Regulatory update from the Complementary & Over-the-Counter Medicines Branch

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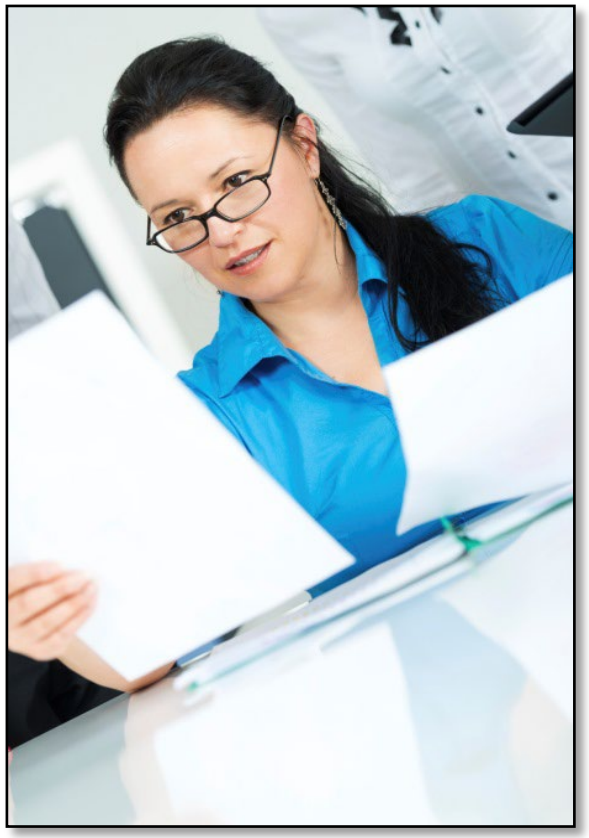
ARCS Annual Conference 2023

Overview

- New and updated guidance for listed medicines:
  - Mandatory requirements for new listed medicine ingredient
  - Australian Regulatory Guidelines for Sunscreens
  - Comparable Overseas Bodies Guidance
  - Requirements for microorganism characterisation in Listed Medicines and Registered Complementary Medicines
  - New sponsor educational tools
- New conditions of Listing Determination
- Listed medicine compliance activities
- Registered Complementary Medicines & Listed (Assessed) Medicines update
- OTC Medicines update
- Current & upcoming activities



New and updated guidelines

New ‘Mandatory requirements for new ingredient applications’

- **Published February 2023**
- Provides minimum data requirements for new ingredient applications
- Clarifies TGA expectations to ensure consistent treatment of all applications, while still offering flexibility
- To prevent deficient applications that are unlikely to succeed from delaying evaluation of other applications in the queue
- Applicants can provide justifications for unique circumstances - merits assessed during evaluation

Update to Australian Regulatory Guidelines for Sunscreens

- **Published March 2023**
- To align with requirements for new dermal substances for use in listed medicines
- Refers to Application requirements for new substances in listed medicines
- Applicants to follow V3.0 ARGS for guidance on new applications for ingredients for use in listed therapeutic sunscreens from date of publishing
- Includes provision of using the COB-based process

Update to ‘Guidance on using evaluation reports from Comparable Overseas Bodies’ (COB)

- **Published January 2023** – significant changes to improve readability and clarity following industry feedback
- Revised SCCS entry to accept reports to support safety and quality of excipient and active substances for dermal use
- Updated references to IN1 application category to align with new Regulations – application based on a COB report for safety, and quality based on a default standard

New ‘Guidance for assessment of microorganism strains (bacteria and fungi) for LM and RCM’s’

- **Published February 2023** – clarifies TGA expectations for applications for new microorganism strains for use in listed medicines
- Consulted extensively with stakeholders to develop guidance & reviewed international approaches
- Bridges a significant gap in current application guidelines - ensures that microorganisms, when identified and characterised, are safe for their intended use
- Aligns with Guidance on Mandatory requirements for new ingredient applications and update to the list of Comparable Overseas Bodies

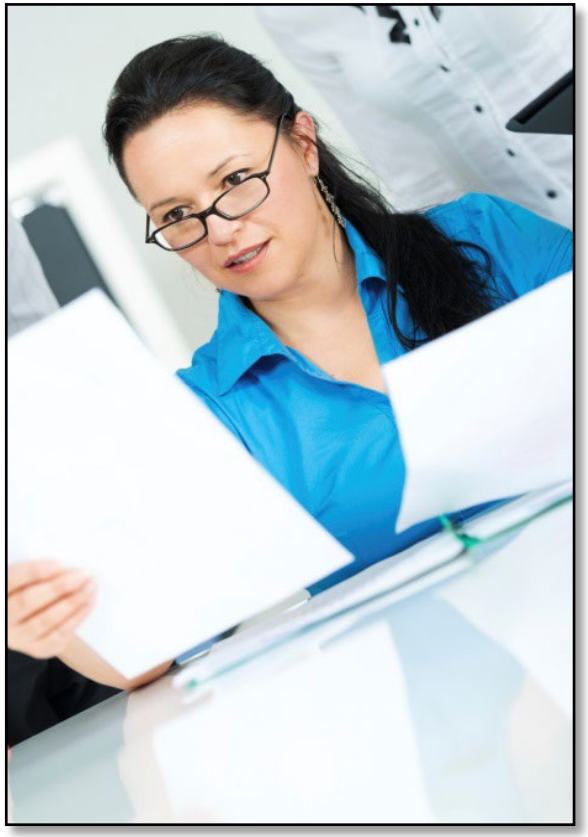
New E-learning courses on evidence guidelines for listed medicines

New Conditions of Listing Instrument

Made under Section 28 of the *Therapeutic Goods Act 1989* (the Act)

- **January 2023** - new Conditions of Listing instrument came into effect
- Sets out the conditions of listing applied to all Listed medicines at the time of listing
- Now see the conditions to which products will be subject to before apply to list products in the ARTG
- Conditions included in the instrument will apply automatically to the goods that the instrument relates to

Listed medicine compliance activities



2022-2023 Listed Medicine compliance priorities

The following non-compliances of concern underpinned all compliance activities for Listed medicines:

- Not holding sufficient evidence to support efficacy
- Advertising indications not in the ARTG entry for the medicine
- Missing mandatory warning statements
- Not meeting restrictions required by the Permissible Ingredients Determination (esp. not monitoring mandatory component quantity restrictions)
- Relisting
- Sponsors who have consistently been non-compliant in previous reviews

2022-2023 Listed Medicine compliance focus topics

Safety:

- Warning statements for *Piper methysticum, Azadirachta indica, Foeniculum vulgare*, *Andrographis paniculata*
- Caffeine content and warning statements
- Medicines containing HICC
- Aerosol sunscreens
- Medicines directed to pregnant women

Efficacy:

- Advertising indications that are not in the ARTG entry of the medicine
- Colecalciferol (Vitamin D) and bone health claims
- Lysine hydrochloride for the management of cold sores
- Listed sports supplements in relation to exercise performance

Compliance assurance of recidivist sponsors

Registered Complementary Medicines & Listed (Assessed) Medicines update

Registered Complementary Medicines

Stats for application types – 2022-2023 (as of May 2023)

New registered complementary medicines	
Status	Count
Applications completed	4
Approved	2
Rejected	1
Withdrawn by sponsor	1
Lapsed	0

Variations to registered complementary medicines	
Status	Count
Applications completed	25
Approved	25
Rejected	0
Withdrawn by sponsor	0
Lapsed	0

Listed(Assessed) Medicines

Stats for application types – 2022-2023 (as of May 2023)

New assessed listed medicines	
Status	Count
Applications completed	1
Approved	0
Rejected	1
Withdrawn by sponsor	0
Lapsed	0

Variations to assessed listed medicines	
Status	Count
Applications completed	1
Approved	1
Rejected	0
Withdrawn by sponsor	0
Lapsed	0

New ingredient applications

2022-2023 (as of May 2023)

New ingredient applications	
Status	Count
Applications completed	13
Approved	8
Rejected	0
Withdrawn at screening	1
Withdrawn at evaluation	4
Lapsed	0

OTC medicines update

OTC Medicines – application timeframes

- Applications in progress - slightly more than same time last year
- Number of applications received in the last 12 months increased from 763 to 820
  - Number of OTC applications received, July 2022 to April 2023 = **651**
  - Number of applications approved, July 2022 to April 2023 = **574**
  - For C2, C3, N1, N2 & N5 – more than **80%** of applications completed within target timeframes
  - For N3 & N4 – **75%** of applications completed within target timeframes

Scheduling decisions

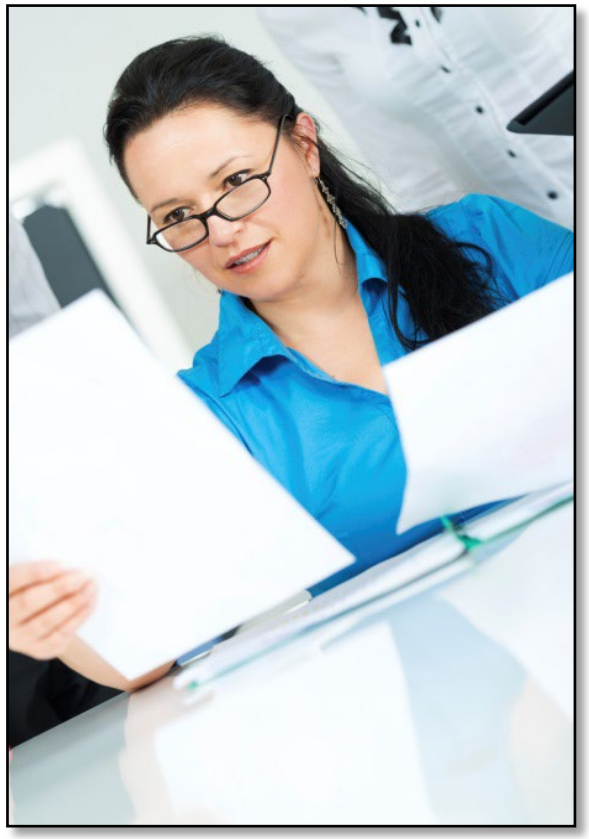
- Continuing trend to down-schedule substances from prescription medicine to non-prescription & within non-prescription schedules
  - E.g. melatonin, triptans, topical mometasone, adapalene, bilastine
- Exception - recent paracetamol decision

- OTC applications for S4 to S3/S2 products:
  - timing of applications
  - various factors require consideration to ensure correct pathway & application type, such as wording of decision, is OTC product a separate & distinct good?
  - label warning/cautionary statements (RASML) may be required

RASML No. 6 (Required Advisory Statements for Medicine Labels)

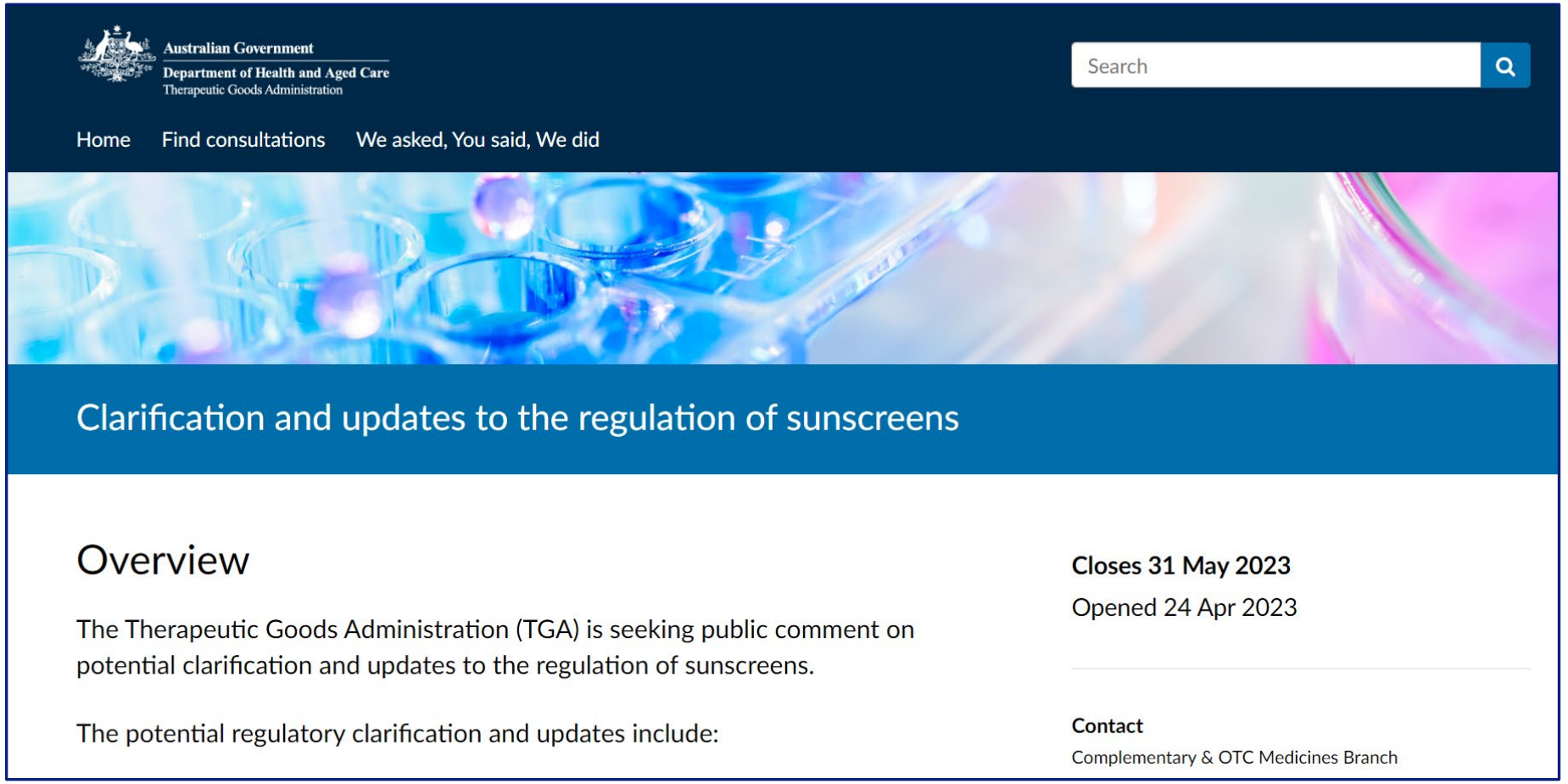
- Published on 1 January 2022
- Comes into full effect on **1 July 2023** after an 18 month transition period
- During the transition, labels could comply with either RASML No. 5 or RASML No. 6
- From 1 July 2023, labels must comply with RASML No. 6

Current and upcoming work



Sunscreen consultation closed 31 May 2023

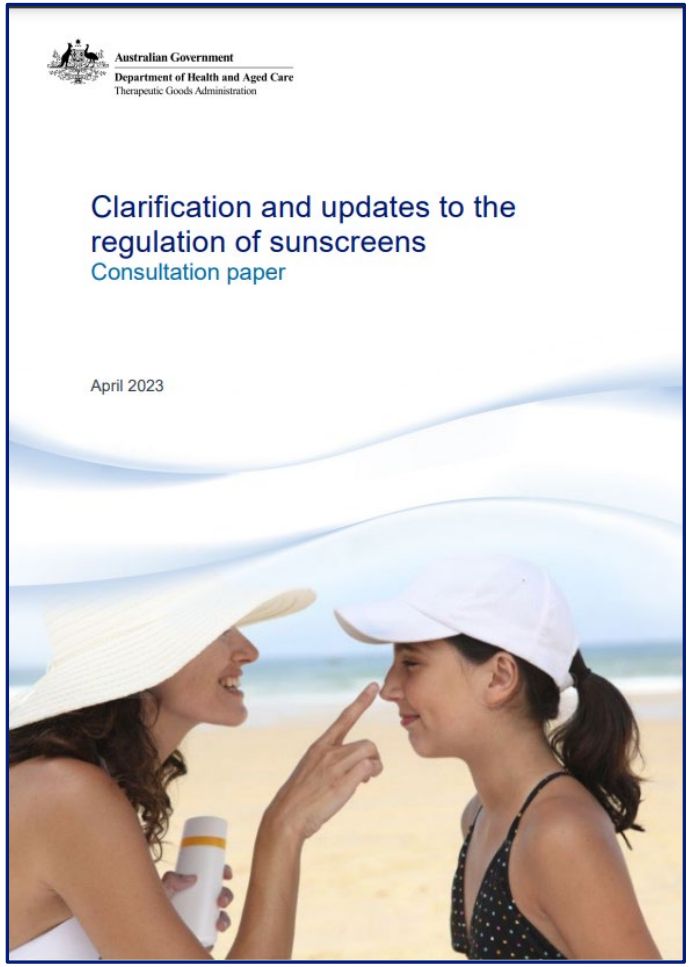
Clarification and updates to the regulation of sunscreens



Sunscreen consultation closed 31 May 2023

The potential regulatory clarification and updates included in the consultation include:

1. Adoption of the Australian/New Zealand Standard Sunscreen products Amd 1:2022 (the 2021 Sunscreen Standard)
2. Removal of the category of ‘exempt’ sunscreens from the regulations - enables sunscreen products with <SPF4 to comply with the superseded 1998 Standard
3. Clarification on the indications (therapeutic uses) that sunscreens can make. Three options proposed for stakeholder consideration

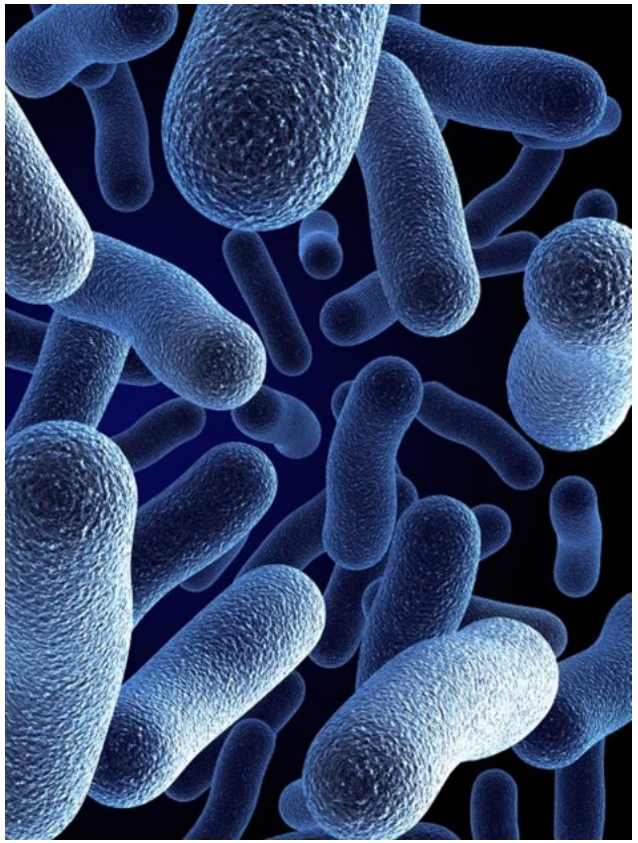


More sunscreen issues…..

Future work and consultation

- Review of the ARGS following consultation outcomes e.g.
  - Clarification of indications permitted for sunscreens
  - Removal of information on exempt sunscreens.
- Revision of the provisions in the Excluded Goods Order in relation to primary and secondary sunscreens.

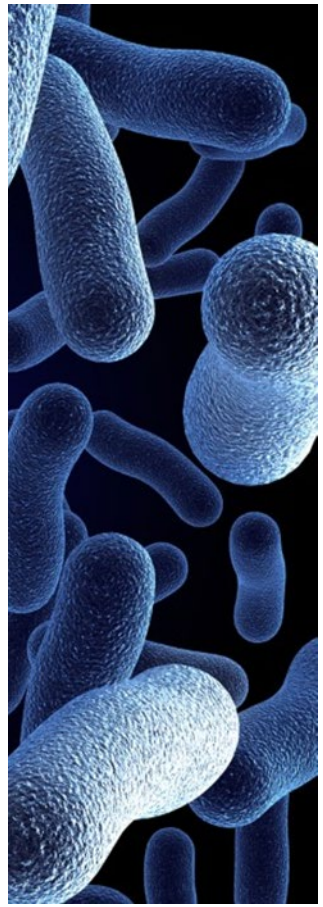
Coming soon: New Guidelines on the quality of listed probiotic medicines



- New Guidelines being developed because compliance reviews identified quality issues for listed probiotic medicines
- Industry have regularly engaged to provide feedback on the new Guidelines
- The revised draft will be subject to targeted consultation mid 2023 with aim to publish in second half of 2023

New Guidelines on the quality of listed probiotic medicines

- The new Guidelines explain:
  - ✓ why active ingredients in probiotics need to be controlled
  - ✓ how the legislation controls probiotic medicine quality
  - ✓ what quality control of probiotics can look like to ensure label claims are truthful – includes microbial ingredient identification & quantification, product stability & bioburden control



Other activities

- TGO92 (‘Labelling Order’) sunsets on 1 October 2026 – requires review
  - number of issues/ambiguities identified
  - targeted consultation mid-2023 to seek ideas & priorities to inform proposals for future public consultation

- ‘Boundary & Combination Product Guidance – medicines, medical devices & biologicals’ - consultation conducted in 2022, closed on 20 Nov 2022. Submissions being considered.
- Quality of OTC applications has generally diminished - looking to develop new guidance tools for certain OTC application types/issues to assist sponsors

Further review of material on TGA website

- Ensure guidance material current
- Accessible, helpful language
- Structured content that supports common tasks
- Automated collections
- Responsive to device being used
- Improved search capabilities
- More guidance tools for sponsors

Website references

TGA website	www.tga.gov.au
Application requirements for new substances in listed medicines	https://www.tga.gov.au/sites/default/files/2023-02/application-requirements-for-new-substances-in-listed-medicines.pdf
Clarification and updates to the regulation of sunscreens - Consultation	Clarification and updates to the regulation of sunscreens - Therapeutic Goods Administration - Citizen Space (tga.gov.au)

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

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Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration