

Seminar: Advertising Obligations & Liabilities

16 April 2020



SEND QUESTIONS VIA Q&A FUNCTION on ZOOM TO DEON SCHOOMBIE



**Consumer Healthcare
Products Australia**

INTRODUCTIONS

Deon Schoombie, CEO of CHP Australia



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AGENDA

1. **Setting the context** (10 minutes)

-Steve Scarff, Regulatory & Legal Director of CHP Australia

2. **Understanding advertising obligations & liabilities** (30 minutes)

-Gillian Mitchell, First Assistant Secretary Regulatory Practice and Support Division, Department of Health

-Nicole McLay, Assistant Secretary Regulatory Compliance from the Department of Health

3. **Industry Perspective & future situation** (30 minutes)

-Steve Scarff, Regulatory & Legal Director of CHP Australia

4. **Questions** (45 minutes)

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SETTING THE CONTEXT

Steve Scarff, Regulatory & Legal Director of CHP Australia



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SETTING THE CONTEXT

There has been a great deal of recent change

1. Increased sanctions and penalties in place
2. New TGAC (advertising code) in place
3. New complaints systems in place
4. 'Grace period' finished
5. Safeguard of mandatory pre-approvals ends 30 June 2020
6. We will be offering an Advertising Advisory Service- AdCheck

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

Obligations & Liabilities: Now and Post- 1 July



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OBLIGATIONS & LIABILITIES NOW AND POST- 1 JULY

Gillian Mitchell,
First Assistant Secretary Regulatory Practice and
Support Division, Department of Health



Nicole McLay,
Assistant Secretary Regulatory Compliance from the
Department of Health



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Australian Government
Department of Health
Therapeutic Goods Administration

The Advertising Reforms and Your Obligations

Your Advertising Obligations & Liabilities Virtual Seminar

Ms Gillian Mitchell / Ms Nicole McLay
Regulatory Compliance
Regulatory Practice and Support Division
Therapeutic Goods Administration

16 April 2020

TGA Health Safety
Regulation

Therapeutic goods advertising reforms

- Mandatory pre-approval of certain ads ends 1 July 2020
- Stronger compliance framework – enhanced sanctions and penalties in the Act
- Amended Therapeutic Goods Advertising Code – more prescriptive
- Single body for compliance and complaints handling
- Education program, Advertising Hub
- Therapeutic Goods Advertising Consultative Committee (TGACC)

Independent review of the reforms to the therapeutic goods advertising framework

- The review of the impact of the advertising reforms has commenced
 - Led by Ms Rosemary Sinclair, AM
 - Workshops have been conducted with members of the TGACC
- Consultation
 - Feedback to be provided via TGACC members by 22 April 2020

Advertising responsibilities

- ✓ be aware of advertising requirements under the Act and Code
- ✓ keep abreast of information in the Advertising Hub and Compliance and Enforcement Hub on the TGA website
- ✓ use the enquiry option on the TGA website to clarify the requirements, or seek the advice of a regulatory affairs consultant or ad assessment service
- ✓ obligations are the same whether you advertise or cause the advertising*
- ✓ report non-compliance to the TGA

* A limited publisher's defence available where they can show they took reasonable steps to determine the ad was compliant with the Code

- applies to a broadcaster, datacaster, the SBS, publisher of print newspaper or magazine

Industry Perspective & and Future Situation



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OUTLINE

- What is happening?
- Why is the Government abolishing mandatory pre-approvals?
- What else has changed?
- What will take the place of mandatory pre-approvals?
- How will the new service work?
- What does it mean to "advertise"?
- What does it mean to "cause" advertising?
- Publisher exceptions?
- Why does CHP Australia support preapprovals (now) and compliance reviews (in the future)?
- Why would you want to use the new AdCheck service?
- Summary

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What is happening?



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

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

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.

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.*

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.***

What else has changed?



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



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



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*

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

RECENT ENFORCEMENT EXAMPLES

2020	2019
ATP Science issued infringement notices for \$302,400	Mundipharma fined \$302,400
Oxymed Australia Pty Ltd fined \$63,000	PharmaCare pays \$12,600 fine
Court proceedings commenced against Evolution Supplements Australia and its sole director (interim injunction granted 3 April)	\$10 million penalty ordered against Peptide Clinics Pty Ltd
Caruso's Natural Health fined \$12,600	Individual fined for alleged importation and advertising of unapproved therapeutic goods
Multi-level marketing company fined \$37,800	
InSkin Cosmedics Group pays \$37,800	

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





CHP Australia will establish an Advertising Advisory Service
From 1 July 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

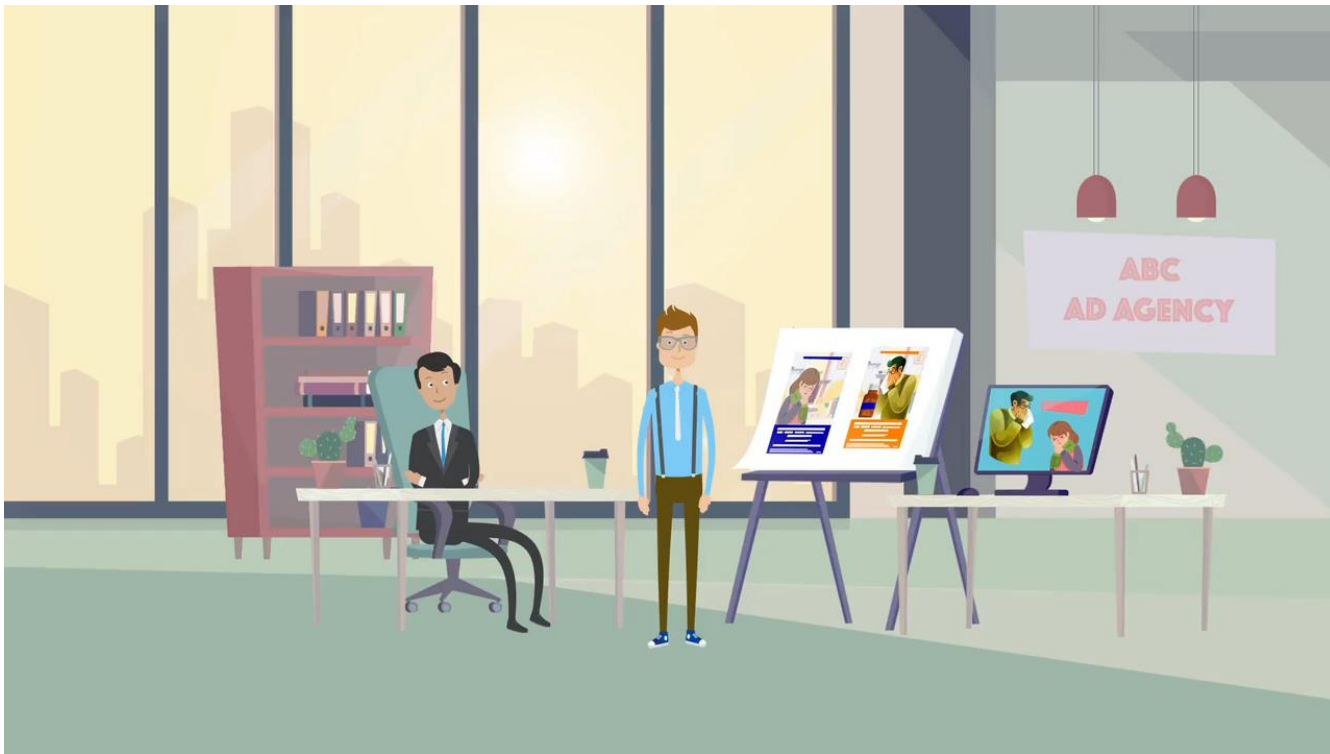
Pricing and Processes

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

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
- If considered compliant
 - 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
- If considered non-compliant
 - 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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VIDEO (ALTERNATE- VIA YOUTUBE)

<https://youtu.be/EBMRhmjxH-8>

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”

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....

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
-

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

Publisher exceptions?



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.

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?

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.

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)

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

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 do not meet 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 do meet 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.**

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?



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.

Summary



KEY POINTS

- Mandatory pre-approvals are being abolished “in favour of a more self-regulatory regime”
- At the same time a number of changes are also being made
- 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 July 2020 which we anticipate will be of benefit to all stakeholders

QUESTIONS?



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