



Australian Government

Department of Health

Therapeutic Goods Administration

# Regulation of Sunscreens in Australia

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**TGA** Health Safety  
Regulation



# Regulation of Sunscreens in Australia



- In Australia, primary sunscreens are regulated as **therapeutic goods** by the TGA and are required to be included in the ARTG prior to being supplied.
- Most secondary sunscreens are regulated as cosmetics by the NICNAS and the ACCC.
- The vast majority of **therapeutic sunscreens** are considered lower risk (listed) medicines.
- Listed sunscreens are required to be manufactured in accordance with the principles of GMP and must comply with the requirements specified in the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012).



# Primary vs Secondary Sunscreens

- **Primary sunscreens** are products that are primarily used for protection from UV radiation, these are regulated as **therapeutic sunscreens** by the TGA.
- **Secondary Sunscreens** are those with a primary purpose other than sunscreensing but which also contain a sunscreensing agent. The TGA also regulate some secondary sunscreen products such as:
  - Moisturisers containing sunscreen with an SPF greater than 15
  - Sunscreens that contain insect repellent (greater than SPF 4)
- **The majority of secondary sunscreens are regulated by the NICNAS and the ACCC** and include products such as:
  - Moisturisers with sunscreen, up to SPF 15
  - Make-up products with any SPF
  - Sunbathing products with SPF between 4 and 15



# Regulation of medicines by the TGA

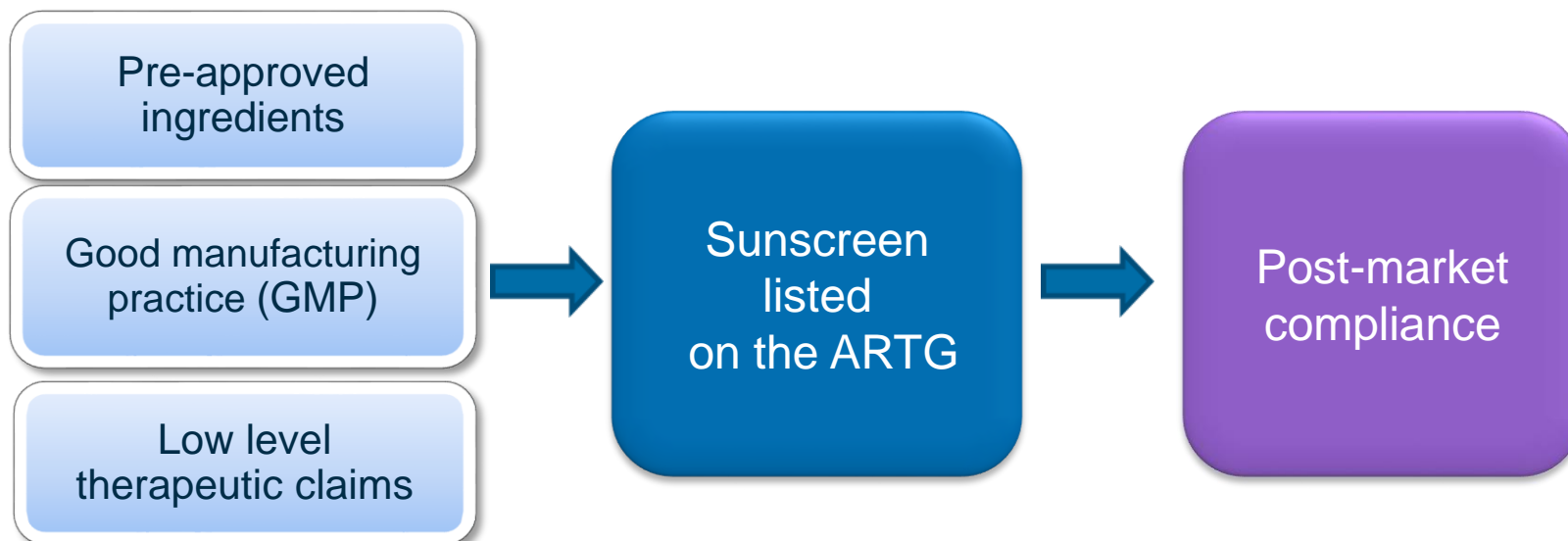
- Medicines supplied in Australia must be on the **Australian Register of Therapeutic Goods (ARTG)**
- Two-tiered system for inclusion on the ARTG according to risk
  - **Listed** (low risk) medicines, or
  - **Registered** (higher risk) medicines





# Regulation of therapeutic sunscreens

- The vast majority of therapeutic sunscreens are **listed** medicines.
  - Required to be included in the ARTG prior to being supplied.
  - No pre-market evaluation of final product
  - Must comply with the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012).





# Pre-approved ingredients for use in sunscreens

- Only approved ingredients may be used in sunscreens
  - Titanium dioxide, Zinc Oxide, 27 organic compounds
- Same list applies to Therapeutic and Cosmetic sunscreens
- Safety of active ingredients assessed and approved (TGA, FDA, etc.)
- Excipients all established pharmaceutical materials
- Microbiological Standards apply
- Label discloses all active ingredients (using AANs) and any excipients with potential for causing sensitivities or allergies



# Quality of sunscreens and GMP

- Manufacture of sunscreens must be in accordance with GMP, ensuring products are of an appropriate quality
  - Licensing and monitoring of Australian and overseas manufacturers
  - Post-market compliance reviews of GMP compliance
- Approved ingredients only (actives and excipients)
  - Pharmaceutical grade
- Other legislated instruments and standards that require:
  - Well-developed, stable formulations
  - Appropriate, comprehensive QC specifications



# Efficacy of sunscreens

- Upon listing, the sponsor must certify that they comply with the applicable legislative requirements; for sunscreens, this includes that:
  - Pre market testing has been conducted in accordance to AS/NZS 2604 for:
    - SPF
    - Broad Spectrum Protection (UVB and UVA)
    - Water Resistance (if relevant)





# Sunscreen post-market compliance

- TGA routinely conducts reviews and testing, both random and targeted towards specific issues, to ensure compliance of listed medicines with requirements.
- Since 2017, TGA has been conducting a desktop review of listed sunscreens (completion anticipated in March 2018)
- TGA laboratories undertook targeted testing of sunscreen formulations in response to consumer concerns in May 2017.
- The TGA Toxicology section updated its literature review on the topic of nanoparticle safety in May 2017.



# Targeted review of listed sunscreens

## Main objectives

- To review a representative sample of sunscreens listed on the ARTG to ensure that they are safe, of good quality and meet the required legislative and regulatory requirements.

## Scope

- 174 products were selected out of 925 listed on the ARTG at that time
  - 81 contained ingredients (methylisothiazolinone and methylchloroisothiazolinone) for which the quantity restriction was scheduled to be tightened (0.01% to 0.001% in the SUSMP)
- Products included those that may also have come under scrutiny by the TGA (advertising, lab testing or adverse event) or the media.



# Information reviewed

- **Product Label** – Compliance to TGO 69 as well as meeting labelling requirements from the Sunscreen Standard AS-NZA 2601-1998
- **Manufacturing documents** – Product Formulations documents, Product Specification Documents and Certificates of Analysis for one batch of product
- **SPF testing data**
- **Water resistance testing data**
- **Broad Spectrum UVA/UVB testing data**
  
- *No laboratory testing was conducted as a part of this review*



# TGA lab testing of listed sunscreens

- In response to consumer concerns , TGA Laboratory tested 31 commonly used sunscreens, including lotions, creams and aerosol sprays
- All products were found to contain the correct amount of active ingredients as listed on the label (90-120% of the label claim)
- Preliminary testing of aerosols indicated that the delivery rate (i.e. the amount delivered per second) differed between brands.
- SPF and broad spectrum testing was not conducted as part of this testing.



# TGA literature review - Nanoparticles

- In January 2017, the TGA published an updated literature [review](#) on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreen
- *In vitro*: in the presence of UV light, these nanoparticles can cause cellular damage through the formation of reactive oxygen species.
- However, the vast majority of studies indicated the inability of nanoparticles to penetrate the skin
- Weight of evidence: nanoparticles do not reach viable skin cells and remain on the skin surface and outer layer of the *stratum corneum*
- If used correctly, nanoparticles from sunscreen will not achieve significant concentration in the systemic circulation





# Emerging issues with sunscreens

- The internet is now being used to provide people with many 'recipes' to make their own 'sunscreens'
  - No SPF or broad spectrum testing has been conducted for these formulations, nor has water resistance, stability or a general safety assessment of the ingredients being used
  - Common ingredients include a combination of zinc oxide with various oils, including coconut oil and essential oils for scent
  - The percentage of zinc oxide is suggested to provide the SPF value, with SPF values being suggested as SPF 20 when a 20% mixture is used
  - Other recipes do not use any ingredients that are approved for sunscreens
- **The TGA does not endorse/regulate the use of homemade sunscreen**
- Where products are found to be in breach of the therapeutic goods legislation the appropriate action will be taken



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