Therapeutic Goods Advertising

AANA

Therapeutic Goods Advertising Obligations & Liabilities

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Advertising & the TGA

- AANA and other stakeholders previously on the TGACC – Therapeutic Goods Advertising Consultative Committee
- The latest TGA advertising code came into effect 1 Jan 2019
- Compliance regime changing – 1 July 2020
- Significant penalties for non-compliance

Therapeutic Goods Advertising Obligations & Liabilities

13 May 2020

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OUTLINE

- How can advertisers and those who “cause the advertising” understand and meet their advertising obligations?

- Today:
    - Background
    - Regulatory detail
    - Future arrangements

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Context

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CONTEXT

There has been a great deal of recent change:

- New TGAC (advertising code) in place
- New complaints systems in place
- Increased sanctions and penalties in place
- Stronger compliance framework
- TGA's Advertising Hub
- "Grace period' finished

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CONTEXT

AND:

- The safeguard of mandatory pre-approvals ends 30 June 2020

SO:

- How confident are you that you know what your obligations are?
- How confident are you that you know what compliance looks like?
- Are you more certain now?
- Or less certain?

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What is happening?

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ADVERTISING PRE-APPROVALS – BACKGROUND

- Some advertisements for Therapeutic goods need to be approved before use:
    - Medicines only
    - Certain media only (broadcast and print)

- Up until Nov 2019 separate industry associations had the delegated responsibilities
    - now CHP Australia does them all

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WHAT IS HAPPENING?

- After decades protecting consumers and advertisers, the mandatory pre-approvals of therapeutic goods advertising to consumers is coming to an end.
- From 1 July 2020, it will no longer be mandatory to have any therapeutic goods advertising to consumers approved before publication.
- Obligations remain, for advertisers and those who “cause” advertising for ALL forms of media
- CHP Australia will be offering a voluntary Advertising Advisory Service called AdCheck which we will launch on 1 July 2020

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Why is the Government abolishing mandatory pre-approvals?

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REGULATORY REFORM-MMDR

MMDR (Medicines and Medical Devices Review)- July 2015

Recommendation #55 to gov't:

The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.

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REGULATORY REFORM-MMDR

Government response to MMDR Recommendation #55 – May 2016

*Accepted … noting that the acceptance of Recommendations Fifty-Seven (**enforcement powers**) and Fifty-Eight (**sponsor education**) is critical for managing potential concerns by consumers and healthcare professionals in accepting this recommendation.*

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REGULATORY REFORM-MMDR

Senate's Community Affairs Legislation Committee- Feb 2018

The committee notes the importance of self-regulatory models and recommends that the Therapeutic Goods Administration investigate ways to better support the effective functioning of ***self-regulatory models by industry, including the potential for further strengthening of the penalties regime if needed.***

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What else has changed?

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THIS CHANGE IS NOT HAPPENING IN ISOLATION

In the lead up to 1 July 2020, and in consequence of the MMDR reforms, there have been significant changes to the whole suite of therapeutic goods regulation, but especially the following related changes:

- ***New*** TGAC (Therapeutic Goods Advertising Code)
- ***New*** Advertising complaints processes
- ***Increased*** Sanctions and penalties

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NEW TGAC
(THERAPEUTIC GOODS ADVERTISING CODE)

- No substantive change in the TGAC between 2005 and 2018
  - Three recent versions of the Code
  - (June 2018, October 2018 and July 2019)
  - More changes coming?

- Members and other stakeholders tell us that the new Code:
  - Still some uncertainty as to precise requirements
  - Still has subjective elements
  - Also has problematic elements
  - Needs to be read together with TGA Guidelines, Advertising Hub, Etc

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NEW COMPLAINTS PROCESS

- New decision maker
- New approach to publication of determinations
- Members and other stakeholders tell us that:
  - The new process makes it difficult to ascertain exactly what is happening.
  - It is difficult to see how the TGA are approaching the more subtle, nuanced, subjective elements of the TGAC

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INCREASED SANCTIONS & PENALTIES

***Increase* in TGA's penalties and sanctions**
(per the Explanatory Memorandum):

- "stronger compliance and enforcement powers"
- "broader sanctions and penalties"
- "to protect the public"
- "to allow the TGA to respond appropriately"
- Broadening the TGA's investigation and enforcement powers "is critical for managing potential concerns by consumers and healthcare professionals in accepting recommendation #55" (the removal of pre-approvals)

RANGE OF SANCTIONS & PENALTIES

The TGA has a wide range of enforcement tools:

- Educational letters and educational visits
- Referrals
- Warning letters
- Substantiation notices
- Directions
- Public warning notices
- Infringement notices
- Enforceable undertakings
- Criminal prosecution

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SERIOUSNESS OF SANCTIONS & PENALTIES

The TGA's enforcement tools range in seriousness depending on:

- "the nature of the breach",
- "the advertiser's attitude towards compliance",
- "history of non-compliance" and
- "potential risk to the public"

And all those who advertise or who 'cause the advertising' are liable

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RANGE OF PENALTIES

Criminal penalties:
- Up to 5 years' imprisonment and up to $840,000 for individuals
- Up to $8.4 million for companies

Civil penalties:
- Up to $1.0 million for individuals
- Up to $10 million for companies

Breach of the TGAC (criminal penalties):
- Up to 5 years' imprisonment and up to $840,000 for individuals

Breach of the TGAC (civil penalties)
- Up to $1.0 million for individuals
- Up to $10 million for companies

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RECENT ENFORCEMENT EXAMPLES (2020)

2020
Promedical Equipment fined **$63,000** (COVID-19 advertising)
Labtest Direct issued infringement notice for **$12,600** (COVID-19 advertising)
Pete Evans' co fined **$25,200** (COVID-19 advertising)
ATP Science issued infringement notices for **$302,400**
Oxymed Australia Pty Ltd fined **$63,000**
Court proceedings commenced against Evolution Supplements Australia and its sole director (interim injunction granted 3 April)
Caruso's Natural Health fined **$12,600**
Multi-level marketing company fined **$37,800**
InSkin Cosmedics Group pays **$37,800**

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RECENT ENFORCEMENT EXAMPLES (2019)

2019
Mundipharma fined **$302,400**
PharmaCare pays **$12,600** fine
$10 million penalty ordered against Peptide Clinics Pty Ltd
Individual fined for alleged importation and advertising of unapproved therapeutic goods

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ADVERTISING HUB & COMPLAINTS DATABASE

- Hundreds of pages
- Thousands of entries in the complaints database

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What will take the place of mandatory pre-approvals?

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SELF REGULATION

As per MMDR, gov't response and Senate Committee recommendations, a ***self regulatory system*** will replace mandatory pre-approvals

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CHP Australia will establish an Advertising Advisory Service From 1 June 2020

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How will the new service work?

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Voluntary, self-regulatory advertising compliance service:

- All advertisers
- All media
- Medicines and devices

Anticipated benefits for:

- Consumers
- Advertisers
- Those who "cause the advertising"
- The TGA

Expert knowledge of TGA Code

- Current CHP Australia ASMs for pre approvals will be performing AdChecks
- Will provide advice, not just a 'yes/no' on compliance

Pricing and Processes

- similar to current pre approvals
- new efficiencies built-in

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HOW AdCheck WORKS

- Online submission via CHP Australia website
- Immediate acknowledgement and generation of invoice
- Assessor provides prompt feedback
- Provision of advice where necessary to achieve compliance

- <u>If considered compliant</u>

    - a unique AdCheck number will be issued
    - the number can be included in the advertisement
    - the number can be verified by other parties via an online request through our website

- <u>If considered non-compliant</u>

    - advice will be provided on achieving compliance
    - if not capable of being made compliant, we will close the application
    - there will be no “rejected” advertisements

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ADCHECK FAQS (PRACTICALITIES)

- Dedicated webpage
- The service will cover ALL media (social media, point-of-sale, catalogues, websites
- The service will principally consider “advertisements”, but will also consider mock-ads, concepts, strategies and campaigns
- The service will not review labels
- Open to members and non-members
- No publication of ads not considered compliant

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ADCHECK FAQS (PRACTICALITIES)

- We are aiming to make the transition as smooth as possible
- We will keep the process, the timings, the prices as close as possible to the current system.
- Not mandatory to include the number in the ad
- Anyone can verify the number through us

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ADCHECK FAQS (BIGGER PICTURE)

- We are independent (and not an extension of the TGA)
- This is not a continuation of the current service
- Not a guarantee (but neither is the current system)
- We will provide assistance with complaints
- Why would you use the service? (see later)
- What about internal reg affairs and external consultants?
- Consistent decisions?

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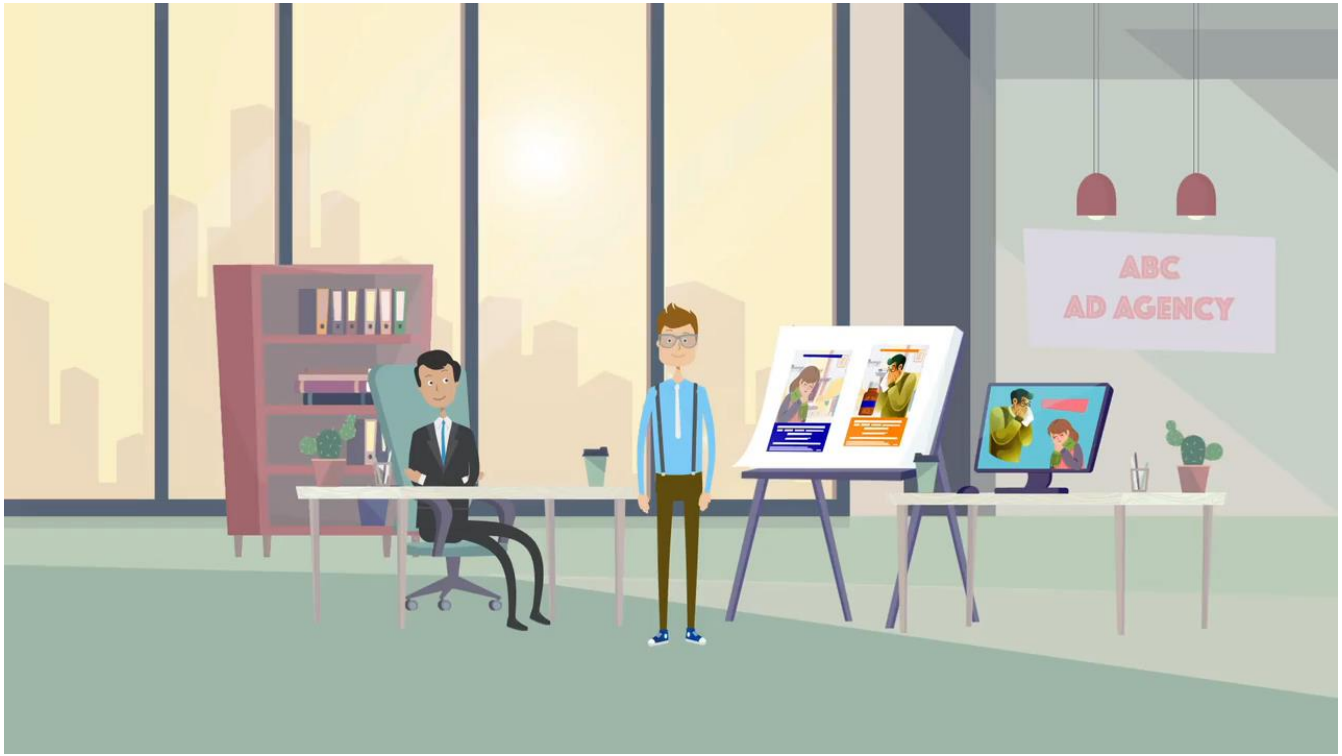
AdCheck



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AdCheck

VIDEO (ALTERNATE- VIA YOUTUBE)

https://youtu.be/EBMRhmjxH-8

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What does it mean to “advertise”?

What does it mean to “cause” advertising?

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COMPLIANCE

- Advertising offences in the Act apply to parties who “advertise” and parties who “cause the advertising”

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TO ADVERTISE…

The *Therapeutic Goods Act* (section 3) provides this (very broad) definition:

Advertise, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods….

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TO “CAUSE” ADVERTISING…

- Not defined, but the TGA provides the following (non-exhaustive) list of parties who might be said to have “caused” the advertising:
    - sponsors
    - manufacturers, wholesalers, **retailers**, franchisees, multi-level marketers
    - **publishers**, **broadcasters**, datacasters,
    - internet or mobile service providers, or any other **media service providers**
    - advertising **agencies**
    - **influencers**, bloggers and product ambassadors
    - any person publicly endorsing the goods
    - print or broadcast organisations
    - health practitioners
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ANY EXCEPTIONS?

- Under the Act, advertisers and those who "cause" advertising are responsible for compliance, but there are some limited exceptions:
    - Section 42DLB (*Civil penalty relating to advertisements—general*)
    - Section 42DMA, (*Civil penalty—non-compliance with the Therapeutic Goods Advertising Code*)

- More about this below

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Publisher exceptions?

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PUBLISHER EXCEPTIONS

- Sections 42DLB and 42DMA, provide some protection for "broadcasters, datacasters and the SBS"

- Regulation 7A extends this protection to any person who is "a publisher of a print edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia."

BUT, only where:

- "*as a result of steps taken by the person, it was reasonable for the person to assume that*" the advertising was compliant etc.

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WHAT DOES THIS MEAN?

- Only these specified parties can take advantage of the protection
- Only these specific sections of the Act are covered by the protection, AND
- In order to take advantage of the defence, the person has to show that it was reasonable to assume that the advertising was compliant because of relevant steps they took to ensure compliance.
- Relatively easy to do that now when the advertising is approved, but…

Without mandatory pre-approvals, what are the options open to these persons?

- Taking the word of the advertiser?
- Assessing the compliance themselves (with in-house expertise)?
- Relying on a credible third-party compliance service?
- Others?

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Why does CHP Australia support preapprovals (now) and compliance reviews (in the future)?

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CURRENT SITUATION WITH PRE APPROVALS

- An estimated **60-70% of advertisements submitted** to the CHP ASMs for pre-approval require some form of amendment.
    - Ranging from relatively small amendments to major reviews of advertisements.

- Without pre-approval consumers would have been exposed to those non-compliant advertisements and sponsors would have been subject to penalties or sanctions.

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CURRENT SITUATION WITH PRE APPROVALS

- **Only 5% to 9% of the complaints found justified by the Complaints Resolution Panel involved advertising that had been pre-approved**.

- The remainder are advertisements which were not subject to mandatory pre-approval (e.g. social media, websites, etc)

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Why would you want to use the new AdCheck service?

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BENEFITS – ADVERTISERS

- Arm's-length, objective, review of materials
- Reducing the likelihood of breaches occurring
- CHP Australia will offer assistance if a complaint is received

- **We think the fact that an advertiser used the AdCheck service should be taken into account as a mitigating factor should a breach subsequently be found (i.e. an advertiser's "*attitude towards compliance*" and past behaviour is relevant in determining the appropriate penalty/sanction if any).**

Also:

- Demonstration of good faith and respect for the relationship with those who "cause" the advertising
- Reassurance for those who "cause" advertising

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BENEFITS – THOSE WHO "CAUSE" ADVERTISING

- The publisher exceptions offer some protection (where "steps taken by the person" make it "reasonable … to assume that" the advertising was compliant)

- What steps can you take?
  - Become an expert yourself?
  - Trust the advertiser completely?
  - Rely on a third-party compliance review?
  - Other steps?

- **If you <u>do not meet</u> the requirements for a publisher exception, should the fact that the AdCheck service was used be taken into account as a mitigating factor? Yes.**

- **If you <u>do meet</u> the requirements for a publisher exception, can a third-party compliance review (like AdCheck) allow you to reasonably assume that the advertising is compliant? We think so.**

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BENEFITS

Consumers

- Protection from exposure to non-compliant advertising

TGA

- Reduction in the number of non-compliant advertising?
- Reduction in the number of complaints?
- Able to focus attention on advertising not subject to review?

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BENEFITS

Industry

In addition to the benefits for individual advertisers, this will be a demonstration to all stakeholders that we are a mature, responsible industry, something we will all benefit from.

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Summary

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KEY POINTS

- Mandatory pre-approvals are being abolished “in favour of a more self-regulatory regime”
- At the same time a number of changes have been made that make compliance less clear
- And penalties and sanctions have been increased
- Advertisers and those who “cause” advertising are responsible for compliance
- CHP Australia is providing AdCheck, a voluntary compliance service from 1 June 2020 which we anticipate will be of benefit to all stakeholders

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QUESTIONS?

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