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Department of Health
Therapeutic Goods Administration

TGA Regulatory update

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Complementary medicine and advertising reform: Policy challenges, successes and failures
PHAA Conference Cairns 26 September 2018

TGA Health Safety Regulation

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TGA's role - Administering the laws and regulations set by Parliament and Government

…TGA does not determine the laws.
We administer the laws

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Complementary medicines regulatory reforms

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Reforms Implemented already

- list of **permitted indications** for listed medicines
- '**Assessed listed'** pre-market evaluation pathway
- application categories, fees and timeframes for pre-market assessments
- **2 years market exclusivity** for new ingredients

Reforms coming soon

- Use of **comparable overseas regulator reports**
- **Efficacy assessment** 'claimer'

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Permitted Indications

- From Mar 2018, sponsors listing a medicine can only use indications from a **permitted indications list**
- **List is controversial** - over 90 % of the indications proposed by industry were not accepted by TGA
  - e.g. for glucose and cholesterol reduction
- Sponsors are **required to hold supporting evidence of efficacy** for their medicine's indications
- There must not be inconsistency between the indications that are listed in the ARTG and on the label
- **3 year** transition period for existing listed medicines

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New assessed Listed Medicine pathway

Permitted ingredients

Intermediate level therapeutic indications

GMP

- To **increase consumer confidence** in these products
- **1,800 new listed medicines in last 12 months alone** so not feasible to assess all prior to marketing
- TGA pre-market assessment of ***scientific evidence*** supporting efficacy of the indications in finished product
- **Safety** (of permitted ingredients) and **quality** (pre-approved GMP) of their medicine required
- **Allows higher-level claims** which are not included on the permitted indications list
- **Option** to use an efficacy 'claimer' statement

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Examples of indications

Low level indications AUST L	Intermediate level indications AUST L(A)
• Helps enhance exercise performance and stamina • Helps maintain blood levels of Vitamin D • Aids/assists healthy red blood cell production • Relieves abdominal bloating and distention • Traditionally used in Chinese medicine to disseminate Lung Qi • Traditionally used in Western herbal medicine to improve digestion	• Prevents muscular cramps and spasms • Prevents cold sores • Reduces symptoms of tinnitus • Alleviates mild dermatitis • Relieves rheumatoid arthritis symptoms, such as inflammation and pain • Relieves symptoms of gastroesophageal reflux disease

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Complementary medicines compliance

TGA Annual Performance Statistics report due out end of this month

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Complementary medicines compliance

Past reviews

- Oral probiotics indicated for vaginal conditions
- **Listed medicines with blood glucose and cholesterol indications**
- Listed medicines that are required to demonstrate the absence of Aristolochic acids
- Folate and folic acid for use in listed medicines

Current reviews

- Listed medicines referencing macular degeneration
- Listed medicines with traditional use indications
- Vitamin 'gummy' products

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Biomarker review

- **89 listed medicines** with indications relating to the management /control/ maintenance; and/or balance of normal/healthy/improved **blood glucose** and **cholesterol levels in healthy individuals** were selected for review
  - The 15 % of these products with the highest likelihood of non-compliance
- **All sponsors were required to amend their product listings as their evidence was insufficient**
  - 58 medicines rectified deficiencies but 31 were cancelled
- Since March 2018 indications referring to maintenance/ management/ control of biomarker levels are **no longer permitted** for AUST (L) medicines

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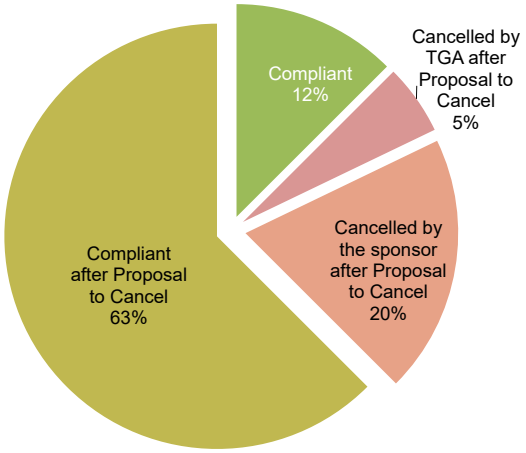
Random and targeted reviews 2017/18

75 % of 171 products assessed as non-compliant on one or more of indications, labelling, advertising

TGA reviews do bring most products back into compliance



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Enhancements to the compliance monitoring program being implemented

- ✓ Greater targeting of sponsors with a significant **history of non-compliance**
- ✓ Enforcing sanctions and penalties for **repeat non-compliance**
- ✓ Increase **transparency** for consumers through publication of review outcomes
- ✓ **Improved guidance and training** for sponsors about their regulatory obligations

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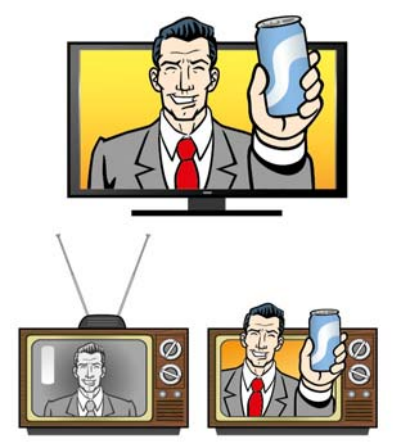
Advertising reforms



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Advertising of therapeutic goods

1. **Advertising of therapeutic goods to the public to continue to be regulated by TGA through a Code**
2. **Abolish mandatory pre-approvals of advertising (fully by July 2020)**
3. **Requirements for advertising to the public to be made consistent** for all medicines and medical devices
4. Advertising to the public **continues to be prohibited** for prescription medicines
5. TGA became the **single body** responsible for handling direct-to-consumer **advertising complaints** from 1 July 2018
6. **Investigation and enforcement powers** broadened
7. **Sponsor education programs** to assist in compliance

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A new, more detailed Code commences Jan 2019 because:

- Introduction of tiered offences and strict liability offences/infringement notices meant that requirements should not be interpreted subjectively
- Ensuring comparable coverage for medicines, devices and other therapeutic goods, and
- Removal of pre-approvals after June 2020 takes away intermediate checks

Some requirements now more clearly stated:

- What **'prominently displayed or communicated'** means
- Advertisements for traditional medicines **must identify the traditional aspect and paradigm**
- New mandatory statements apply where advertising allows for the purchase of **products that are not physically available for consumer examination** before purchase (e.g. internet sales)
- **Comparisons** in adverts must not claim or imply that comparators are harmful or ineffective
- Advertising **must not include offer of a sample** (except sunscreens and condoms)
- **Scientific representations** (cited research studies and scientific claims), **endorsements and testimonials** carry specific disclosure requirements
- Clarification of requirements for advertising **directed primarily to children**

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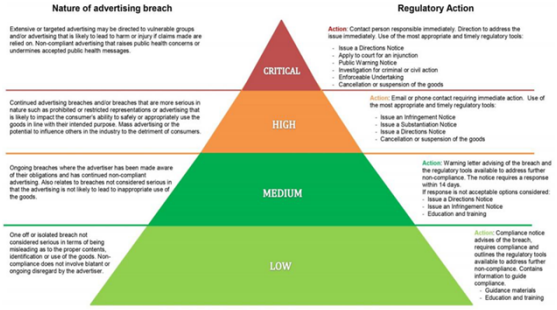
Categorisation of advertising complaints

- Formalised **following public consultation**
- Complaints classified as **low, medium, high or critical**, taking into consideration:
  - whether the claims made or reliance on the claims made in the advertisement is **likely to cause harm to public health**
  - likely impact of the advertising on the ability of consumers to **safely** and appropriately use the goods for their intended purpose
  - frequency and likely impact of the non-compliant advertising and its influence on other advertisers
  - the **advertisers' awareness** of their obligations



TGA determines the classification not the complainant !

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What do we do next ?

Low risk matters

- **Obligations Notice** sent with information on the complaint and reminding the advertiser of their obligations
- **An internal record is created** for consideration in any future complaints
- Since this is **not a regulatory action in law,** for procedural fairness the published outcome needs to exclude the advertiser and product details

Medium, high and critical cases

- **Complaint outcomes** will only be published for matters which have been finalised and closed
- **Individually investigated** - and in the case of a breach - options include a Directions Notice or Infringement Notice, the negotiation of an Enforceable Undertaking, or Civil or Criminal proceedings
- The outcome of the complaint and related notices are published
- The first Directions Notice was issued in relation to a critical complaint on 7 September 2018
- **Establishment of an advertising advisory committee** – oversight of Code, monitor KPIs and currency
- **Guidance updated to reflect 2018 Code** - currently out for public consultation

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Recent TGA compliance actions - public health priorities

- Unlicensed Korean nurses apprehended at airport - prevented import of products for use in dozens of **illegal cosmetic surgeries**
- Large commercial mail order scheme selling **illegal prescription and banned drugs to bodybuilders** closed down
- **Defective operating theatre equipment** used to monitor dangerously ill babies removed
- **Contaminated medical devices** linked to several deaths removed from hospitals
- **Fake herbal medicines** with illegal components known to cause heart attacks identified, public warned and products removed
- **Serious adverse events** for certain prescription medicines identified and communicated to prescribers
- Regulatory reforms to reduce the over 500 deaths a year in Australia due to **prescription opioids**

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