Consumers Health Forum OF Australia

SUBMISSION

Complaints handling - Advertising of therapeutic goods to the public

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Complaints handling - Advertising of therapeutic goods to the public.

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Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with regard for healthcare consumer affairs. It works in the public interest to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomed the Review of Medicines and Medical Device Regulation and, while we did not support removing the required pre-approval of therapeutic goods advertisements, we are pleased to work with the Therapeutic Goods Administration (TGA) to ensure that new arrangements will continue to protect consumer interests.

We applaud the efforts to streamline the management and encourage greater consistency in decision-making relating to complaints about the advertising of therapeutic goods to the public.

Many of the proposed changes are based on sound logic and will simplify the experience of making a complaint. However, CHF is concerned that removing some of the processes of the Complains Resolution Panel (CRP) will discourage consumers from making complaints.

CHF also feels that, whilst educating sponsors is an important component of compliance, we are concerned that too much focus on their interests will detract from the protection of consumers. Given the relatively low level of health literacy in Australia means that many consumers may not have the necessary knowledge or understanding to critically examine advertisements. Consumers may not be aware what constitutes appropriate therapeutic goods advertising or that they have a right to complain in where advertising is inappropriate.

We recommend that that the TGA consider the below points in the final design and implementation of the new process to ensure that consumer interests remain the focal point of decisions around Therapeutic Goods Advertising.

Measuring Successful Implementation

The proposed change from a pre-approval process to a post-advertising complaints process means that successful regulation of therapeutic goods advertising is dependent upon high levels of sponsor compliance or increased consumer complaints.

Sponsor compliance to the new advertising regulation process could indicate that the TGA's education campaign has been effective and the penalties are high enough to deter non-compliance. Alternatively, increased disregard for the advertising code could mean that sponsors do not fear the consequences because the risk outweighs the penalties, or because they do not think consumers will complain.

Where there is a rise in non-compliance, then success could be measured by higher levels of consumer complaints. This would indicate that consumers are aware of the changes, understand their role in the new process, and that the new process is accessible and straightforward.

Raising awareness about the new process

CHF was pleased to see the advertising campaign outlined in the consultation paper. However, to ensure TGA reaches a wide audience we would also suggest including media interviews about the changes, Facebook, and asking health services to display information.

TGA should be conscious that many consumers may not be aware of the TGA's role or that there are regulations around advertising therapeutic goods, so it is crucial for educative material to use plain English and assume no prior knowledge.

Broadening the education campaign for consumers should mean that more people become aware of the regulation around therapeutic goods advertising and know that there is a process for submitting a complaint if they do encounter something inappropriate or misleading.

An easy process for consumers

To ensure that knowledge of the new process equates to consumers submitting a complaint, it is important that the complaints process itself is straightforward and easy to find. Sponsors may take risks if they are aware of low complaint levels and think their advertisement may not be reported.

Consumers may abandon their efforts if the process seems too arduous, so CHF strongly supports the TGA's commitment to accepting complaints via telephone, email, and post. A range of options reduces barriers of literacy and access to digital platforms meaning that more consumers can engage with the process.

As there are several well-known organisations that regulate advertising such as the Australian Competition & Consumer Commission (ACCC), the Medical Board, the Australian Health Practitioner Regulation Agency (AHPRA), Food Standards Australia New Zealand and Ad Standards, it is important that the new complaints process uses the No Wrong Door Approach[1]. This means that consumers whose complaint should be directed to another organisation are not turned away and instead they can consent for the TGA to refer the complaint directly without them needing to resubmit the complaint.

Consumers cannot and should not be expected to know the intricacies of therapeutic goods advertising, it is the role of regulators to ensure information is passed along where appropriate. CHF notes that TGA will strive to provide appropriate organisation information where relevant, however we encourage you to make referral a formal policy instead of declining complaints.

Due to the many organisations in this area, it is also important that consumers can locate the TGA complaints process quickly with simple internet searches. To help consumers submit their complaints correctly, TGA should provide information about the complaints that are handled by other relevant organisations with contact information and a link to the website. Similarly, clear

[1] Department of Communities, *No Wrong Door FAQs*, http://d6.communitydoor.org.au/sites/default/files/No%20wrong%20door%20FAQs.pdf, Date Accessed: 9 May 2018.

information about the new Advertising Code should be available to ensure consumers know what they can and should notify the TGA about.

Communication with consumers

CHF's major area of concern about the proposed new complaints process was the communication with consumers following their complaint. If someone has taken the effort to submit a complaint, they have an interest in the progress and outcome of the matter.

Failing to communicate effectively about the progress and what action is being taken could have negative impacts on the way consumers view the TGA. The consumer may feel that the TGA did not take their concern seriously or that matter was not resolved, raising questions of the TGA's authority as a regulator. A negative interaction may discourage future complaints, which would jeopardize the ongoing success of a complaints-based system.

Accordingly, CHF recommends that the TGA should contact the complainant at three key points during the process:

- Confirm complaint has been received. (We note that this was outlined well in the Consultation Paper.)
- Confirm whether the complaint has been accepted. (If accepted, outline the priority level given to the matter and the timeframe expected for an outcome. If not accepted, outline the reason for decline or the referral information.)
- Notify of the outcome or that the outcome is available on the website.

Informing consumers about the progress of their complaint should give them a sense of confidence that the matter is being addressed or the reasons no action is deemed necessary. This may also prevent unnecessary administration with consumers following up or submitting multiple complaints in cases where they are not sure that the TGA has received their complaint.

Outcome transparency

For the reasons outline above, CHF is also concerned about the level of outcome transparency in the current proposal.

While we note the TGA's intent to publish product details for resolved medium, high and critical priority cases, CHF thinks that outcomes should be published for all cases and include the following:

- The product involved;
- What alleged Code breaches were determined by the TGA to be justified;
- If compliance has been achieved;
- The TGA's decision; and
- Details of sponsor's compliance.

As it stands, the TGA consultation paper places too much emphasis on the sponsors' reputation and potential financial penalties, not providing important information to the public.

CHF appreciates that the TGA intends to monitor the number of complaints made against a sponsor as a necessary means to differentiate between first-time offenders and regular offenders. CHF suggests that along with a more detailed outcome, the number of offences and any steps to rectify the error by the sponsor are published. Allowing the sponsor an opportunity to provide an explanation and demonstrate their regard for regulation should help to reduce negative outcomes such as reputational damage.

Further, weak penalties may breed a disregard for the regulation and encourage sponsors to take risks whereas greater penalties are more likely to ensure sponsors familiarise themselves with the Australian regulations and not advertise therapeutic goods in inappropriate or misleading ways.

Reporting Requirements

The TGA reporting is central to determining whether the new process is successful and must include information about compliance.

CHF notes the TGA's commitment to reporting performance against KPIs and the number and outcomes of reports. We agree that this is an important aspect of ensuring the complaints process is managed well and that consumers are engaged, and the number of complaints received has increased.

We are concerned that compliance measures were not given more detail in the monitoring section and that only the trends will be published in the bi-annual reports. This is a crucial factor of whether the regulatory process and penalties are effective or whether more should be done. Accordingly, compliance should be given a far larger role in the reporting process.