Regulation of Sunscreens in Australia

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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 sunscreening but which also contain a sunscreening agent. The TGA also regulate some secondary sunscreen products such as:
  - Moisturisers containing sunscreen with an SPF greater than 15
  - Sunscreens that contain insect repellant (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
- Good manufacturing practice (GMP)
- Low level therapeutic claims
- Sunscreen listed on the ARTG
- Post-market compliance
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.
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