreens that are not regulated as therapeutic goods, and the Australian Competition and Consumer Commission (ACCC) oversees product issues such as safety and truth in labelling of these products.

While excluded sunscreens are not required to comply with therapeutic goods legislation, excluded sunscreens that are considered cosmetic products are still subject to other labelling and advertising requirements to ensure consumer safety.

# Sunscreens regulated by the TGA

Under the *Therapeutic Goods Act 1989* (the Act) and supporting legislation, sunscreen products that are regulated as therapeutic goods (therapeutic sunscreens) by the TGA include:

- all primary sunscreens, and
- secondary sunscreen products that are not covered under the Excluded Goods Determination.

## *Sunscreens included in the ARTG*

Therapeutic sunscreens must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) before they can legally be supplied in Australia. Each sunscreen carrying an individual product name requires a separate entry in the ARTG, and its unique ARTG number must be included on the product label. Section 16 of the Act, and regulation 11 of the Therapeutic Goods Regulations 1990 (the Regulations) for listable medicines other than export-only medicines, outline the requirements for individual ARTG listing for medicines based on characteristics used to determine a separate and distinct good.

Currently, all sunscreens in the ARTG have been included via the listed pathway. Listed medicines can be sold to the public without undergoing a full pre-market assessment of safety, quality and efficacy by the TGA, because they satisfy certain 'low risk' criteria. A medicine is listed in the ARTG based on information provided by the applicant and certification by the applicant at the time of listing that the goods meet the relevant legislative requirements.

Listed therapeutic sunscreens may only:

- contain TGA pre-approved low risk ingredients included in the Therapeutic Goods (Permissible Ingredients) Determination (Permissible Ingredients Determination), and
- claim pre-approved low risk indications included in the Therapeutic Goods (Permissible Indications) Determination (Permissible Indications Determination).

Some exceptions are in place for listed sunscreens to make certain higher-level therapeutic claims, compared to what is typically permissible for listed medicines, as they act as a primary preventative measure against skin cancer. This is explained further below, under Sunscreen permissible indications.

Products that make therapeutic claims beyond those permitted, or contain ingredients not listed in the Permissible Ingredients Determination, cannot be listed in the ARTG. Instead, they must be evaluated as registered therapeutic sunscreens and included in the ARTG via the registration pathway. There are currently no registered sunscreens in the ARTG.

# Labelling of sunscreens

Therapeutic sunscreen labelling and advertising must meet robust regulatory standards. In addition to the Act and the Regulations, sponsors must comply with the latest version of the Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines (TGO 92), the Therapeutic Goods Advertising Code (the Advertising Code), and the AS/NZS 2604. Together, these requirements provide that all information presented to consumers is accurate, clear and consistent.

Labels for therapeutic sunscreens may include company logos, symbols and additional consumer information, provided that these elements do not cause confusion for Australian consumers. Further, they must not conflict with the requirements of relevant therapeutic goods legislation.

If the sunscreen formulation contains a Proprietary Ingredient (PI)[3], all components of the PI must comply with the Permissible Ingredients Determination. The sponsor is also responsible for confirming

[3] A proprietary ingredient is a formulation, such as a flavour or fragrance, made with a mixture of ingredients. Sometimes details of these formulations are not in the public domain.

with the manufacturer or supplier that the ingredient does not include any specified excipients that must be declared on the label under the current TGO 92.

## Approval of sunscreen ingredients

Sponsors wishing to market a listed therapeutic sunscreen containing an ingredient not included in the Permissible Ingredients Determination must apply to the TGA to include that ingredient in the Permissible Ingredients Determination. Such applications must be supported by data demonstrating the safety and quality of the substance. Applications to add or vary an ingredient in the Permissible Ingredients Determination are generally made under section 26BD of the Act. The requirements for an application are set out in the Mandatory requirements for an effective application to vary the Permissible Ingredients Determination, as incorporated by reference in the Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023.

To reduce evaluation requirements, applicants may use the Comparable Overseas Bodies (COB) process, which allows technical reports from recognised authorities such as AICIS, Scientific Committee on Consumer Safety (SCCS), or Cosmetic Ingredient Review (CIR) to support the application. This process requires submission of the COB report, completed checklists, and a gap analysis to confirm compliance with Australian standards. All substances must meet TGA safety and quality standards before inclusion in the Permissible Ingredients Determination.

Applicants must also submit a separate application to establish an Australian Approved Name (AAN) for the substance. Once approved and included in the Permissible Ingredients Determination, the ingredient may be used in other sunscreens unless subject to a two-year exclusivity period, into which applicants can opt during submission. Any change to the permitted use of an existing ingredient requires a separate application.

New sunscreen ingredients are assessed according to the same principles as other topical substances used in listed medicines, following the requirements outlined in the guidance: Understanding the Regulation of Therapeutic Sunscreens (URTS). These include providing quality and safety data, with justifications required if core information cannot be supplied. Additional requirements specific to sunscreens include establishing the UV absorption range and meeting other safety considerations detailed in the guidance.

## Sunscreen permissible indications

Listed therapeutic goods can only carry indications that are specified in the Permissible Indications Determination. Generally, permitted indications relate to conditions that are benign or self-limiting and can be accurately assessed by the average consumer.

Sunscreens with any SPF can use the following permitted indication:

- *Can aid in the prevention of premature skin aging*

Because sunscreens are a primary preventive measure against skin cancer, the TGA also allows certain higher-level therapeutic claims for listed sunscreens with specific SPF ratings. For broad spectrum sunscreens with an SPF of 30 or higher, permitted indications include:

- *May assist in preventing some skin cancers*
- *May reduce the risk of some skin cancers*
- *Can aid in the prevention of solar keratoses*
- *Can aid in the prevention of sunspots*

To use the above permitted indications, sponsors must include an SPF Indication of SPF 30 or higher in the ARTG listing.

Sponsors must also certify that they hold evidence to substantiate all indications and claims made for their product at the time of listing in the ARTG. This evidence must demonstrate that claims are true, valid and not misleading. The TGA may request this information as part of a compliance review, and failure to provide adequate evidence can result in cancellation of the product listing.

Additionally, sunscreens must comply with the labelling requirements of Australian/New Zealand Standard (AS/NZS) 2604:2021.

Therapeutic sunscreens may also include non-therapeutic claims, provided these are truthful and able to be substantiated. Examples include cosmetic claims like “moisturising,”, content claims such as “contains Vitamin E”, or insect repellent claims. Sponsors must also hold evidence for these claims.

## Manufacture of sunscreens

Manufacturers of listed or registered therapeutic sunscreens intended for the Australian market or for export must be licensed or approved by the TGA in accordance with Part 3-3 of the Act and Part 4 of the Regulations. Manufacture of these products must comply with principles of Good Manufacturing Practice (GMP).

Specific guidance for sunscreen manufacturing is provided in Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE0009-13. This guidance describes how a sunscreen manufacturer may operate to demonstrate compliance with the PIC/S Guide to GMP, and must be read in conjunction with the PIC/S Guide to GMP. The regulatory framework requires that all sunscreen products be produced by pre-approved manufacturers, who are responsible for meeting requirements related to raw materials, ingredients and the manufacturing process.

If an Australian manufacturer is nominated in an application to list or register a sunscreen, that manufacturer must be ‘licensed’ by the TGA and comply with the GMP requirements relevant to sunscreens. For imported products, each overseas manufacturer must adhere to a GMP code equivalent to that applied in Australia, and the TGA must issue a GMP clearance for that manufacturer.

As part of our post marketing monitoring of sunscreens, the TGA performs regular GMP inspections of licensed and certified manufacturers of sunscreens to review compliance with GMP requirements, relevant quality standards and product Marketing Authorisations.

## Testing of sunscreens

Sunscreens are available in a range of formulations, such as lotions, creams, gels and aerosols. In Australia, regardless of the type, all therapeutic sunscreens must hold evidence to support any of the claims of SPF, broad spectrum performance or water resistance performance:

- The ‘SPF’ claim indicates how effective the sunscreen is against UVB, and the numerical SPF value provides the user with a direct indication of the sunscreen efficacy.
- The ‘broad spectrum’ claim indicates that the sunscreen also protects the skin against UVA radiation.
- The ‘water resistance’ claim indicates that the sunscreen also remains effective in water (i.e. during swimming or after sweating) for a certain period, which is up to 4 hours in Australia.

### *Australian/New Zealand standard for sunscreens*

Standards Australia publishes the joint Australian/New Zealand standard *Sunscreen products – Evaluation and classification* (AS/NZS 2604), detailing the procedures for testing the performance of all sunscreen products in Australia. It also provides required label performance statements for sunscreen products. The objective of the standard is to articulate a means of testing and labelling sunscreens that will assist consumers to select a product which best suits their sun protection needs.

The Australian standard for sunscreens is given legal effect by the TGA by adoption in therapeutic goods legislation. The current version, AS/NZS 2604:2021, is referenced in the Regulations and in the Excluded Goods Determination.

All cosmetic and therapeutic sunscreens must comply with AS/NZS 2604 as adopted into therapeutic goods legislation, including requirements for SPF testing and broad-spectrum performance.

While all new products must comply with the AS/NZS 2604:2021, a transition period to ensure that the claimed SPF has been established by testing in accordance with AS/NZS 2604:2021 is in place for products listed before 1 July 2024 and is in force until 30 June 2029. AS/NZS 2604:2012 is the previously adopted version. Sponsors continuing to test to the earlier standard during this period will therefore not be required to comply with new requirements, including those that improve reproducibility of the SPF test.

AS/NZS 2604:2021 adopts the following International ISO standards, but also has Australian-specific requirements over and above these standards:

- ISO 24444:2019, *Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF).* This test is conducted using human subjects and is a measure of protection against UVB. This standard was updated from the 2012 version specifically to improve reproducibility. Therefore, products listed before 1 July 2024 may have less reliable SPF results.
- ISO Standard 24443:2021, *Cosmetics – Determination of sunscreen UVA photoprotection in vitro*. This method measures broad spectrum performance and relies on an *in vivo* SPF value as part of the test. However, the standard indicates that any alternative SPF method published as an ISO method can be used for the SPF value, since the use of *in vivo* methods raises ethical concerns.
- ISO 16217:2020 *Cosmetics – Water immersion procedure for the determination of water resistance*. The procedure involves subjecting the sunscreen, once applied to a suitable substrate or skin surface, to repeated cycles of immersion in water under controlled and specified conditions. After these immersion cycles, the level of sun protection provided by the product is measured to determine how effectively it maintains its SPF rating following water exposure. This method ensures that sunscreens labelled as "water-resistant" meet consistent, international criteria for performance after contact with water.

## *SPF testing*

Table 1 outlines the level of protection for different SPF values claimed on the product label (adapted from the AS/NZS 2604:2021).

**Table 1. Sunscreen category descriptions based on SPF**

| SPF | Labelled SPF | Category description |
|---|---|---|
| 1-3 | Not allowed | Not allowed |
| 4-14 | 4, 6, 8, 10 | Low protection |
| 15-29 | 15, 20, 25 | Medium or moderate protection |
| 30-59 | 30, 40, 50 | High protection |
| 60 or higher | 50+ | Very high protection |

Under ISO 24444:2019, sunscreen SPF testing is performed using an *in vivo* method, by measuring its ability to protect human skin from UV-induced erythema (redness or sunburn). The method is summarised below:

**Volunteer Selection:**

- Healthy adults below 70 years with very light to intermediate skin colour.
- Subjects must be informed of the risks and provide written consent to participate.
- Non-inclusion criteria include recent sun exposure or tanning, existing sun damage, subjects using certain medications.
- Typically, 10–20 subjects are used to meet the statistical requirements specified in the method.

**Test Site Preparation:**

- Small areas (on the back) are marked for testing.
- Each area is assigned a different sunscreen product or control (no sunscreen).
- A precise amount (2 mg/cm²) of sunscreen is applied to each test site except the control area.
- The product is allowed to dry for a set time before UV exposure.

**UV Exposure:**

- A solar simulator emits controlled UV radiation.
- Five to six subsites of each test site are exposed to a geometrically incremented dose of UV light.

**Erythema Assessment:**

- After 16–24 hours, trained personnel assess the skin for erythema.
- The Minimal Erythemal Dose (MED) is determined for both protected and unprotected skin.
- SPF is calculated as:

$$\text{SPF} = \frac{\text{MED protected}}{\text{MED unprotected}}$$

This ratio indicates how much longer protected skin can be exposed to UV before burning compared to unprotected skin.

**Standardisation and Controls:**

- The method includes strict controls for UV dose, application technique, and environmental conditions.
- Products must be tested in a randomised and blinded manner to reduce bias.
- The standard also includes statistical criteria to validate the results and support reproducibility.

## *Sponsors' obligations in relation to SPF testing*

All cosmetic and therapeutic sunscreens must comply with SPF testing specified in AS/NZS 2604, as adopted in therapeutic goods legislation. Sponsors of therapeutic goods are required to hold evidence that the claimed SPF has been established by testing for their sunscreen product at the time of listing in the ARTG, and provide this information to the TGA if requested to do so.

## Advertising of sunscreens

Therapeutic sunscreens must be advertised in a clear, truthful and accurate way, ensuring no false or misleading claims are made. Advertising of listed sunscreens must comply with the Advertising Code, sponsors must hold evidence for any claims made, and the information presented in advertising material must not mislead consumers through exaggeration or omission. Accuracy ensures consumers receive reliable information about the sunscreen product.

Any advertising should provide a balanced presentation of both risks and benefits, and, where relevant, include details such as contraindications and precautions. This approach helps consumers to make informed decisions and prevents advertising from creating unrealistic expectations about a sunscreen's usage or effectiveness. In the case of broad spectrum sunscreens with an SPF of 30 or higher, advertising claims can be made in accordance with the permissible indications outlined above, under Sunscreen permissible indications.

Advertising of listed medicines must not claim that a product is completely safe or without side effects, effective in all cases, a guaranteed cure and/or infallible, unfailing, magical or miraculous, and must not be inconsistent with any current public health campaigns.

## Export of sunscreens

Under the Act therapeutic goods, including sunscreens, must generally be included in the ARTG before they can be manufactured in, or exported from, Australia, unless exemption applies. Sunscreens exported for commercial supply must be either listed in the ARTG as Export Only (EO) [4] medicines or listed or registered in the ARTG for domestic supply.

EO sunscreens must be manufactured in accordance with Part 3-3 of the Act, the Therapeutic Goods (Manufacturing Principles) Determination (Manufacturing Principles) and GMP. The Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024[5] applies to EO medicines.

While EO sunscreens are not legally required to meet Australian domestic standards for supply in Australia, in practice they almost always meet those standards. They must comply with the regulatory and labelling requirements of the importing country.

## Post market monitoring of sunscreens

The TGA conducts post-market compliance reviews of selected listed medicines in the ARTG, including sunscreens, to determine whether these medicines comply with relevant regulatory requirements. As sponsors self-certify compliance with regulatory and legislative requirements during the listing process, these compliance reviews are conducted to ensure these certifications are met and continue to be met.

The post-market regulatory framework for listed medicines is designed to provide early market access to low-risk medicines, and a proportionate approach to risk management. In facilitating early market access, there is greater reliance on a risk- and intelligence-based system of post-market monitoring and surveillance. The TGA reviews, tests and investigates a proportion of listed medicines for compliance with the regulatory requirements to ensure quality, safety and efficacy.

The review process generally begins with a Request for Information from the TGA, requiring sponsors to provide documentation including but not limited to labels, manufacturing documentation and evidence to support the product's claims. If non-compliance is identified, the TGA may take regulatory action, considering a range of factors including but not limited to the risk to the public and the compliance history of the sponsor. Regulatory actions may include lower-level enforcement action (e.g. education and guidance, warning letters) or escalated enforcement action (e.g. suspensions, cancellations, market action) depending on the alleged non-compliance. Where the TGA is

[4] www.tga.gov.au/resources/guidance/exporting-medicines-australia

[5] www.legislation.gov.au/F2024L01211/asmade/versions

contemplating taking regulatory action for a product, it is required to give the sponsor of each product a fair opportunity to respond before making a final decision.

Compliance review results, including cancellations and recalls, are published on the TGA website for transparency.

# Part 2: Matters raised with the current regulatory framework

Recent domestic and international developments have highlighted potential areas for improvement with the current framework.

We have been monitoring international developments relating to sunscreens:

- In 2019, the United States Food and Drug Administration (FDA) published an interim notification that certain sunscreen ingredients may no longer be considered Generally Recognized as Safe and Effective (GRASE)[6].
- In 2024, the International Organization for Standardization (ISO) published new SPF *in vitro* testing methods.

We have also been investigating domestic developments and media reports:

- The Australian consumer advocacy group, CHOICE, published a report[7] on 12 June 2025 that found that 18 out of 20 sunscreens failed to meet their claimed SPF 50 or 50+ ratings, based on independent testing, with one product testing as low as SPF 4.
- An ABC investigation revealed that a number of different products marketed in Australia were being supplied under the one ARTG identification number, as well as raising concerns relating to a number of sunscreen products not meeting their claimed SPF rating.

These developments, alongside our own internal investigations and reviews, have prompted the TGA to review aspects of the current regulatory framework for sunscreens. This paper identifies several key areas of improvement in the current framework.

## Matters being addressed elsewhere under the current framework

The following matters are included in this paper to provide the full context of considerations with the current regulatory framework. However, as they are being considered as part of other TGA consultive processes or reviews, they are therefore considered out of scope for this consultation paper.

### Safety of sunscreen ingredients

A number of the ingredients that can be included in therapeutic sunscreens were included in therapeutic goods supplied in Australia before the Act came into operation. These ingredients were assessed to have an established safety profile based on prior regulatory oversight and a long history of safe human use. Since then, we have undertaken a safety assessment on all new ingredients. If a person wishes to include an ingredient that is not currently approved for use in listed medicines, the substance must be evaluated by us before such use is permitted.

The TGA reviews ingredients used in sunscreens to maintain the highest standards of quality, safety and efficacy for sunscreens in the Australian market. We monitor international developments in sunscreen safety and prioritise our ingredient reviews by considering use of the ingredient in sunscreen products marketed in Australia.

[6] www.fda.gov/media/124655/download

[7] www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/sunscreen-test

In July 2025, we published a Safety review of seven active sunscreen ingredients[8] and a Safety review of benzophenone[9]. We also undertook a public consultation[10] on proposed reductions to the permitted concentrations of homosalate, oxybenzone and benzophenone (a degradant) in listed sunscreen products.

As a result of these reviews, we consulted with the public on proposed scheduling changes to lower the permitted level of the following substances in sunscreens:

- **Homosalate** and **oxybenzone** are active ingredients that can potentially be absorbed through the skin and may cause harmful effects if used in high concentrations, over large areas and over an extended amount of time.
- **Benzophenone** is not a permitted ingredient, but a substance that may be formed in the manufacturing process or from incorrect storage conditions - this is called a degradant. It has possible carcinogenic risks, and its levels should be limited in products.

The proposal to restrict the quantities of these substances in sunscreens is a precautionary measure based on potential signals from animal data studies, not human studies, when animals were exposed to these chemicals in high doses and for long periods of time, far beyond the amount that humans would be exposed to.

The interim decision on these ingredients will be published and subject to public consultation in early 2026. Depending on the outcome of the process, the quantities of these ingredients in sunscreen products may need to be adjusted within a certain period of time.

## Sunscreens marketed for use in children

While some sunscreens in Australia are marketed specifically for use in children, there may be little difference in formulation of active ingredients when compared to corresponding adult products. The TGA does not currently have any requirements or guidance for sunscreens that are targeted for use in children.

Both the Australasian College of Dermatologists and Cancer Council Australia advise that infants under 12 months should not be exposed to direct sunlight when the UV Index is 3 or higher, and sunscreen is not recommended for infants under 6 months (Australasian College of Dermatologists 2018[11]). For infants over 6 months, sunscreen can be applied to small areas of skin not covered by clothing or hats, but it should be considered as the last line of defence after other sun protection measures have been employed, including covering as much skin as possible with clothing.

Listed therapeutic sunscreens may only contain ingredients included in the Permissible Ingredients Determination. The TGA's evaluation of ingredients permitted in sunscreens utilises the Australian Sunscreen Exposure Model (ASEM), which calculates the highest estimated sunscreen exposure as a proportion of kg body weight per day. Risk assessments using the ASEM therefore account for any body weight, including in adults or children. This approach ensures that our risk assessments comprehensively cover the highest exposure for all Australians and ensure ingredients are safe to be used by everyone, no matter their age, weight or outdoor activity.

While the therapeutic goods framework does not require a separate formulation solely on the basis of the target population, marketing a sunscreen as a children's product may imply differences in safety, tolerability or risk that are not reflected in the formulation or in the relevant ARTG entry. Where a product is presented as being for children without any meaningful formulation difference, there is a

[8] www.tga.gov.au/resources/publication/corporate-reports/safety-review-seven-active-sunscreen-ingredients

[9] www.tga.gov.au/resources/publication/corporate-reports/safety-review-benzophenone

[10] www.tga.gov.au/resources/consultation/consultation-proposed-amendments-poisons-standard-relation-homosalate-oxybenzone-and-benzophenone-joint-acms-accs-meeting-september-2025

[11] ACD A-Z of Skin - Sun Protection & Sunscreens

risk of inconsistency between how the product is represented to consumers and how it is regulated and listed, which may have implications for ARTG accuracy, compliance with labelling requirements, and consumer confidence. This raises questions about whether products presented as being for use in children should have a formulation that is distinct from adult products, and considers the specific needs of children as an intended population.

Given we are considering this matter under the provisions of the current framework, it is therefore considered out of scope of the current consultation paper.

## The regulatory environment for sunscreens in Australia

Industry has raised concern that the higher regulatory requirements sunscreens face in Australia, when compared to other markets (such as Europe), are onerous and a barrier to product innovation and international trade, particularly in the approval of new ingredients and excipients. This is significantly driven by the fact that in Australia sunscreens are regulated as therapeutic goods, whereas in other markets they are regulated as cosmetics.

While the TGA maintains that Australian sunscreen requirements are the same as for any other listed medicine ingredient application, we have undertaken to review the requirements for sunscreen ingredient approvals in a separate process. Therefore, this issue is out of scope of this current consultation paper.

## Labelling instructions for novel dosage forms

The AS/NZS 2604 provides the testing requirements for sunscreens marketed in Australia and some labelling requirements relating to sunscreen performance and directions for use. The standard includes specific directions for use for aerosol and spray pump pack sunscreens, but does not specifically refer to other dosage forms.

The TGA is currently consulting[12] on a new standard to replace TGO 92. Included in this consultation is a proposal to consolidate the labelling requirements relating to sunscreen usage instructions from the AS/NZS 2604:2021 with additional information to manage risks associated with any type of dosage form. The labelling requirements will be principle-based, with labelling requirements informed by the potential risk posed by the dosage form.

## Level of sponsor understanding of current listed medicine framework

The TGA acknowledges the complexity of the Australian regulatory framework for therapeutic goods, including sunscreens. Our investigations into matters associated with sunscreens has indicated that inadvertent noncompliance may be caused by the level of understanding of sunscreen sponsors of their regulatory obligations.

The TGA will explore hosting webinars and developing e-learning modules to help sponsors better understand the listed medicines framework for therapeutic sunscreens. Further, the outcome of this current consultation paper and any resulting implementation of regulatory reforms will be accompanied with sponsor education activities.

# Proposed options to improve framework

For each matter identified below options are presented, including maintaining the status quo, introducing targeted enhancements, or more substantial reforms. A number of consultation questions are asked under each matter.

[12] https://consultations.tga.gov.au/medicines-regulation-division/proposed-changes-to-labelling-of-medicines/

# 1. SPF testing matters: Variability, oversight, flexibility and evidence requirements

## 1A: Current SPF *in vivo* testing has variability issues

There is significant variability in results obtained using the current *in vivo* (human) testing method in ISO 24444, and this variability increases with the SPF value. While changes made to ISO 2444 in the 2019 version sought to reduce this variability, these changes have not been sufficient.

At the end of 2024, ISO published methods that can be used for SPF determination, an *in vitro* (ISO 23675) and an *in vivo/in vitro* test (ISO 23698) as part of efforts to provide alternatives to evaluate sunscreen protection without requiring prolonged exposure of test subjects to UV. These methods were developed to overcome the known problems with reproducibility of ISO 24444. Both of the new standards are formally published. Unless there are local legislative differences, both of these standards are currently available for use by international stakeholders.

In Australia, however, under the current regulatory framework, sponsors cannot rely on testing against those standards for listing new products in the ARTG unless those standards are recognised by the TGA in our legislation, or are recognised in (likely a new version of) Australia's sunscreen standard AS/NZS 2604, which is then formally recognised by the TGA in our legislation.

In other words, either the TGA legislation must be amended which requires consultation and Parliamentary consideration, or there is a two-step process that requires two rounds of public consultation—both the relevant Standards Australia committee must agree to adopt them, and then subsequently for the new version of the standard to be adopted into TGA legislation.

***In vivo* SPF vs *in vitro* test methods**

In addition to these issues with reproducibility and variability, the method currently prescribed for SPF, ISO 24444, is considered invasive, requiring exposure of human test subjects to doses of radiation to elicit an erythemal response on the skin. This is costly and ethically problematic, and has longer lead times for test results compared to standard laboratory-based test methods. Further, these factors inhibit product innovation as sponsors will maintain older technology products as the cost of development of new formulations can be prohibitive.

The utilisation of *in vitro* test methods offers significant advantages, as they eliminate the need for human testing and are generally more cost-effective and efficient for industry. From a regulatory perspective, a fully *in vitro* method may be amenable to being performed by the manufacturer as a batch release or periodic test, to monitor the ongoing quality and efficacy of sunscreens.

A suitable regulatory *in vitro* test method would ideally need to demonstrate reproducibility of results and be applicable across as many types of formulated sunscreen products as possible. In developing *in vitro* test methods there has been a significant focus on correlation of *in vitro* results with *in vivo* SPF values, however given the high variation and known reproducibility issues between laboratories this is not necessarily the best measure of a robust method.

**Other ISO sunscreen standards**

In December 2024, ISO published 2 new standards with alternative sun protection test methods:

- ISO 23675 *Cosmetics - Sun protection test methods - in vitro determination of sun protection factor (SPF)*. ISO 23675:2024 is an *in vitro* method based on UV transmittance spectroscopy. Spectroscopic measurements through UV transparent substrates, two different types of polymethylmethacrylate (PMMA) plates, are used to predict an *in vivo* SPF value. The sunscreen product is applied to the PMMA plates using a robot. This method is an alternative to the *in vivo* method in ISO 24444:2019 (SPF).
- ISO 23698 *Cosmetics - Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy*. ISO 23698:2024 is a hybrid *in vivo/in vitro* method for determination of SPF and broad-spectrum performance. This method combines an *in vivo* 'skin analysis' to give a UVA

spectrum with *in vitro* testing on PMMA plates to measure UVA + UVB absorbance spectrum. The results from both tests are combined to produce a hybrid absorbance spectrum for calculations of SPF and broad-spectrum performance. This method is considered non-invasive compared to ISO 24444 because the test does not require a physiological response (i.e. it is non-erythemal) from the test subject. This method is an alternative to both ISO 24444 (SPF) and ISO 24443 (UVAPF) methods.

These methods are alternatives to ISO 24444:2019 for determination of SPF. However, neither of these methods is currently suitable for assessment of water resistance. These alternative SPF test methods were published ISO standards in December 2024. TGA acknowledges that significant efforts were made by ISO to validate these methods and the results have been published in the International Journal for Cosmetic Science in September 2025. There is currently limited data available to assess the suitability of the alternative methods across the full range formulations available in Australia and there will be a lead time before testing laboratories are ready to offer these new tests.

The TGA is currently willing to accept the results generated through these new methods as supporting evidence for sunscreens presently on the ARTG: www.tga.gov.au/products/medicines/therapeutic-sunscreens/manufacturing/advice-sunscreen-sponsors-and-manufacturers-acceptance-additional-spf-testing-information.

## Proposed options to improve reproducibility of SPF testing

### *Option 1: Status quo: maintain the existing testing requirements for sunscreens*

**Reasons for Option 1:**

- Claims for water resistance testing can be established by following AS/NZS 2604: 2021. These standards are already in place.
- ISO 24444 can be used for all types of sunscreen formulations, ensuring broad applicability across the market.
- Avoids the need for further retesting of products already on the market, which does not change regulatory burden.
- There would be no change to the current regulatory status of products and their labels.

**Reasons against Option 1:**

- Significant variability in SPF results that makes it difficult to rely on SPF claims.
- The test method is difficult to implement and requires human test subjects. This increases the cost of testing, and the accessibility of the method, but is also ethically problematic as it requires irradiation of the test subjects.

### *Option 2: Enable sponsors to comply with either in vitro or in vivo testing where appropriate*

**Reasons for Option 2:**

- Allows new products to be tested with a potentially more reproducible, and therefore reliable, test method.
- Sponsors would have the option to choose the testing method that best suits their product and operational needs, potentially reducing costs and barriers for some sponsors and manufacturers.
- Allowing *in vitro* methods could encourage innovation, as these methods are generally less expensive, faster, and do not require human testing.

- *In vitro* testing avoids the ethical concerns associated with exposing human subjects to UV radiation.
- This approach reflects recent international moves to develop and recognise alternative SPF testing methods, such as ISO 23675 (*in vitro*) and ISO 23698 (hybrid method).

**Reasons against Option 2:**

- Implementing this option will require amendments to existing legislation or to existing legislation and to AS/NZS 2604, which can be time-consuming and complex.
- Although there is compelling published evidence that validates the use of the *in vitro* standards, there is little real-world experience with the new standard.
- The new standards do not assess water resistance and therefore sponsors wishing to make these claims will need to understand the relationship between their *in vivo* water resistance results and *in vitro* results if they choose to use both methods.
- Continuing to accept *in vivo* testing in accordance with ISO 24444 would not address concerns with *in vivo* test reliability.

## *Option 3: Mandate in vitro SPF testing only, where appropriate*

**Reasons for Option 3:**

- *In vitro* methods were specifically designed to reduce laboratory to laboratory variability compared to *in vivo* testing, leading to more consistent results.
- *In vitro* testing is generally less expensive and easier to implement, allowing both regulators and sponsors to test SPF more frequently. This could provide greater oversight of sunscreen performance across the market.
- *In vitro* testing eliminates the need for human subjects, addressing ethical concerns associated with exposing people to UV radiation.
- Lower costs and quicker testing times may facilitate product innovation and allow for more frequent batch and shelf-life testing.
- The TGA is currently implementing this test, which allows for independent verification of SPF values using the same test method.

**Reasons against Option 3:**

- ISO 23675 (the *in vitro* method) is not yet officially recognised by Standards Australia in AS/NZS 2604, nor in Australian therapeutic goods legislation. This option may therefore involve both a consensus decision by the relevant Standards Australia committee, and legislative amendments. There is a risk that the Standards Australia committee will not be able to reach consensus or will adopt the method with Australia-only requirements.
- The current *in vitro* method does not cover water resistance and certain dosage forms, so it may not be suitable for all sunscreen products.
- There is limited real world data available generated using this method and there may be few laboratories able to conduct this test until it is more widely recognised.

### *1A: SPF testing consultation questions*

4. Which Option do you prefer?[13]
5. Why is this your preferred Option?
6. Do you have any other comments or feedback on the issue or proposal?

## 1B: Limited regulatory oversight for laboratories performing SPF testing

While a sponsor is required to hold evidence of the SPF testing for their sunscreen product at the time of listing in the ARTG, this information is not included in the ARTG entry nor is it provided to the TGA at the time of listing. The TGA therefore does not have oversight of which testing laboratory a sponsor has used, or the rigour of the testing conducted. However, the sponsor must provide this information to the TGA if the TGA requests it under the provisions of the Act.

Further, as the TGA does not regulate or accredit testing facilities, the onus of responsibility for selecting an appropriate laboratory rests with the sponsor.

The low reliability of certain laboratories used by some sponsors and manufacturers has likely enabled the listing, manufacture and supply of inadequate formulas that do not provide the claimed SPF protection.

Addressing the challenges in SPF testing requires a multifaceted approach. While the development and adoption of more robust standards, such as the recent ISO methods, provides a solid scientific foundation for reproducible and reliable results, they alone cannot guarantee the integrity of testing outcomes.

The selection of laboratories with proven expertise and appropriate accreditation is equally essential. Competent laboratories, operating within stringent quality frameworks, are better equipped to implement these standards effectively, minimise variability between test results, and ensure that claims about sunscreen efficacy are reliably supported.

Harmonising advanced standards with rigorous laboratory selection is therefore vital for enhancing confidence in SPF test data and safeguarding public health. The TGA understands that some SPF testing laboratories do not currently have accreditation to a testing standard such as ISO/IEC 17025: 2018 *General requirements for the competence of testing and calibration laboratories* [14] (ISO 17025), and that gaining this kind of accreditation is challenging. Most of the SPF testing laboratories are overseas, and therefore outside the TGA's jurisdiction.

As outlined in the URTS, release testing of sunscreens for supply is not currently required. Instead, this testing is performed at the formulation development phase, and laboratories performing these tests are therefore also not required under Australian regulatory requirements to hold GMP licence/certification/clearance or any other form of accreditation.

[13] ***Please note that the question numbering correlates with the questions numbers in the consultation hub.***

[14] ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories—This international standard specifies the general requirements for the competence, impartiality, and consistent operation of laboratories. It covers areas such as management system requirements, technical competence and training of personnel, equipment calibration and maintenance, test and calibration methods, results reporting, and continual improvement processes. Laboratories accredited to ISO/IEC 17025 must demonstrate their ability to produce valid and reliable results, implement robust quality management systems, and ensure traceability of measurements. Standards such as ISO 9001 do not specifically address testing competence.

# Proposed options to improve regulatory oversight of testing laboratories

## *Option 1: Status quo - maintain current level of oversight for sunscreen testing laboratories*

The TGA will continue to weight evidence based on the credibility of the laboratory, as per the guidance published on our website.

**Reasons for Option 1:**

- The TGA does not currently require SPF testing for sunscreens when they are released for supply, SPF testing is usually performed during formulation development. Mandating GMP or ISO 17025 accreditation would represent a significant departure from existing practice and international norms for sunscreens (but not other medical products). Introducing GMP licensing for laboratories performing SPF testing would require additional TGA resources for audits and possibly legislative amendments. This could create administrative complexity and delays in implementation.
- The availability of accreditation services for a method such as ISO 24444 internationally is unknown and TGA has no jurisdiction in requiring these services from accreditation bodies. Imposing such requirements on sponsors and manufacturers could create bottlenecks and leave sponsors and manufacturers without viable testing options.
- Maintaining the current approach avoids imposing additional compliance costs and delays on sponsors and manufacturers, which could otherwise impact product development timelines and market availability.

**Reasons against Option 1:**

- Most SPF testing laboratories do not hold ISO 17025 accreditation, raising questions about independent oversight, technical competence and consistency. This can lead to inaccurate SPF claims and undermine consumer confidence.
- Addressing variability in the test methods alone is not sufficient to improve the reliability of SPF test results. The performance of the laboratories conducting these tests must also be addressed.
- Weighting evidence based on credibility of the laboratory can only be done on a product-by-product basis. This is time-consuming and causes significant delays in TGA taking action on sunscreens with potential SPF issues.
- Requiring ISO 17025 accreditation could influence international jurisdictions to adopt similar measures, addressing SPF claim issues globally and improving harmonisation.
- Accreditation ensures robust quality management systems, traceability, and technical competence, reducing variability and errors in SPF determinations. This would strengthen regulatory confidence and consumer trust.

## *Option 2: Require that SPF testing results must come from an accredited or certified laboratory*

**Reasons for Option 2:**

- Requiring ISO 17025 accreditation through a Global Accreditation Cooperation Incorporated signatory ensures laboratories meet internationally recognised standards for technical competence and quality management.
- Requiring accreditation under existing international systems removes the need for TGA to directly audit or certify laboratories, reducing possible regulatory workload while addressing laboratory competence.

- Requiring the use of accredited or certified laboratories provides sponsors with clarity and confidence, while improving consumer trust in sunscreen labelling.
- This approach mirrors systems used by other regulators and other industries, promoting harmonisation and facilitating international trade compliance.
- By restricting sponsors to accredited laboratories, the likelihood of inaccurate SPF claims and unsafe products entering the market is greatly reduced.
- This requirement may influence overseas jurisdictions to follow suit and also require ISO 17025 accreditation for SPF testing laboratories, given sunscreen SPF claim issues are a global challenge[15].

**Reasons against Option 2:**

- TGA does not currently have oversight of accreditation.
- Long lead time for laboratories to achieve accreditation.
- Currently, very few laboratories globally hold ISO 17025 accreditation for any SPF testing method. This means there is very likely a lack of accreditation services for this test method.
- Achieving ISO 17025 accreditation for SPF testing is potentially challenging and expensive, potentially discouraging new entrants and reducing testing capacity.
- Mandating use of accredited or certified laboratories could lead to backlogs, especially during peak periods, impacting sponsors and manufacturers' ability to meet timelines and maintain product availability.
- Sponsors may face limited choice and higher costs, particularly if they previously relied on non-accredited laboratories that offered faster or cheaper services.
- May require legislative amendments.

### *1B Regulatory oversight for testing laboratories consultation questions*


7. Which Option do you prefer?
8. Why is this your preferred Option?
9. Do you have any other comments or feedback on the issue or proposal?

## 1C: Lack of flexibility to accommodate new testing requirements for sunscreens in a timely manner

The legislative framework for sunscreens currently requires that they meet the requirements set out in the joint Australian New Zealand standard for sunscreens, AS/NZS 2604:2021 and its 2012 predecessor (where transitional provisions in the Regulations apply). Standards Australia publishes

[15] https://www.consumerreports.org/health/sunscreens/c33614/; https://themonodist.com/korea-consumer-agency-warns-of-misleading-claims-in-popular-korean-sunscreens/; https://www.euroconsumers.org/over-a-third-of-facial-sunscreen-spf-ratings-mislabeled/; https://www.theportugalnews.com/news/2024-03-24/seven-face-sunscreens-fail-tests/87184; https://www.consumer.org.hk/en/press-release/528-sunscreen-test; https://www.myosh.com/news/many-sunscreens-dont-meet-their-label-claims

the standard, which is given legal effect by being specifically referenced in therapeutic goods legislation.

The Joint Technical Committee, CS-042 Sunscreen Agents, prepares the standard, which is approved by the Council of Standards Australia and the New Zealand Standards Approval Board. The Joint Technical Committee has New Zealand and Australian representatives from peak food, cosmetic and healthcare product industry bodies, manufacturers, testing laboratories, universities, cancer and dermatology organisations, the Australian Radiation Protection and Nuclear Safety Agency, the National Measurement Institute, and the TGA.

The legislative framework currently refers to the AS/NZS 2604:2021 standard. If the AS/NZS 2021 standard is replaced by a new standard, that new standard will not apply unless and until legislation is amended to refer to the latest iteration of the standard.

The standard controls performance statements such as SPF claims. In practice, this means that changes to labelling requirements relating to SPF claims generally cannot be made without amendments to the standard. If changes to AS/NZS 2604 are required, there is a formal process undertaken by Standards Australia before a new standard is published. After this process is completed, should the TGA wishes to adopt the new standard, it must start its own process to incorporate the new standard into therapeutic goods legislation.

While the TGA regularly incorporates industry standards into therapeutic goods legislation by reference, adopting updated versions is inherently complex. Regulatory best practice requires stakeholder consultation, a comprehensive regulatory impact assessment and, where necessary, provision of industry transition arrangements. Amending primary legislation or regulations requires formal legislative drafting and approval either by both houses of Parliament for an Act amendment, or the Executive Council and Governor-General for Regulations. While these measures provide transparency, they inevitably lengthen the implementation timeline for revised standards. For example, while the latest sunscreen standard was published in June 2021, it was not able to be adopted into legislation by the TGA until August 2024. Further, while all new sunscreens have to comply with the testing requirements of the new standard, existing sunscreens were given a 5 year transition time to transition to the new testing requirements, This means some sponsors currently hold data collected using the previous versions of ISO 24444 and ISO 24443, which have both since had revisions to improve reproducibility.

The current situation provides limited flexibility for the regulator to make changes to testing requirements where safety, quality or efficacy issues arise. Critical updates, such as improvements to SPF testing reproducibility, should be able to be adopted by the regulator in a timely manner to protect public health.

Most comparable overseas regulators adopt international standards, such as ISO sunscreen test methods, directly through their own regulatory instruments. To support international alignment and ensure that Australia can adopt validated global methods promptly, the TGA is considering mechanisms that allow more responsive adoption of updated scientific standards, such as establishing a dedicated TGA legislative instrument to clarify performance expectations. Importantly, if any changes are implemented, Standards Australia would remain an important stakeholder and technical contributor, in recognition of the role that AS/NZS 2604 plays in Australian industry practice.

## Proposed options for testing requirements for sunscreens

### *Option 1: Status quo - maintain the current approach of adopting AS/NZS 2604 into therapeutic goods legislation*

**Reasons for Option 1:**

- AS/NZS 2604 is a recognised benchmark developed by Standards Australia, ensuring consistency with local industry norms and technical expertise.

- The current approach accommodates older versions of the standard where transitional provisions apply, reducing disruption for products already in the market.

**Reasons against Option 1:**

- The legislation references AS/NZS 2604 at a fixed point in time. Newer versions of any of the sunscreen standards including AS/NZS 2604, ISO 24444, ISO 23675 and ISO 23678 are not automatically adopted, creating a lag in best practice implementation and potentially Australia-specific barriers to trade.
- Failure to adopt updated standards promptly may lead to inconsistencies with global norms, complicating trade and regulatory harmonisation.
- Any changes to SPF claim requirements or labelling cannot occur without formal amendments to the standard and subsequent regulatory updates, slowing responsiveness to emerging safety or consumer protection needs.

## *Option 2: Directly reference AS/NZS 2604 in new instrument for sunscreen testing requirements*

Under this option, a new instrument would be developed to set sunscreen performance requirements which could directly reference AS/NZS 2604.

**Reasons for Option 2:**

- Unlike the current framework, which requires legislative amendments to adopt new versions of AS/NZS standards, a new instrument can be updated more quickly to reflect emerging scientific evidence or safety concerns.
- A standalone instrument would allow the TGA to set and enforce sunscreen performance requirements in a timely, transparent way, while maintaining collaborative engagement with Standards Australia and industry stakeholders.
- Consolidating requirements in a new instrument will provide a clear, authoritative source for sponsors, reducing ambiguity about expectations beyond the standard.

**Reasons against Option 2**

- Where there are any changes to ISO standards, the TGA would still have to wait for these changes to be referenced in AS/NZS 2604, slowing responsiveness to emerging safety or consumer protection needs.

## *Option 3: Directly reference international ISO standards in a new instrument for sunscreen testing requirements*

Under this option, a new instrument would be developed to set sunscreen performance requirements. This instrument could directly refer to ISO standards or other testing requirements, as appropriate.

**Reasons for Option 3:**

- A new instrument would enable the TGA to set and enforce sunscreen performance requirements independently.
- The TGA would not have to wait for the standard for sunscreens to be updated by Standards Australia to adopt a new ISO standard. This would enable the regulator to adopt new ISO standards in a more timely manner, to protect public health.
- Updates to legislation require extensive consultation, technical input and legal drafting, which is resource-intensive and time-consuming. A new instrument can be updated more quickly to reflect emerging scientific evidence or safety concerns.
- This would also enable targeted improvements for local regulatory needs. Where appropriate, adding requirements beyond AS/NZS 2604 allows the TGA to address gaps in the standard, such

as post-market verification, water resistance, broad spectrum performance and testing expectations.

**Reasons against Option 3:**

- Manufacturers accustomed to AS/NZS standards may resist a new regulatory framework, citing cost and complexity in adapting processes.
- Moving away from AS/NZS standards could reduce alignment with New Zealand, complicating trade and compliance.
- If requirements in the new instrument overlap or conflict with AS/NZS provisions, this could lead to interpretation issues and disputes.
- Sponsors and manufacturers may resist additional requirements, citing cost, complexity, and lack of harmonisation with New Zealand, again complicating trade and compliance.

### *1C Testing requirements for sunscreens consultation questions*

10. Which Option do you prefer?
11. Why is this your preferred Option?
12. Do you have any other comments or feedback on the issue or proposal?

## *1D: Sponsor evidence to support SPF claims is generally based on the base formula and not the final finished product*

The TGA has identified instances where product formulations are modified throughout the product's lifecycle without additional SPF testing being conducted. In some of these cases, the scientific justification provided for some sunscreens has been found insufficient.

While there is a legislative requirement that sunscreens be tested in accordance with AS/NZS 2604, current guidance is limited. Additional guidance from the TGA could assist sponsors in understanding the actions they must take to ensure ongoing compliance. International standards also do not provide information on ongoing testing.

Current TGA guidance on when SPF testing should occur following formulation changes is broad. There are no prescriptive requirements regarding how often testing is to be conducted or how to demonstrate that the testing conducted is reliable, and it is unclear whether testing must be conducted on the market formulation. There is also no obligation for sponsors to generate supporting data that demonstrates sunscreen shelf-life performance for SPF, water resistance, or broad spectrum claims. This lack of clarity leaves a gap in regulatory expectations and may affect the reliability of SPF claims on sunscreen products.

Currently, the TGA permits SPF testing to be conducted during the 'product development' phase, often on pilot batches, rather than requiring ongoing testing of commercially released batches. Due to a lack of clarity as to legal requirements, some sponsors rely on SPF testing conducted on a base formulation, rather than the final marketed formulation which includes all excipients. In some instances, this involves the sponsor SPF testing a representative formulation and providing a justification for why the results can be extrapolated to a particular ARTG sunscreen.

After a product's formulation is scaled up for commercial manufacturing, sponsors typically do not re-test the SPF performance of the final, market-ready batches. This has led to some sponsors not conducting new SPF testing even when a formulation may no longer be 'representative' of their sunscreen. It has also made it difficult to correlate tested batch numbers with market formulations.

## *Proposed options for 1D: Sponsor evidence to support SPF claims*

### *Option 1: Status quo*

**Reasons for Option 1:**

- Current broad guidance allows sponsors to exercise scientific judgment, accommodating diverse product development processes without imposing rigid requirements.
- Maintaining the status quo avoids introducing new compliance obligations, minimising administrative and cost impacts for both industry and regulators.
- Sponsors can make minor formulation adjustments without mandatory retesting, enabling faster product updates and market responsiveness.
- The current approach aligns with historical practice and international norms, reducing disruption for sponsors accustomed to these standards.

**Reasons against Option 1:**

- Testing only base formulations or failing to retest after changes can lead to marketed products that do not meet claimed SPF levels, compromising consumer safety.
- TGA investigations have found that some sponsors provide weak or inadequate rationale for not retesting, highlighting gaps in accountability.
- Broad guidance creates variability in thresholds for retesting, leading to uneven quality standards and potential regulatory uncertainty.
- If products fail to deliver promised protection due to untested formulation changes, public trust in sunscreen labelling and regulatory oversight may decline.

### *Option 2: Keep testing requirements for base formulations with guidance to sponsors on when additional product testing is advised*

Under this proposal, the TGA will provide guidance based on the application of Statistical Process Control (SPC) techniques to encourage sponsors and manufacturers to develop periodic testing over a sunscreen product's life.

Periodic testing will reduce the number of impacted batches when a non-conforming result is observed. More batches tested per year means greater reduction in weighting of individual results, reducing random fluctuations that may influence a mean SPF result.

Any approach to periodic testing would need to be scalable and proportionate, considering factors such as production volume, formulation complexity, and compliance history.

**Reasons for Option 2:**

- Sponsors can continue using base formulation testing as the primary requirement, which is less resource-intensive and aligns with current practice.
- Mandatory retesting obligations would be avoided, minimising compliance costs and administrative complexity for both sponsors and regulators.
- Certain minor formulation changes could be allowed without mandatory retesting, enabling quicker product updates and market responsiveness.
- Providing specific guidance on when additional testing is expected helps reduce ambiguity and promotes more consistent decision-making among sponsors.
- This approach offers incremental improvement without requiring legislative changes or major structural reforms.

- This would not require legislative amendments and could be achieved relatively quickly.
- This will also assist to address SPF claims for products that are not clearly linked to the original formulation tested.

**Reasons against Option 2:**

- Base formulation testing may not reflect the performance of the formulation of the final marketed product.
- Even with guidance, thresholds for retesting remain subjective, potentially leading to inconsistent practices and inadequate scientific justification.
- Without mandatory retesting, products could still enter the market with SPF values that do not match claims, undermining safety and trust.
- Guidance alone may not ensure retesting after significant formulation changes or over the product's shelf life.
- As guidance is not mandatory, it limits the ability to enforce consistent compliance within industry and makes regulatory action more difficult to justify.

### *Option 3: Mandate SPF testing at the time of listing on the finished product and periodically while the product is in the ARTG including over the shelf life of the product*

There is an exemption under Schedule 5, Item 3 of the Regulations that allows the manufacture of samples for laboratory testing before listing.

Under this proposal, manufacturers/sponsors would be required to test the SPF of finished product samples prior to listing a sunscreen on the ARTG in addition to periodically conducting SPF testing of commercial batches based on the application of SPC techniques.

To address the issue of shelf life potentially impacting a product's SPF, sponsors would also need to conduct SPF testing at the end of the product's claimed shelf life to ensure that the SPF claim is supported up until product expiry.

**Reasons for Option 3:**

- Testing the finished product rather than a base formulation confirms that the marketed product delivers the claimed SPF, broad spectrum, and water resistance protection.
- Periodic testing captures any impact of formulation adjustments or ingredient variability, reducing the risk of performance degradation.
- Regular verification strengthens trust in sunscreen labelling and regulatory oversight, mitigating reputational risks for both sponsors and regulators.
- Testing during the product's shelf life ensures SPF performance remains consistent until expiry, preventing underperforming products from remaining on the market.
- If non-conforming results are found, more frequent testing will reduce the time between the most recent non-conforming result and the last conforming one, reducing the number of potentially suspect batches.
- This approach reflects a proactive, risk-based model similar to pharmaceutical stability testing, reinforcing high standards for therapeutic goods.

**Reasons against Option 3:**

- Mandatory periodic testing may add substantial expense for sponsors and may require additional laboratory capacity, increasing compliance costs.

- Testing at listing and during shelf life could be costly, slow product launches, and create bottlenecks, especially if accredited laboratories are limited.
- Defining frequency, scope, and acceptable methods for periodic testing would require detailed regulatory guidance and monitoring systems.
- Few jurisdictions mandate ongoing SPF testing, so this could create divergence from international norms and complicate trade compliance.
- Sponsors may face uncertainty about how to proceed if periodic testing reveals small SPF variations, leading to sponsor initiated voluntary recalls or sponsor initiated relabelling even when consumer risk is minimal. Any guidance would need to provide information on acceptable/non-acceptable deviations.
- This approach alone may not resolve issues related to reliability of data and testing laboratories, especially if sponsors and manufacturers continue using the same potentially unreliable laboratories.

### *1D Sponsor evidence to support SPF claims consultation questions*

13. Which Option do you prefer?
14. Why is this your preferred Option?
15. Do you have any other comments or feedback on the issue or proposal?

### *1E: Sponsors are not required to make their SPF testing data available to the TGA at the time of listing or publicly available to consumers*

Currently, sponsors of sunscreen products are not required to provide their SPF testing data to the TGA at the time of listing. While sponsors must hold evidence to support their SPF claims and provide it to the TGA if required, there is no obligation for this information to be submitted proactively or included in the ARTG entry.

Further, there are no requirements for sponsors to make their SPF testing data publicly available, meaning that both the regulator and consumers have limited transparency regarding the evidence underpinning SPF claims on sunscreen products.

## Proposed options for 1E

### *Option 1: Status quo*

**Reasons for Option 1:**

- Sponsors avoid additional compliance steps, and the TGA does not need to process or store large volumes of SPF data, minimising resource demands.
- Current requirements allow sponsors to hold evidence without mandatory submission, supporting streamlined product listing and faster market entry.
- SPF testing data often includes proprietary formulation details. Not requiring proactive submission or public disclosure protects commercial confidentiality.
- This would allow the regulatory burden to remain consistent across sunscreens and listed medicines as this requirement is not imposed on any other type of listed medicine.

**Reasons against Option 1:**

- Without proactive submission, the TGA cannot easily verify SPF claims at listing, increasing the risk of inaccurate or misleading product claims.
- Consumers have no access to evidence supporting SPF claims, which can undermine trust in sunscreen labelling and regulatory assurance.
- The TGA only reviews data if concerns arise, which may allow non-compliant products to remain on the market until after issues are detected and investigated. This causes significant delays before regulatory action can be taken on SPF compliance issues.
- Sponsors may interpret requirements differently, leading to variability in the robustness of SPF testing and justification provided when requested.
- Proactive submission would enable trend analysis and early identification of systemic issues, improving regulatory effectiveness.

### *Option 2: Require sponsors to provide testing data to the TGA at the time of listing, which will be held in confidence*

While submission of SPF data at the time of listing would not constitute premarket assessment and would not delay listing, it would support post-market oversight.

**Reasons for Option 2:**

- This provides transparency for the regulator and, by extension, the public.
- Prospective submission allows the TGA to verify SPF claims at the time of listing, reducing the risk of inaccurate or misleading products entering the market.
- Access to data at listing enables the TGA to identify gaps or inconsistencies upfront, preventing downstream enforcement issues.
- Having data on file allows the TGA to conduct trend analysis and risk profiling, improving systemic oversight and policy development.
- Holding data in confidence addresses sponsors' concerns about proprietary information, balancing transparency with commercial sensitivity.
- This ensures that marketed sunscreens meet performance claims, enhancing trust in regulatory processes and product safety.
- This may also encourage sponsors to have up to date testing from accredited laboratories to ensure compliance with evidence requirements under the Act, and the efficacy of their product.

**Reasons against Option 2:**

- The TGA would need systems and a significant number of additional staff to manage, store, and review large volumes of data, creating operational challenges. Our systems do not currently support receipt of this information at the time of listing – other than via email – noting listed sunscreens are not assessed pre-market.
- Few regulators require proactive SPF data submission, so this could create divergence from international norms and complicate trade compliance.
- Having data on file does not guarantee ongoing compliance if formulations change post-listing without retesting.
- This proposal would increase administrative burden on the TGA to enable receipt and review of this information.

### *Option 3: Require sponsors to make their testing data publicly available.*

**Reasons for Option 3:**

- Sponsors are likely to ensure robust testing and accurate claims when data is subject to public scrutiny.
- Researchers, consumer groups, and health professionals can verify SPF performance, contributing to better public health outcomes.
- Open data supports modern regulatory trends toward transparency and evidence-based decision-making.

**Reasons against Option 3:**

- SPF testing reports often include proprietary formulation details. Public disclosure could expose trade secrets and intellectual property.
- Technical data may be misunderstood by consumers or media, leading to confusion or unwarranted concern.
- Sponsors would need to prepare data for public release in a clear, accessible format, adding cost and complexity.
- Few jurisdictions require public disclosure of SPF data, so this could create divergence from international norms and complicate trade compliance.
- Publicly available data could be used by competitors to reverse-engineer formulations or benchmark products unfairly.

### *1E Sponsor provision of SPF testing data consultation questions*


16. Which Option do you prefer?
17. Why is this your preferred Option?
18. Do you have any other comments or feedback on the issue or proposal?

## 2. Potential efficacy or quality issues with specific formulations/ingredients

There is a lack of appropriate and robust quality standards for sunscreens, including the absence of legislation comprehensively addressing ingredient-level properties, finished product formulation requirements and performance considerations.

For example, while pharmacopoeia monographs (e.g. United States Pharmacopeia-National Formulary) exist for zinc oxide, they do not address functional attributes such as particle size distribution, which can significantly affect SPF performance and safety (e.g. skin penetration, UV attenuation).

Further, no standardised monographs exist for many chemical UV filters (e.g. avobenzone, octocrylene) or other mineral active ingredients like titanium dioxide, especially in the context of their use in sunscreens.

# Proposed options for 2

## *Option 1: Status quo – maintain current oversight of sunscreen ingredients and formulations*

**Reasons for Option 1:**

- Sponsors and manufacturers are accustomed to existing requirements based on AS/NZS 2604 and ISO methods. Keeping the status quo prevents disruption to established processes.
- Developing ingredient-level standards would require significant resources, technical expertise and stakeholder consultation. Maintaining the current framework avoids these costs and delays.
- In the absence of rigid monographs or detailed formulation standards, manufacturers retain flexibility to innovate with new UV filters and formulations.
- Many jurisdictions do not mandate pharmacopeial monographs for sunscreen actives or enforce detailed formulation standards, so the status quo aligns with international norms.

**Reasons against Option 1:**

- It does not address current gaps in quality assurance. Without robust standards, similar SPF related issues could occur in the market.
- Critical properties like particle size distribution for zinc oxide and titanium dioxide are not standardised, which can affect SPF performance and raise safety concerns (e.g. skin penetration).
- Current standards focus on performance claims but do not address formulation integrity or lifecycle stability, leaving significant regulatory blind spots.
- Variability in SPF results and absence of clear quality benchmarks undermine trust in sunscreen labelling and regulatory oversight.
- Introducing robust standards could position Australia as a leader in sunscreen regulation and improve global harmonisation over time.

## *Option 2: Develop an instrument for ingredient quality requirements to ensure efficacy*

**Reasons for Option 2:**

- Specifying ingredient-level quality standards (e.g. particle size distribution for zinc oxide, testing of particle dispersion, or purity for chemical UV filters) would help ensure consistent SPF performance and reduce variability.
- Addressing gaps in guidance on functional attributes of sunscreen actives would provide clear benchmarks for manufacturers.
- Strong ingredient requirements reduce the risk of underperforming products, reinforcing trust in sunscreen labelling and regulatory oversight.
- Clear requirements for raw materials promote uniformity across formulations, reducing disputes and improving predictability for sponsors.
- Introducing robust ingredient requirements positions Australia as a leader in sunscreen regulation and best practice.

**Reasons against Option 2:**

- Developing detailed ingredient specifications require extensive scientific input, stakeholder consultation, and ongoing maintenance.

- Stricter ingredient requirements may result in cost implications, reformulation needs and supply chain constraints for manufacturers.
- Monitoring compliance with ingredient-level requirements would require additional regulatory resources and possibly new testing capabilities.
- Few jurisdictions mandate ingredient-specific monographs for sunscreens. Diverging from international norms could complicate trade and compliance for global brands.
- Prescriptive ingredient requirements may limit flexibility for introducing new UV filters or novel formulations.

### *Option 3: Require pre-market evaluation for safety, quality and efficacy for all sunscreens (e.g. a registered products model)*

**Reasons for Option 3:**

- Registration requires a TGA pre-market evaluation of quality, safety and efficacy in accordance with the requirements for registered OTC medicines.
- Moving from self-certification to formal assessment would let the regulator verify SPF, broad spectrum and water resistance claims upfront, instead of relying mainly on post-market checks. This addresses the weaknesses highlighted in current practice where listed therapeutic sunscreens do not undergo pre-market efficacy evaluation.
- Requiring robust, reviewable evidence at registration reduces the risk that products supported by poor-quality or fraudulent data reach consumers.
- Pre-market assessment provides greater assurance that sunscreens are of high quality, reliability and performance.
- Australia permits therapeutic sunscreens to make strong preventive claims (e.g. skin-cancer prevention). A pre-market efficacy review may better match the level of public-health impact associated with those indications than the lighter listed-medicine pathway.
- Transparent, evidence-based gatekeeping strengthens trust in labelling and in the regulator's assurance, especially given current public concerns about SPF accuracy.
- Evaluated data at registration, including on stability and shelf-life performance, provides a benchmark to compare against any later formulation changes applied for post-market.

**Reasons against Option 3:**

- The current framework explicitly aims to enable early market access via a streamlined listed medicine pathway. If sunscreens are reclassified as registered medicines, sponsors may need to rework development programs, prepare dossiers and potentially reformulate. This could potentially add cost, time and effort beyond the current listed medicine model.
- Pre-market efficacy reviews for all sunscreens would require new assessment capacity. The TGA has already noted that case-by-case approaches are resource-intensive, and scaling to full pre-market evaluation could be even more demanding.
- Robust, reviewable evidence often depends on competent laboratories and validated methods. Recent work has highlighted limited availability of laboratories with high-assurance accreditation for SPF testing, which could create bottlenecks when pre-market evidence becomes mandatory.
- Many jurisdictions, including Europe, treat sunscreens as cosmetics and do not require medicine-style efficacy registration. A shift to universal registration may increase divergence, complicating trade and dual-market product strategies.

### *2 Potential efficacy or quality issues with specific formulations/ingredients consultation questions*

19. Which Option do you prefer?
20. Why is this your preferred Option?
21. Do you have any other comments or feedback on the issue or proposal?

## 3. Labelling matter: SPF labelling considerations

The SPF rating system was introduced in the 1960s and remains the internationally accepted method for labelling the UVB photoprotective efficacy of sunscreens.

The SPF value for a sunscreen indicates how much longer it will take for a person exposed to the sun to suffer from sunburn or the other adverse effects of sun exposure, compared to a person who is not wearing any sunscreen. The SPF test is conducted under controlled laboratory conditions that may not reliably correspond to the level of protection the sunscreen actually provides in real-world conditions. Although solar energy amount is related to solar exposure time, there are other factors that impact the amount of solar energy a consumer is exposed to and the effectiveness of the sunscreen, such as:

- Intensity of solar exposure: Solar energy is higher at midday compared to early morning. Further, solar intensity is generally greater on clear days than cloudy days.
- Skin type: Fair-skinned consumers are likely to absorb more solar energy than dark-skinned consumers under the same conditions.
- Amount of sunscreen applied: More sunscreen results in less solar energy absorption.
- Reapplication frequency: In general, more frequent reapplication is associated with decreased absorption of solar radiation.
- Activity: Swimming and sweating may physically rub off the sunscreen.

Due to the various factors impacting the amount of solar radiation, SPF is a relative measure of the amount of sunburn protection provided by sunscreens.

There is a general lack of understanding among consumers of the SPF rating scale, and what SPF figures mean in real terms. The SPF scale is not linear. The difference in the amount of sun protection between an SPF of 30 and 50 is minimal, and this difference becomes even smaller as the SPF value increases.

When applied correctly:

- SPF 30 sunscreen filters approximately 97% of UVB rays, and
- SPF 50 sunscreen filters approximately 98% of UVB rays.

SPF values based on *in vivo* testing methods are known to produce highly variable results. The lack of reproducibility in testing methods makes it challenging for sponsors to confidently determine an accurate SPF value for a product, leading to ambiguity in product claims and difficulty in complying with regulatory requirements. For example, a product claiming an SPF 50+ is required to demonstrate an SPF of over 60. This means that if a product has a test result of SPF 55 at a particular point in time, this product may be considered non-compliant (subject to other test results), despite providing a high level of UVB protection.

Current misconceptions and understanding of SPF values, combined with the variability of test results, underscore the need for clearer labelling to ensure that consumers understand the protection a sunscreen offers and to provide sponsors greater certainty of regulatory compliance.

Note that any changes for SPF labelling would include suitable transition times provided to industry, along with a public education campaign.

## Proposed options for SPF labelling matter

### *Option 1: Status quo – maintain use of current SPF rating system for labelling*

**Reasons for Option 1:**

- SPF ratings are widely understood as a benchmark for sun protection, and changing the system could create confusion and require extensive public health education campaigns.
- Current SPF labelling practices align with globally recognised ISO methods and AS/NZS 2604, ensuring harmonisation with other jurisdictions. Australia would not be consistent with international regulators if the current SPF labelling was changed.
- No increase in regulatory burden for sponsors.

**Reasons against Option 1:**

- *In vivo* SPF testing is highly variable, and SPF values may not accurately reflect real-world protection.
- Current labelling does not explain variability or diminishing returns at higher SPF levels, leaving consumers unable to make fully informed choices.
- Clearer labelling that is readily understood by consumers could enhance public health outcomes.
- The lack of reproducibility in testing methods makes it challenging for sponsors to confidently determine an accurate SPF value for a product, leading to potential ambiguity in product claims and difficulty in complying with regulatory requirements.

### *Option 2: Provide additional labelling requirements for the SPF ratings*

For example, “SPF 30 filters X% UVB rays”

**Reasons for Option 2:**

- Adding explanatory statements clarifies what SPF values mean in practical terms.
- Consumers can better compare products when they understand the percentage of UVB filtered, leading to more rational choices based on actual protection.
- Providing scientific context on labels demonstrates regulatory commitment to accuracy and consumer education.
- Adding explanatory text is less disruptive than replacing the SPF system entirely, making it a practical improvement.
- This approach can be paired with campaigns to explain diminishing returns at higher SPF levels, reinforcing sun safety behaviours.

**Reasons against Option 2:**

- Sunscreen labels are already crowded with mandatory information. Adding mandatory explanatory text may require significant redesign or compromise readability.
- Statements like “*SPF 30 filters 97% UVB*” may lead consumers to assume near-complete protection, ignoring factors like application thickness, reapplication and other sun-safe behaviours.
- Sponsors would need to update packaging and marketing materials, incurring regulatory costs.

- Most jurisdictions do not mandate explanatory SPF statements. Introducing this requirement could create divergence and trade complications.
- Consumers accustomed to numeric SPF ratings may find mixed messaging confusing if explanatory text is inconsistently applied across brands.
- Significant public education on the difference between SPF claims will be required.

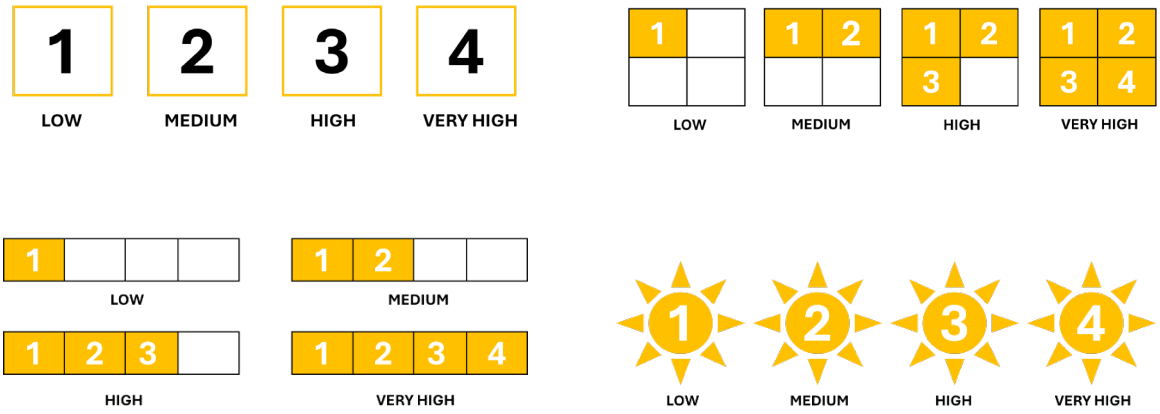
## *Option 3: Change labelling requirements for sunscreen performance ratings*

Replace the current SPF rating system with the words: 'low', 'medium', 'high' 'very high':

**LOW MEDIUM HIGH VERY HIGH**

These words could be used on their own, or combined with an easily identifiable graphic, such as 1,2,3,4, a sun, a grid, or a bar. Potential examples are provided below, for context only. If this option is pursued, further work and consultation will occur to determine the most meaningful and effective labelling graphics for consumers.

Potential examples:




**Reasons for Option 3:**

- Using categories like "low," "medium," "high," and "very high" or other graphics simplifies SPF information.
- Adding an intuitive graphic (e.g. a 1–4 bar or segmented circle) makes it easier for consumers to quickly interpret protection levels, especially for those with low health literacy.
- Category-based labelling is consistent with best practice for conveying complex scientific data in a consumer-friendly way.
- Clear categories help consumers select products based on their needs (e.g. everyday use vs high UV exposure).
- A new system provides a platform for campaigns explaining what each category means, improving overall sun safety awareness.

**Reasons against Option 3:**

- Changing labelling requirements would require legislative amendments, redesign of packaging, and industry investment.
- Moving from SPF numbers to categories could confuse consumers accustomed to the current system, requiring extensive education efforts.

- Most jurisdictions use SPF numbers. Adopting a category system could create divergence, complicating trade and compliance for multinational brands.
- Symbols or bars may be misunderstood without clear explanatory text, leading to incorrect assumptions about protection levels.
- Significant regulatory burden with labelling changes.

### *3 SPF labelling consultation questions*

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22. Which Option do you prefer?
23. Why is this your preferred Option?
24. Do you have any other comments or feedback on the issue or proposal?

## 4. Cosmetic sunscreens able to make high SPF claims

The current provisions in the Excluded Goods Determination 2018 exclude tinted bases, foundations and lip products with SPF claims up to SPF 50+ from being therapeutic goods, provided they meet certain criteria, such as compliance with AS/NZS 2604, not being promoted for therapeutic use, and not including substances included in a schedule to the Australian Poisons Standard. Ingredient safety for these products is overseen by the AICIS, while the ACCC regulates their labelling and overall product safety.

These provisions originated from the historical legislative documents Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, and the Cosmetics Standard 2007.

The TGA regulates all other sunscreen products that make high level SPF claims as therapeutic goods. Australian consumers are familiar with the SPF rating for sunscreens and are likely to select a product with a high SPF rating (e.g. SPF 30, SPF 50 or SPF 50+) for use as a primary sunscreen, regardless of whether the product is being promoted for therapeutic or cosmetic purposes. That is, the SPF ratings are synonymous, from a consumer's understanding, with the therapeutic use of a sunscreen for UV protection.

In addition, primary sunscreens are recommended for reapplication every 2 hours, but makeup and lip balms aren't typically used at that frequency, resulting in potential inadequate protection.

Accordingly, as these goods may be used by consumers as if they are primary sunscreens due to their SPF claims, it could be considered inconsistent that they do not have equivalent regulatory oversight.

In addition, excluded cosmetic sunscreens are primarily for use on the face and lips, a common area for melanomas. In 2023, 18,257 people were estimated to be diagnosed with melanoma, which was the third most common cancer diagnosed in Australia at 11% of all diagnosed cancers. It is estimated that 7.6% of these melanomas occurred in the scalp and neck, equating to 1388 people in one year[16].

## Proposed options to address cosmetics making high SPF claims

### *Option 1: Status quo – maintain current exclusion provisions for cosmetic sunscreens*

**Reasons for Option 1:**

[16] https://uat.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

- The current approach reflects long-standing provisions from the Excluded Goods Determination and Cosmetics Standard, minimising disruption for industry.
- Maintaining the status quo avoids imposing additional requirements and regulatory burden on cosmetic manufacturers, such as labelling, ARTG listing, GMP compliance.

**Reasons against Option 1:**

- While products with high SPF claims may be used as primary sunscreens, they are not subject to the same regulatory oversight as therapeutic sunscreens, creating a safety and compliance gap.
- If these products fail to deliver claimed protection, consumers may unknowingly be under-protected, eroding trust in SPF labelling and regulatory systems and leading to poorer health outcomes.
- Aligning these products with sunscreen regulations could improve clarity and harmonisation across product categories, reducing ambiguity for sponsors and consumers.

### *Option 2: Amend the Excluded Goods Determination to require that excluded sunscreens include 'cosmetic sunscreen' on their primary label*

**Reasons for Option 2:**

- This option provides transparency for consumers and maintains consumer choice.
- It avoids imposing additional requirements (e.g. ARTG listing, GMP compliance) on cosmetic manufacturers, reducing costs.
- It could also improve clarity and harmonisation across product categories, reducing ambiguity for sponsors and consumers.

**Reasons against Option 2**

- While products with high SPF claims may be used as primary sunscreens, they are not subject to the same regulatory oversight as therapeutic sunscreens, creating a safety and compliance gap.
- If these products fail to deliver claimed protection, consumers may unknowingly be under-protected, eroding trust in SPF labelling and regulatory systems and leading to poorer health outcomes.

### *Option 3: Amend the Excluded Goods Determination to provide a consistent limit of the SPF rating that can be claimed for all secondary (cosmetic) sunscreens*

Under this option, all secondary sunscreens that are excluded from therapeutic goods legislation cannot make high-level SPF claims. In other words, excluded secondary sunscreens can only claim 'low' SPF protection.

**Reasons for Option 3:**

- Establishing a uniform SPF claim limit for excluded sunscreens aligns with primary sunscreen regulations and reduces ambiguity.
- Limiting SPF claims reduces consumer reliance on products that are marketed with a high SPF in circumstances where there is minimal regulatory oversight of that testing when compared to the testing of primary sunscreens.
- A consistent SPF cap simplifies messaging and helps consumers understand the relative protection offered by excluded secondary sunscreens.
- This promotes appropriate sun safety behaviours, such as using primary sunscreens for high UV protection.

- Sunscreens are recommended for reapplication every two hours, whereas makeup and lip balms aren't typically used at that frequency. This option would align with that practical reality.

**Reasons against Option 3:**

- Manufacturers may resist SPF claim limits, arguing it restricts marketing flexibility and could impact product competitiveness.
- Lower SPF claims on excluded secondary sunscreens may confuse consumers who have previously relied on high-SPF cosmetics for convenience.
- Sponsors would need to update packaging and marketing materials to a lower SPF, or update their packaging, marketing materials and potentially also reformulate as a part of listing the goods in the ARTG, incurring additional costs.
- Introducing SPF caps may diverge from international cosmetic standards, creating compliance challenges for multinational brands.

### *4 Cosmetics making high SPF claims consultation questions*

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25. Which Option do you prefer?
26. Why is this your preferred Option?
27. Do you have any other comments or feedback on the issue or proposal?

## 5. Opportunities to enhance sunscreen manufacturing guidance

Recent matters relating to sunscreen performance and product compliance in Australia present an opportunity for the TGA to review our current Good Manufacturing Practice (GMP) guidance for sunscreens, particularly given that this guidance was published in 2018 and predates several emerging technical and regulatory developments.

Our recent investigations of sunscreen manufacturers have not revealed any specific manufacturing issues that explain why a number of sunscreens were identified with low SPF results. However, our inspection data has identified matters that could be improved by the TGA providing greater clarity on existing GMP expectations. This includes providing greater clarity on such things as knowledge management, definition and control of critical quality attributes and critical process parameters for ingredients and manufacturing processes, responsibilities between manufacturers and sponsors, responsibilities for product release, and other broad manufacturing issues.

Sunscreen manufacturing is a highly specialised area in which manufacturers often hold the most practical and technical expertise. Robust oversight and contemporary guidance are essential. Clearer, contemporary guidance, particularly at the sponsor–manufacturer interface, could help mitigate potential quality and compliance risks, support more consistent GMP interpretation, and drive improved manufacturing outcomes. A more aligned and practically focused approach would strengthen compliance and enhance confidence in sunscreens supplied to Australian consumers.

### *Proposed options to enhance sunscreen manufacturing guidance*

### *Option 1: Status quo – maintain current GMP guidance for sunscreen manufacturers*

**Reasons for Option 1:**

- Sunscreen manufacturers can continue to observe guidance which is established and understood.

- This avoids the potential need for changes to existing manufacturing practices, avoiding an increase in regulatory burden.

**Reasons against Option 1:**

- Current guidance may not adequately mitigate emerging concerns or risks associated with sunscreen manufacture.
- Lack of guidance for management of sponsor-manufacturer responsibilities and knowledge transfer may result in poor compliance outcomes.

### *Option 2: Review sunscreen GMP guidance to incorporate contemporary information and address any additional risks*

**Reasons for Option 2:**

- This option permits an open review process to consider any developing or additional manufacturing risks for sunscreens.
- It addresses manufacturing risks in a proportional and practical manner.
- It also promotes stronger risk management, more reliable outcomes, and improved confidence in sunscreens supplied to Australian consumers.

**Reasons against Option 2:**

- Updated guidance may present additional regulatory burden for manufacturers and sponsors of sunscreens.

## *5 Sunscreen manufacturing guidance consultation questions*

28. Which Option do you prefer?
29. Why is this your preferred Option?
30. Do you have any other comments or feedback on the issue or proposal?

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Complementary and Over the Counter Medicines Branch (COMB)<br>Therapeutic Goods Administration (TGA) | March 2026 |

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au  Phone: 1800 020 653 Fax: 02 6203 1605
**https://www.tga.gov.au**

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