The first step on the path to broader reform:

reforming the regulation of the advertising of therapeutic goods.

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Introduction

The Public Interest Advocacy Centre

The Public Interest Advocacy Centre (PIAC) is an independent, non-profit law and policy organisation that works for a fair, just and democratic society, empowering citizens, consumers and communities by taking strategic action on public interest issues.

PIAC identifies public interest issues and, where possible and appropriate, works co-operatively with other organisations to advocate for individuals and groups affected. PIAC seeks to:

- expose and redress unjust or unsafe practices, deficient laws or policies;
- promote accountable, transparent and responsive government;
- encourage, influence and inform public debate on issues affecting legal and democratic rights; and
- promote the development of law that reflects the public interest;
- develop and assist community organisations with a public interest focus to pursue the interests of the communities they represent;
- develop models to respond to unmet legal need; and
- maintain an effective and sustainable organisation.

Established in July 1982 as an initiative of the (then) Law Foundation of New South Wales, with support from the NSW Legal Aid Commission, PIAC was the first, and remains the only broadly based public interest legal centre in Australia. Financial support for PIAC comes primarily from the NSW Public Purpose Fund and the Commonwealth and State Community Legal Services Program. PIAC also receives funding from the Industry and Investment NSW for its work on energy and water, and from Allens Arthur Robinson for its Indigenous Justice Program. PIAC also generates income from project and case grants, seminars, consultancy fees, donations and recovery of costs in legal actions.

PIAC's work on Health Consumer Rights

PIAC has undertaken a considerable amount of work on patient and health care rights over its 27 years of operation. Much of this work has focussed on patient safety, complaints and investigation processes and the development of an Australian Charter of Healthcare Rights. For example, PIAC was central to the consultation process leading to the enactment of the Health Care Complaints Act 1993 (NSW).

Recently PIAC made submissions to several health complaint related inquiries, including a response to the review and evaluation of the Aged Care Complaints Investigation Scheme and several submissions about the complaints process and the national registration scheme for health professionals and allied workers.

PIAC welcomes the opportunity to comment on the Therapeutic Goods Administration (TGA) Consultation Paper, *Advertising Therapeutic Goods in Australia*.

This submission will make some general points about the issues raised in the Consultation Paper and then comment specifically on the questions for consideration about complaints mechanisms found at page 5 of the Consultation Paper.

General Comments

PIAC notes that there has been general concern expressed by consumers and consumer groups about the effectiveness of the current regime of regulation of both the advertising and promotion of therapeutic goods in Australia. Although PIAC would reject any assertion that there has been over-regulation of the advertising of therapeutic medicines, PIAC would agree with the quotation from the Productivity Commission report on page 2 of the Consultation Paper that there is a pressing need for the Australian Government to 'streamline and clarify' the rules about both the advertising and promotion of medicines and other therapeutic goods.

PIAC is strongly of the view that the advertising of therapeutic goods and medical services should have to meet stricter standards than the commercial advertising of goods and services. In this light, PIAC strongly supports the continuing ban on the advertising of prescription medication. The consequence of not imposing a regime of strict regulation on the advertising of other medicines and therapeutic goods will be a potential undermining of the relatively high standards of health care accessed by consumers in Australia.

At this time there are various agencies where a consumer can go if they want to complain about the advertising/promotion of health, health products and services (that is, the ACCC, state Fair Trading bodies, the TGA, the various state and now also national Health Professional Registration Boards, and the state based Health Care Complaints Commissions).

A good example of this problem of mixed jurisdictions is the concern that consumers have about some private impotency clinics that operate and advertise nation wide.

Some consumer concerns about these clinics are:

- The validity and efficacy of the clinics' claims to cure/treat erectile dysfunction;
- The efficacy of the sprays etc that the clinics use to cure/treat erectile dysfunction;
- The possible side effects and adverse reaction after using the sprays or other medications and related issues of possible lack of informed consent given the paucity of information received before treatment;
- The general lack of professional information and advice received after the contract is signed, particularly if there are adverse reactions to the medication.
- The claims that medical practitioners are involved in the treatment offered, when, in reality contact with medical practitioners often consists of a short telephone contact with a doctor located offsite and maybe interstate.
- Concerns about commitment to expensive long-term contracts for treatment.

To have their concerns about all these matters dealt with effectively, a consumer would have to complain to the TGA about the efficacy of the medication, the ACCC or a state Fair Trading body about any alleged misleading advertising and the validity of the contract to treat, to a health professional registration board and/or a health care complaints commission about the standard of professional care received and possibly also about the advertising of medical services.

Consumers expect action from one central complaint body if they have a valid complaint about medical services. The sad reality is that they are more likely to get the 'run around'; being referred from one body to another until they often simply give up.

Given the sensitive nature of the treatment in these cases (consumers have often sought treatment with the clinics in the first place because of the relative anonymity that they provide), the effect is that the whole of the treatment provided by such clinics goes unregulated. Alternatively, if the consumer is committed enough to pursue several complaints with several bodies, the care and treatment the clinics provide is reviewed and dealt with by non-coordinated complaints bodies, acting in separate silos.

The provision of health services in Australia is becoming more and more commercialised and corporatised. Private medical practices are now more likely to be part of a much larger corporate and diversified business rather than the rapidly disappearing traditional one or two person GP practice. A medical practice is also likely to be linked (either geographically or through common corporate ownership or both) to other medical services such as pathology, raising questions of conflict of interest and disclosure.

Medical practices also are more and more involved in the marketing of therapeutic devises, and sometimes even complementary medications. As a consequence, the line between the advertising and promotion of therapeutic goods and health services is becoming increasingly blurred. For example, an Australian Google search for 'sleep clinics' leads the searcher to web sites promoting both the medical services provided by the clinics themselves and various therapeutic appliances used in the treatment of sleep disorders.

Response to issues raised in the Consultation Paper

Following on from the above comments, PIAC strongly urges the amalgamation of the two current panels that deal separately with complaints about the promotion and advertising of therapeutic goods.

However, consistent with the comments above, PIAC calls upon the Commonwealth Government to further consolidate the regulation of the advertising of both health services and therapeutic goods to:

- set up an independent 'one stop shop' to coordinate consumers' complaints, concerns and questions about the advertising and promotion of medical services and therapeutic goods;
- draft a national code and regulations (with appropriate civil sanctions for serious breaches) to cover the advertising and promotion of all therapeutic goods and of all medical and related services.

PIAC submits that any reform in this area should cover all types of media, perhaps necessitating the Commonwealth seeking a referral of powers from the states to regulate print media.

PIAC strongly supports the TGA publishing information on its website and elsewhere, about products removed from the Australian Register of Therapeutic Goods for advertising offences.

PIAC supports, in principle, referral of matters related to the efficacy of products to the TGA by the Complaints Resolution Panel. However, when this takes place, a consumer who has made a complaint should be informed fully of the nature of the TGA investigation process, have their complaint dealt with in a timely manner, be fully informed in writing of the results of the TGA determination, and then be fully informed of any potential review or appeal rights they are entitled to exercise.

PIAC also supports an appropriate increase and broadening of the penalties and sanctions associated with breaches of the advertising rules. The *Therapeutic Goods Act 1989* (Cth) should be amended to provide for civil penalties to enforce repeated breaches of the advertising rules. PIAC also supports the Courts being given powers to impose remedial actions to prevent recurrence of breaches of the advertising rules.

PIAC also supports the TGA being given power to refuse to list a product that is substantially similar to one that has been cancelled.

Finally, PIAC strongly supports an independent Complaints Resolution Panel. This can be achieved firstly by not having direct industry representation and professional organisational representation on the panel. Clearly some medical expertise is needed on the panel, but this should also be balanced by community and consumer participation and representation. PIAC agrees that all members of the panel should be seen to be independent of the therapeutic goods and advertising industries.

To be truly independent, such a panel needs an appropriate level of funding, in particular to allow informed participation by community and consumer participants. Consumer representatives will need assistance with research and preparation to make meaningful contributions to determinations of the panel and may also need financial compensation for the time taken to properly deal with the written material required to make a determination.

Conclusion

PIAC strongly urges the TGA to adopt the positive suggestions made in the discussion paper.

However, PIAC believes that these changes should only be the beginning of a wider reform of the regulation of the promotion and advertising of therapeutic goods and health and related services, to strengthen the protection of consumers from all forms of misleading and unethical advertising and promotion of health services and therapeutic goods.