Improving the regulation of sunscreens in Australia

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Acknowledgement of Country

In the spirit of reconciliation, the Department of Health, Disability and Ageing acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

Today's speakers

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What we will be covering in this presentation

Overview/background

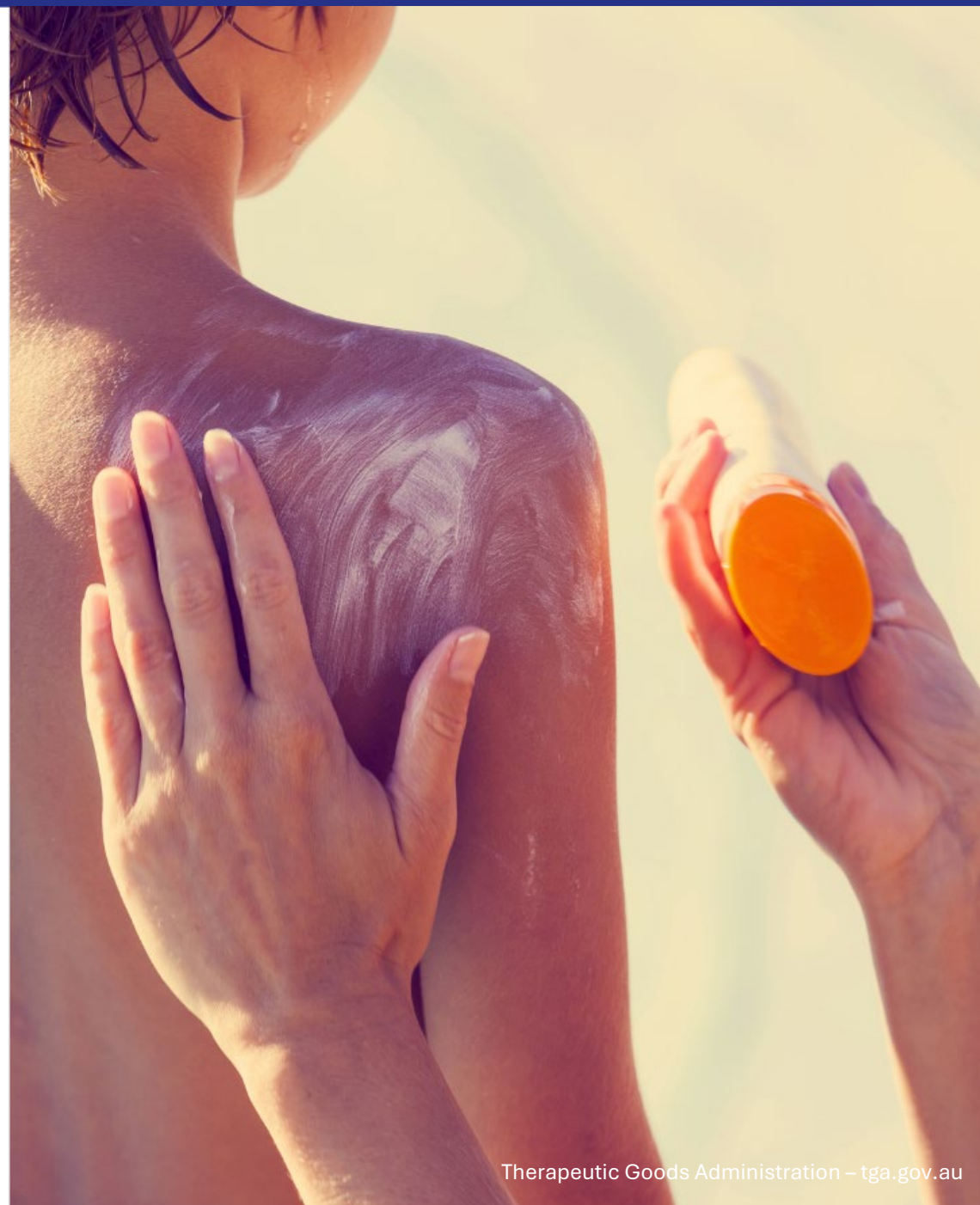
Consultation topics

1. SPF matters
2. Ingredient/ formulation matters
3. SPF labelling
4. Cosmetic sunscreens
5. GMP matters

Questions

Overview/Background

Avinash Clarke



Overview/Background

- In Australia, therapeutic sunscreens are regulated as listed medicines and are subject to post-market monitoring rather than pre-market evaluation.
- Recent domestic and international developments have highlighted potential areas for improvement with the current framework.
- 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.
- In 2024, the International Organization for Standardization (ISO) published new SPF in vitro testing methods.

Overview/Background

We have also been investigating domestic developments and media reports:

- CHOICE published a report in 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.

These developments, alongside our own internal reviews and investigations, have prompted the TGA to review aspects of the current regulatory framework.

What we are trying to achieve

- The current regulatory framework for sunscreens has been in place for some years, and the regulatory landscape has changed over this time.
- These proposals are intended to strengthen confidence in sunscreen performance and provide contemporary SPF testing guidance for sponsors.
- If accepted, options presented in this paper would be implemented in a proportionate and targeted manner.

In scope for the consultation

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.

Not in scope of this consultation

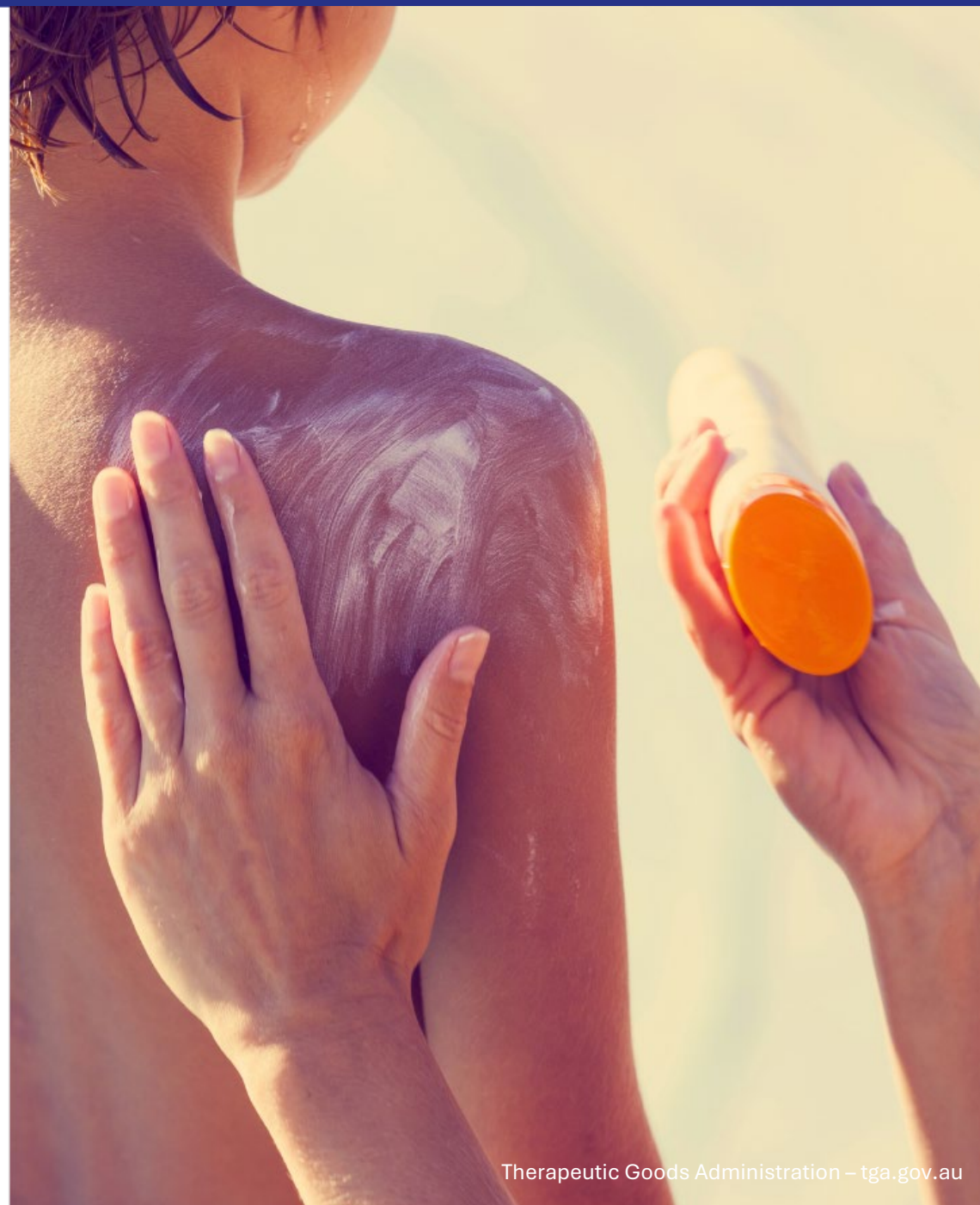
These matters will, or are, being addressed under the provision of the current framework

Safety of sunscreen ingredients.

- Consideration of sunscreens specifically marketed to children.
- The Regulatory Environment for sunscreens in Australia = regulation as medicines
- Labelling instructions for novel dosage forms.

SPF matters

Dr Lisa Kerr PSM PhD MBA



SPF testing matters

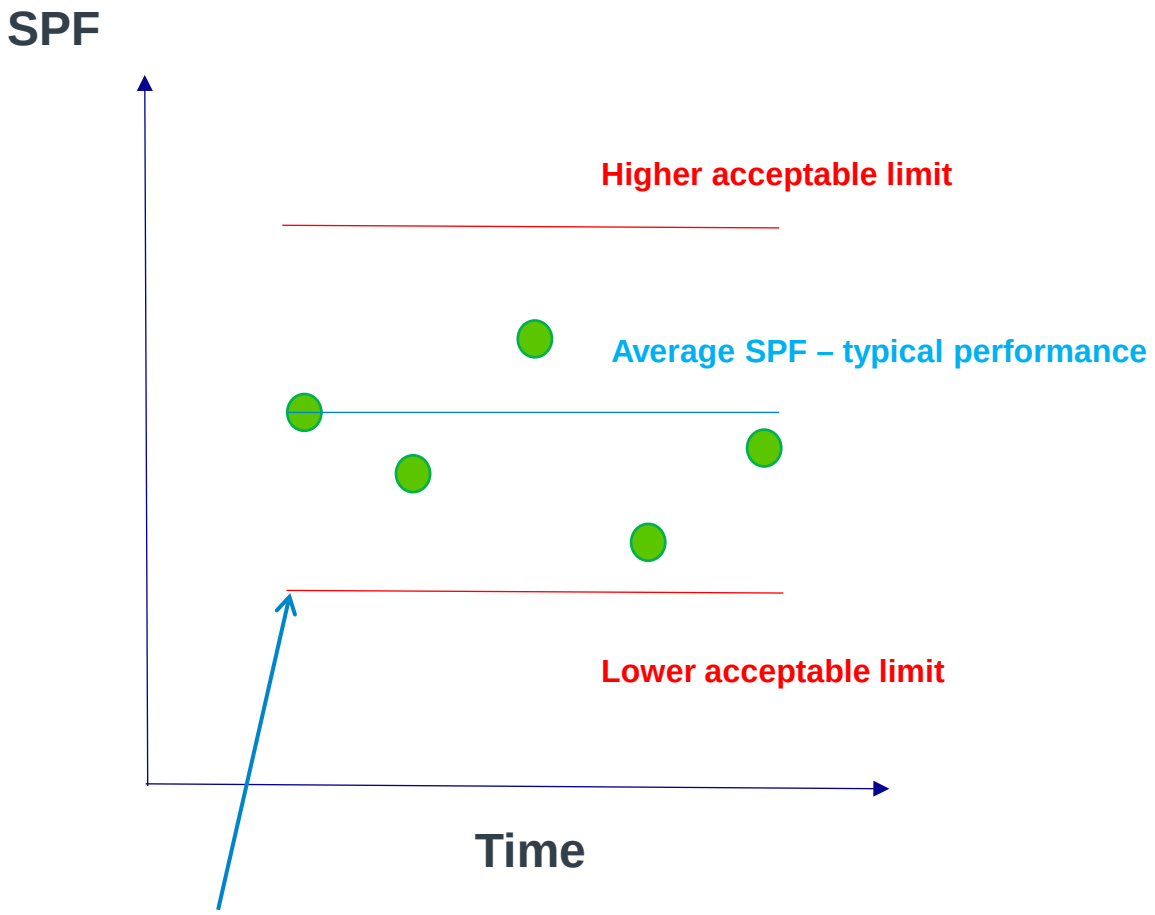
1A: Current SPF *in vivo* testing has variability issues

- Variability of SPF test results associated with the ISO 24444 test is a known problem.
- We have published advice for sunscreen sponsors and manufacturers regarding acceptance of additional SPF testing information.
- We are considering options to adopt ISO new *in vitro* and hybrid test methods.

Proposed options

- Option 1: Status quo: maintain the existing testing requirements
- Option 2: Enable sponsors to comply with either *in vitro* or *in vivo* testing where appropriate
- Option 3: Mandate *in vitro* SPF testing only, where appropriate

Concept of average SPF over time



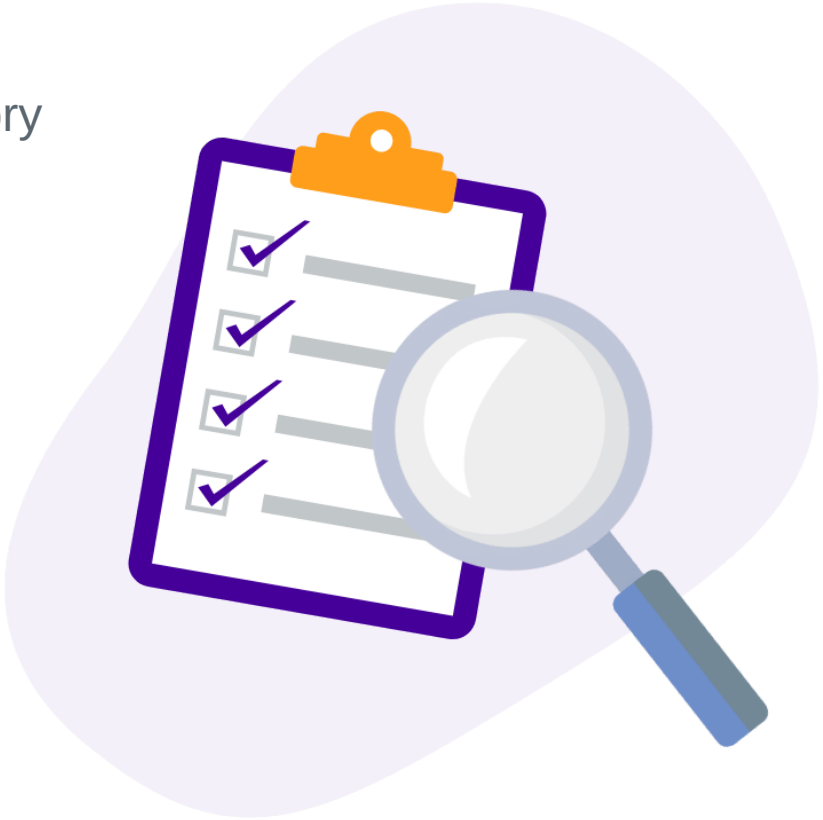
Example only: the lower limit could be used to set the label claim. For example, for SPF 50+ or very high protection the lower limit is SPF 50.

- Sunscreens are expected to perform according to their label claim over time
- There are natural variations in content of active ingredients from batch to batch
- Allowable variation in manufacturing processes is normal and extends to other industries
- It is impractical and unrealistic to expect each and every batch of a sunscreen to hit the target SPF exactly every time
- Variability in test methods is also normal and is accounted for in regulatory / regulated laboratories via a quality system (noting that the variation seen with ISO 24444 is unusual in regulatory settings)
- The new labelling categories have been proposed to support understanding of the normal variation

SPF testing matters

1B: Limited regulatory oversight for laboratories performing SPF testing

- The TGA does not regulate or accredit SPF testing laboratories; responsibility for selecting an appropriate and competent laboratory rests with the sponsor.
- Use of low-reliability laboratories by some sponsors has likely contributed to products being supplied that do not achieve their claimed SPF protection.
- Many SPF testing laboratories—often located overseas—lack formal accreditation (e.g. ISO/IEC 17025) and are outside the TGA's jurisdiction, with no current requirement for release testing or GMP oversight.



Proposed options

- Option 1: Status quo - maintain current level of oversight
- Option 2: Require that SPF testing results must come from an accredited or certified laboratory

SPF testing matters

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

- Sunscreens must comply with AS/NZS 2604:2021.
- Any change to SPF testing or labelling requirements requires a formal Standards Australia process, followed by a separate process for the TGA to adopt the new standard.
- The current framework provides limited regulatory flexibility to respond quickly to safety, quality or efficacy issues; the TGA is therefore considering more responsive mechanisms to adopt updated international standards,

Proposed options

- Option 1: Status quo - maintain the current approach
- Option 2: Directly reference AS/NZS 2604 in new instrument for sunscreen testing requirements
- Option 3: Directly reference international ISO standards in a new instrument for sunscreen testing requirements

SPF testing matters

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

- Sponsors are currently permitted to rely on SPF testing conducted during product development, including pilot or representative formulations, rather than testing commercially released batches.
- There are no prescriptive requirements on when re-testing is required after formulation changes, how frequently testing should occur, or whether testing must be conducted on the final marketed formulation.
- This lack of clarity has created regulatory gaps, reducing confidence in the reliability of SPF claims and making it difficult to link tested batches to products supplied to the market.

Proposed options

- Option 1: Status quo
- Option 2: Guidance to sponsors on when additional product testing is advised
- Option 3: Mandate SPF testing at the time of listing on the finished product and periodically while the product is in the ARTG

SPF testing matters

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

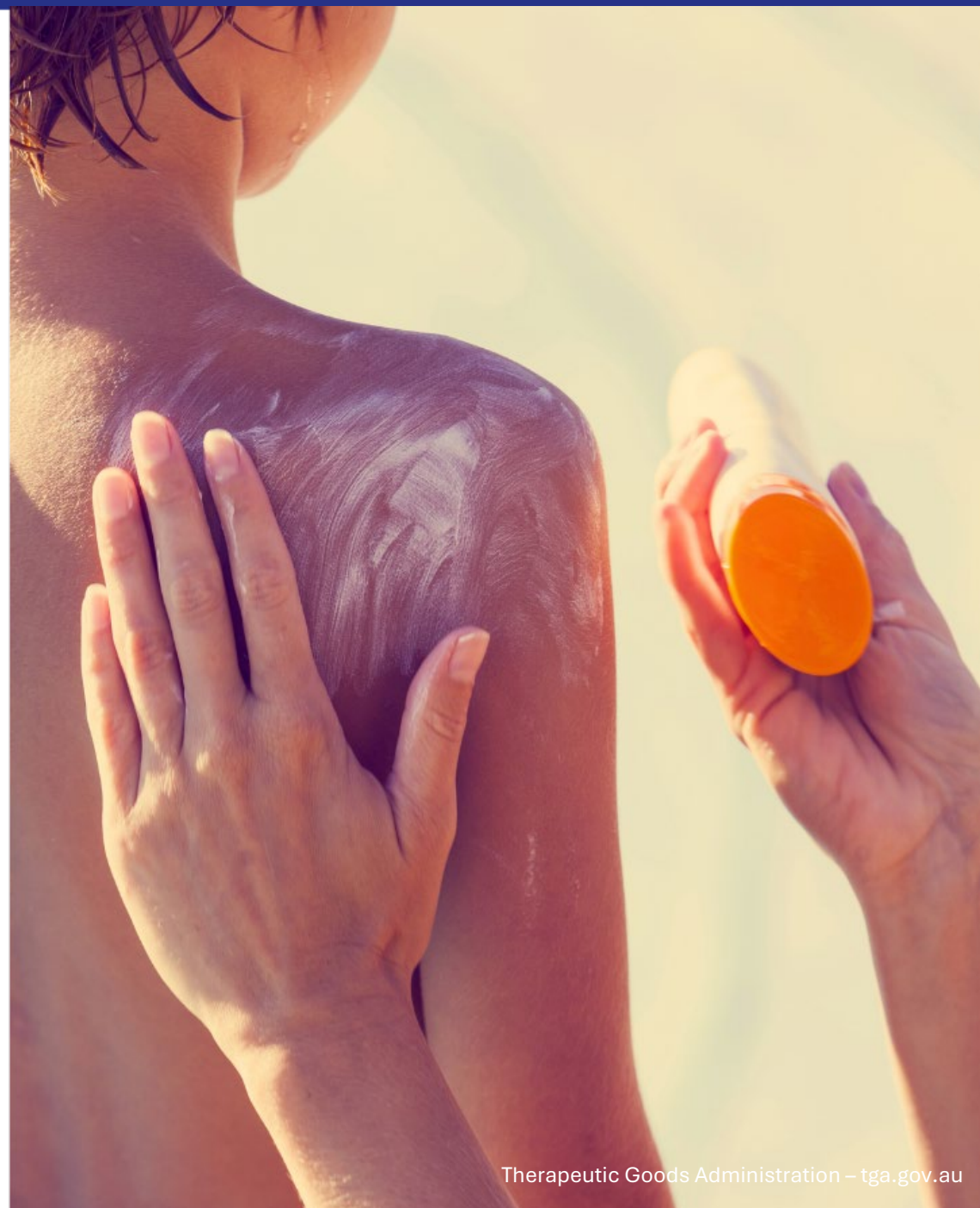
- While sponsors must hold evidence to support SPF claims, the data is only provided to the TGA if requested, limiting proactive regulatory oversight.
- There is no requirement for SPF testing data to be made publicly available, resulting in limited transparency for both the regulator and consumers.
- As a result, the evidence underpinning SPF claims is not routinely visible, reducing confidence in the robustness of claimed SPF protection.

Proposed options

- Option 1: Status quo
- Option 2: Require sponsors to provide testing data to the TGA at the time of listing, which will be held in confidence
- Option 3: Require sponsors to make their testing data publicly available

Ingredient/formulation matters

Dr Lisa Kerr PSM PhD MBA



Potential efficacy or quality issues with specific formulations/ingredients

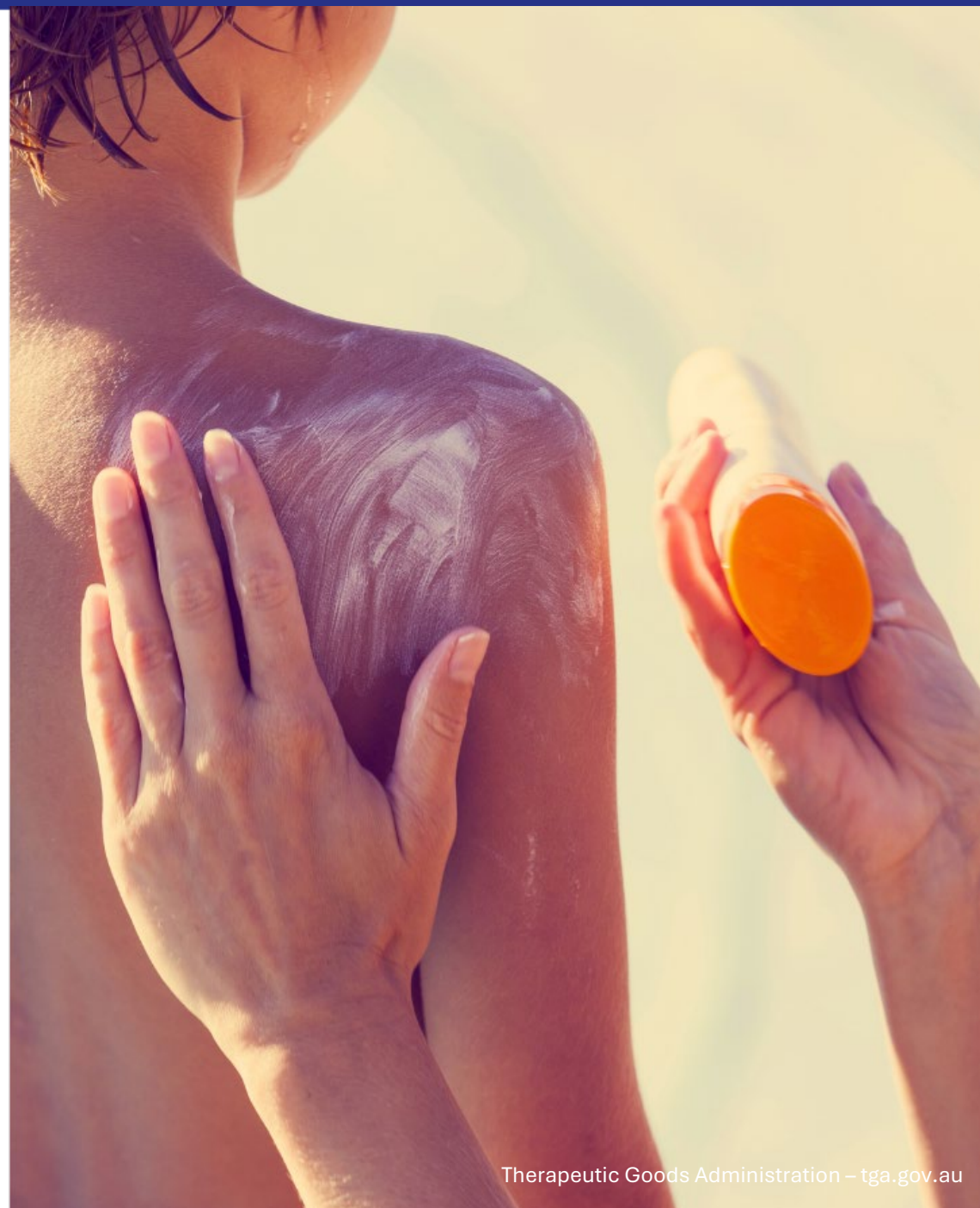
There is a lack of quality standards for sunscreens that address ingredient-level properties, finished product formulation requirements and performance considerations.

Proposed options

- Option 1: Status quo – maintain current oversight
- Option 2: Develop an instrument for ingredient quality requirements to ensure efficacy
- Option 3: Require pre-market evaluation for safety, quality and efficacy for all sunscreens (e.g. a registered products model)

SPF labelling matters

Avinash Clarke

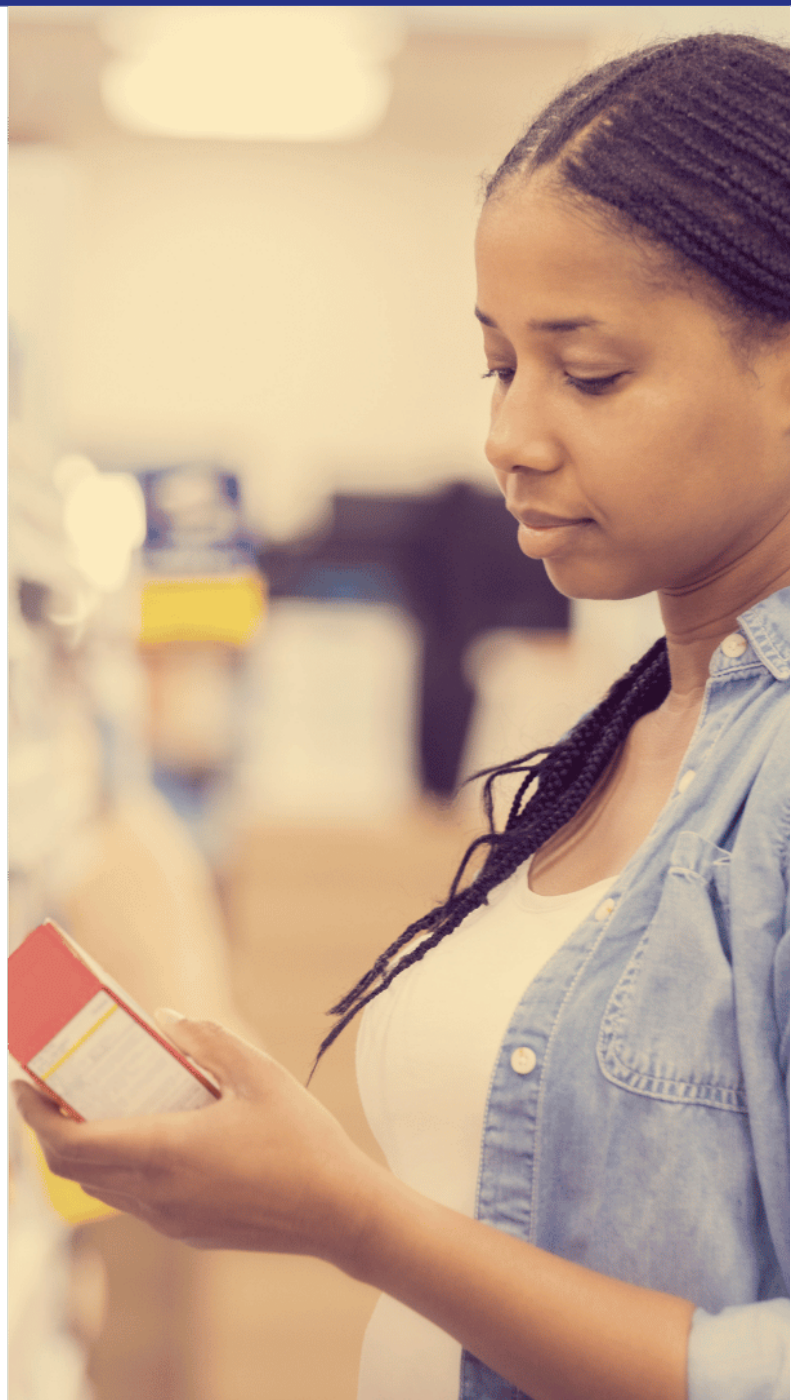


Labelling matter: SPF labelling considerations

- The SPF rating system, introduced in the 1960s, remains the internationally accepted method for indicating UVB protection, but is based on controlled laboratory testing that may not reflect real-world use.
- Misunderstanding of SPF values, combined with test variability, highlights the need for clearer labelling to improve consumer understanding and provide sponsors with greater regulatory certainty.

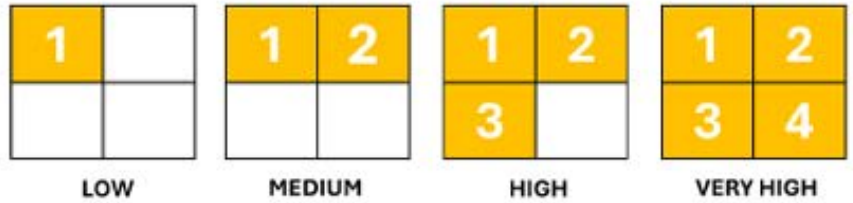
Proposed options

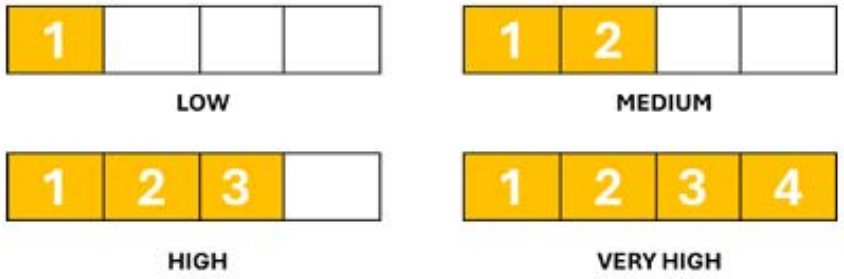
- Option 1: Status quo – maintain current SPF rating system for labelling
- Option 2: Provide additional labelling requirements for the SPF ratings
- Option 3: Change labelling requirements for sunscreen performance ratings



Labelling matter: SPF labelling considerations

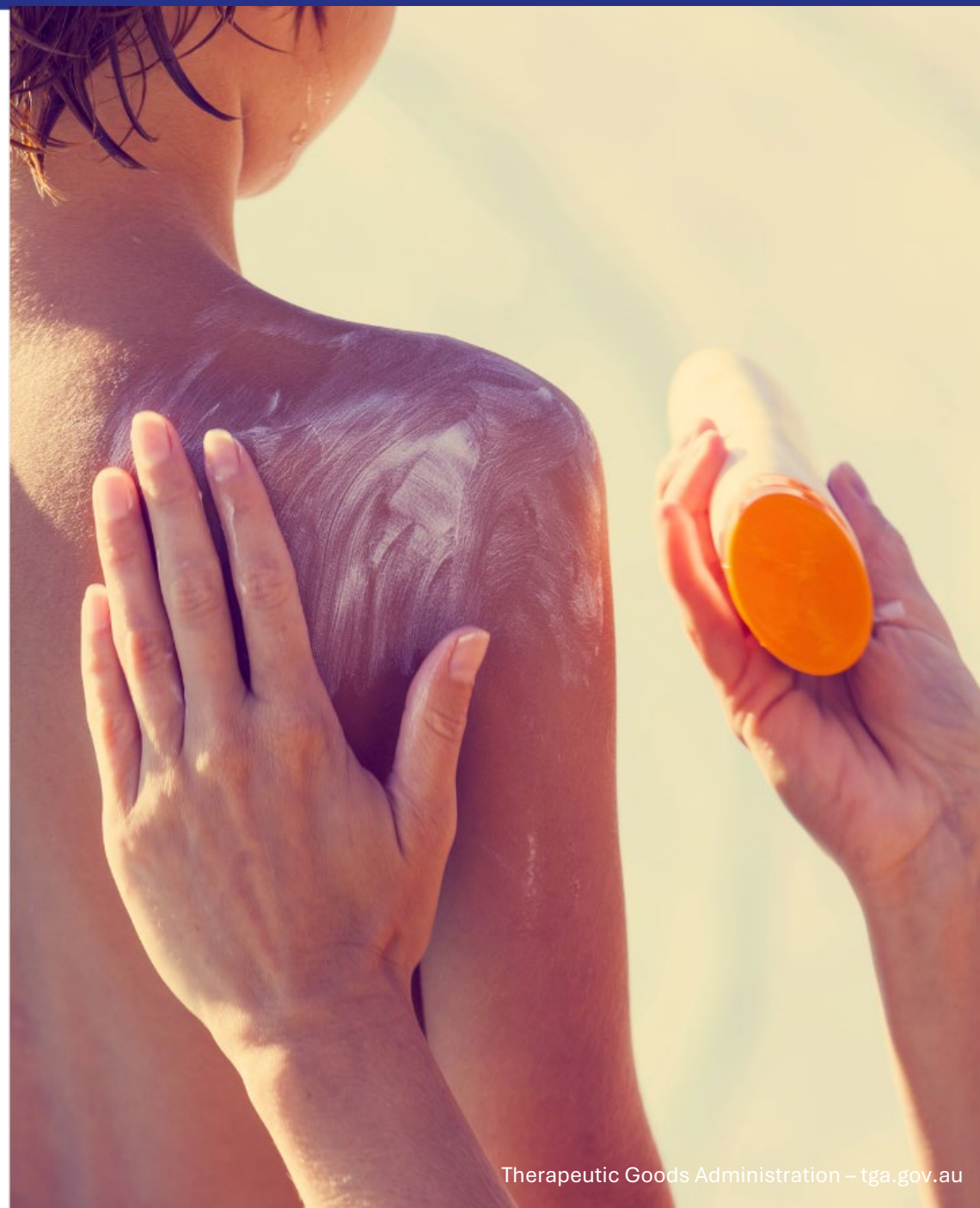
- Replace the current SPF rating system with the words:
- LOW MEDIUM HIGH VERY HIGH
- These words could be used on their own, or combined with an easily identifiable graphic, Potential examples:





Cosmetic sunscreen exclusions

Avinash Clarke



Cosmetic sunscreens able to make high SPF claims

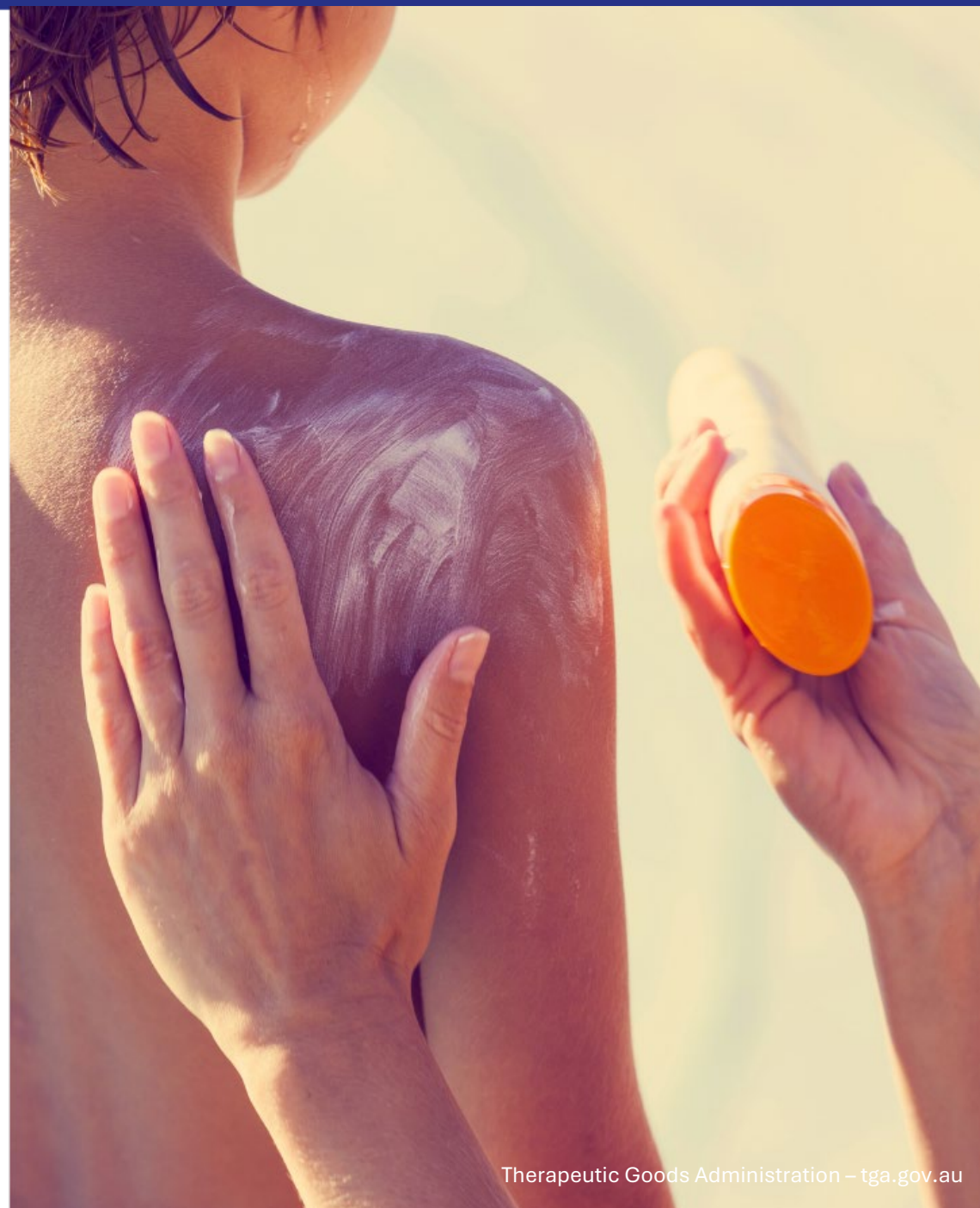
- The Therapeutic Goods Excluded Goods has provisions enable tinted foundations and lip products to make high level SPF claims if the product is being promoted for cosmetic purposes.
- Australian consumers likely to select a product with a high SPF rating (e.g. SPF 50+) for use as a primary sunscreen, irrespective of whether it is promoted for cosmetic purposes.

Proposed options

- Option 1: Status quo – maintain current exclusion provisions
- Option 2: Require that excluded sunscreens include ‘cosmetic sunscreen’ on their primary label
- Option 3: Provide a consistent limit of the SPF rating that can be claimed for all secondary (cosmetic) sunscreens

Good manufacturing practice matters

Hongxia Jin



Opportunities to enhance sunscreen manufacturing guidance

- The recent TGA investigations have not identified specific manufacturing failures that explain the low SPF results of certain products, but inspections have highlighted areas where greater clarity on GMP expectations is needed.
- Key areas for clearer guidance include identification and control of critical quality attributes and process parameters, roles and responsibilities of sponsors and manufacturers, and product release responsibilities.

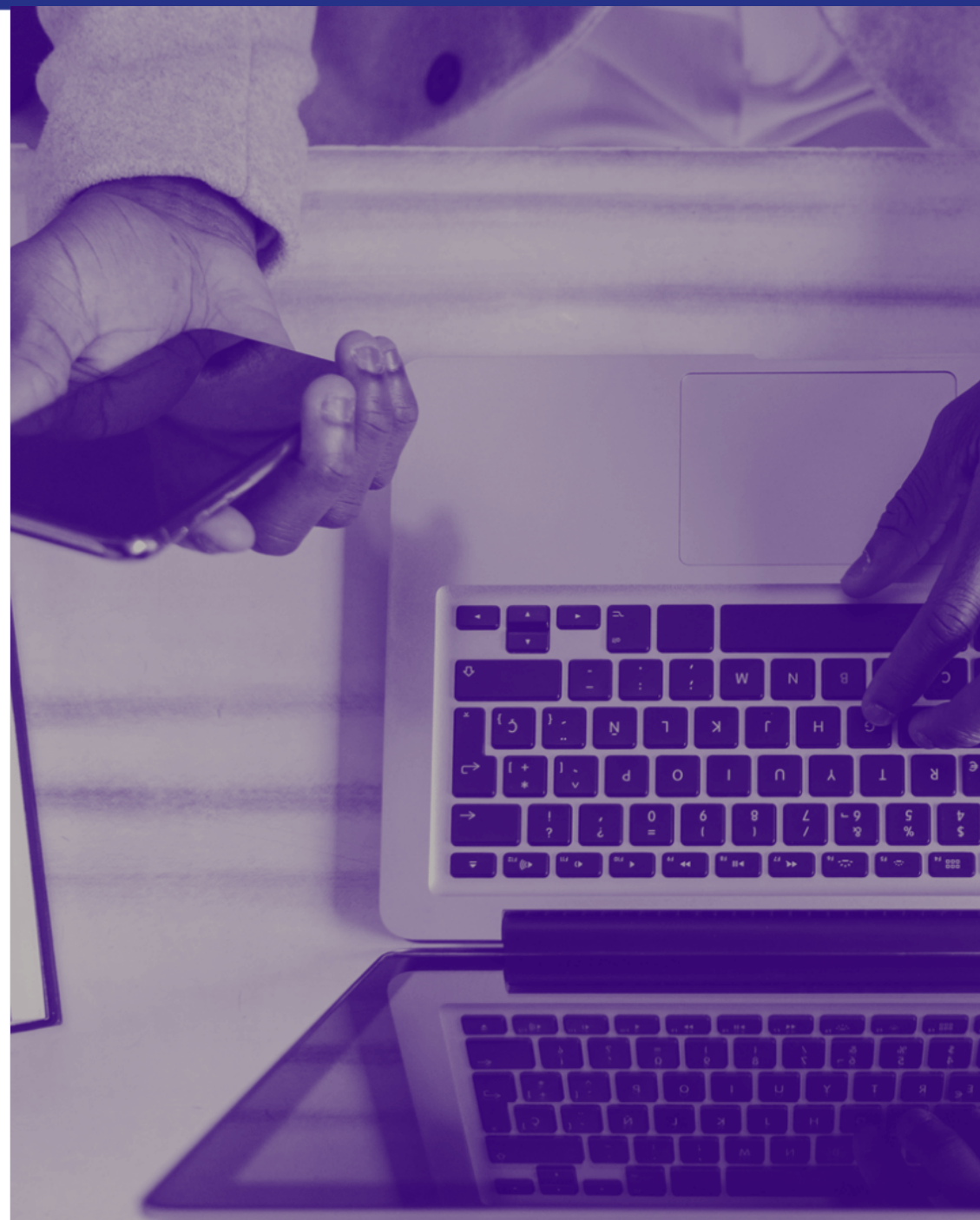
Proposed options

- Option 1: Status quo – maintain current guidance
- Option 2: Review sunscreen GMP guidance to incorporate contemporary information and address any additional risks

Questions?

Contact us

Email: sunscreens@health.gov.au



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration