Submission to TGA Complaint handling Consultation

Dr Paulina Stehlik

Senior Research Fellow/ Assistant Professor, Evidence Based Practice
Professorial Unit Coordinator (Gold Coast University Hospital)

Email: pstehlik@bond.edu.au

Website: http://www.crebp.net.au

Dear Members of the Senate inquiry,

We are members of the Centre for Research in Evidence Based Practice, Bond University. We would like to take the opportunity to submit feedback on the proposed *complaints handling of advertising of therapeutic goods to the public* (V1.0 May 2018).

Of greatest concern in the current version of the complaints handling document is the lack of transparency around complaints handling, both in communications to the complainant and the public, lack of follow-up to ensure breaches have been fixed, and proposed measures of "success" of the new process.

Background

There was considerable support for the concept of single body taking over the existing Therapeutic Goods Advertising Complaint System to provide a single, more efficient, complaint body, with powers to apply timely and meaningful sanctions for regulatory violations.[1] However, the TGA's recent proposals for the implementation of the new Therapeutic Goods Advertising Complaint Handling System have caused concern.[2]

Areas of concern

1. Transparency

We believe that complainants should be told the priority level their complaint is assigned to.

In order to educate complainants, advertisers and the industry, details of specific Code breaches upheld or rejected by the TGA (alleged by the complainant or found by the TGA) must be communicated and published (including product and advertiser details), as has been the practice of the Complaint Resolution Panel CRP).[3] This is also crucial for monitoring the performance of the TGA.

2. Complaint handling

We believe it is essential that the TGA evaluates whether the regulatory action taken on all complaints results in compliance. For example, if a "regulatory obligation notice" or "warning letter" is sent to the advertiser these should be followed-up to ensure compliance is achieved.

[1] https://www.tga.gov.au/submissions-received-response-consultation-regulatory-framework-advertising-therapeutic-goods-november-2016
[2] https://www.tga.gov.au/consultation/consultation-complaints-handling-advertising-therapeutic-goods-public
[3] http://www.tgacrp.com.au/

It is not good enough for the TGA to assume that the problem has been fixed by sending a "regulatory obligation notice" to the advertiser or getting a response from the advertiser to a "warning letter" the problem has been fixed. Experience with the current CRP shows that many sponsors will assert they will fix the problem, but then don't; alternatively, they may correct the breaches pointed out, but then create new ones. Monitoring compliance is essential.

In addition, if more serious enforcement actions, such as court action is instituted, the details of this must be published when initiated, not when the case is closed (which can be many years later). This is current practice with the ACCC.[4]

3. Metrics (time taken to close complaints)

We submit that the time taken to close a complaint should depend on the time taken to achieve compliance, not merely the time taken to send a "regulatory obligation notice" or "warning letter".

Conclusion

We support the TGA taking over the complaint system. However, to ensure that new system is at least as good as the old one, transparency of the new system must be improved, especially with respect to:

- Informing complainants of the priority level their complaint is assigned to;
- Communicating and publishing details of specific Code breaches upheld or rejected by the TGA (including product and advertiser details);
- Evaluating and publishing if the regulatory action undertaken by the TGA on all complaints results in Code compliance.

Yours sincerely

Dr Paulina Stehlik (B.Pharm (Hons I), Grad Cert Pharm Prac, PhD)

On behalf of:

- Prof Chris Del Mar
- Prof Tammy Hoffmann
- Prof David Henry
- Dr Rae Thomas

[4] https://www.accc.gov.au/media-release/accc-targets-alleged-false-and-misleading-nurofen-claims