



Public Health Association
AUSTRALIA

**PHAA Submission addressing
The Position Paper on the Promotion of
Therapeutic Goods**

Therapeutic Goods Administration

Submission to:
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Friday July 30

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30 July 2010

Background

The Public Health Association of Australia Inc (PHAA) provides a forum for the exchange of ideas, knowledge and information on public health. The Association is also involved in advocacy for public health policy, development, research and training.

PHAA has Branches in every state and territory. Membership of around 1500 individuals spans the health spectrum and over 40 public health related occupations are represented. PHAA also has thirteen Special Interest Groups for members to meet with those who have similar interests and passions, to exchange information and to develop policy positions and papers.

The PHAA supports the Australian Government's aim, expressed in the position paper, of ensuring that decisions on therapeutic management, including diagnosis and treatment, are based on sound clinical evidence, not driven by incentives or other influences, and that codes of conduct are effective in minimising the potential for any promotional activities to compromise the quality use of therapeutic goods and to increase cost pressures on the health system.

Concerns

Regrettably, there are many examples where therapeutic goods companies have placed their desire for profits ahead of ethical behaviour. One recent example is Merck and *rofecoxib* (Vioxx). On May 21, 1999, Merck was granted approval by the Food and Drug Administration (FDA) to market *rofecoxib*. On September 30, 2004, after more than 80 million patients had taken this medicine and annual sales had topped \$2.5 billion, the company withdrew the drug because of an excess risk of myocardial infarctions and strokes. By 2001 there was concern about the potential cardiovascular risks associated with *rofecoxib*. Merck's response was to issue a relentless series of publications, beginning with a press release entitled "Merck Reconfirms Favorable Cardiovascular Safety of Vioxx" and complemented by numerous papers in peer-reviewed medical literature by Merck employees and their consultants. The company sponsored countless continuing medical "education" symposiums at national meetings in an effort to debunk the concern about adverse cardiovascular effects. Over the course of this five-and-a-half-year saga, many epidemiologic studies confirmed and amplified the concern about the risk of myocardial infarction and serious cardiovascular events associated with *rofecoxib*. However, each time a study was presented or published there was a predictable and repetitive response from Merck, who claimed that the study was flawed and that only randomized, controlled trials were suitable for determining whether there was any risk. Meanwhile, Merck was spending more than \$100 million per year in direct-to-consumer advertising; a critical mechanism in building the "blockbuster" status of a drug with annual sales of more than \$1 billion. The end result was the unnecessary death of thousands of patients around the world and ongoing legal action.^{1,2,3}

In addition, the release of internal pharmaceutical industry documents by courts as a result of litigation from class action plaintiffs and government prosecutors has confirmed that marketing can supplant science. There has been suppression and spinning of negative clinical trial data, ghost-

¹ Topol EJ. Failing the Public Health — *Rofecoxib*, Merck, and the FDA. *NEJM* 2004; 351:1707-1709

² Waxman HA. The Lessons of Vioxx — Drug Safety and Sales. *NEJM* 2005; 352:2576-2578

³ Fransworth S. Arthritis drug Vioxx doubled heart attack risk. ABC News, March 10, 2010

writing, disease mongering, undue cultivation of key opinion leaders, and failure of peer-reviewed journals and regulatory authorities to redress unacceptable behaviour”.⁴

The government has, in the first instance, urged industry to strengthen and standardise self-regulation through developing an industry framework for universal adherence to consistent industry-wide Codes based on a common set of high level principles. It has also noted the need for mechanisms to extend the application of Codes to non-members of industry associations and align industry codes with healthcare professional standards developed in conjunction with national registration.

The PHAA considers that some self-regulation may be appropriate, but this should always be appropriately overseen, monitored, and checked so that the advantages of self-regulation do not provide circumstances where the advantages of one issue can cover the weaknesses of the other. For example, a company may not be a member of a self-regulatory industry association or may resign rather than face sanctions. Braithwaite’s regulatory pyramid concept is relevant in this regard (Figure 1).⁵

In light of the above, we now comment on Australian government, “Position Paper on the Promotion of Therapeutic Goods”.

Comment

1. There must be a legislative requirement in the Therapeutic Goods Act requiring all industry to commit to transparent self-monitoring, independent monitoring, Code adherence, complaint resolution procedures and education on ethics as a condition of gaining marketing approval from the Australian Therapeutic Goods Administration (TGA). At the moment there is only a requirement for the sponsors of prescription medicines to commit to only some of the provisions of Medicines Australia Code of Conduct. Appropriate penalties and enforcement procedures are appropriate to ensure compliance.
2. The approval and monitoring process should separate commercial and consumer interests
3. Code(s) should be developed co-operatively in genuine partnership with all stakeholders: industry, consumers, health professionals and government in accord with the partnership principle of Australian National Medicines Policy.
4. There must be similar ethical requirements for health professional’s relationship with the therapeutic goods industry through the Australian Health Practitioner Regulation Agency.
5. The PHAA believes that independent monitoring; Code revision and complaint resolution would be more effectively and efficiently carried out under the auspices of one self-regulatory Therapeutic Goods Promotional Authority (TGPA) with representation from all stakeholders; rather than the current plethora of industry sector Code and complaint committees. Each industry sector would contribute to Code formulation (which would include specific provisions

⁴ Spielmans GI, Parry PI. From Evidence-based Medicine to Marketing-based Medicine: Evidence from Internal Industry Documents. *Bioethical Inquiry* 2010; DOI 10.1007/s11673-010-9208-8.

<http://i.bnet.com/blogs/spielmans-parry-ebm-to-mbm-jbioethicinqu-2010.pdf>

⁵ Braithwaite, J. *Regulatory Capitalism: How it Works, Ideas for Making it Work Better*. Cheltenham, Edward Elgar, 2008

for each sector) and also have adequate representation on monitoring and complaint panels dealing with sector specific complaints.

6. High-level ethical principles should include:

6.1. Active promotion within a country must take place only with respect to drugs legally available in the country. Promotion must be in keeping with national health policies and in compliance with national regulations such as a current ARTG listing and PBS restrictions, as well as with voluntary standards where they exist.

6.2. All promotion-making claims concerning medicinal drugs must be reliable, accurate, truthful, informative, balanced, up-to-date; capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable use of therapeutic goods or to give rise to undue risks. The word “safe” should only be used if properly qualified.

6.3. Comparison of products must be factual, fair and capable of substantiation.

6.4. Promotional material must not be designed so as to disguise its real nature.

6.5. All therapeutic goods clinical trial protocols must be logged onto a public national register at their inception, such as the Australian New Zealand Clinical Trials Registry, to be collated by the World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP).

6.6. The complete and full results of all clinical trials must also be placed in the public domain through publication in peer-reviewed journals and/or on the clinical trials registry web site.

6.7. Scientific and educational meetings and activities must not be used for promotional purposes.

6.8. Promotion in the form of financial or material benefits must not be offered to or sought by health care practitioners to influence them in their use or recommendation of therapeutic goods.

6.9. It is recognised that there are legitimate financial relationships between the therapeutic goods industry and health providers and/or their institutions such as payment for conducting research, consultancy and sponsoring educational activities; in all cases these require public financial disclosure.

Thus, therapeutic goods sponsors must publically disclose all payments to individual health care providers and consumer and patient support groups, their institutions or agents whether cash or in-kind transfers including: compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; and any other transfer of value.

In addition, health professionals giving lectures, involved in expert committees, consensus groups and clinical guideline committees must disclose potential conflicts of interest and be excluded from specific activities when a significant conflict exists (as judged by their peers).

6.10. Packaging, labelling and promotional material must place the scientific (generic) name of the active ingredient(s) in a larger and equally prominent type font, in front of, or above the brand name.

6.11. Sales representatives must not receive bonuses (often disproportionate to base salaries) or other rewards for meeting performance targets based on increasing sales, market share and growth ; rather they should be rewarded for ethical behaviour and achieving quality use of therapeutic goods.

6.12. If industry wishes to contribute to funding the education of health professionals then this money should go to an independent central co-ordinating office to coordinate and oversee all requests for, or offers of, industry funding, and to receive and distribute these funds. This arms-length process should negate the possibility for companies to “badge” their products as part of the process. All industry educational scholarships and travel funding should also be coordinated through this independent office, which would evaluate and choose recipients.

Thank you for the opportunity to comment. Should there be interest in any further comment, please do not hesitate to approach the PHAA



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30 July 2010

Figure 1 Regulatory Pyramid (after Braithwaite and others)

