Australian Government

Department of Health
Therapeutic Goods Administration

Dr James Freeman
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By email: james@gp2u.com.au

TGA File Ref: 2015/030225

Dear Dr Freeman

WARNING LETTER – promotion of prescription-only medicines must cease

Thank you for your response of 14 March 2016 in relation to the above matter. I appreciate your response and have considered it carefully. However, immediate attention is required in order to ensure that the Fix Hep C website is fully compliant with the advertising legislation.

1. What is the problem?

The Fix Hep C website (www.fixhepc.com) appears to promote the use and supply of prescription-only medicines[1]. The promotion of prescription-only medicines to the public is an offence under Australian law.

The FixHepC website includes a significant amount of material that focuses on the benefits of specific prescription-only medicines for the treatment of Hepatitis C virus. The website also promotes access to these medicines by facilitating consumer contact with medical professionals and other entities for the purpose of procuring these medicines. As such, we are of the view that the website meets the definition of "advertisement" within the *Therapeutic Goods Act 1989* (the Act).

The FixHepC Facebook page also appears to promote the use and supply of the same medicines.

2. What do you need to do?

You need to review your entire website, Facebook page and any other social media accounts to amend them as necessary to cease the promotion of prescription-only medicines, including Hepatitis C treatments, so as to ensure compliance with the therapeutic goods legislation.

Please respond to this letter, outlining your intended actions to ensure the compliance of your advertising, by COB 15 June 2016.

[1] Prescription-only medicines are medicines, including substances, that are listed in Schedule 4 of the *Poisons Standard,* as amended from time to time.

We appreciate that you hold a strong conviction that your business works in the public interest and that it is consistent with government policy. We also acknowledge that you may hold the view that as a medical professional that you should be able to promote therapeutic goods as a means to achieve positive health outcomes for consumers.

However, the legislation in this matter is clear. It is an offence of strict liability to promote the use or supply of prescription-only medicines to the public, in accordance with section 42DL(1)(f) of the *Therapeutic Goods Act 1989* (the Act). The maximum financial penalty per offence imposable by a court for an individual is $10800 for an individual and $54000 for a corporation. There is no defence or exemption due to public interest or because the person responsible for the advertising is a healthcare professional.

The fact sheet we emailed to you on 5 February 2016, and again on 4 March 2016, sets out specific information that can assist you in re-framing content to focus on health services rather than therapeutic goods if you consider this an appropriate option. Advertisements for services provided by health professionals are unlikely to be captured by the definition of "advertisement" within the Act, provided that you follow the guidance in the fact sheet.

As registrant of the FixHepC website, I remind you that it is your responsibility to ensure that **all** content on the website is compliant with the Act. This includes the blog and public forum sections. The responsibility to monitor forum and Facebook page comments for compliance with advertising legislation is content is consistent with the Federal Court finding in relation to *Australian Competition and Consumer Commission v Allergy Pathway Pty Ltd (No 2) [2011] FCA 74*[2]. Your company should dedicate reasonable resources to ensure that your web content, including content posted by third parties, complies with the relevant legislation.

4. What does the legislation say?

The TGA is responsible for administering the Act and its subordinate legislation.

The Act applies to everyone conducting activities captured by the legislation equally, unless specifically exempted within the legislation.

The Act does recognise that health professionals need to be able to provide patients with some information regarding the use of medicines and medical devices. As such, section 42AA(4) of the Act exempts advice or information passed directly from a health professional to a patient, during the course of treatment of that patient, from most advertising requirements (with the exception of sections 22(5) and 41ML which prohibit the promotion of "off-label" use).

Material published on a website is not considered to be information directly provided by a healthcare professional to a patient in the course of treatment of that patient, and therefore the full gamut of the advertising legislation is applicable to such material. Medical doctors making claims about therapeutic goods are otherwise equally affected by the offence provisions of the Act as any other person.

We remind you that under the National Law regulating health professionals, it is a requirement that advertisements for therapeutic goods comply with the Act and subordinate legislation. As such, medical professionals engaging in non-compliance with the Act and/or

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[2] http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/cth/FCA/2011/74.html?stem=0&synonyms=0&query=allergy%20pathway

subordinate legislation may affect their registration status with the Australian Health Practitioner Regulatory Authority.

As advised above, it is an offence of strict liability under section 42DL of the *Therapeutic Goods Act 1989* to promote the use or supply of prescription-only medicines to the public:

> (1) A person must not publish or broadcast an advertisement about therapeutic goods:
>
> (f) that contains a statement referring to goods, or substances or preparations containing goods, included in Schedule 3, 4 or 8 to the current Poisons Standard, other than a statement authorised or required by a government or government authority (including a foreign government or foreign government authority); or...
>
> Penalty: 60 penalty units.

The value of a penalty unit in accordance with section 4AA of the *Crimes Act 1914* is $180 per unit for an individual and five times that for a body corporate. The maximum penalty imposable by a court is $10800 for an individual and $54000 for a body corporate, per offence against section 42DL(1)(f) of the *Therapeutic Goods Act 1989*.

Section 3(1) in the *Therapeutic Goods Act 1989* provides the following interpretation:

> *advertisement*, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

This definition is quite broad and we note that the concept of 'intention' is not what the producer of the content actually intends, but rather the intention that is perceived by a reasonable viewer of the content.

5. How does the TGA decide what level of regulatory activity to use?

The TGA pursues its regulatory activities in accordance with its Regulatory Compliance Framework. Under this Framework, resources are prioritised on a sliding scale according to the relative risk posed by different regulatory problems, and the level of engagement by regulated entities. The TGA generally focuses on education in the first instance of a regulatory breach for advertising being identified and will resort to regulatory action in cases where the risk is very high or a regulated entity appears to be deliberately non-compliant with the regulatory framework. Should compliance not be achieved through educational means, the TGA will consider escalation of regulatory action.

At this stage we are still engaging with you in the context of education. Should the regulatory problems not be addressed, we shall consider escalation of regulatory action. If it appears that deliberate non-compliance is taking place or insufficient efforts are being made to address compliance issues, we may (for example):

- Consider raising a brief of evidence to seek intervention by a court;
- Advise AHPRA and/or professional bodies of concerns that a registered healthcare professional is not meeting their obligations under the law.

6. Responses to your specific questions

Your letter included a number of questions or comments. We are able to provide the following feedback:

Hepatitis treatment information on other websites

You have noted three webpages that include references to hepatitis treatments. The critical distinction between general information or *bona fide* news and the advertising of therapeutic goods rests in the definition of 'advertisement' in the Act (emphasis mine):

> *advertisement*, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

If a website does not meet this definition, it is not captured by the operation of the Act as an advertisement.

Your website links benefits and the availability of these named prescription-only medicines together with a mechanism to obtain those prescription medicines. Therefore, it is our view that it is captured by the definition of *advertisement* and the operation of the Act.

You are welcome to complain to the TGA about any websites that you may identify as breaching the legislation and the TGA will investigate as appropriate. However, please note that section 42DL(1)(f) contains an explicit defence for statements that have been authorised by government entities – this would apply to the websites you have identified, including 'Better Health' (operated by the Victorian Government) and the 'Department of Health website' (operated by the Commonwealth Government).

'Censorship' and the prohibition of promoting high-risk medicines to consumers

The restriction on promoting scheduled medicines is not censorship. As noted above, section 42AA(4) of the Act explicitly exempts information provided by health care professionals to a patient, during the course of treatment of that patient, from the advertising requirements prescribed under Part 5-1 of the Act.

The Scheduling Policy Framework[3] provides the following rationale for the restriction on supply of certain medicines:

> *"For the quality use of human medicines, which incorporates the selection of appropriate therapeutic management options, appropriate choice of medicines (where a medicine is considered necessary) and safe use; the scheduling classification underpins the need for particular healthcare professionals to be involved in the supply of certain medicinal substances in order to promote safe and quality use. Labelling with specific phrases (signal heading) emphasises this need for intervention by particular health professionals. The scheduling decision involves consideration of a number of factors such as the toxicity of the substance, diagnosis and the purpose of use, potential for abuse, safety in use and the need for access to the substance."*

The law is designed to protect vulnerable consumers. All therapeutic goods have inherent risks that must be weighed against the potential benefit of using the product.

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[3] http://www.tga.gov.au/sites/default/files/scheduling-policy-framework_0.pdf

Prescription-only medicines are included in Schedule 4 of the *Poisons Standard* because they pose a relatively high risk to consumer health. Healthcare professionals have the appropriate scientific and clinical skills to determine on a case by case basis whether such medicines are suitable for individual consumers based on the available evidence and the individual patient's clinical presentation, case history and concomitant medications.

Consumers typically lack these skills and therefore cannot effectively weigh the relative risks of using high-risk medicines. They may therefore be inappropriately influenced by individuals and companies seeking to promote the use and supply of such medicines, and this can influence the doctor-patient relationship to the point where patients seek to influence their medical practitioner to supply specific medicines that may not be appropriate for them.

The TGA takes complaints regarding the advertising of prescription-only medicines very seriously. The advertising of prescription-only medicines is prohibited in Australia to ensure the quality use of these medicines and recognises the vital role that health professionals play in assessing each patient on a case by case basis to determine the appropriate treatment (if any). A summary of the relevant legislation, as well as the TGA's position on this subject, is set out in the fact sheet emailed to you; this fact sheet is also published on the TGA website[4].

7. What is the TGA's role in ensuring compliance?

The TGA notes your request for a detailed explanation of each breach on your website, however, it is not the role of the TGA to help advertisers of therapeutic goods develop or modify advertising material and we are not resourced to do so.

To provide a starting point for your review, we have attached some examples of website and social media problems to this letter for your reference (**Attachment 1**). I recommend that you consider this information in conjunction with the fact sheet on advertising health services in association with the promotion of therapeutic goods that we have previously sent you (and is also attached again to this correspondence for your reference – see **Attachment 2**).

It is the responsibility of advertisers of therapeutic goods to ensure the compliance of their own advertisements with Australian law. If you require assistance to evaluate your website, you may wish to seek the assistance of a regulatory affairs consultant. A list of agencies that can put you in contact with a consultancy service are included on the TGA website. It is important to note that the TGA does not endorse regulatory affairs consultants and that the TGA is not bound to act in accordance with advice provided by regulatory affairs consultancies. Please refer to https://www.tga.gov.au/regulatory-affairs-consultants.

8. Contact details

If you have any questions about this letter, please email TGA.Advertising@tga.gov.au.

Please send your response to this matter, outlining your intended actions to ensure the compliance of your website, to TGA.Advertising@tga.gov.au by **COB 15 June 2016**.

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[4] http://www.tga.gov.au/advertising-health-services-schedule-3-schedule-4-or-schedule-8-medicines

Yours sincerely,

Signed electronically
Peter Holian
Assistant Director, Advertising Complaints
Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch
Regulatory Practice & Support Division
Regulatory Services Group

17 May 2016

R16/222460

Encl:

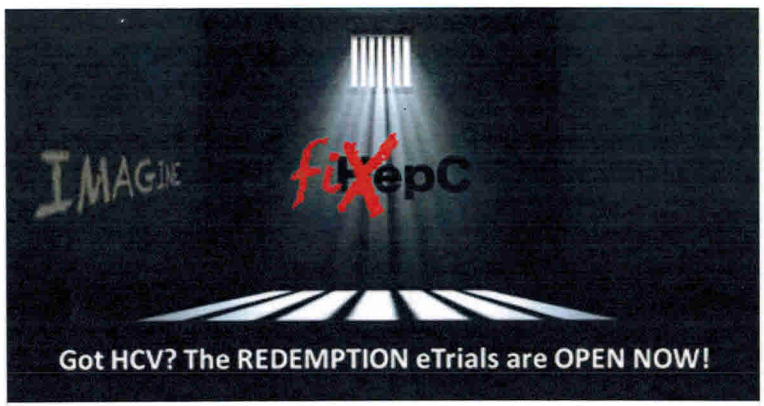
Attachment 1 – Examples of problematic Advertising material
Attachment 2 – Advertising health services in connection with scheduled medicines factsheet

Attachment 1 - Examples of non-compliant aspects of the Fix Hep C website and social media channels

Figure 2 – Facebook post

Fixhepc
19 February ·

Generic hepatitis C medication is affordable and accessible now at a fraction of what you might expect - $1600 for an entire 12 week course delivering 95% cure rates. If you've been bashing your head against a brick wall trying to get access click on the image to find out more....



Imagine Life Free From Hepatitis C

It is entirely possible to access the new Hepatitis C cures at affordable prices via parallel importing. Click here or on the image to learn more about the REDEMPTION eTrials and please share this with your friends. REDEMPTION-3...

FIXHEPC.COM

Like Comment Share

7.1k