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

Avinash Clarke
Complementary and OTC Medicines Branch
Department of Health, Disability and Ageing, TGA

Session overview

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


Listed (Assessed) medicine applications
Registered Complementary Medicine applications
Listed medicine ingredients

Application outcomes

As of May 2025:

Registered complementary medicines

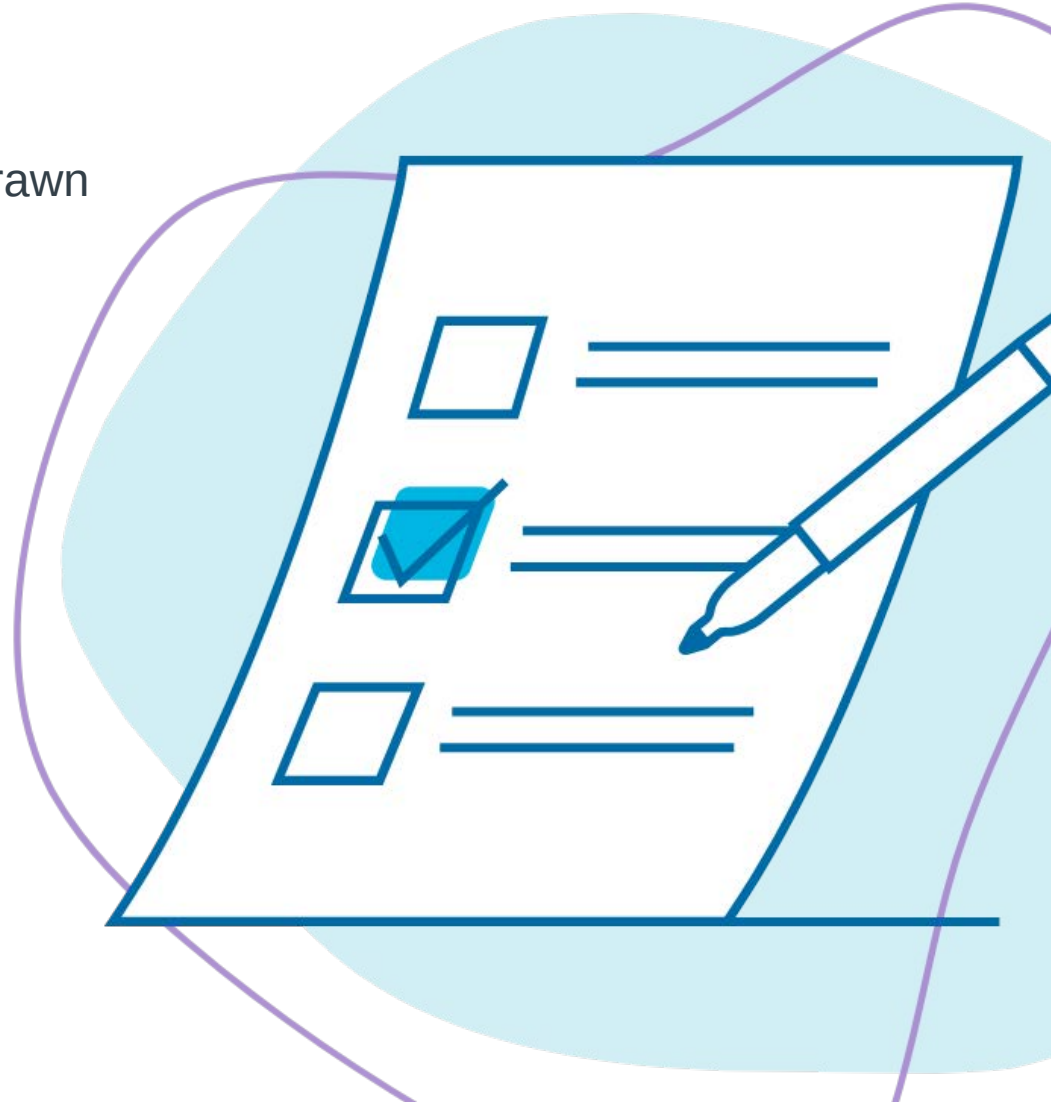
- **New applications:** 5 received, 3 approved, 1 withdrawn
- **Variation applications:** 33 received, 25 approved, 5 rejected at screening, 6 withdrawn

Assessed listed medicines

- **New applications:** 1 approved

Listed medicine ingredient applications

- **New applications:** 10 received, 6 approved, 1 unsuccessful



Pre-Submission Meeting Requests

As of May 2025

Application type	PSM requests
Registered complementary medicines	2
Assessed listed medicines	3
Listed medicine ingredient applications	8

Annual low-negligible risk consultation for listed medicine ingredients 2024-25

In **August 2024**, **public consultation** on proposed changes to:

- Herbal ingredients with pregnancy contraindications and other toxic effects
- Garcinia species, hydroxycitric acid, hydroxycitrate complex and salts, and risk of liver injury
- Xanthium species
- Phenoxyethanol
- Clarification of hydration state for rutoside

Final decisions published in **December 2024**:

- Changes came into force on **1 March 2025**.

Listed medicines compliance activities

Listed medicines post-market framework

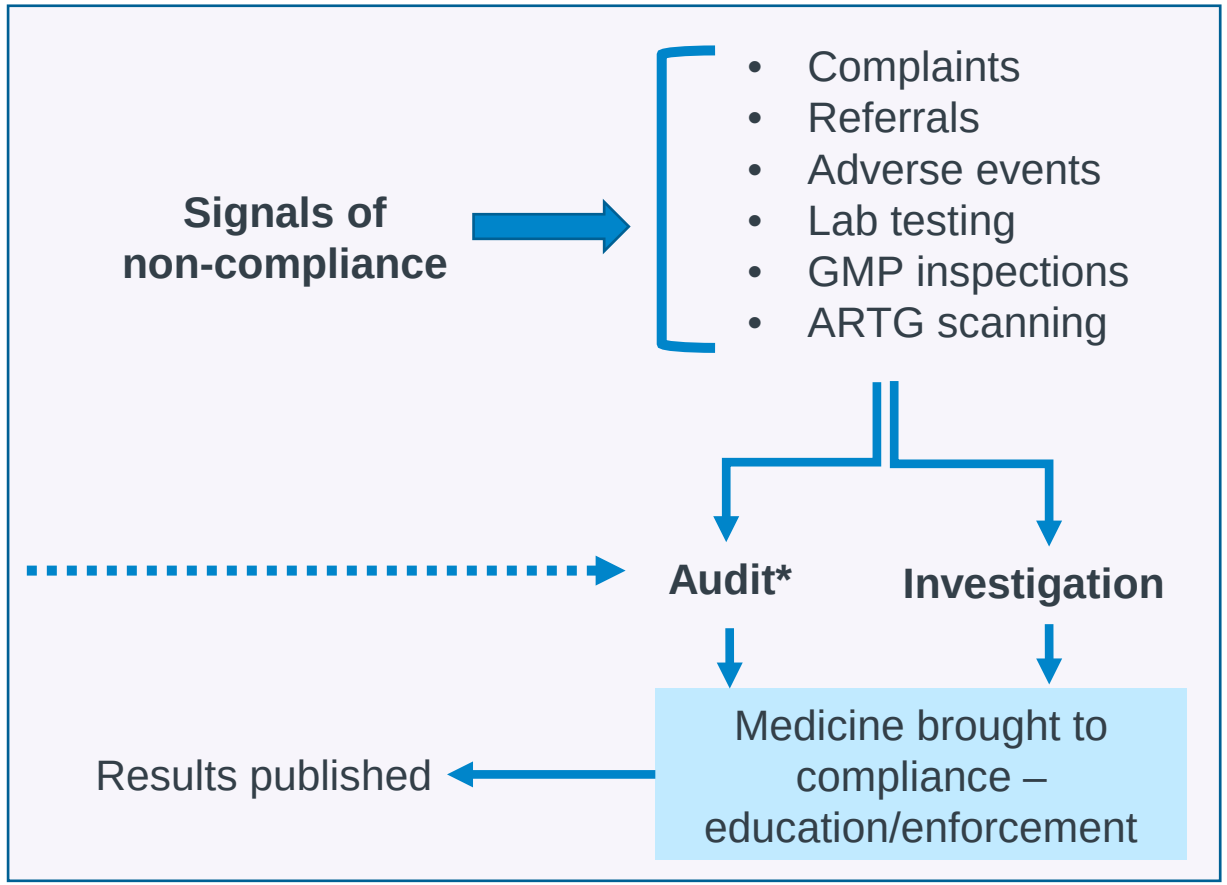
Permissible Ingredients + Indications Determination + GMP

Sponsors enter medicines in the ARTG and **certify compliance**

No pre-market assessment of final product by TGA

Medicine is advertised and commercialised

Post-Market Regulatory Framework – RISK-BASED



*Compliance review

Spectrum of regulatory actions

Compliance and enforcement actions [a]	FY 2022-23	FY 2023-24
Warning notices (cease and desist)	4	21
Educational correspondence (e.g. obligations notices, educational emails, other)	108	58
Mass email education [b]	192	27
Cease review notices	19	9
Conclusion notices	149	83
Deficiencies notices	36	17
Proposal to cancel notices	140	48
Cancellation notices	8	7
Directions/Prevention notice	2	1
Infringement notices	8	6
Published outcomes of compliance reviews	175	153
Referral to another TGA area or government organisation	43	40
Recall actions [c]	21	13
Total actions undertaken [a]	**905**	**483 [d]**

2024/25 Priorities

The following non-compliances of concern underpinned all our compliance activities:

a) Advertising indications not on ARTG and not meeting the Permissible Indications Determination (esp. restricted/prohibited representations)

b) Missing mandatory warning statements

c) Not meeting restrictions required by the Permissible Ingredients Determination (esp. not monitoring mandatory component quantity restrictions)

d) Quality issues that significantly impact safety and/or efficacy

e) Not holding sufficient evidence to support efficacy

f) Relisting of a non-compliant product with no or insufficient change soon after cancellation of an earlier listing

g) Sponsors who have consistently been non-compliant in previous reviews

2024/25 compliance focus topics

How do they relate to the priorities?

a) Advertising indications not on ARTG and not meeting the Permissible Indications Determination (esp. restricted/prohibited representations)

- Compliance reviews from ARTG scanning
- NAD/NMN reviews

b) Missing mandatory warning statements

- Valerian reviews, DIAR warning reviews

c) Not meeting restrictions required by the Permissible Ingredients Determination (esp. not monitoring mandatory component quantity restrictions)

- Lab testing for thujone and ingredients in listed sports supplements

d) Quality issues that significantly impact safety and/or efficacy

- Initial stability reviews

2024/25 compliance focus topics

How do they relate to the priorities?

e) Not holding sufficient evidence to support efficacy

- Vitamin D and sports performance reviews
- Review of best sellers from a repeatedly non-compliant sponsor

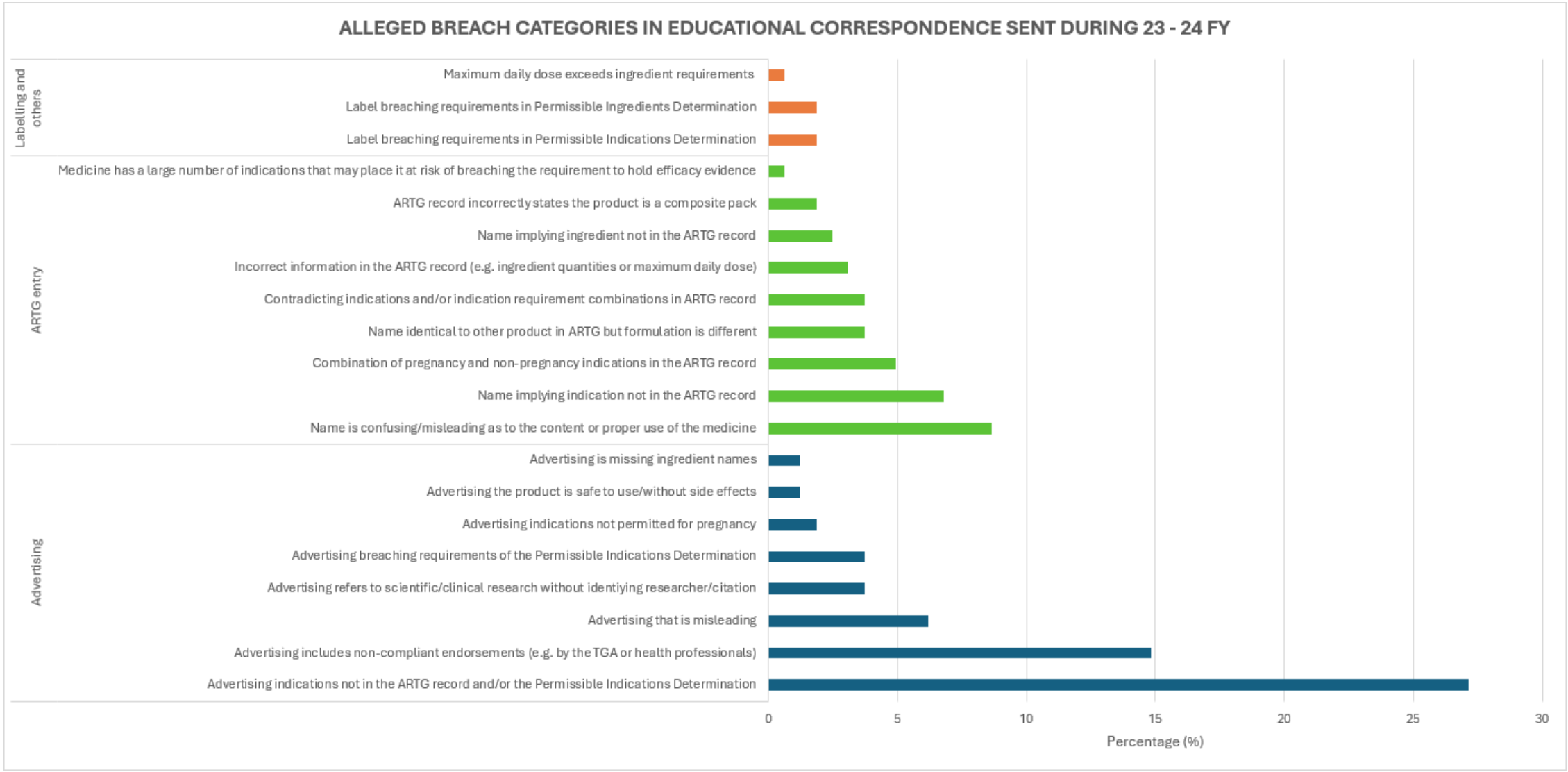
f) Relisting of a non-compliant product with no/insufficient change soon after cancellation of an earlier listing

- Behaviour monitored in all compliance reviews and during ARTG scanning

g) Sponsors who have consistently been non-compliant in previous reviews

- Reviews of a repeatedly non-compliant sponsor

Educational correspondence

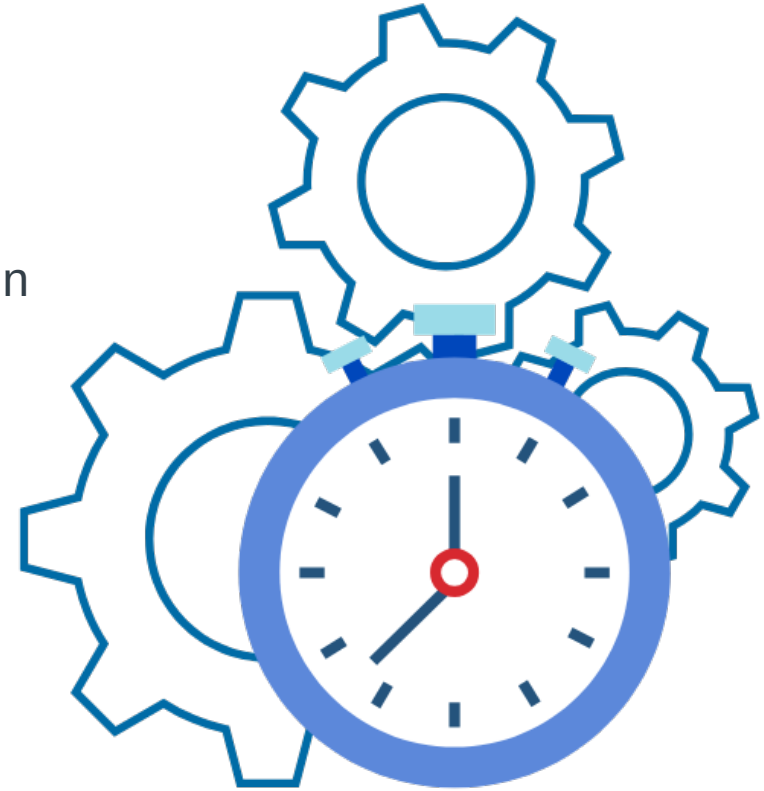


OTC medicines update

OTC Medicines – application timeframes

(at 30 April 2025)

- Applications in progress = **320**
- Number of applications received 1 July 24 to 30 April 25 = **637**
- Number of applications completed 1 July 24 to 30 April 25 = **811**
- For **C2, N1 & N2's**, more than 80% of applications completed within target timeframes
- All other application types below 80% target



Scheduling decisions

- **Desloratadine for oral use**
  - down-scheduled from Pharmacy Medicine (Schedule 2) to unscheduled (‘general sale’)
  - with effect 1 Feb 2025
- **Changes to paracetamol scheduling**
  - with effect 1 Feb 2025
- **Bisacodyl**
  - new S2 entry
  - with effect 1 Feb 2025
- **Glycopyrronium**
  - all preparations now S4 (Prescription Only)
  - S3 (Pharmacist Only Medicine) entry deleted
  - with effect 1 Oct 2024

Other OTC medicine activities

As consequence of the changes to paracetamol scheduling, core Product Information (PI) and Consumer Medicine Information (CMI) documents developed for sponsors to facilitate & streamline the updating of affected products

- Can be submitted at the C1 level provided no changes made to information in the templates (Changing an OTC medicine: Paracetamol solid-dose products | Therapeutic Goods Administration (TGA))

Developed a C1 checklist to assist sponsors in compiling complete, high quality submissions.

New and updated guidance

NEW guidance – Demonstrating the quality of listed probiotic medicines

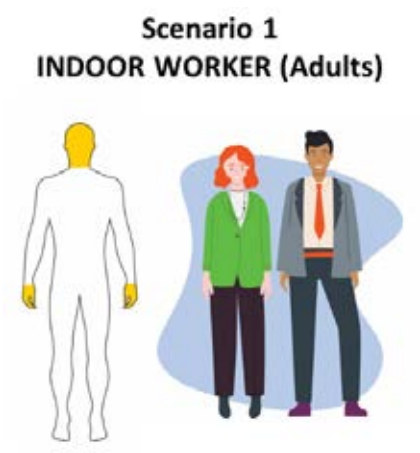
Published in January 2025

Explain:

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

New guidance – Australian Sunscreen Exposure model

- Developed over extensive consultation in 2024 and adopted in 2025
- Provides a simple calculation to determine sunscreen exposure for consumers in Australian conditions
- Provides a standardised method for evaluating sunscreen ingredients, reduces discrepancies in risk assessments.



Update to guidance

Completed:

- Understanding labelling and presentation requirements for listed medicines (formerly Listed medicine and labels) **published 9 April 2025**

Forthcoming in 2025/26:

- Understanding the Regulation of therapeutic Sunscreens (URTS) (currently Australian Regulatory Guidelines for Sunscreens)
- Understanding the legislative framework for listed medicines (formerly General guidance for listed medicines)

Update to guidance continued

Forthcoming in 2025/26:

- Understanding listed and registered complementary medicine regulations (currently Overview of the regulation of listed medicines and registered complementary medicines)
- Permitted indications for listed medicines and new e-Learning module
- Understanding quality requirements for listed medicines (currently Quality for listed medicines) and new e-Learning module

Update to guidance continued

Forthcoming in 2025/26:

- Changing a listed or an assessed listed medicine in the Australian Register of Therapeutic Goods (ARTG) to two separate documents:
  - Changing a listed medicine entry in the ARTG
  - Changing an assessed listed medicine entry in the ARTG
- Australian Regulatory Guidelines for OTC Medicines (ARGOM)

Other current/proposed activities

- Further updates to the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2025.
- Therapeutic Goods (Listed Medicines−Conditions of Listing) Determination 2022 update.
- Therapeutic Goods (Excluded Goods) Determination 2018 update.
- Create a tool for new sponsors to better understand the legislative framework for listed medicines.
- Develop guidance for listed medicine sponsors to understand nitrosamine risks.

Website and link references

Contact Us	Nonprescriptionmedicines@health.gov.au
Guidelines – Demonstrating the quality of listed probiotic medicines	https://www.tga.gov.au/resources/guidance/demonstrating-quality-listed-probiotic-medicines
Guidance - Understanding labelling and presentation requirements for listed medicines	https://www.tga.gov.au/resources/guidance/understanding-labelling-and-presentation-requirements-listed-medicines
Changing an OTC medicine: Paracetamol solid-dose products	https://www.tga.gov.au/resources/resource/user-guide/changing-otc-medicine-paracetamol-solid-dose-products

Therapeutic Goods Administration (TGA)

Exhibition booth **No.60**

Want to chat with me further? Come visit us.

2025 ARCS
ANNUAL CONFERENCE

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration