Friends of Science in Medicine

Consultation Regulation Impact Statement

Regulating the advertising of therapeutic goods to the general public

Submitted to TGA - July 2013
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FSM supports the concept that the regulation of advertising must contribute to the efficacy, quality and safe use of therapeutic goods. We strongly support the contention contained in the introduction to the Consultation document that an improved regulatory framework could be achieved if changes were made to the pre-approvals arrangements, to the complaints handling processes and to the sanctions and penalties that apply to advertising breaches.

FSM is concerned about the real and potential harm from both unproven or disproven complementary medicines and the diagnostics and treatments advertised by both the sponsors of and practitioners using a wide range of unproven or disproven 'low risk' medical devices. All our media outlets are vehicles for the dissemination of ever increasing numbers of advertisements for products that make false claims for therapeutic benefits. When our national health objectives are based on efforts to promote the prevention of life style induced diseases many advertisements, particularly for “supplements” suggest that such products can neutralise an unhealthy lifestyle. Vitamins do not relieve stress nor provide energy etc.

FSM acknowledges that, at best, many of the therapeutic benefits are aimed at ameliorating minor ailments and that they may not be inherently dangerous, as they usually work (if they work at all) by means of the well-known ‘placebo effect’. At worst, however, the claims made for these therapeutic goods, and (for devices) the services provided by alternative therapists using them, are unnecessarily dangerous - either because they cause direct harm or because they delay effective treatments, sometimes resulting in considerable cost. Our organisation and many of our leading scientists and clinicians find it increasingly necessary to complain to the Complementary Health Care Council about advertisements that have been approved but do not have an evidence base to support claims made. The system certainly needs improving and we welcome the TGA’s initiative in consulting widely on how to do that.

In summary then, FSM remains concerned at *the failure of the TGA to validate the claims made in the 'intended purposes'/'indications' listed in Public Summaries, which may be the only accessible source of TGA-based information available to consumers.*

“Friends of Science in Medicine” (FSM) has no links to industry and our interests are therefore not affected financially by the proposals outlined in the Impact Statement.

Objective of RIS

The objectives of the reforms are stated as:

- Improve the timeliness and simplicity of the advertising controls
- Ensure that the regulatory framework for advertising of therapeutic goods to the general public is adequate to manage the public health risks posed by exposure to false, misleading and socially irresponsible advertising of therapeutic goods
- Establish systems that effectively monitors and achieves compliance with advertising requirements and efficiently resolves complaints about non-compliance
- Improve transparency of advertising decision-making by government
- Develop more appropriate controls to facilitate timely, effective and efficient responses to breaches of the advertising controls in and under the Act
- To improve public confidence and trust in the system by avoiding potential conflicts of interest on the part of individuals or organisations that undertake advertising functions on behalf of the TGA.

FSM supports these objectives.

Consumer information

The general public perceive goods accepted onto the Australian Register of Therapeutic Goods (ARTG), (and often promoted by alternative practitioners as 'TGA approved'), to have been tested by the TGA for efficacy. They also see advertising approved by the industry (such as CHC endorsements) as additional proof that the products advertised work for the claims listed.

Apart from limited and often misleading and extremely limited information published on the Public Summary, the general public have no effective way of obtaining accurate and balanced information to validate the quality, safety and efficacy (performance) of the claims made for the therapeutic goods. Consumes are therefore unable to make an informed assessment of the suitability of the good for their particular health needs.

Pre-Approval Delegation

The Secretary's power to pre-approve (or refuse or withdraw pre-approval of) advertisements has been delegated to the Complementary Healthcare Council of Australia (CHC) and the Australian Self-Medication Industry Incorporated (ASMI).

FSM believes that these organisations, which have vested interests, have consistently failed to discharge their responsibilities. Their representatives continue to publicly make false statements that these products are *"rigorously tested",* are *"effective, safe and contains the right dosage"* and that *"consumers are more educated about complementary medicines now than they ever have been before".*

With a long history of inappropriate advertisement pre-approvals by the CHC and ASMI, FSM believes these organisations do not have the technical expertise available, or the motivation, to verify advertising claims. They are not trained to assess the available scientific evidence and therefore cannot make informed judgements about whether the advertising requirements have actually been met.

The failure of the CHC and ASMI to adequately pre-approve advertisement, along with deliberately deceptive labelling, is contributing significantly to the overload of the complaint process and the exploitation of vulnerable consumers.

Centralising pre-approvals with the TGA would remove redundancy and confusion while significantly improving the quality of pre-approvals.

FSM believes that the TGA has the expertise to assess the scientific data relevant to the type of product and therapeutic claims made for it , that are proposed to be advertised.

'Low risk' medical devices

'Low risk' medical devices are currently exempt from the pre-approval scheme, which has led to a proliferation of false and misleading claims for diagnosis and treatments, targeting vulnerable consumers and an explosion in complaints for these goods and the practitioners who use them.

FSM believes that the TGA has the expertise to evaluate the efficacy of 'low risk' medical devices and therefore recommends that it undertake the pre-approval of their advertising.

Complaints Resolution Panel

FSM is satisfied with the outcome of complaints submitted to the Complaints Resolution Panel, but remains concerned about timeliness of the complaints process and the inability of the panel, for example, to impose penalties, enforce sanctions or take any other regulatory action.

Recommendations of Proposals

FSM has evaluated the proposals listed in the RIS and recommend the following:

Proposal 1**: Option 4 (c.)**

- That the TGA undertake advertising pre-approvals.

Proposal 2: **Option 2 (a.)**

- That all complaints about advertising of therapeutic goods to the general public to be handled by a single body, the TGA.

Proposal 3**: Option 2**

- Establish an expert advertising advisory committee

Proposal 4: **Option 4**

- Enhance investigation and enforcement powers

Proposal 5: **Option 2**

- Prohibit the advertising of higher risk medical devices.

Proposal 6: **Option 2**

- Update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the Health Practitioner Regulation National Law.

Proposal 7: **Option 2**

- Transfer from the scheduling framework the responsibility for approving advertising of Pharmacist-Only (Schedule 3) medicines to the general public.

Proposal 8: **Option 2**

- Provide legislative underpinning to the Price Information Code of Practice.

Summary: - FSM believes this is an important review. For far too long the self-interest of many of the suppliers of products with dubious claims to efficacy have managed to pervert the current regulatory system which, as a result is not protecting the public as the current legislation anticipated. The very sensible options for change canvassed here will be controversial but strongly supported by all but those with vested interests who will oppose them for this reason. The TGA is aware of the numerous deficiencies in the current regulatory system and we would wish to provide the strongest encouragement for a commitment to real and effective change. If not now when? We are more than happy to engage in more discussion with the reviewers if that could be helpful

Yours Sincerely

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Friends of Science in Medicine.