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

Gaelene Pyke

Acting Assistant Secretary

Complementary and OTC Medicines Branch

Department of Health and Aged Care, TGA

Agenda

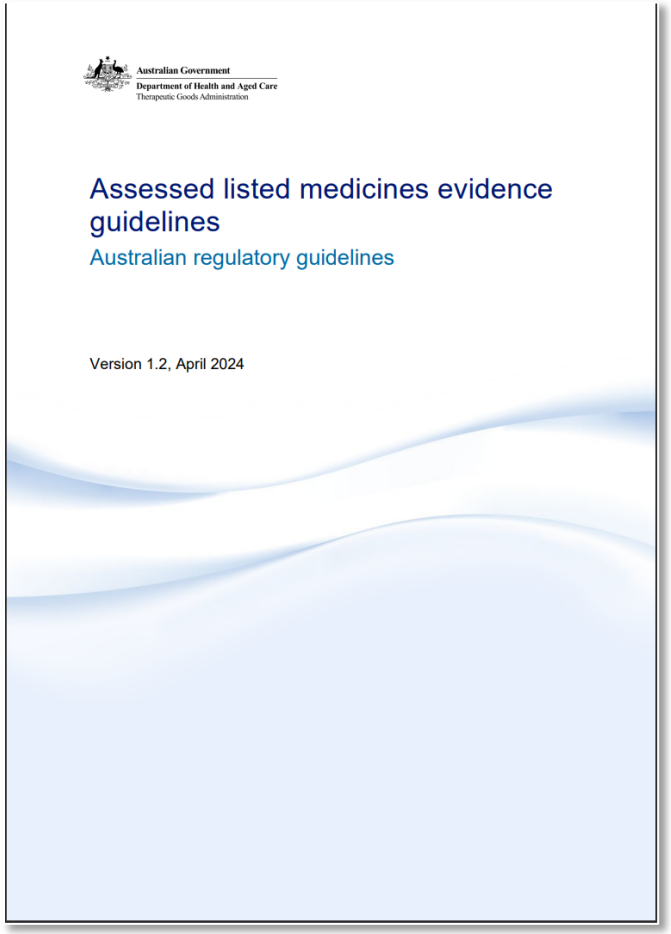
- Updated guidance
- Listed medicine compliance activities
- Registered Complementary Medicines & Listed (Assessed) Medicines update
- OTC Medicines update
- Current & upcoming work
- Other current/proposed activities

Updated guidelines

Assessed Listed medicine evidence guidelines update

Published April 2024

- Updated information since the first version of the guidelines in 2018.
- Consulted extensively with ACCM and industry to improve clarity and ease-of-use.
- Information covers broad principles, and references are made to established guidelines for specific information.



TGA adoption of the 2021 Sunscreen Standard

Current Australian/New Zealand Sunscreen Standard (AS/NZS 2604:2021 Amd 1:2022) adopted into therapeutic goods legislation on 1 July 2024.

Transition arrangements:

- All new sunscreen products included in the ARTG must comply with the new sunscreen standard.
- Existing **aerosols and spray pump packs** included in the ARTG prior to 1 July 2024 will have a 1-year transition period to comply with the new labelling requirements
- All existing sunscreens products (**aerosol and non-aerosol**) included in the ARTG prior to 1 July 2024 will have a 5-year transition period where they can comply with the testing requirements of either the current or the previous standard.

Listed medicine compliance activities

2023-2024 Listed Medicine compliance focus topics

Safety:

- Warning statements for: *Artemisia* species, molluscs, *Bacillus coagulans.*
- Removal of products with HICC.
- Aerosol sunscreens.
- Vaginal pessary dosage forms.
- Advertising that suggests products contain NAD.

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 enhancement.
- Compliance assurance of recidivist sponsors.

2024-2025 Listed Medicine compliance priorities

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

- Not holding sufficient evidence to support efficacy.
- Not meeting requirements of Permissible Indications Determination.
- 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/scheduled quantity restrictions).
- Relisting.
- Sponsors who have consistently been non-compliant in previous reviews.
- Quality requirements that have safety implications.

Registered Complementary Medicines

& Listed (Assessed) Medicines update

Application outcomes

Registered Complementary Medicine, Assessed listed medicines and listed medicine ingredients (as of May 2024)

- **Registered complementary medicines**: 10 applications for new medicines, 8 new medicines approved, 7 applications unsuccessful (18 variations approved)
- **Assessed listed medicines:** 1 application for a new medicine, 1 new medicine approved
- **Listed medicine ingredient applications**: 7 applications received, 5 approved, 1 unsuccessful

Annual low-negligible risk consultation for listed medicine ingredients - 2023-24

In **August 2023**, **public consultation** on proposed changes to:

- *Curcuma* species and curcumin and the risk of liver injury.
- Green tea extract and the risk of livery injury.
- Safe levels of benzophenone as component of octocrylene (sunscreen active).
- Clarification of the requirements for soy phosphatidylserine-enriched ingredients.
- Clarification of the requirements for *Terminalia ferdinandiana.*

Final decisions published in **December 2023**

- Amendments in relation to octocrylene to address safe levels of benzophenone were deferred pending further consultation.

Changes came into force on **1 March 2024**.

OTC medicines update

OTC Medicines – application timeframes (at 30 April 2024)

- Applications in progress = **424**
- Number of applications received July 23 to April 24 = **652**
- Number of applications completed July 23 to April 24 = **570**
- For C2 & C4's, more than 80% of applications completed within target timeframes
- All other application types below 80% target

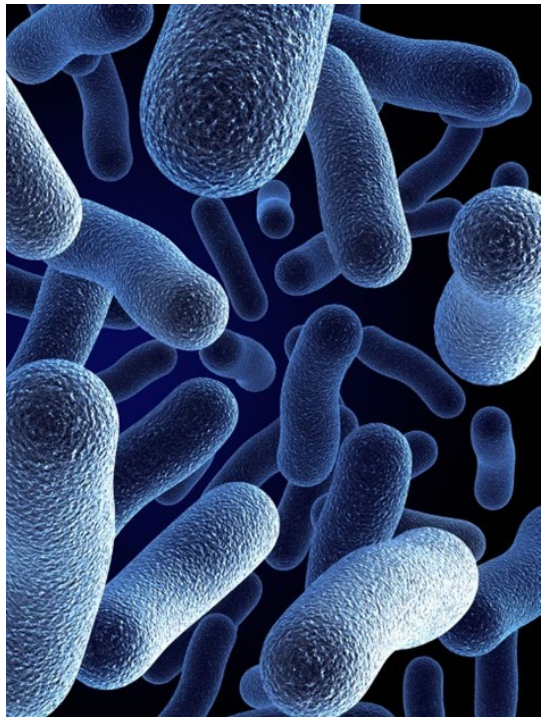
Scheduling decisions

- Continuing trend to down-schedule substances from prescription medicine to non-prescription & within non-prescription schedules
  - E.g. olopatadine (S2), celecoxib (S3), naratriptan (S3), methenamine (S3)

- Paracetamol scheduling: final decision made 3 May 2023
  - max pack sizes reduced from 20 to 16 tablets/capsules for general sale
  - max pack sizes reduced from 100 to 50 tablets/capsules and 50 to 25 sachets for S2
  - other pack sizes up to 100 tablets/capsules S3
  - takes effect on 1 Feb 2025

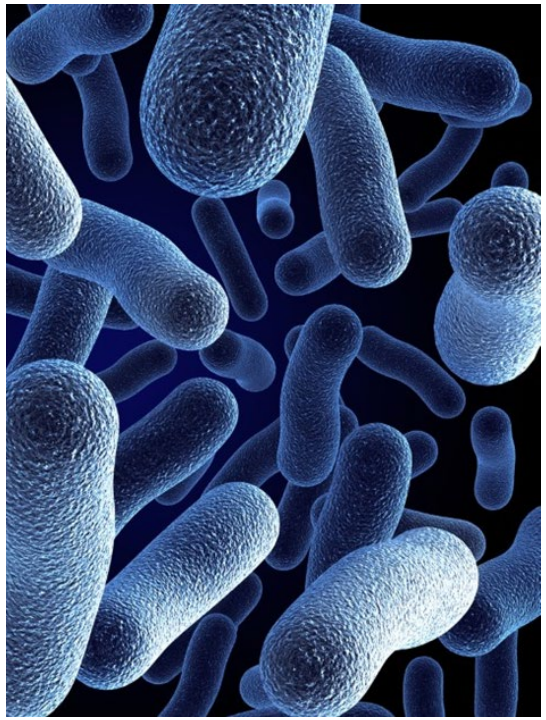
Current and upcoming work

Coming soon:
Guidelines on the quality of listed probiotic medicines



- New guidelines to clarify the quality requirements for listed probiotic medicines.
- Industry have regularly been engaged to provide feedback on the new Guidelines.
- Public consultation completed end of 2023.
- Guidelines updated based on stakeholder feedback.

Guidelines on the quality of listed probiotic medicines



The new guidelines will 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 current/proposed activities

- New OTC guidance tools to assist sponsors.
- Review of existing OTC guidance (ARGOM) to ensure current and fit for purpose
- Factsheet/guidance on data requirements for potential RCM applicants seeking to register products for a common vitamin/mineral (including immediate and modified release dosage forms, salts/complexes).
- Consultation on a proposed Australian Exposure Model for Sunscreens.
- Updates to the Permitted Indications Determination.

Website and link references

Updated guidelines for Assessed listed medicines	https://www.tga.gov.au/news/news/updated-guidelines-assessed-listed-medicines
Updates to the Sunscreen Standard	https://www.tga.gov.au/updates-sunscreen
Compliance and education for listed medicines	https://www.tga.gov.au/products/medicines/non-prescription-medicines/listed-medicines/compliance-and-education-listed-medicines
Final decision on paracetamol access controls in the Poisons Standard – Question and Answers	Final decision on paracetamol access controls in the Poisons Standard – Question and Answers | Therapeutic Goods Administration (TGA)

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

Want to chat with me further? Come visit us.

2024 ARCS ANNUAL CONFERENCE

Contact us

Complementary and OTC Medicines Branch

Complementary.medicines@health.gov.au

Stay connected

Subscribe to updates

Social media

LinkedIn

X (Twitter)

YouTube

Instagram

Facebook

www.tga.gov.au/about-tga/social-media
www.tga.gov.au/news/subscribe-updates

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration