Australian Government

Department of Health

Request for access to documents under the *Freedom of Information Act 1982* (Cth)

The Department of Health (Health) does not generally hold personal health records about individuals such as; medical practitioner notes, hospital records, pathology and other diagnostic test results or allied health practitioner records. Such documents may be obtained either directly from an individual's practitioner, or relevant private hospital. State/Territory public health records may be sought through State/Territory Freedom of Information processes. Details of other processes can be found on the relevant State/Territory health department website.

Applicant's Details

Title	Dr
Surname	Harvey
Given name	Ken
Company/Representative (if applicable)	
Postal Address	35a Mary St, Hawthorn, Vic 3122
Email and Telephone	ken.harvey@medreach.com.au 0419181910

Representative/ Consultant's Details

If you are lodging a Freedom of Information (FOI) request on behalf of another person, you must provide evidence to demonstrate that you are authorised to act on their behalf to:

- Make an FOI request on their behalf;
- Communicate with the Health in relation to the FOI request; and
- Receive copies of documents that may be released by Health.

Authorisations may be in the form of a letter (eg. on company letter head), signed by the person, confirming the above or a copy of current power of attorney documentation.

Title	

Surname	
Given name	
Company (if applicable)	
Postal Address	
Email and Telephone	
Client authorisation attached	Yes ☐ No ☐

Documents requested

Access to the following documents is requested:

(Please describe the documents you want access to as clearly as possible)

Background:

Prior to 1 July 2018, the Therapeutic Goods Advertising Complaint Resolution Panel (CRP) handled advertising complaints; thereafter the TGA took over this function.

Except for complaints judged vexatious, frivolous or lacking in substance, the CRP sent to the advertiser complained about, the complaint and a letter (appended) requesting a response. A determination was them made about each complaint which was published on their web site: http://www.tgacrp.com.au/complaint-register/. This was educational for the complainant, the advertiser and the industry.

The TGA now prioritises complaints according to their perceived impact on public health and safety. For complaints judged low priority (the majority) the TGA closes the complaint, usually on the day of receipt by a, "Compliance Notice sent with educational material".

"Low priority" has been assigned to advertised products that have had detailed allegation of Code breaches and numerous previously upheld complaints by the CRP; even a complaint that received a Choice Shonky award.

I have asked to see a copy of the "educational" letter the TGA has sent to advertisers that I have complained about as I was concerned that detailed allegations of Code breaches may not have been passed on. The TGA have refused to make these letters available. I submit that it is in the public interest to make these documents available to me to reassure me that the TGA is accurately passing on the detailed allegations made.

I do not trust TGA reassurances as there are instances where they appear to have sent their educational letters to web sites that do not exist and individuals that appear to have no relation to the advertisers complained about.

Documents requested:

All letters sent to advertisers listed in complaints:

- AC-KD45638R/2018
- AC-UA26W8I4/2018

After correspondence, restricted to one letter about complaint AC-KD45638R/2018 because of cost considerations.

- AC-5TMWIYHC/2018
- AC-E7JS15BB/2018

Sincerely,

Dr Ken Harvey AM
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If there is any additional information that would assist Health to process your request, please attach it to this form.

- See document, 'CRP letter to advertisers' attached.

The applicant's preferred means of accessing the documents identified above is:

- To receive a copy by post ☐
- To receive a copy by email ☒
- To inspect the documents at the office of Health ☐

Consultation with third parties

If the documents identified relate to an individual/organisation (other than the applicant) it may be necessary for Health to consult that individual/organisation in order to obtain their views about the potential release of documents.

Where consultation with a third party is necessary:

- the client/ applicant consents to the disclosure of their identity for the purposes of third-party consultation.

  Yes ☐ No ☒

FOI Charges

The costs relating to FOI requests for other documents, such as policy documents or reports, are determined by the *Freedom of Information (Charges) Regulations 1982*. Where considered appropriate an estimate of charges will be provided to you by Health.

There is no charge to access your own documents.

It is requested that no charge be made for this application because it is in the public interest to make these documents available to me to reassure me that the TGA is accurately passing on the detailed allegations made.

Lodging an FOI request

Lodge your FOI request to Health by:

Post	Director Freedom of Information Ministerial, Parliamentary Executive Support & Governance Branch Department of Health MDP 41 GPO Box 9848 Canberra ACT 2601
Email	foi@health.gov.au

Further information

If you have any questions about making an FOI request to Health, please contact the FOI Unit on 02 6289 1666 or at foi@health.gov.au

Privacy Statement

Health is subject to the *Privacy Act 1988* (Cth) and must comply with the Information Privacy Principles. Personal information provided in this form will be used for the purposes of processing the FOI request.

Therapeutic Goods Advertising Code Complaint Resolution Panel – Letter to Advertiser

The Complaints Resolution Panel (the Panel) has received a complaint about an advertisement for xyx which appeared on abc on date. ZYZ has been identified as apparently responsible for the advertisement. A copy of the advertisement and the complaint are attached.

Your action is required to:

1) Acknowledge receipt of this complaint immediately.
2) Prepare and lodge a response to the complaint by date (preferably by email).

This is the opportunity for you to provide a response to the complaint, address the alleged breaches and submit evidence supporting the claims made in the advertisement.

You should respond fully to the complaint by the due date. After this date, the Panel can determine the complaint based on the material before it, even if no response has been received or only a partial response has been provided.

If you are not responsible for the advertisement, or are not solely responsible for it, you must advise the Panel in writing – see section below on 'Responsibility for the advertisement'.

Please read the following information carefully before preparing the response, as it needs to address the issues described below in relation to the advertisement.

Preparing your response:

Your response to the Panel must be provided in full, including copies of all supporting materials. The response should consist of:

1) A cover letter setting out:
    a) responses to the alleged breaches made by the complainant, as set out below and in the order in which they have been raised, including copies of any relevant supporting information
    b) responses to the additional possible breaches raised by the Panel, as set out below (if any) and in the order in which they have been raised, including copies of any relevant supporting information
    c) how the supporting information provided supports the claims made and linking your explanations to identified/highlighted relevant parts in the supporting material
2) The completed Response Form and Checklist for Advertisers (attached), including the statement as to whether the subject matter of the complaint is also the subject of legal proceedings that have not been finally disposed of (regulation 42ZCAJ).
3) For advertised products that are included in the Australian Register of Therapeutic Goods (ARTG), a copy of the full ARTG entry (with manufacturers' and complete formulation information) for each advertised product.
4) Copies of any approval (showing the approved advertisement) issued by the Australian Self-Medication Industry (ASMI) or the Complementary Healthcare Council (CHC) that was required for the broadcast or publication of the advertisement.
5) A copy of the approval issued by the Therapeutic Goods Administration (TGA) for each restricted representation appearing in the advertisement, if any.

Breaches alleged by the complainant

Your response should address each of the allegations raised by the complainant and include relevant supporting information where appropriate.

Therapeutic Goods Advertising Code Complaint Resolution Panel – Letter to Advertiser

As set out in the complaint, the complainant alleges breaches of the *Therapeutic Goods Act 1989* (the Act) and/or the *Therapeutic Goods Advertising Code 2015* (the Code).

Additional possible breaches raised by the Panel

Your response should also address the following matters raised by the Panel and include relevant supporting information where appropriate [3].

Responsibility for the advertisement

Under regulation 42ZCAA, the person apparently responsible for an advertisement (or generic information) is the person or company that, based on the complaint and the assessment of the Panel, appears to be responsible for requesting the publication or insertion of the advertisement in specified media. It is possible for more than one person or company to be responsible for an advertisement and for parts of the advertisement to be the responsibility of different persons or companies.

Should you propose to argue that your organisation is not responsible for the advertisement or any part of it, you must provide documentary evidence to support this argument. You should also provide a response to the particulars of the complaint noted above, as the Panel may not seek any further response from you when determining the complaint.

Other useful information

If you do not understand the complaint or are unsure as to how to respond, you may wish to seek legal advice or the advice of a regulatory consultant.

The Panel must consider a complaint and decide whether or not the complaint is justified. The Panel will make a decision based on the information available to it at the time the complaint is considered. Consequently, provisional responses (e.g. a response indicating that further material is available at the Panel's request) are not acceptable.

Information or evidence submitted after a determination has been made will not be considered by the Panel.

When the Panel considers the complaint (including your response), it may decide to seek a further response from you on any other matters identified during consideration of the complaint, over and above those raised above. If it does so, you will be notified in writing and asked to provide a further response.

The Panel makes its decision about remedial requests at the same time as making a decision about the particulars of the complaint. Therefore, if you wish to make any submission about these actions, you should do so in your response to the complaint.

For example, on receipt of the complaint, you may wish to consider suspending the publication/broadcast of the advertisement or taking other remedial action as soon as possible in relation to the advertising that is the subject of the complaint, until the complaint has been finally determined. When considering what actions are needed to address any breaches found justified, the Panel may consider any steps you have taken to comply with the legislation following your receipt of the notification of the complaint.

Additional information on the Panel's procedures has been attached for your reference.

Possible outcomes of complaint considerations

The Panel's final determinations (findings) concerning advertising complaints are published in the Panel's Complaint Register at www.tgacrp.com.au.

Therapeutic Goods Advertising Code Complaint Resolution Panel – Letter to Advertiser

If the Panel is satisfied the advertisement contravenes the legislation, it may formally request an advertiser to do any or all of the following:

- withdraw the advertisement(s)
- withdraw specific representations
- advise relevant third parties to withdraw specific representations
- publish or broadcast correction(s) or retraction(s)

Where an advertiser does not fully comply with all of the requests made by the Panel in a determination within the specified time limit, the Panel generally refers such matters (as a "recommendation to the Secretary") to the Secretary of the Department of Health (the Secretary) for consideration. The Secretary has the power to:

- order an advertiser under regulation 9 to take certain steps with respect to its advertising, including complying with aspects of the Panel's determination; and/or
- suspend or cancel the entry of goods in the ARTG.

If the Secretary exercises these powers, the decision is published on the TGA's website. The TGA will also publish on its website the outcomes from recommendations to the Secretary where compliance with the advertising requirements is achieved without the need for a regulation 9 order.

Attachments

- Response Form and Checklist for Advertisers
- the Therapeutic Goods Advertising Code 2015
- the Complaints Resolution Panel procedures
- an extract of applicable provisions from the therapeutic goods legislation

The Code and procedures document also can be found on the website at www.tgacrp.com.au. Should you require any further information, please let me know.

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[1] The Complaints Resolution Panel (the Panel) is established under Australian law (Regulation 42R of the Therapeutic Goods Regulations 1990) to receive and consider complaints about the advertising to the public of therapeutic goods (such as medicines and medical devices).

The Panel can only consider complaints about advertising (or generic information) to the public for medical devices, non-prescription medicines (including complementary medicines) and other therapeutic goods that has appeared in broadcast (including internet) or mainstream media or other specific types of advertising, as described in Regulation 42ZCAB.

In this correspondence, references to the Code, Regulations, and Act are references to the Therapeutic Goods Advertising Code 2015, the Therapeutic Goods Regulations 1990 and the Therapeutic Goods Act 1989. References to the Register are references to the Australian Register of Therapeutic Goods.

Therapeutic Goods Advertising Code Complaint Resolution Panel – Letter to Advertiser

References to the Panel or the CRP are references to the Complaints Resolution Panel established by the Regulations. References to the TGA are references to the Therapeutic Goods Administration.

[2] Translations by National Accreditation Authority for Translators and Interpreters are preferred.

[3] Regulation 42ZCAH permits the CRP to deal with other breaches of the therapeutic goods advertising legislation that have not been specified in the complaint.

Yours sincerely.

Etc.

on behalf of Executive Officer Complaints Resolution Panel