NATURAL HEALTH PRODUCTS NZ™

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Advanced Wellness Regulatory Solutions

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Changing Landscapes – Australian Regulations

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Change overview

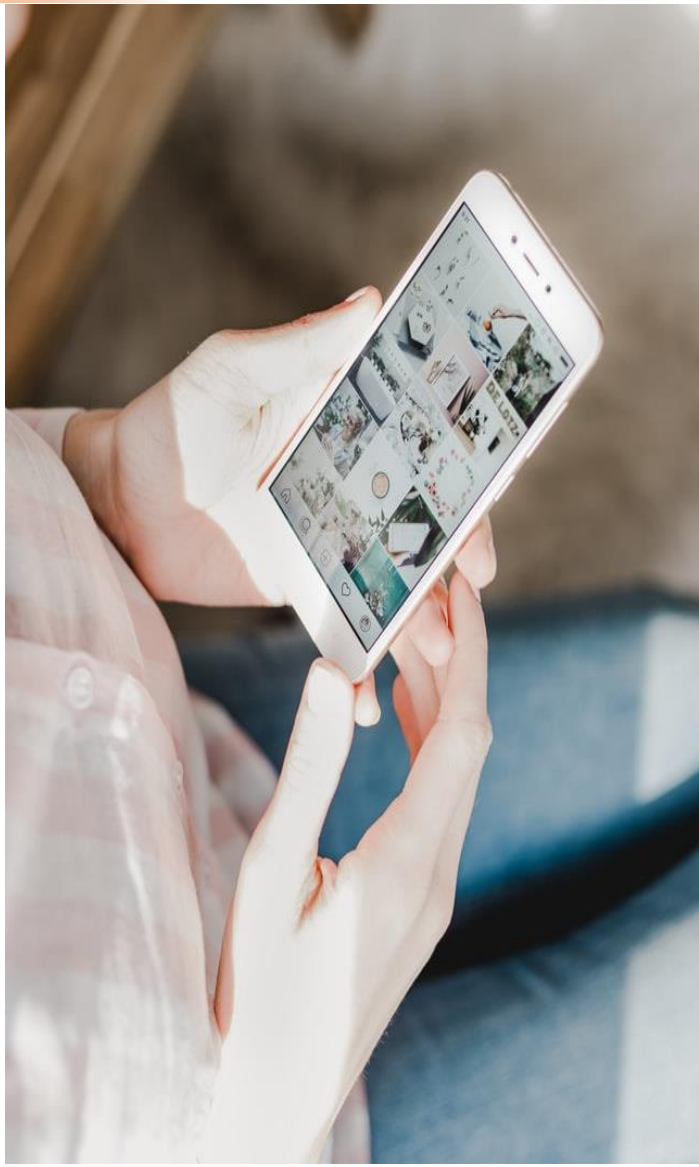
1) Therapeutic Goods Advertising
2) TGO 92 - labelling regulations
3) Permissible Indications
4) Caffeine
5) Permissible Ingredients

Proceed with Caution

Therapeutic Goods Advertising

- Listed medicines are no longer required to have pre-approval by CMA or CHP delegates for advertising in specified media

- Complaints handled by TGA - CRP disbanded
  - Recently seen heavy infringements

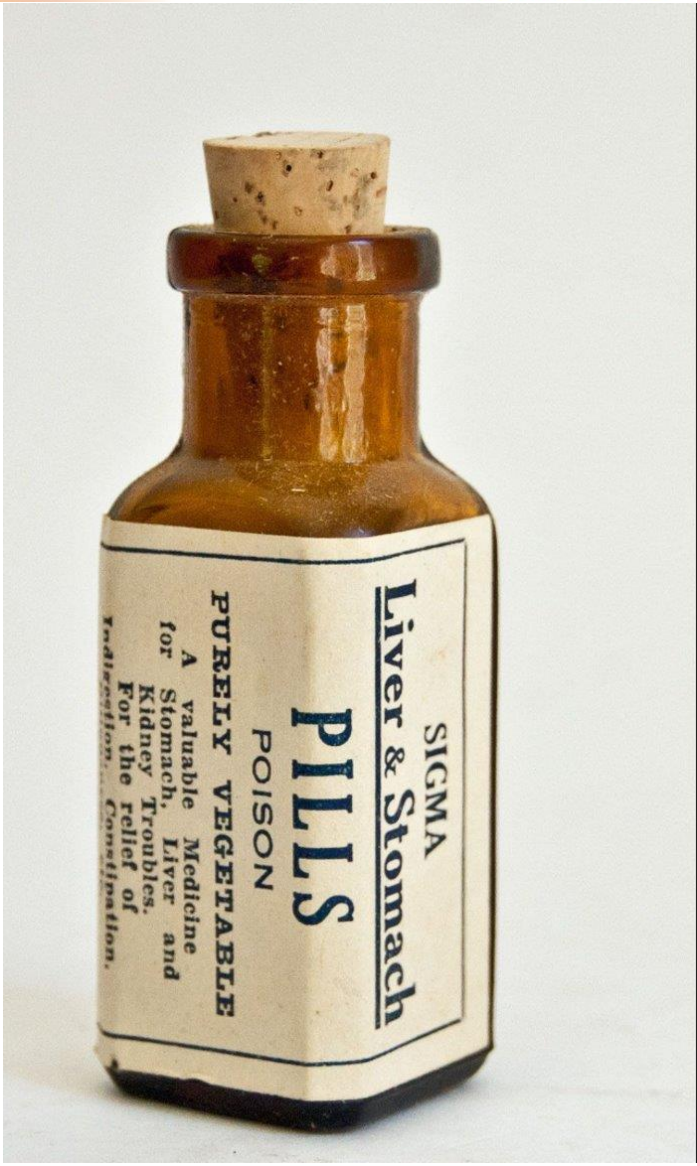


Therapeutic Goods Advertising

- Therapeutic Goods Advertising Code 2018 implemented a number of new requirements
  - Mandatory health warnings in Schedule 1 related to certain ingredients
  - Requirement for certain warnings and advisory statements to be ‘prominently displayed or communicated’
  - Clarification of ‘direct marketing’ and ‘internet marketing’; advertisements now defined as ‘advertisements where the goods are not available for physical examination prior to purchase’

Labelling: Therapeutic Goods Order TGO 92

- TGO 92 Order implemented on 31 August 2016
- 4-year phase-in period with deadline for change-over 1 September 2020
- All products released for supply from 1 September 2020 must comply with TGO 92



Labelling: TGO 92 main changes

Main label:

- Product name - as per ARTG
- Product name presented in a continuous, uninterrupted manner S9(2)

  Section 14/14A application form relating to subsection 9(2) of TGO 92

  Application for consent to supply goods that do not conform with subsection 9(2) of TGO No. 92 - Standard for labels of non-prescription medicines - section 14/14A

  Exemption granted until 1 September 2020

Labelling: TGO 92 main changes

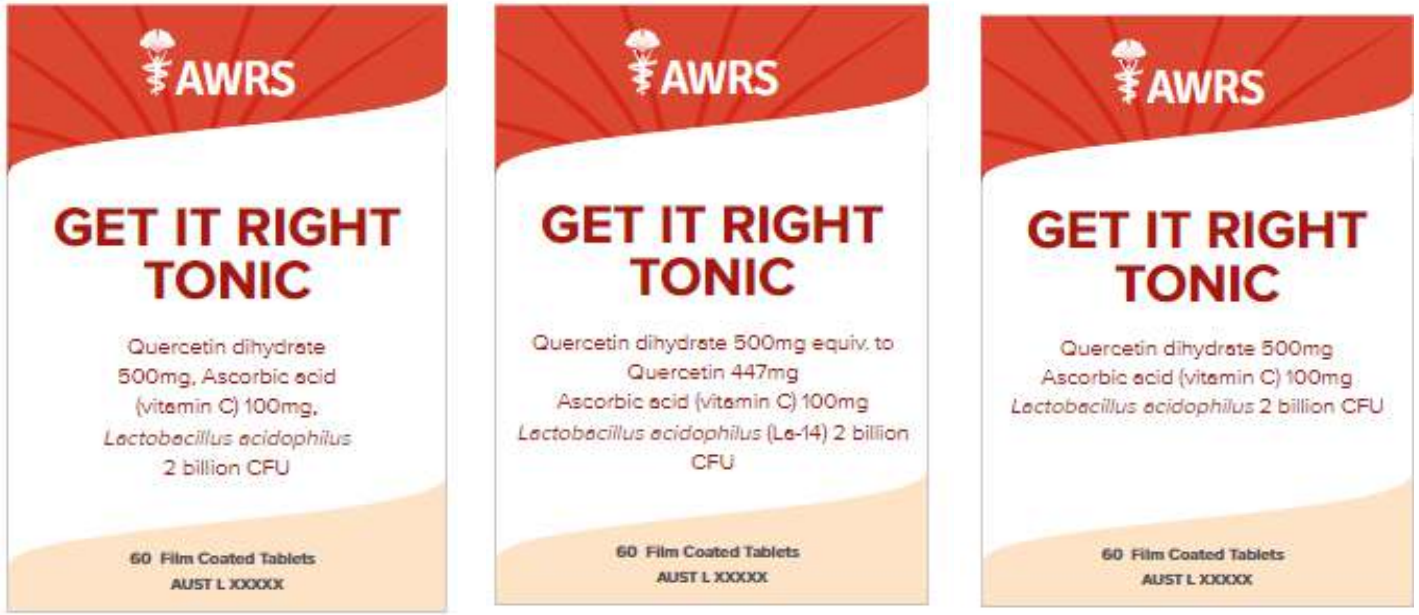
Main label: Product name - as per ARTG in continuous uninterrupted manner:

ARTG name of the medicine: AWRS Get It Right Tonic

Labelling: TGO 92 main changes

Main label:

- Name of the dosage form - as per ARTG e.g. Hard capsule NOT capsule
- Ingredients on main panel to be continuous with product name, each ingredient listed on a separate line of text and not be interrupted by additional text (unless permitted)



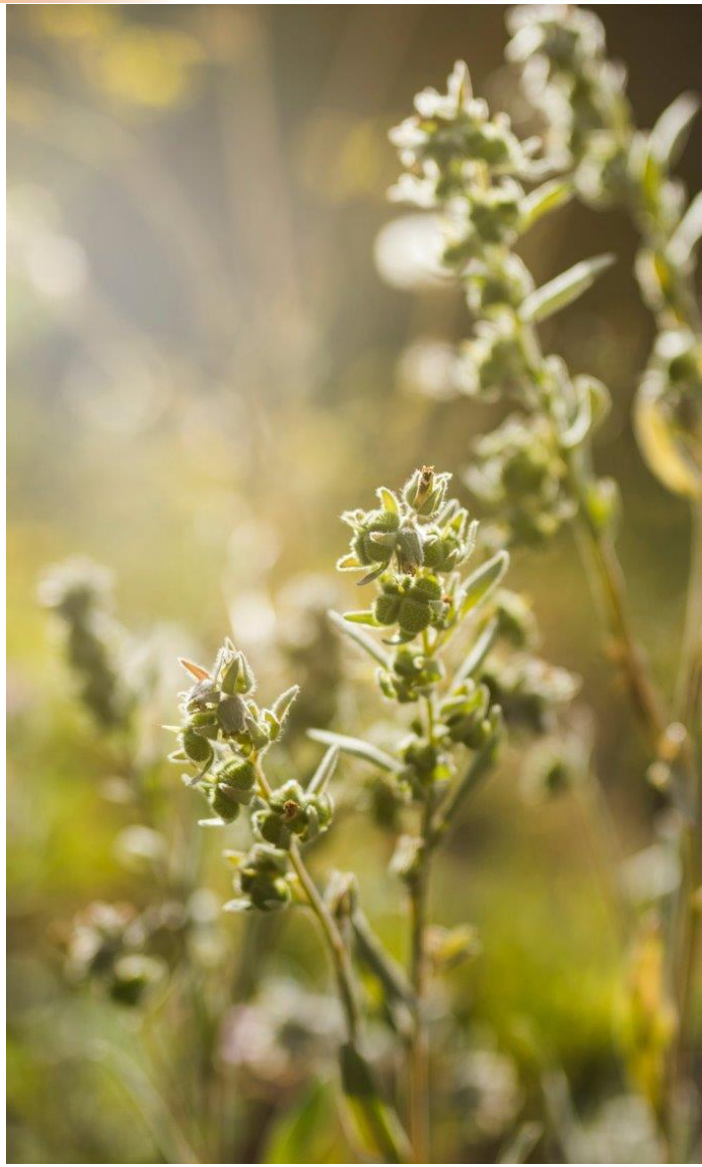
Labelling: TGO 92 main changes

Other:

- Herbal preparations (e.g. extracts) now a 2-part presentation:
  - Herbal extract name and quantity
  - Quantity of starting material from which the extract was derived from OR;
  - For standardised herbal extract the **minimum** quantity of starting material from which the extract was derived from AND standardised component name and quantity
- Enzymes - must be expressed in activity units identified in Schedule 3
- Substance declarations Schedule 1
- ‘micrograms’ must be expressed in full, and not ‘mcg’ or ‘µg’

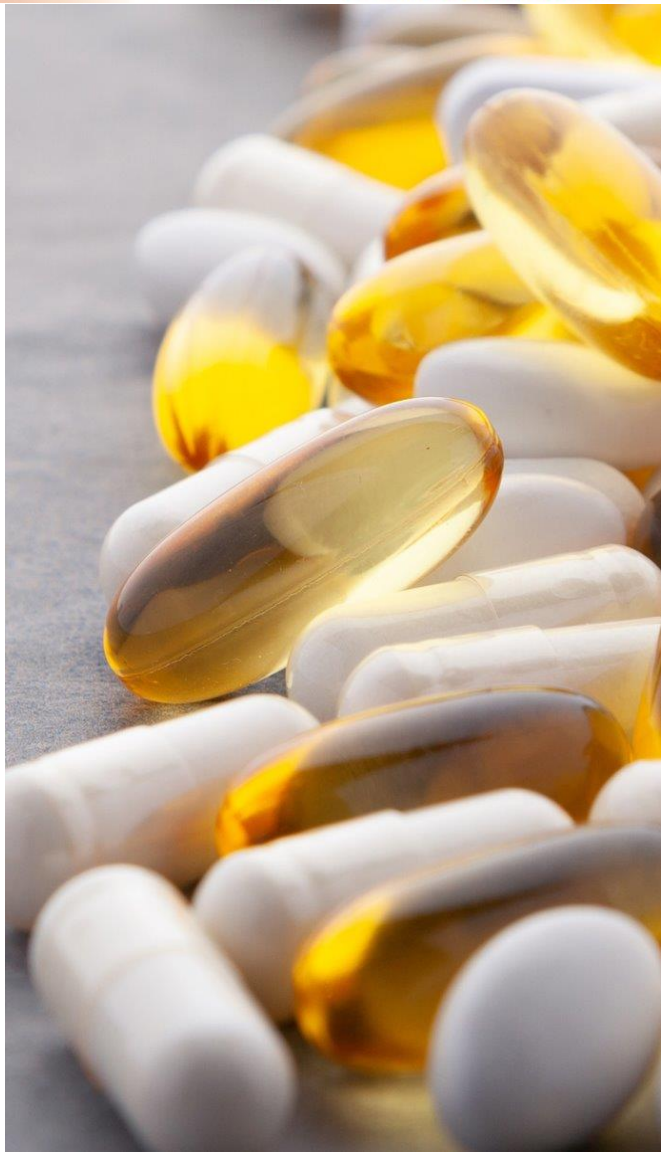
Permissible Indications

- Listed medicines must only use indications selected from a TGA pre-approved list of indications, known as ‘Permissible Indications Determination’ (26BF)
- Came into effect on 7 March 2018
- All new listed medicines after this date are required to select from the list



Permissible Indications

- Existing medicines have a transition period of 3-years. All ARTG entries must be updated to Permissible Indications by 6 March 2021. Updates are fee-free.
- Failure to have updated indication by this date may result in the medicine being cancelled.
- Permissible Indications Determination also contain the relevant label warning and advisory statements that must accompany the indication use.

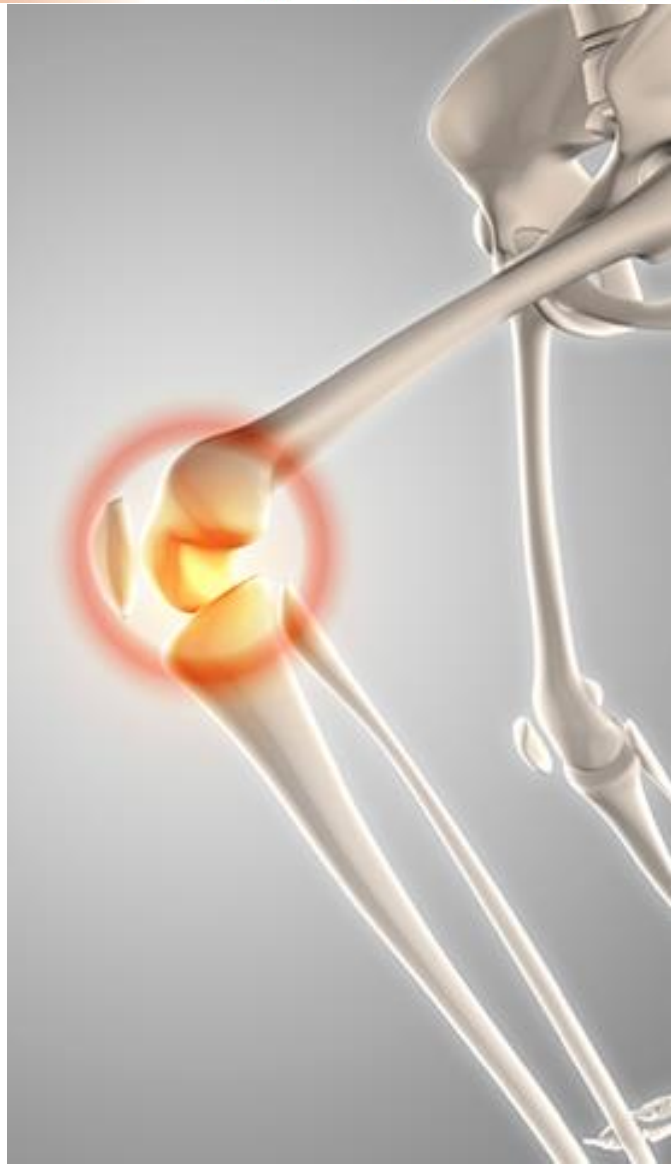


Permissible Indications

Already been changes within Permissible Indications Document e.g.

- ‘If symptoms persist, seek the advice of a healthcare professional’, to
- ‘If symptoms persist, talk to your health professional’

Before re-printing any label you must check the current Permissible Indications Determinaton to ensure you have the correct indication and warning/advisory statement wording.



Caffeine in Listed Medicines

- Concentration limits, maximum daily amount limits and new warnings
- Came into effect on 2 September 2019, with immediate and transition requirements;
- Changes with immediate effects for existing medicines listed prior to 2 September 2019:
    - Undivided preparations must not contain a concentration of total caffeine greater than 4%.
    - Divided preparations must not contain a concentration of total caffeine greater than 33%.

Caffeine in Listed Medicines

- Changes for all products listed on or after 2 September 2019 OR supplied after 2 March 2021 - for internal and oral use:

  1) TOTAL caffeine in max. recommended daily dose must be ≤ 400 mg
  2) Undivided preparations must not contain a concentration of total caffeine greater than **1%**
  3) Max. caffeine recommended daily dose must not be >100 mg in a 3-hour period

  Existing products listed prior to 2 September 2019 can have up to 4% caffeine conc. for undivided preps and MAY comply with 1) - 3)

  After 2 March 2021, all products must comply with 1) - 3)

Caffeine in Listed Medicines

- Caffeine as an active ingredient (not a herbal component)
    - Must be used in combination with another active ingredient
    - Internal and oral use - the max. recommended daily dose must not provide more than 100 mg from this ingredient.

" The books on THIS shelf contradict all the books on THAT shelf. "

CartoonStock.com

Permissible Ingredients Determination (26BB)

- Permissible Ingredients Determination (26BB) was designed to be a ‘one-stop shop’, bringing together all ingredients available for use in Listed medicines and their associated requirements.
- Ongoing omissions, inconsistencies and incorrect information in 26BB results in it not being a reliable instrument.
- TGA now state that as well as 26BB, all other relevant instruments must be referred to, as sponsor responsibility.
- Raft of new label warnings: e.g. Androdraphis, Withania, Boron, Vitex now in Permissible Ingredients with implementation date.
- Due to ongoing issues in the reliability of the information, TGA I in discussion regarding some information in 26BB being removed next year.

Permissible Ingredients Determinations

Cannot be relied upon as a ‘one-stop shop’.

Ensure EVERY label print run you check current warnings and advisory statements for labels, and compliance with the following:

- Permissible Ingredients Determination (26BB)
- MASS/RASML (Required Advisory Statements for Medicine Labels)
- SUSMP (Poison Standard)
- TGO 92 Labelling Legislation
- TGO 95 Child Resistant Packaging Requirements
- Permissible Indications Determination (26BF)
- ARTG Public summary (for excipients that may require warnings in PIs)

THANK YOU
FOR JOINING US

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