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Sunscreen in Australia: a roadmap to more effective & efficient regulation

Accord Australasia

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Executive summary

Sunscreen is a critical preventive health tool in Australia, where skin cancer is both one of the most prevalent and one of the most preventable diseases. Despite its importance, Australia faces a public health crisis with melanoma diagnoses projected to grow and skin cancer treatment costing an estimated $2.47 billion annually. By 2030, the total economic impact of melanoma is expected to reach $8.7 billion.

Despite the high risk and costs of skin cancer, consumer use of sunscreen remains alarmingly low. While regulators presume an annual consumption of 9 litres per adult, the actual average used by each person is only 115 ml. This reluctance is largely driven by "skin feel" issues, such as stickiness, greasiness and visible residue, which discourage appropriate application.

The Regulatory Landscape and "Regulatory Creep"

Australia maintains some of the strictest regulatory settings globally, treating sunscreens with SPF 15+ as therapeutic goods rather than cosmetics. One consequence of this is that, while sunscreens were explicitly excluded from national licensing in 1989, they were brought into the scheme in 1994 exposing them to onerous Good Manufacturing Practice (GMP) standards which are designed for medicines.

Over time, "regulatory creep" also occurred, such as the 2010 decision to apply full PIC/S GMP and the 2015 introduction of the Permissible Ingredients Determination. Each incremental step has compounded a complex, expensive and slow system for approving new products. Excessive cost and regulatory burden has consistently discouraged the introduction of innovative sunscreen products and ingredients into Australia.

Currently, the Therapeutic Goods Administration (TGA) uses a risk-minimisation model that focuses heavily on potential adverse effects of ingredients while failing to weigh them against the health costs of underuse.

Existing Barriers to Safety and Innovation

Australia suffers from significant delays in approving new ingredients, lagging behind the European Union and even the United States.

This is particularly evident in the approval of excipients which are vital for improving "skin feel" and water resistance. The number of new sunscreen excipients approved has dropped radically due to the high costs and long wait times associated with TGA processes. Furthermore, current reviews of common UV filters like homosalate and octocrylene pose further risks with for example, proposed limits on homosalate which could result in the removal of 50% of all currently used sunscreens from the Australian market. This is despite the fact that the UK Scientific Advisory Group has determined concentrations of 20-30 times higher than the proposed Australian level to be safe.

Impact on Effectiveness and Consumer Confidence

Accurate determination of effectiveness of sunscreens is currently hampered by variability in *in vivo* (human) SPF testing which can be biased by subject skin type and other individual factors. This variability, highlighted by media reports during 2025, is a significant threat to public confidence.

Additionally, Australia's lack of alignment with international ISO standards creates export barriers for local companies while preventing Australians from accessing innovative products available elsewhere. Labelling also causes confusion. For instance, some products claim and can prove four-hour water resistance but mandatory requirements mean that they are forced to include instructions to reapply every two hours.

Economic Barriers and Quality Requirements

Regulating sunscreens as medicines requires pharmaceutical-grade ingredients and audited GMP facilities, which are often unnecessary for sunscreens. The error here is to draw an equivalence of risk between ingestion of ingredients and their topical application.

These requirements add up to $212,000 in additional costs per product compared to markets where sunscreens are regulated as cosmetics. Given that Australia represents only 2% of the global market, these high regulatory costs and data requirements, including such unnecessary insistences as medical-grade fragrance, make it unattractive for global innovators to enter the Australian market.

A New Proportionate Regulatory Approach

To address these issues, a proportionate approach is needed which distinguishes between minor iterations of existing products and genuinely novel ingredients and formulations. This roadmap recommends two pathways as follows:

1. A pathway similar to that used for medical devices, whereby new products from existing sponsors which are broadly similar to existing products may be approved for sale with post-market data collected as an assurance of quality and safety. This is the simpler path; and,

2. A pathway similar to that used for pharmaceutical products where, for genuinely novel products and formulations, potential costs are considered in proportion to potential benefits.

By shifting the counterfactual to the cost of underuse, the regulatory system can better support the introduction of formulations that Australians are actually willing to use. A more detailed exposition of these approaches is outlined later in this paper.

From this, a number of direct recommendations are provided that form a forward roadmap.

A Roadmap for regulatory reform

Recommendation One: Adopt a proportionate approach to regulation, recognising the significant risks associated with non- or under-use of sunscreens compared to the risks identified with sunscreens to date

Recommendation Two: Given this proportionate approach, introduce a dual pathway approach towards Australia's regulatory approach to sunscreens:

1. A pathway similar to that used for medical devices, whereby new products from existing sponsors which are broadly similar to existing products may be approved for sale with post-market data collected as an assurance of quality and safety. This is the simpler path; and,

2. A pathway similar to that used for pharmaceutical products where, for genuinely novel products, potential costs are considered in proportion to potential benefits.

Recommendation Three: Remove duplication of regulatory effort locally: Eliminate duplicative regulatory efforts between the TGA and the Australian Industrial Chemicals Introduction Scheme (AICIS) through mutual recognition or cooperative evaluation and scheduling.

Recommendation Four: Remove duplication of regulatory effort through recognition of the international regulatory environment: Recognising that sunscreens are highly regulated globally, Australia should introduce post-market surveillance-based regulation for ingredients and products already approved by trusted international authorities. Regulatory effort should focus on new UV filter actives as opposed to excipients, truly novel ingredients, verifying the bona fides of new sponsors and any identified real risks for specific ingredients and sponsors.

Recommendation Five: Streamline GMP requirements: Consider GMP requirements for sunscreen products globally and reduce duplicative GMP audits by accepting certifications from reputable international regulators, such as US FDA-approved sites, regardless of their location.

Recommendation Six: Undertake consumer surveys to contextualise and inform the cost and benefits of sunscreen regulation and its impact on Australians and their use of sunscreen.

Recommendation Seven: Adopt into regulation all relevant ISO standards for SPF testing of sunscreens

Recommendation Eight: Develop transparent and realistic regulatory guidelines for the acceptance of different SPF testing methods and their variability to facilitate the transition to new SPF testing methods.

Recommendation Nine: Consider regulatory mechanisms to benchmark and track acceptable variations across formulations, testing methods and laboratories.

Recommendation Ten: Working with stakeholders, improve the process of keeping regulations up to date with international developments.

Recommendation Eleven: Working with stakeholders, develop clear and easy to understand SPF efficacy claims that align with major markets.

Recommendation Twelve: Develop sunscreen labelling requirements that assist consumers to make informed choices.

Sunscreen in Australia

Sunscreen is an essential preventive health tool which – when used properly – plays a critical role in reducing the risk of skin cancer: one of Australia's most preventable diseases.

It is critical that Australians can access safe, effective and high-quality sunscreens that they are willing to use and that are reasonably priced.

The current consumer experience of sunscreens in Australia is not positive with multiple studies reporting that the discomfort associated with traditional sunscreen formulations is a significant disincentive to appropriate application. Studies show that barriers to using sunscreen include that it makes the skin feel too sticky or greasy; leaves a white film on the skin; and/or makes consumers feel unattractive.[1] This critical issue of 'skin feel' results in many Australians either not using appropriate amounts of sunscreens or not using them at all.

The importance of 'skin feel' to the use of sunscreens is supported by a study examining the attitudes of Americans which found that greasiness is one of the most commonly cited reason for not using sunscreen, amongst 35.9% of respondents. This figure is for those who identify as white whereas the response rate increases to 56.7% for those of Asian/Pacific Islander descent,[2] a population especially relevant for Australia.

The impact of the current consumer experience with sunscreens is clear in Australians' use of sunscreen. While the TGA in its calculations presumes that consumption of sunscreen is 9 litres per adult annually,[3] the reality is that the average use by an Australian adult is actually around 115 ml per year.[4] The low annual usage is strong evidence of people's reluctance to use sunscreen and has significant impacts for Australians' health.

The consequences of sub-optimal use of sunscreen are significant. While the full economic impact of improved sunscreens is outside the scope of this paper, the landmark Nambour Study demonstrated that consistent and appropriate use of sunscreens of at least SPF15 for people living in sunny climates reduces the risk of melanoma by 50%.[5]

[1] Katharina Diehl et al, "Who Are the Nonusers of Sunscreen, and What Are Their Reasons? Development of a New Item Set", *Journal of Cancer Education*, 2021

[2] Heike I M Mahler, "Reasons for Using and Failing to Use Sunscreen: Comparison Among Whites, Hispanics, and Asian/Pacific Islanders in Southern California", *JAMA Dermatology*, 2014

[3] This type of volume would only apply to a small percentage of the population, typically working outdoors, applying sunscreen several times a day to a significant area of the body, for most days per year.

[4] Moving Annual Total (MAT) data of grocery and pharmacy sale of sunscreen (August 2023) data, divided by the Australian population over the age of 15 (Australian Bureau of Statistics data from the 2021 Census).

[5] Adèle C Green et al, "Reduced Melanoma After Regular Sunscreen Use: Randomized Trial Follow-Up", *Journal of Clinical Oncology*, 2011.

Historical Background

By international standards, Australia has very strict regulatory settings with respect to production, permissions and claims around sunscreens. In contrast, many jurisdictions, including the United Kingdom and European Union, treat sunscreen as a cosmetic product, despite its value in health prevention.

Australia has evolved to a more onerous regime over time with one example of this being the progressive implementation of Good Manufacturing Practice (GMP), a requirement strongly justified in the case of medicines manufacturing but arguably less necessary for sunscreens.

In 1989, a new single national licensing scheme for therapeutic goods explicitly excluded sunscreens. However, in 1994, they were brought into the broader scheme, which in turn exposed them to GMP standards explicitly developed for medicines.[6] Recognising that sunscreens are different from medicines, a lighter touch version of GMP was applied.

Then, in 2010, a decision was made to apply the full GMP (PIC/S GMP) to sunscreens. This appears to have been an arbitrary policy decision rather than a response to any observed negative outcomes.

Following this, in 2015, another similar decision was taken with the introduction of Permissible Ingredients Determination. While this was aimed at consolidating information within the TGA, it had in turn the impact of bringing the regulation of sunscreens even closer to that required for medicines.

These events are noted simply as evidence of a form of regulatory creep which has led to the current complex, expensive and slow consideration of new sunscreen products.

This evolution of regulation – rather than structured and planned regulation – has also meant that some important elements relating to sunscreens have become arguably under-regulated, such as validation of efficacy testing, or confused, as in the case of consumer communication and labelling.

These appear to be unintended consequences which have increasingly held back Australia's options in the battle against skin cancer.

Impact of the regulatory environment

While recognising that the TGA has a critical role in ensuring the safety of products making therapeutic claims and supporting appropriate regulation, as outlined above, Australia's current regulatory environment for sunscreens risks Australians being unable to access emerging technology and innovations that could reduce the rate of skin cancer by preventing them from accessing the types of sunscreens they might want to use at reasonable prices.

This is largely caused by the approach currently being taken to sunscreens and their regulation in Australia which adds costs, time and other barriers to the introduction of newer sunscreen ingredients and

[6] Therapeutic Goods Administration, "Cod of GMP for Therapeutic Goods: Sunscreen Products", February 1994.

formulations, despite the fact that many of these would reduce sunscreen reluctance, primarily by addressing concerns about skin feel, appearance and efficacy.

At present, the TGA's approach appears to be a uni-directional risk minimisation model, which accounts for potential adverse effects of both current and new proposed ingredients but does not compare these to the costs of not using sunscreen. It seems likely that this approach is taken because sunscreens are still available and consequently the risk of skin cancer is addressed. However, this does not take into account the impact on consumer behaviour or use of sunscreens of their aversion to current formulations and especially their excipient ingredients or higher sunscreen prices due to increased regulatory costs. A more complete model would account for low or non-users of sunscreens as a group who require access to new products to address their preventive health needs.

The current approach reflects a broader challenge across the Australian health system, where the value of prevention is discounted relative to treatment. Where the TGA is considering, for example, a new pharmaceutical, side-effects and adverse reactions are weighed against the opportunity cost of not making the medicine available, such as illness, deterioration and mortality. These same opportunity costs are present with the high incidence of skin cancer but do not seem to be included in the risk calculations for sunscreen. The consequence is that the risk/return matrix is imbalanced with excessive focus on risk minimisation without proper recognition of the potential benefits of better protection – in practice, at present Australians are being protected from sunscreens rather than from potentially lethal sun damage they can prevent.

Purpose of this paper

This paper builds on an earlier scoping paper prepared for an industry forum held in Melbourne on 21 November 2025 and designed to guide and inform discussion. This paper, while including much of the earlier work done in relation to barriers to optimising the safety, effectiveness and quality of sunscreens in Australia, goes further, proposing regulatory solutions to help overcome and address these barriers.

Accord Australasia

Accord Australasia is the peak national association representing manufacturers and sponsors of personal care, cosmetic, hygiene and specialty products.

Together, Accord's members deliver products used in homes, workplaces, institutions and industries every day — from cleaning, oral care and personal hygiene to cosmetics, sunscreens, fragrances and specialty products.

Accord exists to represent and advance Australia's hygiene, cosmetic, personal care and specialty products industry and does this by:

- Advocating for responsible, evidence-based policy and regulation
- Supporting members with insights, networks and services that strengthen their businesses

- Championing the industry's contribution to health, wellbeing, innovation and sustainability

Accord's ultimate purpose is to help create a responsible, competitive and sustainable industry that delivers lasting benefits for Australians and the communities it serves, and its work is guided by its values and principles which include collaboration, inclusion, solutions-focus, science- & evidence-based, and responsible and ethical practice.

Uniting the industry, Accord builds consensus and provides a strong voice to regulators, government and the community. Accord advocates for policies that support innovation, sustainability and responsible business practices; equips members with knowledge, connections and services that strengthen their businesses; and promotes the essential role its industry plays in safeguarding health, supporting wellbeing and enhancing everyday life.

The Australian regulatory environment for sunscreens

In Australia, the Therapeutic Goods Administration regulates most sunscreens as therapeutic goods (therapeutic sunscreens). Therapeutic sunscreens therefore need to meet all the legal requirements for therapeutic goods before they can be supplied in Australia and are then listed on the Australian Register of Therapeutic Goods (ARTG), usually as "listed" or lower risk medicines.

Therapeutic sunscreens include:

- Primary sunscreens: Products that are used primarily for protection from UV radiation; and,
- Some secondary sunscreens: Products with a primary purpose other than sun protection, that also contain sun screening agents and are not excluded from therapeutic goods legislation, e.g., sunbathing and moisturising skin care products with an SPF of over 15.

Many secondary sunscreen products are not considered to be therapeutic goods and are 'excluded' from therapeutic goods legislation (cosmetic sunscreens). These product types are outlined under the *Therapeutic Goods (Excluded Goods) Determination 2018.*[7]

What this means is that, while sunscreens are not medicines, therapeutic sunscreens in Australia are currently regulated under the *Therapeutic Goods Act* in the same way as 'listed' or oral medicines.

This significant regulatory environment exists despite the fact that, in 2017, a government consultation paper *Options for the future regulation of 'low risk' products* focused on a range of products considered to pose little or no risk to the health of consumers. Sunscreens were included in this and six broad criteria for risk assessment were considered when considering how to define 'low risk'. These included:

- The safety of the ingredients;
- The route of administration;
- The risk associated with the claims including labelled use;
- The nature of the condition being treated or prevented;
- The nature and number of the population using the product; and
- The impact of poor quality in manufacture.

These criteria formed the basis for the Low Risk Classification System which found the risk rating outcomes for both primary and secondary sunscreens to be "low".

[7] Therapeutic Goods Administration, "About sunscreens", 28 July 2021. https://www.tga.gov.au/news/news-articles/about-sunscreens#:~:text=Primary%20sunscreens:%20Products%20that%20are,an%20SPF%20of%20over%2015. Accessed November 2025.

The outcome of the consultation, as it related to sunscreen, noted that there would be no changes to the way sunscreens were regulated in Australia 'however a number of ongoing activities will be pursued to reduce regulatory burden associated with these products'[8] implicitly acknowledging that the current regulatory burden is onerous.

Existing barriers to optimising safety

Process to approve new excipient ingredients

The Therapeutic Goods Administration (TGA) states in its introduction to sunscreen regulation:

> "Most therapeutic sunscreens are listed in the Australian Register of Therapeutic Goods (ARTG). They can only use our approved ingredients and indications for sunscreens. A sunscreen needs to be registered in the ARTG if it contains non-permitted ingredients or non-approved indications. Where this is the case, we assess the quality, safety and efficacy of products that are registered in the ARTG before they go on the market."[9]

Currently there are significant delays for the approval of ingredients for sunscreens and Australia lags behind the range of ingredients that can be used in other countries, including the European Union (EU). It is also worth noting that Accord is unaware of any other country that requires approval of sunscreen excipients, including the US where the FDA regulates sunscreens as a medicine. Australia's approach to approvals and the delays associated with it means that Australians – despite our high levels of skin cancer – are missing out on new innovations and developments in sunscreens and at least one Australian company is unable to sell its product in its country of origin.

Approval of ingredients is relevant in two ways as follows:

1. The approval of active ingredients, which are part of the formal therapeutic claim and which reduce the impact of UV exposure on the skin; and,
2. The approval of excipients, which may variously:
    a. Have relevance to the therapeutic claim, separately from the SPF assessment. Of particular relevance here are elements of sunscreen formulation which increase water resistance; and,
    b. Have significant consequences for the optimal consumption and application of sunscreen, particularly those which affect the all-important 'skin feel'.

[8] Therapeutic Goods Administration, "The future regulation of low risk products", Last updated 13 April 2023. https://www.tga.gov.au/products/regulations-all-products/tga-reforms/medical-devices-reforms/medical-devices-reforms-low-risk-products/future-regulation-low-risk-products Accessed November 2025.
[9] Therapeutic Goods Administration, "Therapeutic Sunscreens". https://www.tga.gov.au/products/medicines/therapeutic-sunscreens Accessed November 2025.

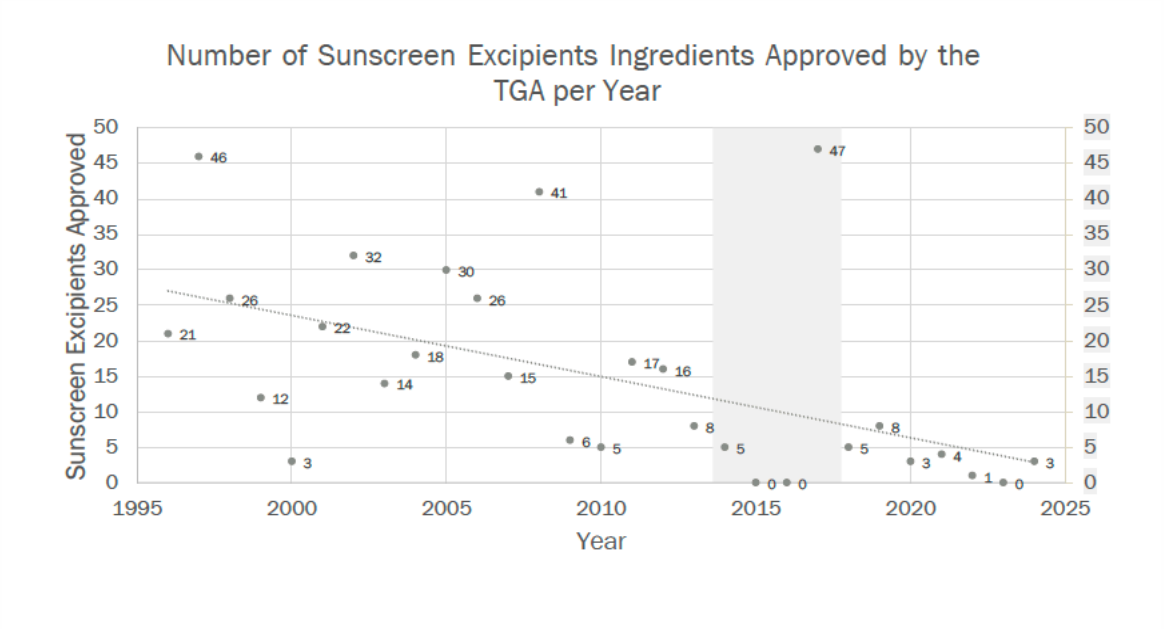
It is important to note here in relation to item 2a that water resistance and the persistent efficacy of sunscreens during water activities is an unusual if not unique concern of the Australian market, given the dominance of coastal living and water-related leisure activities. This means that multiple formulations of sunscreens are made only for the Australian market – approximately 2% of aggregate global demand – and which are consequently made in Australia.

This may be positive from a domestic economic viewpoint but it also means that there is little corporate appetite for incremental expense for individual formulation testing for any share of such a small proportion of the global market.

Herein lies the challenge. The development of new sunscreen formulations to address sunscreen reluctance is expensive and the addition of further excipient elements, such as the Australian market's demand for water resistance, only increases this expense while simultaneously diluting the potential return. Added to this, any increased regulatory impost makes development of sunscreens for, and registration within, the Australian market most unattractive.

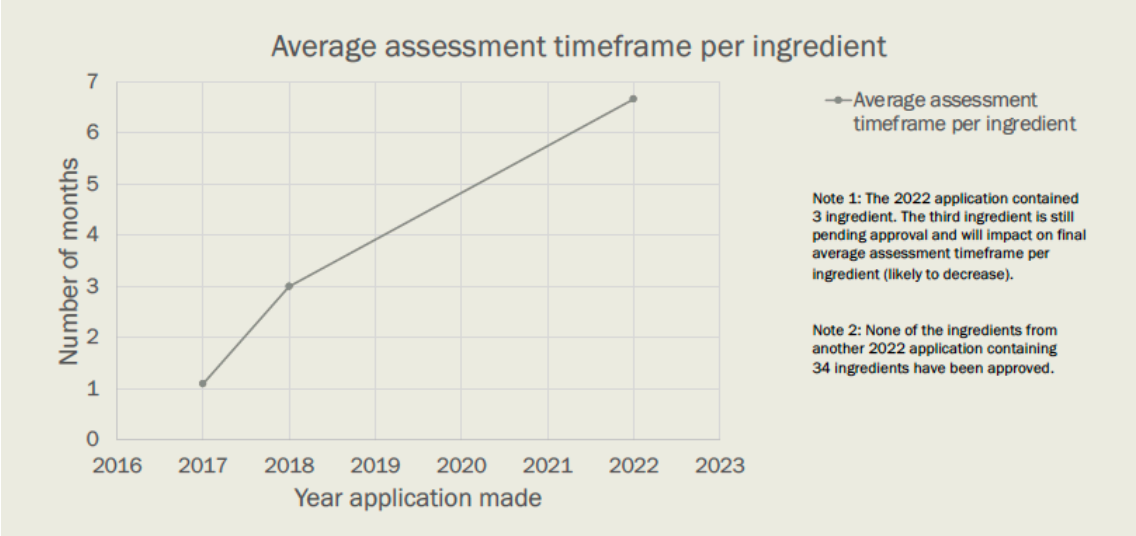
This is illustrated by Figure One which shows the radical reduction in new ingredient approvals by the TGA over recent years.

Figure One: Number of new sunscreen excipients approved in Australia, 1995-2023



This is in part explained by the non-inflationary cost increase of each approval and by the increasing time between application and approval as demonstrated by Figure Two.

Figure Two: Average time for ingredient approval, 2017-2023



The combination of increasing cost with accelerating delays makes Australia a particularly unattractive market into which to introduce new products.

Reviews of UV filters

The TGA is currently reviewing the use of multiple UV filters, including homosalate, oxybenzone and octocrylene. In these reviews, two key issues need to be considered including how the risk assessment of any filter is undertaken or approached; and what range of UV a filter may address and how filters actually interact with each other.

Approach to risk assessment of filters

Homosalate, oxybenzone and octocrylene, either individually or in combination, are currently present in around 75% of all sunscreens on the Australian market.

The danger inherent in the TGA's current proposal is that the avoidance of potential risk is valued and acted upon over an actual, quantified risk with negative consequences for the majority of available sunscreens despite no established reduction in risk.

Benzophenone, a known degradant of octocrylene,[10] a UV filter, is noted in various research as an 'established carcinogen'[11] and the review of it is used here as an example of how any risk associated with a UV filter is currently approached.

The significance of benzophenone's carcinogenicity in relation to sunscreens is somewhat disputed, particularly the question of whether benzophenone can be absorbed from skin contact with carcinogenic

[10] Therapeutic Goods Administration, "TGA to consult on additional controls for some sunscreen ingredients", 8 July 2025.
[11] C A Downs et al, "Benzophenone Accumulates over Time from the Degradation of Octocrylene in Commercial Sunscreen Products", *Chemical Research in Toxicology*, 2021.

consequences. More importantly, it is pointed out that the theoretical cancer risk associated with benzophenone should properly be weighed against the much clearer cancer risk from unprotected sun exposure and the known burden of that risk.[12]

It is further identified that the animal studies showing carcinogenicity of benzophenone are all from oral intake with no evidence of risk arising from skin exposure to the same product.[13]

Part of the issue which emerges is that the rate of degradation of octocrylene into benzophenone over the shelf life of a sunscreen is somewhat unpredictable. Nonetheless, there are expected ceilings and a practical and safe limit – e.g., 780 parts per million which is a tiny percentage – is eminently achievable. Tighter thresholds risk manufacturers removing large numbers of products from the market for compliance reasons without any evidence to support lower limits.

The bigger issue is for homosalate with proposed allowable use of <1% which would not deliver the necessary UV protection, the key reason for the ingredient. If the TGA goes ahead with this proposal, this alone would remove 50% of sunscreens from the Australian market.

In a review of homosalate finalised earlier this year,[14] the UK Scientific Advisory Group on Chemical Safety in Consumer Products (SAG-CS) concluded that homosalate is safe for use in sunscreens at up to 10%, a concentration that can deliver UV protection and 20-30 times the TGA's proposed limit.

The assumption of unreasonable risk is exacerbated by TGA modeling which presumes what could only be called maximum consumption of sunscreen is somehow modal: 9 litres per adult annually, when the mean annual use is actually around 115 ml.[15] The low annual use by Australians is the strongest evidence of sunscreen reluctance and the approach to octocrylene/benzophenone and homosalate is a signal example of the hurdles to new ingredients.

Range and interactivity of UV filters

It is also important when considering UV filters to recognise that these agents do not all act to filter out the same UV light range and also that some of them interact to reinforce the benefits offered by others. Filters are not simply interchangeable and a systematic approach to replacing any ingredient is required in order to ensure that the safety and/or effectiveness of the end product is not negatively impacted.

[12] Lucy Howard, Andrew Birnie & Robert Sarkany, "Comment on Benzophenone Accumulates over Time from the Degradation of Octocrylene in Commercial Sunscreen Products", *Chemical Research in Toxicology*, 2021.
[13] IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. *IARC monographs on evaluation of carcinogenic* risks to humans, volume 101 Some Chemicals Present in Industrial and Consumer Products, Food and Drinking-Water, 2013. https://www.ncbi.nlm.nih.gov/books/NBK373192/
[14] Scientific Advisory Group on Chemical Safety in Consumer Products, *Opinion 17: Homosalate use in cosmetic products*. https://assets.publishing.service.gov.uk/media/682dde88a599d03a16bff3b3/sag-cs-opinion-17-homosalate-in-cosmetic-products.pdf
[15] Moving Annual Total (MAT) data of grocery and pharmacy sale of sunscreen (August 2023) data, divided by the Australian population over the age of 15 (Australian Bureau of Statistics data from the 2021 Census).

Existing barriers to optimising effectiveness

Variability in SPF testing

The current *in vivo* testing – or testing on humans – required by Australia's Sunscreen Standard is prone to inherent variability as highlighted by media reports in 2025. Results can be affected by numerous factors, including:

- Differences in people's skin types and response to UV;
- Subjective assessment of the degree of skin redness that occurs; and,
- Variation in lighting and calibration conditions within the laboratory/ies where testing occurs.

Lack of consumer understanding/mandated label claims

As various media reports demonstrated in 2025, testing methods and their inherent variability are not well understood and any ambiguity about them potentially undermines public confidence in sunscreens as a preventive health category. Given the importance of sunscreen in reducing the risk of skin cancer, this uncertainty cannot continue and clear guidance needs to be provided as to how sunscreens are tested and public confidence in the products effectively restored. Possible strengthening of regulations may be needed with the specific goal of improving transparency and accountability in the testing 'supply chain'.

In addition, various of the mandated claims regarding sunscreens are not well understood by consumers and consideration should be given to how labelling, with improved consumer education, might better inform consumers and allow them to discern between different sunscreen options. An example here is the apparent conflict between label claims of 4-hour water resistance – backed up by testing data – yet accompanied by mandatory label advice to reapply every 2 hours.

Consideration of aligning SPF testing standards to facilitate trade

SPF testing in Australia is currently governed by Australia/New Zealand standards as outlined in *AS/NZS 2604 Sunscreen products – Evaluation and classification* (Sunscreen Standard). There is no equivalent international standard to AS/NZ 2604 and, in fact, AS/NZ 2604 incorporates some elements of International Standard Organization (ISO) standards while adding others.

Table One details ISO Standards that are adopted in Australia via the Sunscreen Standard and those that are not.

Table One: ISO Standards adopted/not adopted in Australia

Test type	Adopted	Not adopted
SPF	ISO 24444:2019	ISO 23675:2024 In vitro determination of sun protection factor (SPF) ISO 23698:2024

	Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)	Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy
UVA/UVB (broad- spectrum)	ISO 24443:2021 Cosmetics — Determination of sunscreen UVA photoprotection in vitro	ISO 24442:2022 Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection
Water resistance	ISO 16217:2020 *(with Australian modifications)* Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance	ISO 18861:2020 Cosmetics — Sun protection test methods — Percentage of water resistance

The TGA considers the adoption of the Australian Sunscreen Standard once the decision on whether to adopt an ISO Standard into the Sunscreen Standard has been finalised, leading to additional layers of complexity and time to the process.

The lack of alignment with ISO standards creates challenges for companies, especially those seeking to sell their products internationally. For example, at present, while for UVA (broad-spectrum) testing Australia requires *in vitro* testing – or testing without human subjects – some countries, such as Korea, accept only *in vivo* testing – or testing with human subjects – which means that two separate tests need to be performed – one to ISO 24442 and another to ISO 24443.

Consideration should be given to aligning Australian and international standards on sunscreen to facilitate ease of export and trade for Australian companies seeking to sell their products into other markets as well as to enable Australians to access newer, innovative sunscreens that are available elsewhere in the world.

It is noted here that there will remain for the foreseeable future some requirement for *in vivo* testing, particularly with respect to water resistance.

Existing barriers to optimising quality

Pharmaceutical grade excipients and GMP

Regulating primary sunscreens as therapeutic goods means that the ingredients in these sunscreens must be of medical grade regardless of whether they are active or excipient ingredients and that manufacturing facilities for sunscreens are subject to TGA inspections and so forth as GMP facilities.

These requirements in turn create challenges in a variety of ways including:

- Requiring suppliers to provide data regarding medical grade ingredients where this is not required in the vast majority of markets globally;

- Products being impacted by delays in excipient ingredient approvals as identified above, especially where the ingredient does not have a pharmacopoeial standard;
- Time and costs involved, including delays, to inspect and audit manufacturing, packaging and other facilities;
- Costs to undertake Product Quality Reviews (PQRs) as well as for stability trials for at least two production scale batches initially followed by one annually; and,
- Costs in registering new active and excipient ingredients.

These challenges lead to idiosyncratic outcomes. Many common ingredients that are used in sunscreens overseas and in cosmetics in Australia, e.g., laminaria saccharia extract, are not allowed to be used in therapeutic sunscreens in Australia.

Auditing of sites

It should be noted here that the requirement for GMP and the associated auditing of sites is extremely onerous.

Australia is only around 2% of the global sunscreen market. To stay competitive, Australian manufacturers look to export overseas. Export markets, such as the US, have their own stringent GMP requirement which must be met by the Australian manufacturer. Adding the TGA licensing requirement over the top of this is a redundant cost. Similarly for importers, for many overseas manufacturing sites, there is already certification by competent local authorities. The TGA licensing requirement for 2% of the global market is a substantial and redundant cost.

Consideration should be given to the true need and benefit of this process. It is a cost which is either passed on to Australian consumers, which will reduce sun safety, or a cost which is prohibitive and will lead to removal of advanced formulations from the Australian market.

At the very least, it is recommended that the TGA explore alignment and acceptance of certification by similar international regulators.

Cost of the barriers

While sunscreens are not medicines as highlighted above, currently in Australia primary sunscreens are regulated under the Therapeutic Goods Act in the same way as 'listed' or oral medicines. This means that:

- Products must undergo validated SPF testing to the Australia/New Zealand Standard (AS/NZS 2604), partially aligned with international ISO methods;
- Sponsors – the legal entity responsible for the product – must retain robust, scientific evidence supporting all claims made about the product; and,

- Clear regulatory consequences exist for non-compliance with the regulations, including fines, recalls and market withdrawal.

One of the most comprehensive regulatory systems for sunscreens in the world, this treatment of sunscreen products as medicines also means that there is a significant cost impost to introducing a new product into Australia – up to $212,000 more per product than in markets where these products are recognised and regulated as cosmetics, such as New Zealand, Europe, South Africa, ASEAN, Mexico and Russia.

This creates a significant disincentive to introduce new products into Australia and limits consumer choice. This is particularly the case given that research and development in sunscreen innovation is driven principally by the cosmetic – not the pharmaceutical – industry globally and access to this innovation is currently being limited by Australia's regulatory approach.

In 2020, prior to the introduction of more onerous ingredient assessment requirements, Accord members estimated the additional costs of classifying sunscreens as therapeutic goods as opposed to cosmetics to be as presented in Table One. Given the time that has elapsed since these data were collated and the known significant increase in cost of obtaining ingredient approvals, the current costs are likely higher.

Table Two: Regulatory costs for sunscreen in Australia

Cost item	Estimated costs ($ value)
Costs in sourcing raw materials that meet OTC- monograph specifications for actives, excipients and water	$10K per ingredient
Costs for TGA GMP inspections	$30K - $60K
Costs for inspecting warehouses	$20K - $50K
Costs to undertake Product Quality Reviews (PQRs)	$7.5K - $10K per formulation
Costs to undertake stability trials for at least two production scale batches annually	$10K minimum per formulation per packaging per batch ($270K in sunk costs has been reported)
Costs in registering new actives	$50K minimum
Costs in registering new excipients	$15K - $20K
Costs in local retesting if water resistance is claimed	$7.5K - $20K per formulation
Costs in labelling changes to meet ARGS + TGO69 + AS/NZS 2604 requirements	$5K - $10K depending on volume of print run
BP PET/Stability	$2K per product
Opportunity Costs and/or Delays to Market	Extensive and unquantifiable *"In essence, as a sponsor of a sunscreen, once commercial evaluation is complete, it would be cheaper to forego the introduction of that sunscreen formulation in Australia as it ends up costing the sponsor much much more than any realisation of sales value".*

Costs to long term public health outcomes

Further study needs to be undertaken into the opportunity costs of excluding current and new ingredients from the Australian sunscreen market. This requires a formal economic model which values, amongst other things:

- The under-utilisation of sunscreens attributable to aversion to current formulations, which could be detailed using recent survey data and current literature;
- The health and economic losses associated with this type of underuse, utilising projections from the Nambour study and other similar international studies; and,
- The expected reduction in sunscreen avoidance associated with particular ingredients and formulations.

Accord would welcome the opportunity to work with the TGA on this type of study.

Other challenges that require addressing

Impact of ATO activity and the GST

As highlighted throughout this paper, the TGA regulates sunscreen as a therapeutic good to ensure it is safe and effective – it essentially determines whether the sunscreen complies with the standards for the sun protection it claims. At the same time, the Australian Taxation Office determines whether a sunscreen is subject to Goods and Services Tax (GST) depending on what its marketing suggests is its primary purpose.

This can lead to the same sunscreen being classed as a therapeutic good by the TGA and therefore theoretically GST-free while the ATO determines that it is subject to GST. This is especially the case where, for example, a sunscreen's marketing highlights additional or other purposes to the product, such as 'moisturising' and 'antiaging', or being an insect repellent, rather than its principal focus being on its role solely as a sunscreen.

This difference in focus creates a conflict between the classification applied by the two government bodies with a product being a regulated therapeutic good under the TGA's regulations but not GST-free given the ATO's ruling regarding its marketing.

Moving forward: a proportionate approach to regulation

A proportionate first principles approach to sunscreen regulation should be grounded in the recognition that the overwhelming purpose of sunscreen is to prevent skin cancer.

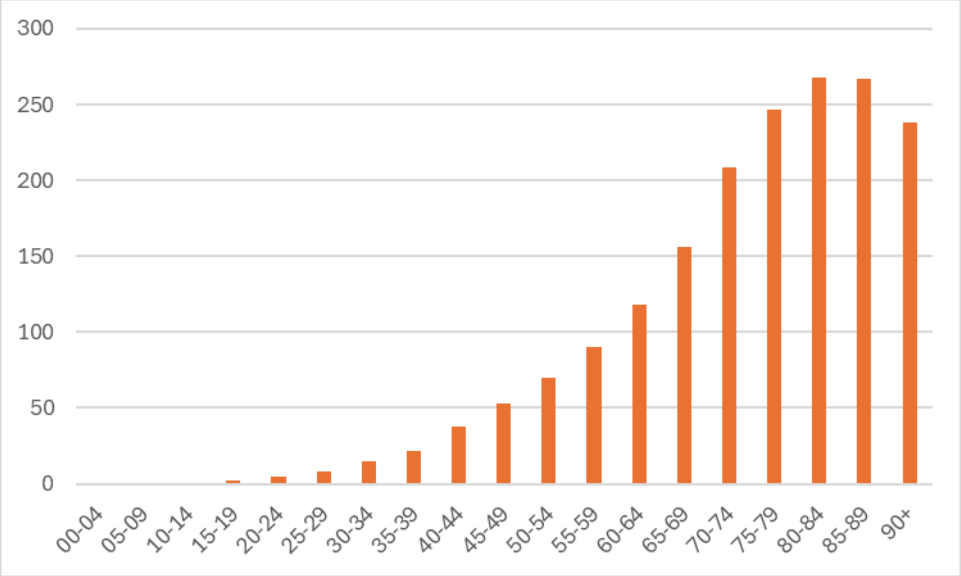
Looking at the burden of skin cancer in Australia, the Australian Institute of Health and Welfare (AIHW) reports that skin cancer is the most commonly diagnosed cancer in Australia each year[16] and further:

- New melanoma of the skin diagnoses were projected to grow from 17,024 or 62.6 per 100,000 persons in 2024 to an estimated 17,443 or 63.1 per 100,000 in 2025;[17]
- Estimated 1,455 deaths attributed to melanoma of the skin in 2025 representing 2.7% of all Australian cancer deaths;[18]
- The estimated (year 1) healthcare costs of newly diagnosed skin cancer in Australia in 2021 were $824 million, made up of $398 million for melanoma and $426 million for keratinocyte skin cancer, with the costs of first year treatment for melanoma ranging from $644 to $100,725;[19]
- Overall healthcare costs are estimated for all skin cancer patients are estimated at $2.47 billion annually;[20] and,
- Total economic impact of melanoma by 2030 is estimated to be $8.7 billion, including $3.1 billion in public healthcare costs, $1.2 billion in out of pocket costs and 136,000 years of life lost.[21]

The age distribution of the new melanoma case rate is shown in Figure Three.

[16] Australian Institute of Health and Welfare, "Skin Cancer in Australia", 13 July 2016. https://www.aihw.gov.au/reports/cancer/skin-cancer-in-australia/summary Accessed December 2025
[17] AIHW, "Cancer data in Australia", Table Book 1a, 8 October 2025. https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/data Accessed December 2025.
[18] Cancer Australia, "Melanoma of the skin statistics". https://www.canceraustralia.gov.au/cancer-types/melanoma-skin/melanoma-skin-statistics Accessed December 2025.
[19] Louisa G Gordon et al, "Estimated Healthcare Costs of Melanoma and Keratinocyte Skin Cancers in Australia and Aotearoa New Zealand in 2021", *International Journal of Environmental Research and Public Health*, 8 March 2022.
[20] Australasian College of Dermatologists, "Impact of skin cancer in Australia", November 2025.
[21] Insight Economics, "State of The Nation: A Report into Melanoma – A National Health Priority", Melanoma Institute Australia, February 2022.

Figure Three: Projected number of new melanoma cases per 100,000 persons, by age group, Australia, 2025[22]



This is a public health crisis, particularly for older Australians and the growth in incidence will only be stemmed with increased uptake of sunscreens. Accordingly, it is necessary that any costs of skin cancer which would be avoided by permitting new sunscreen formulations and ingredients are clearly reflected in cost-benefit models.

It is expected that this will be highly productive. Public education programs focused on primary prevention of skin cancer in Australia are found to have a return of $8.70 for every $1 spent.[23] This combines the benefits from various activities to reduce UV exposure but is at root focused on behavioural change. Given that much of the reformulation of sunscreens internationally is to address behavioural barriers to adoption, approving new formulations will only increase this ratio with more effective preventive health and consequent reduction in cancer incidence.

Recommendation One: Adopt a proportionate approach to regulation, recognising the significant risks associated with non- or under-use of sunscreens.

Foundations for a proportionate approach

The barriers to availability and affordability of desirable new sunscreens in Australia are not a matter of 'over-regulation'. Rather they are characterised by inappropriate and disproportionate design of the evaluations which support current regulatory standards.

[22] AIHW, "Cancer data in Australia", Table Book 1a.
[23] Louisa G Collins, "Cost-effectiveness analysis and return on investment of SunSmart Western Australia to prevent skin cancer.

This includes problematic risk assessment calculations as well as duplication. An example of the latter is that sunscreen elements are often simultaneously evaluated and listed by both the TGA and the Australian Industrial Chemicals Introduction Scheme (AICIS), who may have differing and competing standards for both approval and labelling. This typically has to do with different emphases with the TGA's being principally on medicine and device safety and AICIS' principally on industrial chemical safety and environmental effects.

However, the most significant challenge is that there is not sufficient weight given to what sunscreens actually do which, as noted above, is reduce the incidence of skin cancer.

The foundational pathway to more effective regulation lies in defining the appropriate cost-benefit approach to sunscreens and their ingredients, both active ingredients and the increasingly important excipients.

In practice, this means drawing on approaches elsewhere in the TGA particularly in its approaches to pharmaceuticals and to medical devices. The two broad principles which might be followed here are:

1. A pathway similar to that used for medical devices, whereby new products from existing sponsors which are broadly similar to existing products may be approved for sale with post-market data collected as an assurance of quality and safety. This is the simpler path; and
2. A pathway similar to that used for pharmaceutical products where, for genuinely novel products, potential costs are considered in proportion to potential benefits. This will enable situations, as in the case of oncology medicines, where quite significant risks may be considered acceptable if there is no comparably effective treatment available.

Consideration might be usefully given to a number of questions or filters which distinguish between which path to follow. Suggested examples are:

- Is the sponsor an experienced market supplier with a good record of safety and compliance in Australia?;
- Fundamental similarity: is the new product a relatively minor iteration of an existing offering?;
- If the element in question is present in other products currently in the market;
- Particularly in the case of excipients, are they already present in unregulated products, including non-therapeutic sunscreens?;
- Has there been extensive evaluation by a competent regulatory authority in another international jurisdiction?;
- Has international assessment led to the presence of this sunscreen or ingredient in:
    - Multiple markets;

- For multiple years; and/or

- Is there a reputable published literature survey on the efficacy or safety of the product?

Where one or more of these is clear, there is a case for pathway 1: post-market evaluation.

However, Accord recognises that there are circumstances where either:

- There is no significant track record for the product or sponsor in Australia or elsewhere; and/or,
- There are overarching concerns about the safety of a particular chemical or combination.

In this case, path 2 may be more appropriate. This is a more complete pre-market evaluation, which is the approach currently applied by the TGA to new sunscreens and new sunscreen ingredients including excipients.

However, Accord is of the view that the current model for pre-market evaluation needs to be amended to be fit for purpose for sunscreens. In particular, when looking at individual ingredients, the current model appears to excessively weigh the risks presented by new and existing chemicals, against a counterfactual which assumes a suitable substitute is readily available.

This is not however a realistic view. Where existing ingredients need to be substituted, there is commonly a significant increase in price. And where new formulations are held back either due to excessive cost of assessment and registration, or through excessive risk avoidance, there is often not an acceptable replacement.

Critically, this view intersects with research cited above, which clearly shows that there are significant behavioural barriers to sunscreen adoption, which can only be transcended with new ingredients and formulations: particularly new excipients which address concerns about skin feel and appearance.

When considering new ingredients and formulations which increase the rate of sunscreen consumption, the proper counterfactual is the cost of underuse. Specifically, this should be calculated as costs associated with the higher rate of skin cancer, including both public and private costs.

In its simplest form, the question is whether:

$$\Delta Health\ Burden_{New\ Formulation} > C\ Adverse\ Effects_{New\ Formulation}$$

In this case, health burden includes both the hospital and other medical costs of skin cancer treatment, as well as the reduction in morbidity and mortality associated with increased sunscreen use. On the other (risk) side, the cost of $Adverse\ Effects$ will similarly include both public and private health costs, as well as any increase in morbidity and mortality.

The critical questions which arise with this form of evaluation are:

- What is the reliability of the data on either side of the equation?; and,

- How much do we want prospective benefits to dominate expected costs in order to be comfortable?

There is a further minor complexity insofar as not all consumers who take up a new formulation will be those who currently avoid sunscreen. A more comfortable product will also be attractive to current users of sunscreen. In practice, for these consumers, there are potentially some adverse effects, but less likely any reduction in health burden.

This is however an illustration of the problem with the current model in that a simple risk minimisation approach would be appropriate if all users of the new formulation were current users of sunscreen but this is an incomplete counterfactual if new adopters are excluded.

Recommendation Two: Given this proportionate approach, introduce dual pathways in Australia's regulation of sunscreens:

1. A pathway similar to that used for medical devices, whereby new products from existing sponsors which are broadly similar to existing products may be approved for sale with post-market data collected as an assurance of quality and safety. This is the simpler path; and,
2. A pathway similar to that used for pharmaceutical products where, for genuinely novel products, potential costs are considered in proportion to potential benefits.

A Roadmap: delivering safety, effectiveness and quality via a proportionate approach

In addition to the two recommendations above, the following considers what applying a proportionate approach to some of the barriers identified earlier in this paper might look like in practice, noting that all of these proposed ideas are focused on delivering access to safe, effective and quality sunscreens that Australians want to use and can afford. This will help address the healthcare burden caused by cancers related to sun exposure and capture the benefits available from broad-based sunscreen use.

Importantly though, applying a proportionate approach will require designing a regulatory environment and regulations that are specific to sunscreens rather than trying to fit sunscreens into existing regulatory models and regulations.

As noted above, there is often duplicate regulation and assessment between the TGA and AICIS. This should be avoided where possible via domestic mutual recognition or other cooperative scheduling.

Recommendation Three: Remove duplication of regulatory effort locally

Eliminate duplicative regulatory efforts between the TGA and the Australian Industrial Chemicals Introduction Scheme (AICIS) through mutual recognition or cooperative scheduling.

Aligning approvals and access to new sunscreens

As highlighted above, a balance needs to be achieved between timely and effective approvals and Australians being able to access sunscreens that they want to and will use.

Recognising the difference between active ingredients, which are part of the formal therapeutic claim and reduce the impact of UV exposure on the skin, and excipients, which may have relevance to the therapeutic claim but have significant consequences for the optimal consumption and application of sunscreens, a proportionate approach to these may differ.

As identified above, there are two pathways that could be adopted in relation to these ingredients, either a post-market surveillance model or a full evaluation.

Accord would anticipate that, for example, adopting the above model would lead to:

- Excipients used in other products, including unregulated products and non-therapeutic sunscreens, would largely be subject to pathway 1 and post-market surveillance;
- Genuinely novel active ingredients where extensive evaluation has been undertaken by another competent regulatory authority in another jurisdiction would be likewise subject to pathway 1 and post-market surveillance;
- Genuinely novel active ingredients where extensive evaluation has not been undertaken by another competent regulatory authority would be subject to pathway 2 with a more complete pre-market evaluation being undertaken that weighs the costs and benefits of the new ingredient in light of the alternative, that being the risk of skin cancer for Australians;
- Where significant documented concerns exist regarding the safety of a particular chemical or combination of chemicals, pathway 2 would be adopted; and,
- Where no significant track record for the sponsor exists in Australia or elsewhere, automatic post-market audit would be triggered under pathway 1 and the post-market surveillance process.

While the details and regulations need to be worked upon, Accord is keen to work with the TGA to identify how to implement this new approach, noting that, for some elements, an annotation to the ARTG may suffice.

Adopting this model would also help address the many issues that currently exist in relation to the amount of data that must be submitted under the current regulatory approach. Examples where regulatory burden would be eased include:

- The requirement to provide data regarding medical or pharmaceutical grade ingredients where this is not required elsewhere and is frequently unavailable. For example, one Accord member was unable to source pharmaceutical grade aloe, only cosmetic grade, therefore could not include it in their product.

- A large majority of fragrance ingredients available and accepted globally are currently unavailable for use in sunscreens without further Australian assessment. Fragrance components are cited as one of the key reasons behind some international formulations not being available in Australia.; and,

- Low-risk excipient ingredients that can improve the performance of sunscreens that are available globally e.g. polymers that can improve water resistance and SPF efficacy, cannot be used in Australian sunscreens without further Australian assessment.

Aligning data requirements coupled with the broader regulatory approach outlined above would avoid these situations being repeated and facilitate Australians having access to sunscreens they want to use at prices they can afford.

Recommendation Four: Remove duplication of regulatory effort through recognition of the international regulatory environment.

Recognising that sunscreens are highly regulated globally, Australia should introduce post-market surveillance-based regulation for ingredients and products already highly regulated globally. Regulatory effort should focus on new UV filter actives, truly novel ingredients, verifying bona fides of new sponsors and any identified real risks for specific ingredients and sponsors.

A safe and proportionate approach to UV filters

The review of current and assessment of new UV filters, and especially their safety, would also be subject to this new approach with a firm focus on the need to make sure that the TGA and Accord work together to recognise the timeframes involved in developing and introducing new UV filters.

This is particularly important in the current environment where homosalate and octocrylene are relatively cheap compared to the new UV filters which are still under patent and relatively expensive in comparison. While this will change over time, the newer UV filters will become available in multiple markets over many years.

Recognising that safer ingredients are critical for both humans and for environmental purposes, establishing a shared understanding of this and mapping out how the evolution of the UV filter environment will be managed in Australia is critical to ensuring that sunscreens remain available to Australians during these changes.

Accord would anticipate that, for example, adopting the above model would lead to:

- The same approaches being taken to UV filters, both existing and novel, as being adopted in relation to active and excipient ingredients; and,

- An agreed anticipated timeframe of the evolution of UV filters being mapped out between the TGA and Accord to help guide future discussions and ensure Australians have access to sunscreens.

Improving mutual recognition of audited GMP sites

Likewise, in relation to the auditing of manufacturing and other sites associated with sunscreen, significant benefits could be captured by expanding the mutual recognition afforded to sites already reviewed and accredited by other respected and reputable agencies.

This approach is adopted by the TGA currently in relation to pharmaceuticals and a similar approach should be adopted in relation to sunscreens.

Examples of this could include:

- Recognition of FDA approved sites regardless of their location, including outside the USA;
- Recognition of sites approved by Health Canada, including those approved by Health Canada that are not in Canada;
- Given the particular risks of skin cancer for people from Asian backgrounds, consideration of the rigorous approvals required in the Japanese and South Korean markets;[24]

Recommendation Five: Streamline GMP requirements.

Consider GMP requirements for sunscreen products globally and consider options to minimise duplicative GMP audits for the same manufacturing site by accepting certifications from reputable international regulators, such as US FDA-approved sites, regardless of their location.

Aligning regulatory costs with safety

One critical question which needs to be asked in reviewing the regulation of sunscreens is what changes might assist in enhancing affordability.

This is particularly critical when considering:

- How changes to the regulation of common ingredients may lead to inflation in sunscreen prices, typically when a cheap ingredient is excluded and the only substitutes are considerably more expensive;
- Similarly, where there are substantial costs associated with reformulation, which must then be passed on to the consumer; and,
- Where new formulations and ingredients offer the prospect of significantly reducing sunscreen avoidance but the cost of bringing them to market is prohibitive or will put them out of reach of many consumers.

[24] For overview see: "Understanding Sunscreen Regulations in Japan and South Korea: SPF Testing, PA Ratings and Labeling Standards", Xingyuan, March 9, 2025. https://ahpackaging.com/understanding-sunscreen-regulations-in-japan-and-south-korea/ Accessed December 2025.

This is an important lens to adopt in relation to the imposition of costs but is potentially one that requires further work to ensure appropriate alignment. As such, a useful next step would be to survey consumers to better understand the price elasticity of demand with respect to sunscreens. This is particularly important in the current economic environment.

Recommendation Six: Undertake consumer surveys to contextualise and inform the cost and benefits of sunscreen regulation and its impact on Australians and their use of sunscreen.

A smooth transition to new SPF testing

Accord notes that the TGA is currently reviewing the legislative requirement that sunscreen testing be conducted in accordance with AS/NZS 2604 prior to applying to list their sunscreen on the ARTG. Accord also notes that the TGA recognises that ISO 23675:2024 – *Cosmetics – Sun protection test methods – In vitro determination of sun protection factor SPF* and ISO 23698 – *Cosmetics – Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy* were specifically developed to overcome the known challenges with ISO 24444 and finds the validation data for the suitability of these *in-vitro* methods for supporting SPF indications compelling.

Given this, and the known challenges with ISO 24444, Accord is keen to work with the TGA to identify a timeframe for a transition to in vitro testing and alignment of other standards which have not yet been adopted in Australia noting that this may require a policy focus to be adopted, not purely a technical one. Achieving alignment however would provide greater clarity for all stakeholders involved in the formulation and manufacture of sunscreens and facilitate building public confidence in a new testing regime.

In identifying a timeframe for this transition, there are other matters that also need to be factored in, including any suggestion that existing products be re-tested under the new model. Considering the importance of maintaining already shaken public confidence in sunscreens, Accord recommends that all current approved and registered sunscreens be grandfathered from re-testing unless there is a compelling counter-argument, such as evidence of fraud.

This approach is critical given that, if a new test suggested the original claim is inadequately supported, it takes a minimum of 15 months to reformulate, transition and relaunch a product, time during which the Australian public's access to sunscreens is further limited.

As part of this transition, Accord also recommends consultation with manufacturers, importers and sponsors of sunscreen products in Australia to understand in greater detail how potential regulatory changes – including but not limited to SPF testing – could help deliver more open markets and willingness to both:

- Increase the presence of innovative products for Australian consumers; and,
- Increase exports of products from Australia, noting that Australia exports less sunscreen currently than New Zealand.

Recommendation Seven: Adopt into regulation all relevant ISO standards for SPF testing of sunscreens.

Recommendation Eight: Develop transparent and realistic regulatory guidelines for the acceptance of different SPF testing methods and their variability to facilitate the transition to new SPF testing methods.

Recommendation Nine: Consider regulatory mechanisms to benchmark and track acceptable variations across formulations, testing methods and laboratories.

Recommendation Ten: Working with stakeholders, improve the process of keeping regulations up to date with international developments

Aligning label claims to support consumer understanding

The approach to labelling likewise needs to align with the overarching imperative that people are supported to wear sunscreen and, as such, needs to be clear, consistent and easily understood to avoid misunderstanding.

With European industry in the process of establishing standardised categories of 'low', 'medium', 'high' and 'very high' protection and looking to adopt these categories instead of SPF ratings in future, an opportunity exists for Australia to leverage these changes to better align label claims to support consumer understanding.

Given that the market for sunscreens is global, the public's lack of real understanding about the non-linear nature of SPF ratings and the issues of variability in testing, adopting similar labelling standards re protection categories to the new European standards should be done as closely in parallel with Europe as possible. This would provide the opportunity to educate the public about the new protection categories and clearly explain the new SPF testing regime/s assuming timings align.

The protection categories are not the only area in which labelling claims could better support consumer understanding. Currently, for example, where a sunscreen has been tested and approved for four hours of water resistance, it still needs to include the instruction to be applied every two hours. This is extremely confusing to consumers and does not support either their understanding or, critically, appropriate use.

Aligning labelling to the full suite of the sunscreen's properties should be encouraged and in a way that does not confuse consumers. In this instance, an instruction to re-apply every four hours would be appropriate.

Recommendation Eleven: Working with stakeholders, develop clear and easy to understand SPF efficacy claims that align with major markets.

Recommendation Twelve: Working with stakeholders, develop sunscreen labelling requirements that assist consumers to make informed choices.

Next steps

Accord welcomes the TGA's prioritisation of sunscreen in their workplan for 2026 and is keen to work together on the details needed to give effect to the new approach to regulating sunscreen outlined above. This is critical to ensuring that the Australian public has access to safe, effective and quality sunscreens that they want to wear and can afford.

Accord notes that, moving forward, it will be important to educate Australians about any changes to sunscreen protection ratings and potentially other changes proposed in this roadmap. Building consumer understanding of, and confidence in, sunscreens is especially important when considering the capacity for people to purchase these products online and have them delivered to Australia regardless of whether these products comply with Australian labelling, safety and other regulations.

At the same time, however, a more balanced and less costly pathway for Australian registration and regulation will provide consumers with greater safety while, at the same time, increasing their protection against sun damage and associated cancers.