Bayer HealthCare

The Project Officer
Advertising Consultation
Regulatory Reform
Therapeutic Goods Administration
PO Box 100
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# Advertising Therapeutic Goods in Australia: Consultation Paper

Dear Sir / Madam

Thank you for the opportunity to provide comment on the advertising consultation paper.

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Bayer Consumer Care offers the following comments on the Consultation Questions for consideration:

***Are the current arrangements for advertising of therapeutic goods in Australia known to you? Should these be better known or understood?***
The current arrangements for advertising are known and understood by Bayer.

***Do you have comments or complaints about the current advertising arrangements?***
Bayer has a number of comments about the current arrangements and suggestions for improvement. They are as follows:

1 The system should comprise both co-regulatory and self-regulatory components. The system should be simple, flexible, responsive, transparent and effective and allow both consumers and healthcare professionals to receive good quality information about therapeutic products.

2 A review of the TGAC and industry codes of practice should be undertaken. At present advertising is controlled by multiple codes, both mandatory and voluntary. Not all companies are members of an industry organisation and there is an unlevel playing field in relation to complaints resolution and monitoring of advertising not subject to pre-approval. In addition the industry codes are not aligned and for companies that are members of more than one organisation or have multiple product categories the proliferation of codes makes compliance more challenging.

3 The complaints handling process should have an adequate robust appeals system.

***Do you currently use the arrangements to place approved advertisements?***
Yes. Bayer uses the current system to place approved advertisements.

***Should the current pre-approval process for advertising be retained?***
No. The current process should not be retained and should be reviewed and improved.

Suggestions for improvements include:
1 Central clearance body
Both the ASMI and the CHC are delegated under the legislation to approve certain media. At present depending on the type of product (OTC or Complementary) elements of the same advertising campaign (print, radio, TV etc) may need to go to both associations for clearance. This creates an environment that is both complex and conducive to inconsistent decision making. It would be preferable if there was one centralised clearance body that approves all advertising or' at a minimum a redistribution between each association so that companies only need to apply to one organisation for clearance regardless of their product type or media. This would ensure consistent decision making and offer efficiencies for the users of the clearance system.

2 Delegation of advertising approval to accredited sponsors
The New Zealand Therapeutic Advertising Pre-Vetting System (TAPS) delegates advertising approval rights to individual companies under certain circumstances. This system could be adopted in Australia to reduce approval timing, reduce complexity, decrease costs and provide a degree of harmonisation with New Zealand for companies advertising in both markets.

3 Increased timeliness and reduced complexity of the appeal process
If an advertisement is rejected by an Advertising Services Manager the appeal process is very lengthy and is a disincentive to use given the dynamic lead times for media. In most instances companies work with the ASMs and compromise on advertising material as the appeal option is rarely practical to consider. There should an expeditious, efficient appeal process to consider reviews of approval decisions.

4 Review of efficacy data
Currently the ASMs routinely call for and evaluate efficacy data to support indications made in advertisements. This results in a approval process that is more complex, lengthy and subjective. The pre-approval of advertisements does not protect the advertisements from complaints once they are published and many complaints made about advertisements are efficacy related. The evaluation of product efficacy should be the sole responsibility of the regulator and not a function of the advertising approval process.

5 Statutory approval timelines
There should be short statutory timelines for advertising pre-approval and applications to approve restricted representations

***If so, should all forms of advertising be considered in this process?***

The pre-approval process should remain as it currently and restricted to specified media as per the current TGAC. Pre-approval should not be extended into other forms of advertising such as the internet or other "below the line" material.

***Should the Therapeutic Goods Administration (TGA) publish on its website information related to products removed from the Australian Register of therapeutic Goods (ARTG)?***

Yes. The removal of products from the ARTG as a result of advertising breaches should be as transparent as possible.

***Should the Complaints Resolution Panel (CRP) be reconstituted as an independent body?***

No. A thorough review of the complaints handling mechanisms should be undertaken to ensure they provide a timely, responsive and transparent process for complaints to be heard and adjudicated. There have been a number of concerns raised over a period of some time about complaints handling and it would seem prudent to review the different delegated bodies established to hear complaints and ensure the best options have been considered. Presently, complaints handling involves at least three different bodies and creates an environment that is both complex and conducive to inconsistent decision making. In that respect the CRP should not be reconstituted as an independent body unless there is a clear and demonstrable need to retain the CRP in it's current form.

***Should the CRP consider complaints about all forms of advertising?***

A review of the complaints handling mechanisms should be undertaken to ensure they provide a timely, responsive and transparent process for complaints to be heard and adjudicated. A review could identify the best options to consider complaints about 'above' and 'below the line' advertisements. This review should include assessing mechanisms in place in other countries and international best practice.

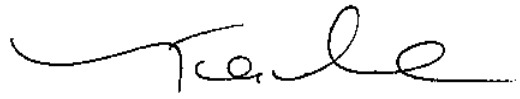
Whichever complaints mechanisms are in place they should not consider efficacy related complaints. These are more appropriately handled by the regulator.

***Should civil penalties apply for breaches of the regime?***

No. Effective sanctions do not necessarily mean the existing civil penalties legislation should be strengthened to include advertising breaches. Imposing suitable sanctions for breaches need to be considered on a case by case basis. A review of the complaints handling mechanisms should be undertaken to ensure they provide a timely, responsive and transparent process for complaints to be heard and adjudicated. A review could identify the best options to consider complaints and the most effective options to handle sanctions for non-compliance.

Bayer would be pleased to provide any further information if required.

Yours sincerely



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