Consumers Health Forum of Australia

SUBMISSION

THERAPEUTIC GOODS ADVERTISING CODE

October 2017

Consumers Health Forum of Australia (2017)
Submission on Therapeutic Goods Advertising Code . Canberra, Australia

P: 02 6273 5444
E: info@chf.org.au

twitter.com/CHFofAustralia
facebook.com/CHFofAustralia

Office Address
7B/17 Napier Close
Deakin ACT 2600

Postal Address
PO Box 73
Deakin West ACT 2600

Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the Health Peak and Advisory Bodies Programme

CONTENTS

Contents

Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in 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. Consumers constantly raise with us their concerns about safety and quality of medicines and medical devices often giving us examples of when the system has failed. We have heard some terrible stories. For many people, this is what leads them to be active consumers as they see the need for systemic change and want to be part of that change.

We have also heard positive stories and many consumers acknowledge that the existing regulatory framework, despite its many flaws, has delivered peace of mind and confidence for many Australians when they take a medicine or use a medical device.

CHF accepts the need for there to be a balance between protecting the consumer and reducing the burden of regulation. However, throughout this process, CHF has maintained the key principle that any reforms to the regulations must:

- ensure Australians have access to medicines and medical devices that are of high quality and safe: and
- increase consumer confidence in the regulatory system.

The relatively low level of health literacy in Australia means many consumers may not have the necessary knowledge or understanding to critically examine advertisements of pharmacist-only (schedule 3) medicines and make an informed choice on the appropriateness of the product for their needs. For this reason, we regulate what can be advertised and how that advertising can be done.

We welcomed the previous consultations on advertising. We do not agree with all the decisions, in particular with the decision to remove the requirement for pre- approval of advertisements, however we are happy to work with TGA on the implementation of the new arrangements to ensure consumers' interests are protected.

Issues

Advertising Framework for Schedule 3 (pharmacist only) medicines

CHF has been consistent in its opposition to direct to consumer marketing for this group of medicines. In our submission to the Review of Medicines and Medical Devices regulation we opposed any relaxing of the current laws around direct to consumer advertising (DTC) as the

evidence from the USA shows it leads to increased sales and there is little or no evidence that this practice will improve consumers' health.[1]

The paramount interest must remain the safety and well-being of the consumers. Given that we have low levels of health literacy in this country, we question the capacity of many consumers to make informed decisions about the optimal use of over the counter medicines. We do not believe there is any real evidence that advertising of such products will have an educative outcome or improve health literacy, let alone health outcomes.

It is worth remembering that a medicine is made a pharmacist-only or schedule 3 because it is deemed to warrant pharmacist intervention and advice to ensure its quality use and that there may be potential for harm if used inappropriately. There is also some doubt about some consumers having the ability to self-monitor the safe ongoing use of medicines[2]. We believe the pharmacist involvement should be a discussion about symptoms and suggestions about suitable products not just the consumer asking for a product by name and brand. Some healthcare professionals have reported that consumers demand certain treatments, often found through "Dr Google", and that they feel a level of pressure to supply it. Whilst we think this is overblown it does suggest that pharmacists may find it even more difficult to refuse service or supply of particular brands when a consumer names the product they have seen through DTC.

Our concerns about DTC advertising are exacerbated by the move away from preapproval of advertising to a self-regulation/ monitoring approach. The protections for unsuspecting consumers are just not there and the recent action by the ACCC on the Nurofen range of products showed the power of advertising that was not in the consumers' best interests.

If there is to be a loosening of the DTC advertising regime then the approach of keeping the positive list with only products that are listed on Schedule H being able to be advertised in this way is the best way forward. We do not support the proposal in the consultation paper that Schedule 3 medicines should be automatically on the positive list unless the delegate determines otherwise. The manufacturer/sponsor should have to make a strong case as to why there might be consumer benefits from advertising.

The suggested approach for all existing Schedule 3 substances to be considered by a working group for suitability for the positive list seems sensible accepting our argument above that there needs to be a sound evidence-based reason for advertising not just a lack of evidence for not doing so. We also support the proposal that there should be a public consultation as part of the process.

If more products are accepted onto Schedule H then we support the product advertising requirements as outlined in the consultation, namely the additional proposed requirements that advertisements for medicines containing schedule 3 substances clearly display the following two messages:

---

[1] CHF 2015 Submission to the Review of Medicines and Medical Devices Regulation
[2] AHMAC Scheduling policy framework for medicines and chemicals

"Your pharmacist *must decide* if this product is suitable for you"

"Ask your pharmacist about side effects relevant to you"

Proposed Code Changes

CHF supports the move to minimise the subjectivity in the interpretation of the code. We believe it is in consumers interests to have as little ambiguity as possible around the requirements of the code as this should improve adherence by advertisers and make it easier for consumers to decide if a complaint is warranted. It is pleasing to see that the TGA will roll out a formal education program for sponsors and provide them with tools so that ignorance will certainly not be a defence for non-compliance. This is particularly important as we move away from preapproval of advertisements, something CHF did not support.

Core objectives

CHF believes the four core objectives as outlined are appropriate.

On Objective 2 we support the inclusion of specific warning information for certain categories of therapeutic goods that are known to have possible adverse effects if misused. It will be important that these warnings are prominently displayed on the product /product label as wells being obvious in any advertising material.

On Objective 4 we have some concerns about how the requirement that "an advertisement about therapeutic goods must not encourage or be likely to encourage inappropriate or excessive use of the goods and must not unduly glamorise or prey on the vulnerability of particular consumers". Whilst we agree with the public interest criteria as listed we have serious questions about how compliance with this will be monitored in the absence of a preapproval regime. Whilst an advertisement can be removed or cancelled after a complaint, the harm to consumers will already be done and they will, in many cases, be able to continue to buy the product.

Council recommendations

CHF supports the inclusion of all the recommendations from the Council as outlined in section 4.3 of the consultation paper.