Pharmaceutical Society of Australia

SUBMISSION TO THE THERAPEUTIC GOODS ADMINISTRATION

ADVERTISING THERAPEUTIC GOODS IN AUSTRALIA: CONSULTATION PAPER

PURPOSE

1. The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) on the June 2010 consultation paper on *Advertising Therapeutic Goods in Australia*.

BACKGROUND

2. PSA is the peak professional organisation representing some 75 per cent of pharmacists across Australia. PSA's core functions are: supporting pharmacists' commitment to high standards of patient care; providing continuing professional development, education and practice support to pharmacists in all sectors of professional practice; and representing pharmacists' role as frontline health professionals.

COMMENTS ON THE PROPOSED OPTIONS

The TGA could publish on its website information related to products removed from the Australian Register of Therapeutic Goods (ARTG) for advertising offences.

3. While PSA is agreeable to this proposal, it is our belief that not many products are subject to removal from the ARTG. Our understanding is that there are many more complaints about items which are not on the ARTG.

4. It would be important to ensure robust processes and meaningful sanctions are in place to minimise any offences from being committed in the first place.

5. In addition, we believe more open, transparent and wider reporting of outcomes of complaints is necessary. Reporting must also include any cases where sponsors may have misled the public by making claims that it could not substantiate.

The Complaints Resolution Panel (CRP) could refer directly to the TGA all matters related to efficacy of products.

6. PSA agrees with this proposal in principle but would contend that more information relating to the findings of any TGA investigation on evidence of efficacy of a product would need to be made available to health professionals and consumers.

7. For example, PSA is aware that the TGA has been working on developing evidence requirements for listed medicines with indications and claims for weight loss. We note that this process has been time-consuming and to our knowledge, no information has been provided about any implementation plans.

The Government could move to increase and broaden the level of penalties and sanctions associated with breaches of the advertising arrangements.

8. It is PSA's firm belief that currently available penalties and sanctions for breaches of advertising arrangements are inadequate.

9. For example, a request to publish corrective advertising is a reflective measure which occurs after an offending advertisement has been exposed to the public and most likely made some impact on consumers. Corrective advertisements are also issued in

isolation to the offending material and therefore have minimal connection with the actual breach. PSA believes more significant and effective measures must be implemented so that sponsors are deterred from committing breaches and repeating similar breaches, and from ignoring requests to publish corrective advertising.

10. While increasing fines is one option, we believe stricter sanctions such as deregistering a product from the ARTG, or even deregistering the sponsor, must also be considered as part of the framework for dealing with significant or repeated breaches in a rigorous and timely manner.

11. However, it is equally important to pay attention to having clear advertising rules, effective pre-approval and monitoring processes, and education of sponsors, health care professionals and consumers. The aim must be to minimise the possibility of committing any breaches in the first place.

The Government could reconstitute the membership of the CRP to ensure greater independence.

12. PSA believes the current membership of the CRP brings a broad range of very valuable skills to the table with the highest level of integrity and independence. We are not aware of any public perception or feedback that the CRP is not exercising its duties to the public. It will be vital to continue to maintain this level of independence. PSA is not aware that there is any need to reconstitute the membership.

RESPONSES TO THE CONSULTATION QUESTIONS

Overall awareness of the arrangements for advertising therapeutic goods

Are the current arrangements for advertising therapeutic goods in Australia known to you? Should these be better known or understood?

13. PSA agrees with the consultation paper that there are many aspects to the current advertising arrangements that can be improved. PSA would support a robust and timely system which is simple for and transparent to all Australians.

14. It is vital that more information in an easily understandable form is made available to advertisers, health care professionals and consumers so that the benefits of advertising can be enhanced and false, inaccurate or misleading advertisements can be removed or minimised.

Do you have comments or complaints about the current advertising arrangements?

15. The current advertising arrangements do set some parameters and guidance for conscientious advertisers but generally they are too complex. This can result in confusion and potentially lead to inadvertent breaches. PSA believes a major shortcoming is that the arrangements are ineffective in responding to breaches where rules are broken in an irresponsible manner or where advertisers may intentionally push the limits of the rules.

Using the advertising arrangements

Do you currently use the arrangements to place approved advertisements? OR **Do you find advertisements of therapeutic goods helpful?**

16. The benefits of advertising therapeutic goods can be enhanced by providing balanced information about the product or treatment and alerting consumers on where to obtain further advice.

The pre-approval process

Should the current pre-approval process for advertising be retained?

17. PSA believes the current pre-approval process should be retained. However, we are also concerned about the portion of advertisements which currently do not require pre-approval eg. internet, in-store promotion.

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

18. We believe consideration should be given to having some form of pre-approval process to internet advertising by Australian advertisers. An alternative might be to have better processes in place to monitor such advertising.

19. While we acknowledge it would not be possible or necessary to require pre-approval of all advertising material, we believe other processes or initiatives should be considered where pre-approval is not a requirement.

Complaints mechanisms

Should the TGA publish on its website information related to products removed from the ARTG?

20. See our response under paragraphs 3–5.

Should the CRP be reconstituted as an independent body?

21. See our response under paragraph 12.

22. We would also suggest that an appropriate level of continuity of membership is useful for the overall development of skills and knowledge of the CRP which is likely to support good decision-making and timely outcomes.

Should the CRP consider complaints about all forms of advertising?

23. PSA strongly believes that complaints for all forms of advertising should be lodged and managed through a single body or committee even if that body could refer matters to specific sub-committees for advice.

Should civil penalties apply for breaches of the regime?

24. PSA believes civil penalties should apply to breaches of advertising and this would strengthen the system. See also our response under paragraphs 8–11.

SUMMARY

25. PSA agrees it is necessary to review the current advertising arrangements with a view to enhancing the rigour in the processes and outcomes and to ensure public health objectives are optimised. PSA wishes to continue to contribute to the reform of regulatory arrangements for advertising therapeutic goods. We would also welcome the opportunity to work in partnership with relevant agencies to facilitate greater understanding of the advertising arrangements by pharmacists.

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